This Handbook was written with the intent of aiding researchers at the Ochsner Clinic Foundation through the clinical research process. This handbook does not replace the guidance or policies put forth by federal guidelines, the institution or pertinent departments at Ochsner. The efforts in revising this handbook were lead by the Clinical Research Department, with input from various departments including the Ochsner IRB, Pharmacy Department, and Office of Research Operations.
TABLE OF CONTENTS

1.0 RESEARCH ETHICS ................................................................. 4
  1.1 THE BELMONT REPORT ......................................................... 4
  1.2 THE INTERNATIONAL CONFERENCE ON HARMONISATION (ICH) .......... 5

2.0 CLINICAL RESEARCH REGULATIONS & GUIDELINES .............. 5
  2.1 GOOD CLINICAL PRACTICES ............................................. 5
  2.2 FEDERAL REGULATIONS .................................................... 6
  2.3 OCHSNER CLINIC FOUNDATION, RESEARCH DIVISION POLICIES ....... 8

3.0 ROLES AND RESPONSIBILITIES OF THE RESEARCH TEAM ....... 11
  3.1 PRINCIPAL INVESTIGATOR (PI) ............................................. 11
  3.2 CLINICAL RESEARCH COORDINATOR (CRC) ......................... 16
  3.3 SUB-INVESTIGATOR (SUB-I) ................................................ 17
  3.4 SPONSOR ............................................................................ 18
  3.5 CLINICAL RESEARCH ASSOCIATE (CRA) OR STUDY MONITOR ........ 18
  3.6 CLINICAL RESEARCH ORGANIZATION (CRO) .......................... 18

4.0 PROTOCOL DEVELOPMENT RESOURCES .................................. 19

5.0 INDUSTRY SPONSORED RESEARCH ....................................... 19
  5.1 TYPES OF CONTRACTS ........................................................ 20
  5.2 OTHER DOCUMENTS ......................................................... 22
  5.3 DETERMINING STUDY FEASIBILITY ..................................... 24

6.0 DEVELOPING A STUDY BUDGET ........................................... 27
  6.1 NEGOTIATING THE AGREEMENT .......................................... 27
  6.2 BUDGET CONSIDERATIONS ................................................ 27
  6.3 BUDGET DEVELOPMENT CONTACTS ..................................... 27

7.0 SPECIAL CONSIDERATIONS & APPROVALS ............................. 27
  7.1 THE INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) ..................... 27
  7.2 RADIATION CONTROL COMMITTEE (RCC) ............................. 29

8.0 THE INSTITUTIONAL REVIEW BOARD (IRB) [21 CFR 50, 45 CFR 46] 32
  8.1 DEFINITION AND OVERVIEW OF THE IRB ............................... 32
  8.2 SCOPE OF AUTHORITY: FEDERAL WIDE ASSURANCE (FWA) .......... 32
  8.3 IRB MEMBERSHIP ................................................................ 33

9.0 PREPARING THE IRB SUBMISSION ........................................ 33
  9.1 RESEARCH EDUCATION REQUIREMENT: CITI COURSE IN THE PROTECTION OF HUMAN
      RESEARCH SUBJECTS ................................................................. 33
  9.2 COMPLETING THE INITIAL FULL IRB APPLICATION ...................... 34
  9.3 COMPLETING THE RETROSPECTIVE CHART REVIEW APPLICATION ....... 36
  9.4 COMPLETING THE CONTINUING REVIEW APPLICATION ................ 37
  9.5 COMPLETING THE STUDY REVISIONS & AMENDMENTS APPLICATION ... 38
  9.6 EXEMPT RESEARCH REQUESTS ............................................. 39

This handbook is designed as a guide and reference for clinical research and is not intended to be a comprehensive statement of the knowledge, policies, and procedures of Ochsner Clinic Foundation. Updates to the Handbook are available on the Ochsner intranet. Use of the materials in this handbook is limited solely and exclusively to Ochsner Clinic Foundation personnel. Use by any other party is strictly prohibited. Copyright © 2004 by Ochsner Clinic Foundation. All rights reserved.
1.0 RESEARCH ETHICS

1.1 The Belmont Report

The National Research Act (Pub. L. 93-348) was signed into law in July, 1974, thus creating the National Commission for the Protection of Human Subjects in Biomedical Behavioral Research. One of the Commission’s responsibilities included identifying basic ethical principles when conducting research involving human subjects, and developing guidelines to assure that research is performed in accordance with these principles. The Belmont Report, which was released in 1979, summarizes the basic ethical principles identified by the Commission. The report was published in the Federal Register with the intent that it be readily accessible to the research community.

The Belmont Report addresses important considerations for ethical conduct in research. It is MUST reading for all individuals involved in human subjects’ research.

The Belmont Report outlines three basic ethical principles which must be incorporated into the treatment of research subjects:

1. **Respect for Persons:** This is an acknowledgement of a person’s autonomy, and of the fact that vulnerable people (people with diminished autonomy) should be protected from harm. Autonomy means that the individual is mentally capable of understanding and processing information, and that the individual’s decisions are free from coercion or the improper influence of others. Respect for persons demands that individuals are provided adequate information about the study, and that the individual’s choice to participate in research is truly voluntary. This principle is captured and applied in the consent process.

   Respect for Persons also provides protections for individuals. Examples of vulnerable populations include members of the military, prisoners, pregnant women (protection of fetus), children, and mentally impaired members of society. These are people with limited autonomy. Special protections must be in place for these groups.

2. **Beneficence:** This means that a clinical study should “do no harm” and that possible benefits should outweigh risks. It requires us to minimize risks/harms and maximize benefits. Research which involves more risks than potential benefits should not be performed.

3. **Justice:** The principle of justice advocated in the Belmont Report requires fairness in distribution when conducting research studies. Research studies should not be restricted only to a particular group of people, and subject selection should be scrutinized to determine whether certain groups (e.g. racial/ethnic groups, socioeconomic groups, etc.) are being systematically selected exclusively because of
their vulnerability (e.g. financial situation, lack of insurance, easy availability, etc.) rather than for reasons directly related to the purpose of the study. **Study participants must be selected and treated equitably.**

For further reading, a copy of the Belmont Report may be found at the following website: [http://ohsr.od.nih.gov](http://ohsr.od.nih.gov)

### 1.2 The International Conference on Harmonisation (ICH)

The International Conference on Harmonisation (ICH) guidelines evolved from a collaborative effort which brought together the regulatory authorities of Europe, Japan and the United States as well as experts from the pharmaceutical industry.

The purposes of the ICH guidelines are to recommend methods to attain harmonization in research and reduce the duplication of testing carried out during the research and development of new medicines. The intent of harmonization is to produce a more economical use of human, animal and material resources, and to eliminate unnecessary delays in the global development and availability of new medicines, as well as to maintain the quality, safety and efficacy, and regulatory obligations to protect public health.

The U.S. has chosen to adopt section E6 of the ICH guidelines. Section E6 supplies guidance on Good Clinical Practices (GCP). This and other sections of the ICH guidelines can be found at the following website: [http://www.ich.org/](http://www.ich.org/)

### 2.0 CLINICAL RESEARCH REGULATIONS & GUIDELINES

#### 2.1 Good Clinical Practices

Good Clinical Practice (GCP) is the “standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.” *International Conference on Harmonization (ICH) Guidelines 1.24.*

Good Clinical Practices are regulations and guidelines found in the Code of Federal Regulations (CFR) and ICH Guidelines, which standardize the way clinical trials are conducted. They are based on principles outlined in the Nuremberg Code, Declaration of Helsinki, Belmont Report, and hence are firmly rooted in research ethics.

All Investigators and Clinical Research Coordinators should be familiar with these “rules of research”.

To review Good Clinical Practice (GCP), please access section E6 of the ICH Guidelines at the following web address:

2.2 Federal Regulations

Research conducted in the United States is most often governed by the Department of Health & Human Services (DHHS) and/or the Food & Drug Administration (FDA).

2.2.1 The Department of Health & Human Services (DHHS):

This federal department oversees all federally-funded studies, such as those sponsored and/or conducted by the National Institutes of Health (NIH). DHHS is governed by the Federal Policy for the Protection of Human Subjects, which is also referred to as the “Common Rule” (Subpart A, 45 CFR part 46). The Common Rule includes requirements for assuring compliance by research institutions, requirements for obtaining and documenting informed consent, and requirements for Institutional Review Boards (IRB) in regards to membership, functions, operations, review of research and record keeping practices.

Investigators conducting a federally-funded study must follow Title 45 CFR 46.

DHHS has also adopted three subparts in addition to the Common Rule. These subparts provide additional protection for vulnerable populations, including:

- Pregnant Women, Human Fetuses and Neonates (Subpart B, 45 CFR 46.200)
- Prisoners (Subpart C, 45 CFR 46.301)
- Children (Subpart D, 45 CFR 46.401)

2.2.2 Food & Drug Administration (FDA)

The FDA, regulates all drugs, biologics and devices used for diagnosis, treatment and prevention of disease in humans and animals. Investigational new drugs and devices are heavily regulated by the FDA under numerous parts of Title 21 CFR, such as:

- Part 11 (Electronic records; electronic signatures)
- Part 50 (Protection of Human Subjects)
- Part 54 (Financial Disclosure)
- Part 56 (Institutional Review Boards)
- Part 312 (Investigational New Drug Application (IND))
- Part 314 (Applications for FDA approval to market a new drug)
- Part 600 (Biological Products)
Part 812 (Investigational Device Exemptions)
Part 814 (Premarket approval of medical devices)

Investigators conducting a study with an FDA-regulated product must follow the FDA regulations that apply. The FDA reserves the right to inspect and audit institutions to determine compliance.

2.2.3 Organization of Federal Regulations

<table>
<thead>
<tr>
<th>Department of Health &amp; Human Services (DHHS)</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Institutes of Health (NIH)</td>
</tr>
<tr>
<td>Other Agencies under DHHS</td>
</tr>
<tr>
<td>Food &amp; Drug Administration (FDA)</td>
</tr>
<tr>
<td>45 CFR 46, 94</td>
</tr>
<tr>
<td>21 CFR 11, 50, 54, 56, 312, 314, 600, 803, 812, 814</td>
</tr>
</tbody>
</table>

2.2.4 Regulatory Web Sites

For additional Guidance, please refer to the following regulatory websites:

<table>
<thead>
<tr>
<th>Web Site</th>
<th>Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Belmont Report</td>
<td><a href="http://ohsr.od.nih.gov">http://ohsr.od.nih.gov</a></td>
</tr>
<tr>
<td>Center for Biologic Research &amp; Evaluation (CBER)</td>
<td><a href="http://www.fda.gov/cber">http://www.fda.gov/cber</a></td>
</tr>
<tr>
<td>Center for Devices &amp; Radiological Health (CDRH)</td>
<td><a href="http://www.fda.gov/cdhr">http://www.fda.gov/cdhr</a></td>
</tr>
<tr>
<td>Center for Drug Evaluation &amp; Research (CDER)</td>
<td><a href="http://www.fda.gov/cder">http://www.fda.gov/cder</a></td>
</tr>
<tr>
<td>Declaration of Helsinki (1987, recognized by the FDA)</td>
<td><a href="http://www.fda.gov/cder/guidance/fstud.htm">http://www.fda.gov/cder/guidance/fstud.htm</a></td>
</tr>
<tr>
<td>Department of Health &amp; Human Services (DHHS)</td>
<td><a href="http://www.os.dhhs.gov">http://www.os.dhhs.gov</a></td>
</tr>
<tr>
<td>European Agency for the Evaluation of Medicinal Products</td>
<td><a href="http://www.emea.eu.int">http://www.emea.eu.int</a></td>
</tr>
<tr>
<td>Food &amp; Drug Administration (FDA): Homepage</td>
<td><a href="http://www.fda.gov">http://www.fda.gov</a></td>
</tr>
<tr>
<td>FDA Information Sheets</td>
<td><a href="http://www.fda.gov/oc/ohrt/irbs/default.htm">http://www.fda.gov/oc/ohrt/irbs/default.htm</a></td>
</tr>
<tr>
<td>Federal Register Online</td>
<td><a href="http://www.gpoaccess.gov/ft/index.html">http://www.gpoaccess.gov/ft/index.html</a></td>
</tr>
<tr>
<td>International Conference on Harmonization (ICH)</td>
<td><a href="http://www.ich.org">http://www.ich.org</a></td>
</tr>
<tr>
<td>ICH Guidelines</td>
<td><a href="http://www.ich.org">http://www.ich.org</a></td>
</tr>
</tbody>
</table>
2.3 Ochsner Clinic Foundation, Research Division Policies

The Ochsner Clinic Foundation Research Division has established policies for appropriate conduct of research at the institution. Below please find a list of research policies, which contains the policy name, policy number, and a brief description. The complete policies are available on the Ochsner intranet. To access the complete policy from the intranet, select the Policies, Procedures, & Protocols link. Under Departments, scroll down to the Research department and click on the Search button. You are responsible to follow Ochsner policies and procedures.

Please note that the list of policies is not all-inclusive. The Research Division frequently updates and develops new policies to comply with the regulatory environment and institutional needs.

The Ochsner Clinic Foundation, Research Division Policies include:

2.3.1 Orientation to Clinical Research (Policy No. 8042-1)

All newly hired clinical research personnel, personnel re-entering or new to clinical research will complete research orientation offered by the Clinical Research Support Department.

2.3.2 OMIS (Ochsner Medical Information System) for Patient Identification on Research Studies (Policy No. 8042-2)

The purpose of entering patients into the OMIS system is to help facilitate patient safety throughout the Ochsner Network. Protocols that involve human participation with drugs or devices will be entered into the OMIS system and maintained by personnel in research. When a patient (subject) is enrolled in a clinical trial, the subject’s start dates for the specific protocol will be entered into OMIS by a member of the research study team. The research study team is responsible for maintaining accurate information in OMIS, which includes the start and stop dates of a research subject in the clinical trial.

If a patient enrolled in a research study is admitted to the hospital or seen in the emergency department, a notice will be sent to the principal investigator. The principal investigator should in turn follow-up promptly with the patient to report all adverse events and serious adverse events (SAE).
2.3.3 Study Participant Education: Requirements for Investigators and Clinical Research Coordinators (Policy No. 8042-3)

This policy provides a standard to which principal investigators (PI), sub-investigators, clinical research coordinators and other staff, designated by the PI will be held accountable with respect to patient education and documentation of study subjects’ education.

2.3.4 Educational Requirements for Personnel Involved in Clinical Research (Policy No. 8042-4)

This policy provides a standard to which principal investigators (PI), sub-investigators, clinical research coordinators and other staff, designated by the PI will be held accountable with respect to their research education and documentation of education.

2.3.5 Management of Test Articles (Policy No. 8042-5)

This policy provides a standard to which principal investigators (PI), sub-investigators, clinical research coordinators and other staff, designated by the PI will be held accountable with respect to the handling of test articles (e.g. study drugs). These standards are set to maintain compliance with Federal regulations and to provide safety precautions for patients participating in clinical research trials which involve the use of a test article.

2.3.6 Electronic Data Capture and 21 CFR Part 11 Compliance for FDA Regulated Studies (Policy No. 8042-6)

In all Food and Drug Administration (FDA) regulated research at Ochsner Clinic Foundation where creating, modifying, maintaining and transmitting of data is performed electronically, the electronic data capture systems must be compliant with rules governing electronic records and signatures (21 CFR Part 11).

2.3.7 Double Enrollment (Policy No. 8042-7)

The principles of Good Clinical Practice (GCP) generally do not allow patients to be enrolled in more than one study simultaneously. However, occasions exist where enrolling a patient into a second research study may have no impact on the data for either study, or on the well-being of the patient.

This policy sets forth the conditions and procedures under which contemporaneous enrollment of patients in two studies (double enrollment) is permissible.

2.3.8 Research Misconduct (Policy No. 8042-8)

Scientific integrity is an essential value of the Ochsner Clinic Foundation. Medical and scientific staff, residents, students, management and support staff share the responsibility for maintaining a climate of trust and honesty in which pursuit of knowledge can occur. The procedures outlined
2.3.9 HIPAA Privacy Research Policy (Policy No. 8042-9)

Ochsner Clinic Foundation (OCF) will comply with all applicable laws including the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule. The purpose of this policy is to clearly define the circumstances under which PHI may and may not be used internally or disclosed externally in connection with research activities. This policy will specify how the covered entity (OCF) delegates its HIPAA responsibilities within research.

2.3.10 Payment to Study Subjects (Policy No. 8042-10)

Payment to research subjects for participation in studies is not considered a benefit. Rather, it is considered compensation for time and inconvenience, or reimbursement for travel. As such, payments to any given subject in excess of $600 per calendar year must be reported to the Internal Revenue Service (IRS) using Form 1099.

2.3.11 Research Contracts (Policy No. 8042-11)

All Confidentiality Agreements, Clinical Trial Agreements (CTA), Contracts, Letters of Indemnification (LOI), Budget Agreements, Materials Transfer Agreements (MTA) associated with research studies, and Amendments to each, (hereinafter called “Agreements”), must be reviewed by the Director of Research Operations and be approved by the Executive Vice President and Chief Academic Officer.

2.3.12 IRB and ORA Administrative Fees (Policy No. 8042-12)

Institutional Review Board (IRB) fees and Office of Research Administration (ORA) administrative fees will be assessed on all protocols submitted for review by either the Ochsner IRB (OIRB) or Western IRB (WIRB), unless they are exempted according to this policy.

2.3.13 Good Laboratory Practice (GLP) (Policy No. 8042-13)

The Basic Science Research Department at Ochsner Clinic Foundation (OCF) is not a Good Laboratory Practice (GLP) facility. An Investigator must obtain written acknowledgement from any commercial sponsor of research that any study data submitted to the FDA will not be represented as having been derived in a GLP facility. He/she must provide this written statement to the Vice President and Director of Research before the study can receive final approval.

2.3.14 Limited Data Set (Policy No. 8042-15)

Ochsner Clinic Foundation (OCF) will comply with all applicable laws including the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule. The purpose of the HIPAA Privacy Rule is to protect the privacy rights of individuals regarding their protected health information (PHI).
2.3.15 Adverse Event Reporting (Policy No. 8042-16)

Adverse events related to a research study will be reported to the study sponsor and the Institutional Review Board (IRB) of record within the prescribed time frames set forth in Federal Regulations, IRB Policy and protocol requirements.

2.3.16 Human Subject Research (Policy No. 8042-17)

All research involving human subjects conducted under the aegis of OCF will be conducted in compliance with all applicable federal regulations and internal OCF policies.

2.3.17 Travel (Policy No. 8516-4)

Employees will be reimbursed for necessary and reasonable expenses incurred in the conduct of company business. This policy initiates a system for providing clarity and structure to the process required to reimburse medical staff, employees, and students for all levels of business and education related travel and expenses. Employees are expected to be conservative in their spending and managers are expected to be diligent in their review. Original receipts are required to be presented for reimbursement. No Travel Advance will be given. Travel expenses for family members or companions are not reimbursable. All physicians and doctoral level professionals, who have signed employment agreements, must follow CME Reimbursement guidelines. The Trip Request form can be found in Appendix F. This form must be completed and submitted to the Director of Clinical Research Support for all work-related travel.

3.0 ROLES AND RESPONSIBILITIES OF THE RESEARCH TEAM

A team of researchers typically carry out a clinical research study. This team may include the Principal Investigator (PI), Sub-Investigators, the Clinical Research Coordinator (CRC), Research Assistants, the Institutional Review Board (IRB), and the sponsor and its representatives, all of whom need to be educated and knowledgeable about research in order to maintain the accuracy and integrity of the study and to protect the rights and confidentiality of the study participants.

Here at Ochsner, members of the research team must comply with the institution’s research education policy (research policies # 8042-4 and 8042-1). For more information about the specific research education requirement, please refer to section 6.1.

3.1 Principal Investigator (PI)

For each study performed at Ochsner, only one individual may take on the role of Principal Investigator (PI). The PI takes full responsibility and accountability for the conduct of the study and integrity of research data.
In the situation where the investigator also acts as a sponsor, the investigator is responsible for following the regulations for both the investigator and the sponsor.

Residents and fellows, who are considered to be in training, are not permitted to be a PI at Ochsner. Instead, a staff physician, who will mentor the resident, takes on the role of PI. The resident may be a Sub-Investigator.

Title 21 CFR and the FDA 1572 (Statement of the Investigator for studies involving investigational new drugs) discuss the obligations of a PI. It is highly recommended that PI’s read through these regulatory documents prior to initiating or agreeing to take on the role of PI. Some of the guidance includes:

3.1.1 1572 Commitments (FDA Form 1572)

Prior to participating in an FDA regulated study, the PI must sign the 1572, which is a two-page document providing information about the site, sub-investigators and the qualifications of the investigator. By signing the 1572, an investigator agrees to ensure, “…that an investigation is conducted according to the signed investigator statement, the investigational plan, and applicable regulation.” (21 CFR 312.60). The 1572 states the investigator’s commitments, and is considered a contract between the FDA and the investigator.

In signing the FDA 1572 Form the PI agrees:

- To personally supervise the conduct of the study, and conduct the study in accordance with the protocol
- To report adverse events to the Sponsor
- To report any changes in research activities to IRB, and to ensure that an IRB compliant with 21 CFR part 56 performs initial and continuing review of the study
- To read the Investigator brochure
- To ensure appropriate Informed Consent is obtained from study participants
- To ensure that all employees/associates involved in the study are aware of their obligations for meeting study requirements
- To maintain adequate and accurate study records, and to make those records available for inspection as required
- To accept complete responsibility for the study at his/her site and agree to comply with all requirements listed in 21 CFR 312 regarding investigator obligations.
The FDA 1572 is a legal document. Never discard an outdated FDA Form 1572; keep it in the study binder. Never alter a Form 1572 or use correction fluid on it. Send the original to the Sponsor, send a copy to the IRB, and keep another copy on file in the regulatory binder. Make sure that the form has not expired; if this is the case a new FDA 1572 should be completed and sent to the sponsor, a copy sent to the IRB, and another copy kept on file in the regulatory binder. Keep all expired copies.

It is required that all sub-investigators (including residents and fellows) be listed on this form. Please be advised that anyone who administers the study intervention or study-related procedures must be listed on the 1572 as a sub-investigator. (NOTE: this also applies to the Investigator Agreement for device studies)

A downloadable version of the FDA 1572 form may be found at the following web address: http://forms.psc.gov/forms/FDA/fda.html.

3.1.2 Study Conduct (21 CFR 312.53 (c))

The PI will personally conduct or supervise the investigation.

3.1.3 Human Subject Protection (21 CFR 312.60)

The investigator is responsible for protecting the rights, safety, and welfare of subjects under the investigator’s care.

3.1.4 Investigator’s Brochure (21 CFR 312.53 (f), ICH 4.1.2)

The investigator will read the Investigator’s Brochure and understand the potential risks and side effects of the study drug.

3.1.5 Investigational Drug (21 CFR 312.59, 312.61, 312.62 (a); ICH 4.6)

The drug will be administered only to subjects under the investigator’s personal supervision or under the supervision of a sub-investigator responsible to the investigator.

The investigator will give the investigational drug only to those authorized to receive it.

Adequate records will be maintained of the dispensing of the investigational drug, which includes dates, quantity and use by subjects.

Unused supplies of the drug will be returned to the sponsor, or otherwise provide for their disposition under section 312.59.
3.1.6 Subject Records & Source Documents (21 CFR 312.62 (b), 312.68)

Maintain adequate and accurate case histories of study subjects that records all observations and relevant data required by the sponsor. These records should be made available to the sponsor and for inspections by authorized agencies (e.g. FDA).

Provide the original source of documentation (i.e. where the information was first entered) for audits and inspections.

3.1.7 Record Retention (21 CFR 312.62 (c))

All records obtained for participants involved in a research study must be kept in a locked area with limited access.

According to 21 CFR 312.62 (c), “An investigator shall retain records…for a period of 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and the FDA is notified.”

Ochsner Policy 8042-5 (Management of Test Articles) states that study records must be kept for a minimum of 10 years or as detailed by the Investigator’s agreement, whichever is longer.

In the event an Investigator leaves Ochsner Clinic Foundation, the original study data must be transferred to Research Administration to be kept on file at Ochsner Clinic Foundation. The Investigator may retain copies of the data.

3.1.8 Investigator Reports (21 CFR 312.64, 21 CFR 54, ICH 4.10.4.11)

The investigator is required to submit the following reports to the sponsor:

- Progress reports
- Safety reports: Report any adverse effects that may be related to the drug (i.e. adverse events (AE) & serious adverse events (SAE)). The sponsor defines the SAE criteria and timeframes for reporting adverse events in the protocol.
- Final report: Provided after completion of the study investigator’s participation in the investigation.
- Financial disclosure reports
3.1.9 Institutional Review Board (IRB) (21 CFR 56, 21 CFR 312, ICH 4.4, 4.5)

Submit initial and continuing review applications to the IRB, and obtain IRB approval for the proposed clinical study.

Report all changes in the research activity and unanticipated problems involving risk to human subjects or others.

Changes in the research (e.g. protocol) should not be made without prior approval from the IRB and sponsor, except in cases where it is necessary to eliminate immediate hazards to human subjects.

3.1.10 Informed Consent Requirements (21 CFR 50, 21 CFR 56, ICH 4.8)


Obtain IRB approval of the informed consent (IC) prior to initiating the consent process with any potential subject.

Obtain informed consent prior to enrolling a patient in the study.

Provide sufficient time for a potential subject to decide whether or not to participate in the study.

Confirm that the consent form contains the required elements (21 CFR 50.25).

Make sure the consent form is written in language understandable to the subject or the subject’s representative. The consent form should not contain language that is exculpatory or that waives or appears to waive any of the subject’s rights.

3.1.11 Research Staff (21 CFR 312.53 (g), ICH 4.1.5)

The investigator is responsible for making sure that staff are qualified, capable and trained to carry out study-related responsibilities or procedures. Suggestions for demonstrating adequate training include:

- Develop a list of Delegated Authority, which indicates the study-specific procedures assigned to each staff member.
- Document staff training. Provide information on how staff members were trained to perform their study-specific duties (e.g. on-site training by team member, licensing, etc.).

Maintain effective communication with research staff about study-related issues and changes.
3.2 Clinical Research Coordinator (CRC)

The Clinical Research Coordinator is an important member of the team. The CRC takes on a variety of duties during the course of a study, and these study-related duties are delegated by the Principle Investigator. The responsibilities of the CRC are varied but may encompass the following activities:

**Administrative Tasks**
- Markets the site
- Assists the PI in determining study feasibility
- Assess the study protocol
- Assist with development of study budgets
- Maintains relationship with the study sponsor
- Interacts with the IRB, office staff, and other department personnel
- Educates patients and staff about the protocol
- Prepares, submits, and maintains regulatory documents (e.g. IRB, FDA, etc.)
- Tracks the study budget & payments
- Documents study progress and communication
- Documents participant study visits
- Resolves queries on study data
- Transcribes source information onto Case Report Forms (CRFs)
- Coordinates, prepares for and participates in monitoring visits, audits & inspections
- Orders study supplies as necessary
- Closes out the study, and assures appropriate storage of study documentation

**Subject-Oriented Tasks**
- Recruits and enrolls study subjects
- Develops and manages advertising for the study
- Screens subjects for eligibility
- Discusses the study with subjects and carries out the consent process
- Schedules study visits and assessments
- Ensures that tests, procedures and assessments are conducted in compliance with the protocol
- Interviews & evaluates subjects within the required time intervals provided in the protocol
- Reviews laboratory and clinical information to detect adverse events
- Identifies, documents, reports and follows-up on adverse events
- Maintains test article (drug or device) accountability
- Oversees storage and administration of study medications
- Provides documentation to Pharmacy for investigational drug dispensing
- Coordinates study subject reimbursement

The CRC works closely with the Principal Investigator, and keeps the Principal Investigator updated on all information pertaining to the study. A CRC may be a registered nurse, a public health graduate, or someone from another discipline with appropriate documented training in clinical research.

Note: If a CRC is not available for the study, then the Principal Investigator or other designee will be responsible for carrying out the above activities.

3.3 Sub-Investigator (Sub-I)

A sub-investigator may be a physician, nurse, pharmacist, professional or other member of the research team who supports the conduct of the investigation. ICH Good Clinical Practices (GCP) defines a sub-investigator as, “any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions…” (ICH E6: GCP, Section 1.56). The sub-investigator carries out those study-related tasks or procedures that are delegated by the PI.

Sub-investigators must be listed on the FDA 1572 Form for investigational drug research, and on the Investigator Agreement for device trials. Anyone who administers the study intervention or any study-related procedures must be listed on the FDA 1572 as a sub-investigator. These are the people who make study-related medical decisions regarding the diagnosis and treatment of the disease under investigation.
Please note that although sub-investigators may help conduct the study, the Principal Investigator still maintains 100% responsibility and accountability for study conduct and regulatory compliance. The Principal Investigator is responsible for personally supervising the research team as well as ensuring that, “all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting…” the FDA 1572 commitments (FDA 1572).

3.4 Sponsor

A sponsor is an organization that initiates a clinical investigation, engages qualified investigators, maintains an IND, reports Serious Adverse Events to the FDA, and also monitors the clinical trial to ensure protocol compliance. A sponsor usually also funds the study.

3.5 Clinical Research Associate (CRA) or Study Monitor

In clinical trials, this person represents the study sponsor and is responsible for monitoring the study to verify that each of the local study sites remains compliant with Good Clinical Practices (GCP) and clinical protocols. This individual verifies study data for clinical trials.

The Clinical Research Associate or study monitor is responsible for the following tasks:

- Verifies case report forms (CRFs) and source documentation
- Reviews regulatory documents
- Reviews informed consent procedures
- Monitors protocol and regulatory compliance
- Audits study supplies and storage of test article.
- Generates queries about case report forms, and assists the CRC in resolving queries.
- Reports all concerns or queries immediately to the Principal Investigator.

3.6 Clinical Research Organization (CRO)

The sponsor may elect to transfer some responsibility (usually for monitoring the study) to this organization, via a written contract with the CRO. The contract with the sponsor may also include providing other types of support such as assistance with preparing a manuscript, statistical analysis etc, this is dependent on the contract. The quality of these organizations varies. The Principal Investigator and research staff must treat this organization as an agent representing the sponsor. Should there be any questions or concerns about the conduct of research, the Principal Investigator should share them with the sponsor.
4.0 PROTOCOL DEVELOPMENT RESOURCES

Most often in clinical drug and device trials, it is the study sponsor who writes a protocol and gives this to the investigator to follow when conducting his/her study. However, there are also investigator-initiated studies where the investigator develops the research protocol. In order to comply with federal regulations, the investigator must include the following requirements (21 CFR part 312.23 (a) (6) (iii) and ICH GCP Guidelines) when writing the protocol:

- A statement of the objectives and purpose of the study.
- The name and address of each investigator as well as a statement of their qualifications (e.g. curriculum vitae). The names of each sub-investigator working under the supervision of the investigator. The name and address of the research facilities to be used, and the name and address of each reviewing IRB.
- An estimate of the number of patients to be studied, including the criteria for patient selection and exclusion of patients.
- A description of the study design, including the controls to be used (if any), and methods to be incorporated to minimize bias on the part of the subjects, investigators and analysts.
- The method for determining the dose(s) to be administered, the planned maximum dosage, and the duration of patient exposure to the drug.
- A description of the observations and measurements to be made to fulfill the objectives of the study.
- A description of clinical procedures, laboratory tests, or other measures to be taken to monitor the effects of the drug in human subjects and to minimize risk.

For protocol writing, Ochsner offers the following resources:

- A sample protocol template is available on the Ochsner IRB website, which is located at the following web address: https://ersa.ochsner.org
- The Clinical Research Support Department provides assistance with protocol development and protocol writing materials. For more information, please contact the Senior Research Educator at extension 2-5931 or 2-4680.

5.0 INDUSTRY SPONSORED RESEARCH

A general schema of the industry-sponsored clinical trial process can be found in Appendix A.
5.1 Types of Contracts

Contracts associated with research that are funded by an industrial sponsor (e.g. pharmaceutical or device companies) must be reviewed, negotiated and approved by the Office of Research Administration (ORA). It is strongly recommended that investigators contact ORA prior to outside communication or immediately after initial contact from an outside sponsor. Please see OCF Policy # 8042-11 regarding research contracts.

ORA ensures that all sponsor agreements and contracts are reviewed by the necessary Ochsner legal and administrative departments, who makes sure that the agreements are in compliance with Ochsner’s institutional policies and guidelines. Some of the sponsor documents include:

5.1.1 Confidentiality Agreement

This is often a precursor to a Clinical Trial Agreement (CTA). An industry sponsor may want to send a protocol to the investigator to assess the feasibility of conducting the trial and decide whether or not to participate in the trial. This agreement states that the Investigator and designated research team members (e.g. CRC) will not divulge any information about the protocol to a third party (e.g. a rival pharmaceutical company, the media, or another investigator not involved in the project). The protocol is considered to be similar to a “trade secret” and is the exclusive property of the sponsor.

The agreement will define the confidential information, the purpose for which it is being released and the terms, conditions and interval of time under which the obligation of confidentiality shall be maintained. Written confidential information should be stamped as such, and oral disclosures should be reduced to writing and stamped “confidential” as soon as practical.

5.1.2 Clinical Trial Agreement (CTA)

Clinical Trial Agreements are contracts with private industry for the clinical testing of drugs and/or devices. The Agreement will include terms and conditions that will extend legal protection to the study subject, Investigator, the Sponsor, and the Institution. This is the agreement that permits a study to be performed at the institution, with financial support from the industry sponsor.

5.1.3 Consortium Agreement

Consortium Agreements are established between institutions when the research is supported (in whole or in part) by federal funds. This Agreement defines the terms and conditions governing the research relationship between the prime and participating institutions. The participating institutions must attest to and certify their compliance with Public Health Services policies. In clinical research, this includes the institution’s compliance with federally mandated programs for the protection of human subjects in research, etc.
5.1.4 **Sponsored Research Agreement**

A Sponsored Research Agreement is negotiated between a sponsor (usually a for-profit entity) and the Institution when the sponsor provides the funding, materials or other resources for a particular research project. The agreement includes terms and conditions, a statement of work or protocol, and a budget that includes direct and indirect costs.

5.1.5 **Sub-Contract Agreement**

Sub-contract agreements are established when an investigator from one institution receives funding from a sponsor (Prime Sponsored Research Agreement), however, participation of investigators from other institutions is needed to accomplish research goals. The terms and conditions governing the research relationships between the institutions are described as well as the time-dependent schedule of deliverables and rates of compensation. Sub-contract agreements are usually established for one-year intervals, with annual amendments developed and executed to extend the life of the study and to specify payment arrangement rates for each study interval. The terms of the sub-contract must be consistent with the terms in the Prime Sponsored Research Agreement or award.

5.1.6 **Material Transfer Agreement**

A Material Transfer Agreement (MTA) is used when an exchange of biomedical materials is anticipated between two or more institutions (or industry) for the conduct of research. The MTA ensures mutual understanding of how the materials are to be used; and specifies any restrictions on the use of the materials. The MTA also describes the conditions under which licensing rights shall be obtained. These agreements are contractually binding upon the parties, and a breach of an MTA can potentially create legal and financial risk for the Institutions and Investigators involved.

5.1.7 **Research Contract**

Research contracts are legal documents that describe the terms and conditions that impact the development and delivery of products or services required. Any modification in the scope or direction of the research project or adjustment in the budget requires written approval from the funding agency.

5.1.8 **Letter of indemnification**

Indemnification is a statement of legal liability which covers the institution and the research staff in the event of a lawsuit. If a sponsor refuses to provide indemnification, it does not mean that the study cannot be done at Ochsner. For example, federally funded projects or In-House funded projects may not be required to provide a letter of indemnification. Such situations are dealt with on a case-by-case basis with the ORA. In any scenario, however, this issue must be resolved prior to initiating the study. Usually, the indemnification is included in the Clinical Research Agreement which when signed by the Sponsor’s official, is acceptable. However, if the CRO...
5.1.9 Clinical Trial Budget

The Clinical Trial Budget is an itemized list of expected study costs. The budget provides a reasonable degree of detail for the costs of performing study procedures outlined in the research protocol. Both direct and indirect costs are shown, and a cost per patient is established. OCF conducts research on a “no profit/no-loss” basis; therefore, research study budgets must incorporate the full costs of the research (both direct & indirect costs).

Please see section 6.0 for more information on Developing a Study Budget.

5.2 Other Documents

5.2.1 Investigator’s Brochure (IB)

The ICH Guidelines state that, “The Investigational Brochure is a compilation of the clinical and non-clinical data on the investigational product(s) that are relevant to the study of the product(s) in human subjects. Its purpose is to provide the investigators and others involved in the trial with the information to facilitate their understanding of the rationale for, and their compliance with, many key features of the protocol, such as the dose, dose frequency/interval, methods of administration: and safety monitoring procedures. The IB also provides insight to support the clinical management of the study subjects during the course of the trial...” (ICH, E6, section 7.1)

The Investigator’s Brochure must be received and read before a PI signs the FDA 1572.

Generally, the sponsor is responsible for ensuring that a current, up-to-date version of the IB is made available to the investigators. The investigators, in turn, are responsible for providing the up-to-date version of the Investigator’s Brochure to the respective Institutional Review Board (IRB).

5.2.2 Investigational New Drug Application (IND)

This is a request for FDA authorization to administer an investigational drug to human beings. It is required before shipping an investigational drug across state lines. IND regulations are found in 21CFR Part 312. A Form 1571 should be sent to FDA with accompanying documentation (CVs, results of prior studies, study protocol etc.) Upon receipt of the IND, an IND number is assigned, and the application is forwarded for review. Studies can be initiated 30 days after the FDA receives the IND application unless told otherwise by FDA.

Investigators interested in filing his/her own IND must contact the Office of Research Administration for assistance.

This process also applies to off-label use of an approved drug for research purposes.
Examples of when an IND is warranted because of greater risk include:

- Increased dose
- Different route of administration
- If the product is not being used according to product labeling (i.e. used for a different indication)
- The research population is “vulnerable”
- Longer duration
- There is reason to believe that this population has different pharmacokinetic or pharmacodynamic responses from the indicated population

An IND is also required if a previously approved drug is being used for a new indication.

### 5.2.3 Investigational Device Exemption (IDE)

Federal regulations require that all devices have an FDA-approved IDE for use in clinical research.

An IDE pertains to medical device studies that involve significant risk devices. Such medical device trials are governed by 21 CFR part 812. These regulations require that all devices have an FDA-approved IDE for use in clinical trials.

**Investigators interested in filing his/her own IDE must contact the Office of Research Administration for assistance.** The IRB may determine if a study represents a “significant” or “non-significant” risk to study participants.

A non-significant risk (NSR) device study is considered to have an approved IDE application (no application needs to be filed with FDA). This type of study still requires IRB approval, informed consent, compliance with regulations pertaining to the IDE, study monitoring and labeling of the device. Significant risk (SR) device studies require an FDA-approved IDE application, and compliance with regulations, IRB approval, etc.

**Definition of Significant Risk (SR) Devices:**

Defined in 21 CFR 812(m) as a device which is:

- Intended as an implant and presenting a serious risk to the health, safety or welfare of a subject.
- Represented to be for use in supporting or sustaining human life, and presenting a serious risk to the health, safety and welfare of a subject.
- Is for use of substantial importance in diagnosing, mitigating or curing disease and presents a potential for serious risk to the participant.
- Otherwise presents a potential for serious risk to the health, safety or welfare of a subject.

**Definition of Non Significant Risk (NSR) Devices:**

There is an FDA information sheet which can be used as a guide to determining if a device is NSR. An NSR device study is one that does not meet the definition of a significant risk device study. The risk determination should be based on the proposed use of a device in an investigation, and not on the device alone. There is a list of examples of NSR and SR devices in the FDA Information Sheets. (See [www.fda.gov](http://www.fda.gov))

**5.2.4 New Drug Application (NDA)**

Application to FDA to market a new drug in the United States, after safety and efficacy studies have been accomplished to evaluate the use of the drug (phase I, II and III studies).

**5.3 Determining Study Feasibility**

When approached to perform a clinical research trial, it is the responsibility of the investigator to carry out a thorough evaluation of any protocol under consideration. The investigator, with the necessary support from his/her research staff, should evaluate the study feasibility. A Feasibility Checklist can be found in Appendix B. In addition, when evaluating feasibility, the protocol should be reviewed with the following perspectives in mind: protocol-specific requirements, regulatory requirements, ethical considerations, and feasibility of conducting the clinical trial at the clinical site.

**5.3.1 Protocol Requirements:**

Some important aspects to consider when reviewing the protocol include:

- Is the protocol provided by the sponsor a draft or final version?
- What are the study objectives?
- Does the study’s design support the objectives?
- Who comprises the study population?
- What are the inclusion and exclusion criteria? Are the criteria realistic for the condition under investigation?
- What phase is the study?
- Is the proposed study a single or multi-center study?
- How many study subjects does the study aim to enroll? How many subjects at this site?
- How many study visits are required?
- What procedures, tests and assessments are performed at each study visit?
- What data will be collected? Is the data collected appropriate for evaluating the given objectives of the study?
- What is the duration of the study?

5.3.2 Regulatory Requirements

A protocol is required by federal regulations (21 CFR 312.23 (a) (6) (iii)) to contain the following information:

- A statement of the objectives and purpose of the study.
- The name and address of each investigator as well as a statement of their qualifications (e.g. curriculum vitae). The names of each sub-investigator working under the supervision of the investigator. The name and address of the research facilities to be used, and the name and address of each reviewing IRB.
- An estimate of the number of patients to be studied, including the criteria for patient selection and exclusion of patients.
- A description of the study design, including the controls to be used (if any), and methods to be incorporated to minimize bias on the part of the subjects, investigators and analysts.
- The method for determining the dose(s) to be administered, the planned maximum dosage, and the duration of patient exposure to the drug.
- A description of the observations and measurements to be made to fulfill the objectives of the study.
- A description of clinical procedures, laboratory tests, or other measures to be taken to monitor the effects of the drug in human subjects and to minimize risk.

5.3.3 Ethical Considerations

Ethical considerations may include:

- Are the risks to subjects minimized?
- Risk/Benefit Ratio: Are the risks reasonable in relation to the knowledge or benefits to be gained?
- Is subject selection equitable?
Do errors or inconsistencies in the protocol exist, and do they affect the site’s ability to recruit subjects ethically?

5.3.4 Site Feasibility

- Does the investigator have the time to participate in the study given other responsibilities such as clinic schedules and other professional obligations? The FDA expects to see evidence of appropriate oversight of staff involved in the study.
- Does the site have the necessary resources to meet all the protocol requirements? This includes the study population, staff, facilities, equipment, supplies, and time.
- Is the site able to enroll subjects and treat subjects according to protocol?
- Does the Ochsner IRB have ample time to review and provide approval so that the investigator may begin enrolling subjects within the specified study time frame?
- What is the timeline for enrollment? Will the site be able to enroll the number of subjects within the given time frame?
- Will the sponsor provide a budget for advertising materials? How much?
- Will enrollment compete with other clinical trials that occurring at the site?
- How will inclusion and exclusion criteria affect recruitment?
- Will subject compliance with the protocol be difficult, given the requirements of participation?
- Do requirements for drug or device storage and dispensing pose any potential problems?
- Is the space adequate?
- Does the site have the necessary equipment for study procedures and tests? If not, will the sponsor provide the equipment, or can the equipment be borrowed from other departments?
- Are other departments able to meet protocol requirements for performing study procedures and tests?
- Are laboratory tests required at times when the laboratory is closed?
- Will study procedures be required at inconvenient times (e.g. on weekends, evenings, etc.)? Will this result in overtime costs?
- Will demands on key personnel be excessive?
- How will staff be trained? Will the sponsor train staff on how to administer procedures and tests? Will new staff need to be hired and/or trained?
- Are the staff members qualified to conduct the procedures, tests and assessments required by the study protocol? Can more than one individual perform the tasks if reassignment becomes necessary?
• Is the staff motivated to participate in the study?

It may be helpful to have other staff review the protocol and provide feedback. Also, ensure the patient population exists at the institution.

6.0 DEVELOPING A STUDY BUDGET

The following information is to be used only as a guide in the process of preparing the budget. Each budget must be individually negotiated.

6.1 Negotiating the Agreement

SECTION UNDER CONSTRUCTION

6.2 Budget Considerations

SECTION UNDER CONSTRUCTION

6.3 Budget Development Contacts

SECTION UNDER CONSTRUCTION

7.0 SPECIAL CONSIDERATIONS & APPROVALS

7.1 The Institutional Biosafety Committee (IBC)

7.1.1 Overview & Scope of the IBC

The Institutional Biosafety Committee (IBC) establishes and implements policies that assure all activities involving recombinant deoxyribonucleic acid (DNA) research, infectious biologicals and biological toxins, and radioisotopes meet the ethical and legal requirements for the responsible use of these agents. The IBC ensures compliance with the National Institutes of Health (NIH) Guidelines and provides guidelines for the biosafety operation of research laboratories and the performance of laboratory and clinical research involving potentially hazardous biological agents.

The IBC is responsible for providing a safe working environment for all activities and compliance with all applicable federal, state, and local regulations concerning the research use of biological agents, biological toxins, and recombinant DNA.

Studies involving Recombinant Deoxyribonucleic Acid (rDNA) in humans must first be approved by the National Institutes of Health rDNA Advisory Committee (RAC), then by the Ochsner IBC, and finally by an Ochsner IRB. The Chair of the Institutional Biosafety
Committee can be reached through extension 2-6734 for any questions concerning this committee or gene therapy research in humans.

A gene therapy protocol cannot be submitted to IRB without prior approval by the Institutional Biosafety Committee. For more information, please contact the IBC at extension 2-6734.

7.1.2 IBC: Investigator’s Responsibilities

The investigator is responsible for full compliance with the NIH Guidelines in the conduct of recombinant DNA research and all conditions stated in the protocol approved by the IBC and must be appropriately trained to safely use biohazardous materials. (Please refer to Basic Science Administration Policy # 8465-B-2, “Roles and Responsibilities”)

An IBC protocol application must be submitted for all activities or modifications of activities involving recombinant DNA, infectious disease or biohazardous materials to the IBC for review and approval or disapproval prior to initiation.

IBC protocol applications may be obtained from the IBC Coordinator, who may be reached at extension 2-6734. All items on the IBC protocol application must be addressed, and the application must contain the investigator’s signature and date.

An updated Curriculum Vitae (CV) is required for each of the research personnel listed on the protocol application. The CV must be updated at least every two years for open protocols. The CV must be maintained for at least seven years on all closed protocols.

For additional information on the IBC application process, please contact the IBC office at extension 2-6734. Additional guidance may also be found on the Ochsner IRB website, by clicking on the link BioSafety Committee (IBC) Rules.

7.1.3 IBC Review

The IBC may take the following actions on protocols reviewed:

- **Final Approval**: The IBC considers that all significant points have been addressed by the investigator and that no question has been raised by any elements of the proposed study. As a result of this approval, the investigator has permission to conduct the experiments described in the proposal.

- **Approval Pending Clarification**: The proposal has no major problems but clarification on specific minor points is required. The Final Approval will be issued when the information is supplied without the necessity of further discussion by the full Committee.
• **Conditional Approval:** The IBC considers specified areas of the proposal inappropriate or problematic. The Final Approval will be issued when all the questions are answered and accepted by the full Committee.

• **Disapproval:** The reasons for disapproval are to be attached to the protocol and signed by the Chairperson.

• **Deferment:** It should also be noted that action on a protocol may also be deferred (i.e., the protocol tabled) pending the receipt of additional information and/or clarifications. Any such tabled protocols shall be reconsidered at the next convened meeting after receipt of requested information.

### 7.2 Radiation Control Committee (RCC)

#### 7.2.1 Overview & Description of the RCC

The RCC is responsible for the proper and safe use of all applications of ionizing radiation at all Ochsner sites and facilities. The safety of patients, employees, and visitors are all included in this responsibility.

Ionizing radiation is radiation from radioactive materials, as well as radiation from machines designed to produce such radiation (e.g., x-ray machines, linear accelerators). **Most research studies that involve the use of radioactive materials or machines that produce radiation must be approved by the Radiation Control Committee (RCC) prior to submission to the Institutional Review Board (IRB).** Studies which require, but do not have this approval will be tabled by the IRB until this approval is obtained. This will likely delay the start of the research study.

It is sometimes unclear to researchers whether a proposed research protocol requires RCC approval. The guides are as follows:

1. Any study using ionizing radiation with animals must have RCC approval.
2. Any study using ionizing radiation on pregnant women must have RCC approval.
3. Any study using ionizing radiation with humans must have RCC approval if the radiation exposure is done solely for the purposes of the study, and is not part of the standard of care of these subjects. If the radiation use is part of the accepted standard of care of these subjects, then RCC approval is not needed. This is true whether the radiation is from an accepted type of exam (e.g., a bone mineral density scan, or a CT scan), or a new, investigational exam.
If you are not sure whether your protocol requires Radiation Control Committee approval, please feel free to contact the Radiation Safety Officer (RSO) (ijones@ochsner.org) or the Chairman of the Radiation Control Committee (lwitherspoon@ochsner.org) for a clarification or ruling.

For additional information, please consult the RCC Rules Policy at the following web address: http://ochweb/documents/Academics/irb/IRBResearchRulesv2.rtf

Sometime in 2005, the RCC expects to have an Ochsner Intranet web site which will contain all forms and publications of the Committee, answers to FAQs, and other information deemed appropriate by the Committee.

7.2.2 RCC Application Materials

The following materials are required for submissions to the RCC for review of a research study involving radiation:

- The PI and/or research lab doing their own radiation procedures must have a current copy of the Ochsner Radiation Protection Manual. The manual contains explanations of the radiation safety procedures that are required, as well as a hardcopy of all the forms needed for submission to the RCC. Electronic copies of all the forms can be obtained from the Radiation Safety Officer via e-mail, or from the IRB website at: http://ochweb/documents/Academics/irb/IRBResearchRulesv2.rtf

- Depending on the type of radiation used, the PI must complete and submit one of the following applications:
  - For research involving the use of radioisotopes, the Application for Research Use of Radioisotopes form.
  - For all other types of radiation, the Application for Research Use of Radiation Producing Devices form.

- The informed consent form is required if the study uses human subjects.

- A copy of the research protocol itself is always required.

- If the researchers are going to perform the radiation exposures themselves, the PI must be an Authorized User of the radiation type to be used, which includes radioactivity, radiography, fluoroscopy, or accelerator. The RCC maintains a list of authorized users. The PI may apply to become an authorized user by submitting a completed Application for Approval as Authorized User form if needed.

- If the researchers are using a clinical service for the radiation exposure, they should indicate on the application that all the radiation safety measures will be handled by the clinical service. In this case, none of the researchers needs to
be an authorized user of radiation, because the clinical services have their own authorized users.

- Please submit the packet of materials to the Radiation Safety Officer or the Chairman of the Radiation Control Committee. A cover letter is recommended. Either hardcopy or electronic copy can be submitted.

7.2.3 RCC Review & Approval

Research submissions are evaluated by the RCC for radiation safety and compliance with regulations only. Protocols are not evaluated for scientific content or validity by the RCC. The Committee allows the Chairman (lwitherspoon@ochsner.org) and Radiation Safety Officer (jejones@ochsner.org) to review the submissions, request changes, and make a “preliminary approval,” but final approval is made by the Committee at one of its quarterly meetings. This is allowed so that IRB review of a proposed protocol may proceed without having to wait as long as a quarter for RCC review and approval.

Communications from the Committee chairman or RSO, such as requests for information or approval of the protocol, can be directed to either the PI or the person who submitted the forms (if different). As a result of an internal audit, the RCC also notifies the IRB or IACUC (as appropriate) and the Office of Research Administration of each preliminary approval.

Changes to the consent form requested by the RCC are generally independent of any requested by the IRB, and vice versa. If not, these two committees will work out the changes. This is to prevent the PI/submitter from being caught between these two committees. The version of consent form actually used in the research study should be the one finally approved by the IRB, and with the radiation-related changes requested by the RCC.

Following RCC approval, the PI/submitter should continue with the application process. It is also recommended that the preliminary approval note and final approval note, when issued, be kept by the PI/submitter as proof of approval.

Adverse Effects

Any adverse effects involving the radiation exposure must be reported to the RSO immediately. This is because for certain types of adverse effects, the RSO is required by law to make notifications within 24 hours.

Annual Reviews

The RCC also makes annual reviews of approved protocols. The RCC must be notified annually by the PI/submitter of any changes in procedure, equipment, or personnel (employees) in the protocol, and these changes must be approved by the RCC. While the RCC evaluates only the radiation safety and compliance with regulations, all changes must be reported to the RCC, since some changes can have hidden implications for radiation safety.
8.0 THE INSTITUTIONAL REVIEW BOARD (IRB) [21 CFR 50, 45 CFR 46]

All Ochsner Institutional Review Board (IRB) documents, policies, submission requirements, guidance documents and links to federal regulations are available on the Ochsner intranet through Academics ⇒ Institutional Review Board: http://ochweb/body.cfm?id=785 and on the IRB application site at https://ersa.ochsner.org.

8.1 Definition and Overview of the IRB

21 CFR Part 50, 56.102 (g) defines an Institutional Review Board (IRB) as, “…any board, committee or other group formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of, biomedical research involving human subjects. The primary purpose of such review is to assure the protection of the rights and welfare of the human subjects.”

The Institutional Review Board reviews research prior to implementation and on an ongoing basis. The primary function of Board review is to assure the protection of the rights and welfare of human subjects. The IRB also reviews the scientific method and merits of a study, although this is not the primary responsibility of the Board.

The IRB has authority to approve, disapprove, or require modifications to all research activities involving human subjects. The Board acts under the authority of the CEO of Ochsner Clinic Foundation and the federal human research subject protection regulations.

8.2 Scope of Authority: Federal Wide Assurance (FWA)

Under the terms of the Ochsner Clinic Foundation’s Federal Wide Assurance entered into with the Department of Health and Human Services Office of Human Research Protection, Ochsner has given the Institutional Review Board the authority to protect all human subjects involved in research at Ochsner, or in all other activities which even in part involve such research, regardless of sponsorship, if one or more of the following apply:

- The research is sponsored by the institution
- The research is conducted by or under the direction of any employee or agent of the institution in connection with his or her institutional responsibilities
- The research is conducted by or under the direction of any employee or agent of the institution using any property or facility of the institution or
- The research involves the use of the institution’s non-public information to identify or contact human research subjects or prospective subjects.
The Ochsner FWA is available for review on the IRB Website. A link to the FWA on the OHRP website is also available on the ERSA website at https://ersa.ochsner.org in the Related Links folder.

8.3 IRB Membership

Ochsner currently has three IRB Panels. Each panel meets the requirements of the regulations and includes representatives from:

- Scientific staff such as physicians, nurses, pharmacists, therapists
- Non-scientific staff such as OCF employees from non-clinical departments such as Information Services (IS), medical editing and pastoral care
- Non-affiliated members who are individuals from the community with no links to Ochsner through employment or immediate family relationships.

The panel has the option of inviting special consultants to attend the meeting if a study being reviewed includes a special population or procedure that may require a level of expertise to better understand the implications of the study for the subjects involved. Consultants may participate in discussion, but are not voting members.

There are special regulations that address panel membership for studies that include prisoners in the study population. This includes a human subject that becomes a prisoner after enrolling in a study. Should you find yourself in this situation, you should contact the IRB Office for special guidance.

9.0 PREPARING THE IRB SUBMISSION

9.1 Research Education Requirement: CITI Course in the Protection of Human Research Subjects

The CITI program site provides a comprehensive selection of educational modules that can be used to satisfy institutional requirements to educate researchers in the Protection of Human Research Subjects.

Ochsner requires completion of the CITI Course, Learner Group II: Investigators and Clinical Research Coordinators—drug or device studies NOT including the VA This level CITI course must be completed by all persons involved in research regardless of the use of drug or device in the protocol.

Required modules to be completed will be indicated on the CITI course site in the researcher’s Grade Book under “Required Modules.” As the researcher completes modules, the Grade Book will be updated with quiz scores and completion dates.
Verification of successful completion of this course will be required PRIOR to submitting a protocol to the IRB. Each module has a short quiz of approximately 2-5 questions. To have a successful completion, researchers must obtain a 70% or better on the total number of questions for the required modules. The modules do not have to be completed all at once. The researcher may login/logout at his/her pace.

To obtain a username and password and to access the CITI course please go to the following web address: www.citiprogram.org. For questions regarding the CITI Course, please contact the IRB office (ext. 2-3535 or IRB@ochsner.org).

9.1.1 Instructions for Registering & Accessing the Basic CITI Course

1. Access to the CITI Course website at: http://www.citiprogram.org
2. Click on the link, Register for the CITI Course.
3. Select Ochsner Clinic Foundation from the list of selections under All Others, and click on the Submit button.
4. Create your username, password and reminder phrase. Click on the Submit button.
5. Fill in the required fields and complete the CITI Registration Page. When the Registration Page is filled out, click on the Submit Information button.
6. Review the Information from your institution by clicking on the link provided.
7. Select groupII and click on the Submit button.
8. Answer the question as to whether you have previously completed the Basic CITI Course by clicking on the appropriate response (Yes or No). Click on the submit button.
9. Click on the Basic Course (Required) link, and begin the CITI course modules.

9.1.2 CITI Course Completion

When all Group II CITI Course modules are complete, click on the link to View completion report. Print out a copy of the completion report for your records. The University of Miami will send a completion report to the Ochsner Clinic Foundation. Upon receipt of your completion report from the University of Miami, the Ochsner Clinical Research Department will issue you a CITI Certificate indicating successful completion of the Basic CITI.

9.2 Completing the Initial Full IRB Application

Known as ERSA (Electronic Research Study Application), the IRB’s application system is completely electronic and available on the internet at https://ersa.ochsner.org.

The following is a list of items that must be completed and/or electronically attached in with the initial application for a new research project. These items apply to all studies, except studies that...
are solely retrospective chart reviews. Please note that IRB approval must be granted PRIOR to carrying out any study-related procedures.

- All researchers listed in the application (e.g. PI, Sub-I, CRC) must complete the CITI Course in the Protection of Human Research Subjects (please see section 6.1).

- The initial IRB application is only available through the IRB’s ERSA system. All materials related to the research must be attached in electronic format.
  - In order to access the online system, you must first register for a user name and password by going to https://ersa.ochsner.org and click on the Registration link in the box to the right of the screen. Please complete all registration fields, not just those marked as required. User names and passwords are only issued after verification of CITI completion and user-appropriate training in the system.
  - ERSA can also be accessed from the Ochsner intranet, go to the IRB website (“Academics” → “Institutional Review Board”). Click on the “ERSA” link.
  - Training is available in small groups or one-on-one for entering a new application to the system. Please contact the IRB office at x23535.
  - Guidebooks are available on the ERSA home page in the Guidance Documents folder.

- Research Protocol

- Informed Consent Document (see Section 11.0). Note that only the approved version(s) of the informed consent templates, found in the Forms and Templates folder on the ERSA home page, can be used.

- Copy of the PI’s Medical License [not required for those formally on staff at Ochsner. The Ochsner credentialing department or GME has these documents and will make them available to the IRB as needed]

- Copy of all investigators’ (PI’s & Sub-I’s) Curriculum Vitae (CV) [not required for those formally on staff at Ochsner or in an Ochsner residency program. The Ochsner credentialing department or GME has these documents and will make them available to the IRB as needed.]

- Other supporting documents (when applicable):
  - Research Grant
  - Advertisement for study recruitment
  - Patient education documents or tools
  - Telephone script
Letters to be sent to patients or doctors

Investigator’s Brochure

IND Exemption Form

Device study documentation

Radiation Safety Committee Review (for studies that involve use of radiation such as X-rays, CT scans, or radioactive substances. See section 7.2). [Note: Confirmation that this review has been conducted, when applicable, is electronically documented in the ERSA system. RCC must electronically issue approval prior to the study’s advancement to the IRB office.]

Biosafety Committee Review (for studies that involve gene therapy or biohazardous materials). Please see section 7.1 for more details. [Note: Confirmation that this review has been conducted, when applicable, is electronically documented in the ERSA system. The Biosafety Committee must electronically issue approval prior to the study’s advancement to the IRB office.]

Employee non-coercion statement (for studies that recruit OCF employees). This form is available on the ERSA website in the Forms and Templates folder.

When all fields are completed, click on Check Required Data to make sure nothing has been missed. Incomplete fields will prevent the PI from submitting the study for review.

If the names of investigators appear in the financial disclosure box, please click Notify for financial disclosures. Check the boxes for those to whom a reminder message should be sent. Until all financial disclosures are completed (no names appear in the box), the PI will not be able to submit the study for review.

When all questions have been properly entered, click on Notify PI Data Entry Complete. An e-mail will be sent to the PI to submit the study application for IRB review.

You may use the Printer Friendly button to print a copy of your application for your regulatory files.

9.3 Completing the Retrospective Chart Review Application

The ERSA system is programmed to provide the user only the applicable pages of the application based on the answers to identified key questions. On the initial application in ERSA,
the user should check retrospective chart review box on the Type of Research. **Please do not check any other boxes on that page.** The following is a list items that must be completed and/or turned in with studies that involve only retrospective chart reviews. Please note that IRB approval must be granted **PRIOR** to carrying out any study-related procedures.

- All researchers listed in the application (e.g. PI, Sub-I, CRC) must complete the CITI Course in the Protection of Human Research Subjects (please see section 9.1).

- Data Extraction Form. This form lists the general data that will be extracted from the medical record. This could be in the printout of the excel spreadsheet you have set up for your data collection, or a memo that details what your data fields will be (i.e., what data will you be abstracting from the charts?)

- Other supporting documents (when applicable):
  - Research Protocol
  - Informed consent document (See section 11.0). The majority of retrospective chart reviews will qualify for a waiver of informed consent under 45 CFR 46.116(d).
  - CV for Ochsner non-physician investigators
  - CV for non-Ochsner investigators
  - When all fields are completed, click on Check Required Data to make sure nothing has been missed. Incomplete fields will prevent the PI from submitting the study for review.
  - Note: Financial disclosures are not necessary for chart review studies. Although investigator names will populate to the disclosure box, the PI should still be able to submit the study with out completion of disclosures. This is for retrospective chart reviews **only**.
  - When all questions have been properly entered, click on Notify PI Data Entry Complete. An e-mail will be sent to the PI to submit the study application for IRB review.
  - You may use the Printer Friendly button to print a copy of your application for your regulatory files.

**9.4 Completing the Continuing Review Application**

Federal regulations allow the IRB to approve a study for a period of no greater than one year. A study requires completion of a continuing review application if the IRB approval date is approaching expiration **and** participant involvement is ongoing or data analysis is ongoing.
If data analysis is complete, the study must be closed-out with the IRB. To close out or terminate the study with the IRB, indicate study completion on the Continuing Review application under Study Status.

Continuing review applications should be submitted far enough in advance to allow sufficient time for IRB review prior to the expiration date. The IRB approval must not lapse if patient involvement or data analysis is ongoing.

The following is a list of items required for the continuing review application:

- The IRB continuing review application is created through the approved study in the ERSA system.
  - Login to the ERSA system, click on the study title on the Approved Studies tab, and click on New Continuing Review.
  - Complete all required fields as well as those fields that are not tagged as required but for which you have related information.
  - When all questions have been properly entered, click on Notify PI Data Entry Complete. An e-mail will be sent to the PI to submit the continuing review application for IRB review.
  - You may use the Printer Friendly button to print a copy of your application for your regulatory files.

- When applicable, a summary of adverse events and/or a DSMB report should be submitted with the continuing review application for panel review and consideration.

9.5 Completing the Study Revisions & Amendments Application

Revisions to the protocol, informed consent, or any other aspect of the study may not be implemented prior to IRB approval.

The following is a list of items required for the study revisions application:

- Verify that all researchers not already listed in the application who are to be added to the study staff (e.g. PI, Sub-I, CRC) have completed the CITI Course in the Protection of Human Research Subjects (please see section 9.1).

- Login to ERSA. From the Approved Studies tab, click on the study title. Click on New Amendment. [Note: ERSA will only allow one amendment application in the system at any given time. However, you can have multiple amended items attached to a single application. Please call the IRB office at x23535 if questions arise.

- The system will present the user with the required application pages based on the revisions indicated on page one of the application.
• Complete all required fields in the application and provide additional information where appropriate.

• Other supporting documents (when applicable):
  
• Revised protocol (for revisions to the protocol). Please highlight the revisions to the protocol.

• Revised Informed Consent (for revisions to consent). Please use the approved version of the consent form from the Documents tab of the study. Changes made will be automatically tracked (redlined). Attach only the redlined copy to the electronic application. Remove any documents automatically populated by the system.

• Investigator CV (for addition of a non-Ochsner investigator)

• Other supporting research documents that require revisions. Please track revisions to these documents using Track Changes.

9.6 Exempt Research Requests

Exempt research does not require IRB approval; however, Ochsner policy assigns the determination of exempt status to the IRB Chairman. This determination is not at the discretion of the investigator.

Research may be exempt from IRB review if one or more of the following applies (from the Ochsner IRB policy on Exempt Research):

1. There is no intervention or interaction with a living person that would not be occurring or would be occurring in some other fashion but for this research AND there is no identifiable private information/data obtained for the research in a form that can be associated with an individual (i.e. the identity of the subject is or may readily be ascertained or associated with the information). 45 CFR 46.102 (f)

   OR

2. The research uses solely existing data or specimens (i.e. already on the shelf and collected prior to the research for a purpose other than the proposed research) AND either the data or specimens are publicly available, or the information will be recorded in such a way that it cannot be linked to the subject. 45 CFR 46.101 (b) (4)

   OR

3. Research involving survey or interview procedures with adult subjects unless the information obtained is recorded in such a manner that the subjects can be identified, and the information obtained could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation. 45 CFR 46.101 (b) (2)
• To obtain this determination, an initial application must be submitted in ERSA.

Additional guidance on exempt research can be found at:

• 45 CFR 46.101 (b) [Protection of Human Subjects]

9.7 Research Registry Applications

Research Registries are databases that contain data/information on specific patient populations that are maintained for future, yet-to-be-determined research. To submit a research registry for approval, please follow the instructions for an initial application/retrospective chart review (section 9.3).

Please note that any proposed research using the data from the registry must have approval from the IRB as a separate study prior to beginning the study. The IRB approval of the registry does not transfer to any study using that data.

9.8 Emergency Research

Emergency research is rarely utilized. Emergency use is defined as, “…the use of a test article on a human subject in a life-threatening situation in which no standard acceptable treatment is available, and in which there is no sufficient time to obtain IRB approval” (21 CFR 50, part 56.102 (d)).

Emergency use of a Research Device is also subject to Federal Regulations and must meet certain conditions. For additional information and requirements for emergency research, please consult the IRB intranet site or contact the IRB Office (ext. 2-3535).

10.0 IRB REVIEW OF APPLICATIONS

10.1 Criteria for IRB Approval (21 CFR 50, 56.111)

When reviewing applications, the IRB takes into consideration the following elements:

• Risks to the human subjects are minimized
• The risks to subjects are reasonable in relation to anticipated benefits.
• Selection of subjects is equitable.
• Informed consent will be sought from each prospective subject or legally authorized representative (LAR).
- Informed consent will be documented appropriately.

- Provisions exist for monitoring the data collected and overseeing the safety of subjects.

- Provisions to protect the privacy of subjects and confidentiality of data

- Ensure advertisement and recruitment methods are consistent with the protocol and consent process.

- Adequate measures exist to protect the privacy of subjects and to maintain confidentiality of the data.

- Additional safeguards are in place to protect the rights and welfare of vulnerable subjects.

10.2 Types of Review

10.2.1 Full Panel Review

Full Board Review is required for all research that is greater than minimal risk, particularly those studies involving the use of investigational drugs, investigational devices, or procedures (any federally regulated study).

The Ochsner IRB has three approved panels that meet on a monthly basis. Protocols for review must be received 10 working days before the panel meeting. However, if the panel agenda is full, protocols will be moved to the next available panel. All applications are processed on a first-come first-served basis. Incomplete submissions will not be accepted for review and are placed back in the cue for processing based on the date the completed application is received. (Dates and deadlines for meetings are available on the ERSA home page in the Contact Us folder).

10.2.2 Expedited Review (50 CFR 56.110, 45 CFR 46.110)

Expedited review is allowed for minimal risk studies and for minor changes in approved research. Categories of research that may be reviewed by an IRB using an expedited review procedure include:

- Research on drugs for which an investigational new drug application is not required (21 CFR Part 312).

- Research on medical devices for which an investigational device exemption application is not required; or the medical device is cleared/approved for marketing and the medical device is bind used in accordance with its cleared / approved labeling

- Collection of blood samples by finger stick, heel stick or venipuncture if specific criteria are met
- Prospective collection of biological specimens for research purposes by non-invasive means, for example, hair or nail clippings or placenta removed at delivery.

- Collection of data through non-invasive procedures routinely employed in clinical practice (excluding procedures that involve x-rays or microwaves)

- Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis)

- Collection of data from voice, video, digital or image recordings made for research purposes

- Research on individual or group characteristics or behaviors, or research employing survey, interview, oral history, focus group, program evaluation, or quality assurance methodologies.

- Continuing review of research previously approved by the convened IRB where
  - the research is permanently closed to the enrollment of new subjects
  - all subjects have completed all research related interventions
  - the research remains active only for long term follow up or subjects
  - no subjects have been enrolled and no additional risks have been identified
  - the remaining research activities are limited to data analysis

- Continuing review of research not conducted under an investigational new drug application or investigational device exemption where the above categories do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Please note that “expedited review” does not imply that the study is reviewed more quickly. Expedited review indicates that the review does not need to be done by a full board review; it can be done be a single reviewer. The determination of expedited review is at the discretion of the IRB using the listed criteria. It should also be noted that an expedited reviewer cannot disapprove a study. If there are concerns on the part of the expedited reviewer, the study must go to a full board for review.

An investigator submitting a protocol for expedited review can use the “Check list for expedited review” available on the IRB intranet site to assist in determining if the protocol will meet expedited criteria. Retrospective chart reviews are the types of studies most commonly meeting the expedited review criteria.
11.0 INFORMED CONSENT

Informed consent is an ongoing process that is designed to provide information to a potential study subject to enable him/her to make an informed decision as to whether or not to participate in the research. It is designed to ensure that subjects’ rights are protected and that subjects understand that participation is voluntary.

Informed consent is based on the three basic ethical principles of the Belmont Report, 1979 (Product of Nuremberg, Helsinki and the National Research Act of 1974): Respect for Persons, Beneficence and Justice. For more information on the Belmont Report, please see section 1.1.

The Informed Consent document is paramount to the protection of human subjects. It must be written in lay terms that realistically addresses the risks and benefits of the study. It should state fairly and objectively the purposes of the research study and information about subject participation.

11.1 Consent Requirements

11.1.1 Basic Required Elements of Informed Consent

The FDA, DHHS, OHRP and the respective Institutional Review Board regulate informed consent to assure compliance with the regulations. The Code of Federal Regulations (21 CFR Part 50.25 and 45 CFR Part 46.116) outline the basic required elements for informed consent. These basic required elements include:

1. A statement that the study involves research; an explanation of the purposes of the research and the expected duration of the subject’s participation; a description of the procedures to be followed, and identification of any procedures that are experimental.

2. A description of any reasonably foreseeable risks or discomforts to the subject.

3. A list of any benefits to the subject or to others that can be reasonably expected from the research.

4. A disclosure of any alternative procedures or treatments, if any, that may be advantageous to the subject.

5. A statement describing the extent, if any, of which the confidentiality of records that identify the subject will be maintained. Include a statement of the possibility that the FDA may inspect the records (21 CFR).

6. For research involving more than minimal risk, an explanation of whether any compensation and whether any medical treatments are available if injury occurs, and if so, what they consist of or where further information may be obtained.
7. Information on who to contact for answers to questions about the research, research subjects’ rights and who to contact in the event of a research-related injury to the subject.

8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time.

11.1.2 Additional Required Elements of Informed Consent

When appropriate, 21 CFR Part 50.25 (b) and 45 CFR 116 (b) require that one or more of the following elements should also be provided to subjects:

1. A statement that the treatment or procedure may involve risks to the subject (or to the embryo or fetus if the subject is or may become pregnant) which are unforeseeable.

2. A description of anticipated circumstances under which the investigator may terminate the subject’s participation without the subject’s consent.

3. A description of any additional costs to the subject that may result from participation in the research.

4. Describe the consequences of a subject’s decision to withdraw from the research and procedures for the subject’s orderly termination of participation.

5. A statement that significant new findings developed during the course of the research which may relate to the subject’s willingness to continue in the study will be provided to the subject.

6. The approximate number of subjects involved in the study.

11.2 Informed Consent Template

The approved version(s) of consent form templates are found in ERSA’s Forms and Templates folder. The website is updated frequently, and the latest version of the informed consent must always be used.

Additionally, any informed consent should be written clearly, in lay terms, and at a fifth grade reading level. For assistance with lay language, there are resources available in the IRB office as well as a useful website listed in the Related Links folder in ERSA.

11.3 Revisions to the Informed Consent

In the event that changes in the protocol require changes to be made to the informed consent during the study, then the new version of the consent form must be reviewed and approved by IRB and sponsor prior to implementation. If necessary, each currently enrolled patient must be re-consented as directed by the IRB using the approved, revised version of the informed consent.
All versions of the informed consent must be kept on file and never discarded.

11.4 Basic Informed Consent Process

11.4.1 General Information About the Consent Process

In order for consent to be valid, the following items should be attained:

- The participant must be **COMPETENT** to begin the informed consent process. If the participant is not competent because of age, illness, incapacity, or any other reason, special provisions apply, or the participant may not be included in the research.
- The research team must **DISCLOSE** all relevant information to the potential participant. The information must be sufficient to allow the potential participant to decide whether to participate. It is generally accepted that the participant must be given the following information: the purpose of the study; nature of the procedures; reasonable alternatives to the proposed intervention; and risks, benefits, and uncertainties of each possible intervention.
- The participant must **COMPREHEND** the information. The research team must evaluate the potential participant’s ability to understand the proposed intervention in the study.
- The participant must **AGREE** to the proposed intervention in the research study.
- The participant’s agreement must be **VOLUNTARY** and free from coercion.
- Participants must be informed that even after they have made a voluntary agreement to participate in the study, they may **WITHDRAW** such agreement at any time without penalty.
- **Advertisements, fliers, or brochures prepared to recruit and inform potential participants about a study are considered part of the informed consent process** and, as such, also require review and approval by the IRB prior to implementation. These items should be included in the initial application or, if not available at that time, submitted as an amendment.
- Study protocols are often changed during the course of the study. When these changes require revision of the informed consent document, the IRB should have a system that identifies the revised document, in order to preclude continued use of the older version and identify file copies. **The most recently approved version of the informed consent should always be used.**

11.4.2 PI Responsibilities

The PI has several responsibilities in regards to ensuring that the informed consent document complies with federal regulations and that the informed consent process is carried out correctly and in compliance with federal regulations and institutional policies. These responsibilities include:
1. Confirm that the Informed Consent Form (ICF) contains the required elements (21 CFR Part 50.25 and/or 45 CFR Part 46.116). Confirm that the consent is in compliance with Good Clinical Practices (GCP) guidelines. The PI may delegate the development and processing of the ICF to appropriate personnel.

2. Ensure that the consent form is written in a language that human subjects can comprehend. The consent form should not contain language that is exculpatory or that waives or appears to waive any of the subject’s rights.

3. Obtain IRB approval of the informed consent (IC) prior to initiating the consent process with any potential subject.

4. Provide sufficient time for a potential subject to decide whether or not to participate in the study.


6. Obtain informed consent prior to enrolling a patient in the study. No study procedures may be performed prior to obtaining informed consent.

7. The P.I. is responsible for making certain that the written consent form and any other written information provided to subjects is revised whenever important new information becomes available that may be relevant to the subject’s willingness to participate. The P.I. may delegate to appropriate clinical research personnel the development and processing of the revised consent form or any other written information to be provided to subjects. Any such revisions should receive IRB approval prior to use.

8. The principal investigator may delegate the duty of obtaining informed consent to appropriate clinical site research personnel. However, the principal investigator is responsible for assuring that any such designated member of the research team is knowledgeable about the specific research study and the process of informed consent.

11.4.3 Consent Procedures:

The following is an outline of the basic procedure for obtaining written informed consent. Please note that this is a guide for obtaining informed consent in accordance with the major ethical principles outlined in the Belmont Report and federal regulations.

1. Informed consent will be obtained for each research subject prior to altering a subject’s care for the purpose of research. The consent must be obtained according to sponsor, IRB and GCP requirements.

2. Upon identification of a potential subject, the P.I. or designee will be responsible for identifying who is legally authorized to give consent. If the potential subject is physically or mentally unable to provide consent, then the
legally authorized representative may be approached to give consent. Careful attention should be given to reviewing the potential subject’s medical history to alert the researcher to any potential impairment to informed consent.

3. The P.I or designee will fully inform the potential subject or the subject’s legally authorized representative of all pertinent aspects of the trial including the written in formation as approved by the IRB. Provide the potential subject with adequate information concerning the clinical investigation in language that is as non-technical as possible (lay terms).

4. Provide ample time and opportunity for the potential subject to read the information provided in the ICF and any other educational materials. Allow sufficient time for the potential subject to discuss the information with his/her support group (e.g. family, friends, clergy). Allow potential subjects the opportunity to inquire about the details of the clinical trial and to decide whether or not to consider other available options, if any.

5. Respond to subject’s questions – all questions about the trial should be answered to the satisfaction of the subject.

6. Ensure that the subject has comprehended the information. Have the subject repeat the purpose of the study back to the individual obtaining consent (the principal investigator or the investigator’s designee).

7. Obtain the subject’s voluntary consent. The written consent should be signed and personally dated by the subject or the subject’s legally authorized representative and by the person who conducted the informed consent discussion. In addition, the subject or subject’s legally authorized representative must initial/date each page of the informed consent document themselves; no one else should initial/date the pages for the subject. Other signatures must be provided as required by the sponsor and/or IRB if specified on the IRB-approve consent.

8. Informed consent is documented by using the current written ICF as approved by the IRB. The investigator or designee must file the original signed ICF with the subject’s research records and/or case report forms (CRF). A copy of the completed ICF must be provided to the subject (or the subject’s LAR).

9. The investigator or his designee will document in the subject’s medical records that informed consent was obtained. This documentation should include that informed consent was obtained prior to the subject’s participation in the investigation; and that no study-related procedures were performed prior to obtaining informed consent.

10. Informed consent is an on-going process throughout the course of the study. At each visit, the investigator or the investigator’s designee should ask the study participant if he/she wishes to continue on the study. If the study participant wishes to discontinue being on the study at any point, then the
participant should be taken off the study. It is important to document this information with each study visit.

11. The subject should be informed in a timely manner if new information becomes available that may be relevant to the subject’s willingness to participate in the trial. The communication of this information should be well documented.

12. If the written consent is revised during the course of a subject’s participation in the trial, then the subject shall be re-consented by the P.I or designee with the revised IRB-approved consent form. The investigator or designee will file the newly obtained, signed ICF with the subject’s research records and/or case report forms (CRF). A copy of the completed consent form will be provided to the subject (or the subject’s LAR). Another copy will be filed in the subject’s medical record.

11.5 Special Circumstances and Considerations throughout the Consent Process

11.5.1 IRB Oversight of the Consent Process

The IRB has the authority to observe, or have a third party observe, the consent process and the research. (Ochsner IRB SOPs Section VI (b)).

11.5.2 Subjects Who Cannot Read (Illiterate) or Write

If a study subject cannot read or write, the consent form should be read to him/her in full, in the presence of a witness. The witness should sign the consent form attesting to the fact that the study participant has voiced an understanding of what he/she is signing. It is preferable that the witness be a third party impartial witness. This entire procedure should be documented in the medical record by the investigator/CRC.

If the subject or the subject’s legally authorized representative is unable to read, the IRB-approved consent must be read in its entirety in the presence of an impartial witness. This should be documented directly onto the consent and signed by the witness accordingly.

11.5.3 Subjects Who Do Not Speak English

If the subject does not speak English, the consent form must be translated into whatever language the subject speaks and understands. The informed consent document must be translated in its entirety, and sections should not be omitted. This version of the consent form must be approved by the IRB prior to the patient being consented and enrolled.

For more information on this topic, please refer to Ochsner Policy 8614-3, Translating Documents in a Foreign Language.
11.5.4 Pediatric Assent (45 CFR 46.408; 21 CFR 50.27, ICH 4.8.11)

**Assent** is a child’s affirmative agreement to participate in research. Mere failure to object, absent affirmative agreement, should not be construed as assent (45 CFR 46.402b).

**Permission** means the agreement of parent(s) or guardian to the participation of their child or ward in research (45 CFR 46.402b).

Children (minors) are persons who have not attained the legal age for consent to treatments or procedures involved in the research. Pediatric assent must be obtained according to federal regulations and institutional policy.

**Children age 12 years or younger** are not required to provide written assent. However, the PI must document that an appropriate conversation with the child was conducted. The 0-12 assent form, completed by the PI, is available in Forms and Templates folder on the ERSA homepage.

**Children ages 13 -17 years** must provide assent using the Assent Box at the end of the consent form. A copy of the Assent Box is located in the Forms and Templates folder in ERSA.

**A minor’s dissent** (refusal to participate) overrides parental permission except when the research offers the child the possibility of a direct benefit that is important to his/her well-being and is only available in the context of research.

The following categories apply to research involving children:

- **Category 1 (45 CFR 46.404)**—Research not involving greater than minimal risk
- **Category 2 (45 CFR 46.405)**—Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subject.
- **Category 3 (45 CFR 46.406)**—Research involving a minor increase over minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subjects disorder or condition.
- **Category 4 (45 CFR 46.407)**—Research not fitting into categories 1 through 3, which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

The IRB makes the determination for the category of research.

If the research is Category 1 or 2 research, only one parent is required to give permission for the child to participate in the research study. The IRB does not require both parents to give permission.

If the research is classified as Category 3 or 4 research, federal regulations require both parents to give permission for a child to participate in research.
State law determines who the Legally Authorized Representative is if parents are absent

11.5.5 Research Involving Prisoners

Prisoners may only be consented and enrolled in clinical trials if specific written approval is obtained from the IRB.

11.5.6 Revisions to the Informed Consent

If the Sponsor or IRB requires any changes to the consent form during the study, then currently enrolled study participants affected by the changes will need to be re-consented with the new, revised consent form. Your IRB approval letter will state the requirement for re-consent when applicable.

11.6 Documentation of Consent (45 CFR 46.117)

All study documents should be retained for at least 10 years after the close of the study per Ochsner Policy 8042-5 (Management of Test Articles). The Sponsor may request that documents be preserved for a longer time period. This information must be kept in a locked area with restricted access, and the sponsor should be consulted prior to disposing of any study related information.

- In addition to signing the informed consent, study participants must initial each page of the informed consent themselves and each page must be numbered “page 1 of 6” etc.
- A signed copy of the consent form must be given to the patient and a note placed in the medical record to this effect. It is essential to document that a copy of the signed consent form was given to the patient.
- The original signed consent document must be placed in the study binder or research file.
- A copy of the signed informed consent must be placed in the medical record.
- Both the investigator and the Clinical Research Coordinator (CRC) must document in the medical record that the patient signed the consent form after it was explained in detail and after the patient’s questions were answered. Assessment of his/her understanding and willingness to volunteer should be noted.
- Documentation should also state that no study-related procedures were completed prior to the consent being signed by the participant.
- All versions of the consent form are legal documents and must be kept as part of the study file.
- Informed consent is an ongoing process throughout the course of the study. The study participant should be asked at each visit if he/she wishes to continue participation. If the study participant wishes to withdraw their consent to participate at any point, then
the subject should be taken off the study. It is important to document this information with each study visit.

- A sedated patient should never be asked to sign a consent form.

11.7 Helpful Reminders

- No study-related procedures should be performed without an informed consent being signed first.
- Documentation of consent should state that no study-related procedures were completed prior to the consent being signed by the participant.
- The most recently approved version of the ICF must be used.
- A sedated patient should never be asked to sign a consent form.
- Study participants MUST initial each page of the informed consent themselves and each page must be numbered “page 1 of 6” etc.
- All versions of the completed ICF must be kept in the subject’s study file.
- If there is a new version of the informed consent, then all subjects currently on study must be re-consented with this current version (if required by IRB).
- The date of each version should be on each page, and the IRB approval date should be clearly marked on every page of the informed consent.
- Informed consent is an ongoing process throughout the course of the study. The study participant should be asked at each visit if he/she wishes to continue participation. If the study participant wishes to withdraw their consent to participate at any point, then the subject should be taken off the study. It is important to document this information with each study visit.

12.0 ADVERSE EVENT REPORTING

12.1 Definitions

12.1.1 Adverse Event (AE)

ICH Guidelines state that an adverse event is “Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment” (ICH 1.2)

12.1.2 Adverse Drug Reaction

This is defined as “all noxious and unintended responses to a medicinal product related to any dose” (ICH 1.1), where a causal relationship is possible.
12.1.3 Serious Adverse Event (SAE)

A Serious Adverse Event (SAE) is any experience resulting in one or more of the following outcomes:

- Death
- Life-threatening event
- Requiring or prolonging hospitalization
- Causing significant and persistent incapacity or disability
- Causing a congenital abnormality
- An important medical event necessitating intervention to prevent one of the above outcomes

12.2 Reporting Adverse Events to the Sponsor

This adverse event reporting process is guided by federal regulations (21 CFR 312.64). It is the investigator’s responsibility to determine the severity, relationship and causality of all adverse events (AEs) and serious adverse events (SAEs).

It is very important for patient safety purposes to report adverse events promptly. All adverse events must be reported by the investigator to the sponsor in a timely manner, regardless of causality or severity. Adverse events must be reported to the sponsor using the appropriate case report form.

The investigator is responsible for reporting serious adverse events to the sponsor and the IRB of record. Serious adverse events (as defined in section 11.1.3 and/or in the research protocol) must be reported to the sponsor immediately. The reporting time frame requirements (i.e. within 24 hours of discovery) for SAEs should be specified either in the protocol or in a standard operating procedure (SOP).

Adverse experiences which are probably related to study drug should be reported promptly to the sponsor. All others should be recorded on the appropriate CRF and submitted to the sponsor in a timely manner.

Following the initial report of a serious adverse event, it is usually necessary to send the sponsor follow-up reports and final reports on the outcome of the SAE. Copies should be maintained in the study file.
12.3 Reporting Adverse Events to the IRB

FDA regulations are silent on AE reporting and IRBs. The term adverse event is not in the IRB/consent regulations of either FDA or HHS. However, Federal regulations require prompt reporting to the IRB, OCF, and federal officials of “Any unanticipated problems involving risks to human subjects or others” [21 CFR 56.108(b)(1) for FDA and 45 CFR 46.103(b)(4)(iii) for HHS]. Some AEs fall into this category. Other events that are not AEs also fall into this category.

According to federal FDA regulations, adverse events are the responsibility of the sponsor and not the IRB. Only when an adverse event rises to the level of an unanticipated problem involving risks to subjects and others (or an unanticipated adverse device effect) do the regulations require reporting to the IRB. As the FDA guidance at http://www.fda.gov/OHRMS/DOCKETS/98frc/07d-0106-gdl0001.pdf clearly states, isolated external adverse events rarely fall into this category because they require analysis with some knowledge of denominators and comparisons to event rates in similar populations that neither an IRB nor a PI will know. Therefore, most external adverse events should be reported to the IRB only indirectly through Data Monitoring Committee reports or similar sponsor-analyzed aggregate analysis reports.

In accordance with the above-referenced FDA Guidance, a summary statement from the sponsor of the aggregate data analysis stating whether any changes are needed to the consent and protocol of the study must accompany external adverse events reported to the IRB.

Best practice is to submit regular reports from the study’s Data Monitoring Committee, sponsor adverse event committee or similar group in lieu of submitting detailed individual external adverse event reports to the IRB.

An exception exists if an event is deemed to have a direct link to the test article that is so important that everyone must be notified immediately. In this case, the aggregate analysis from a DMC or other sponsor group should be bypassed (refer to the previously mentioned FDA guidance which explains such exceptions, e.g., agranulocytosis, hepatic necrosis, Stevens-Johnson syndrome).

12.4 Reporting unanticipated problems involving risks to subjects (not necessarily an adverse event) (45 CFR 46.103(b)(5)).

Required reporting to the IRB of “Any unanticipated problems involving risks to human subjects or others” includes events that are not usually considered AEs. Examples might include:

- A research laptop is stolen that has confidential information on your AIDS research subjects
- The PI is arrested on an illegal drug charge and the state suspends his/her medical license
- In a study that requires close monitoring of drug levels, the lab contacts the PI and states that levels reported last week were significantly in error.
- A subject becomes pregnant in a thalidomide study

These might not be considered AEs, but must be reported to the IRB within 10 days, and may be brought to the full IRB Panel for review.

12.5 IND/Medwatch Reports

IND/Medwatch reports are safety reports generated by the sponsor and FDA concerning adverse events occurring at other sites involved in a particular clinical study. These reports must be reviewed by the Investigator. The CRC at the participating site should keep them as part of the study file. Outside AE reports should only be reported to the IRB as indicated in the exception in section 1.1 of this manual.

13.0 INDEPENDENT DATA MONITORING COMMITTEE (IDMC, DMC, OR DSMB)

An independent data monitoring committee is established to review interim results of a research study and to evaluate safety reports. In the event that a clinical trial does not appear to be safe or if results show that the trial should be stopped early (either due to dangers or due to the scientific goals being reached early) then the IDMC would recommend this and report to the Sponsor who would report this to the FDA and IRB. The IDMC could be comprised of independent physicians and other individuals who have been appointed to monitor the progress of the study. The preferred ICH term is DMC or IDMC. Another common term for this is a data safety monitoring board or DSMB. These are all interchangeable terms. For more information consult the IRB Website at http://ochweb/documents/Academics/irb/DSMB.doc and http://ochweb/documents/Academics/irb/DSMB.pps

14.0 RESEARCH DOCUMENTATION

Study documentation is a very important component of research. A study should not commence until the necessary documents are on file. Furthermore, all study visits and communication with research subjects should be documented. Below are some types of research documentation to consider prior to initiating a study.

14.1 Regulatory Binder(s)

The Study Binder contains all the regulatory information for the study. This binder must be maintained at the site, and it should be updated throughout the course of the study. The Regulatory Binder provides an audit trail and indicates how the study was conducted. The regulatory binder should never be destroyed or dismantled. The Regulatory Binder, along with all other study documents should be retained in a locked area with restricted access. After the research study is closed, the Regulatory Binder should be stored with the other study documents.
for the amount of time specified by federal regulations, the sponsor or the institution (whichever is longest).

In the event an Investigator leaves Ochsner Clinic Foundation, the original study data must be transferred to Research Administration to be kept on file at Ochsner Clinic Foundation. The Investigator may retain copies of the data.

14.2 Documents to maintain in the Regulatory Binder(s)

Regulatory documents consist of all study-related paperwork; any records, reports, or correspondence generated regarding the clinical trial. It is necessary to maintain a Study Binder as it documents the course of the study, and provides an audit trail of information about the study.

Before beginning a clinical trial, the Principal Investigator or CRC must compile the following documents (and retain respective copies in the study file):

- **FDA Form 1572** for pharmaceutical trials, or the **Investigator Agreement** for device studies.
  - This form is a legal document; it is signed by the PI as an agreement to comply with federal regulations.
  - Never discard an outdated FDA Form 1572; keep it in the study binder. Never alter a Form 1572 or use correction fluid on it.
  - Send the original to the Sponsor and keep a copy of the FDA 1572 on file.
  - Make sure that the form has not expired; if this is the case a new FDA 1572 form should be completed and sent to the sponsor. A copy should be sent to the IRB, and another copy kept on file in the regulatory binder.
  - Keep all expired versions of the FDA 1572.

- **Regulations require that all sub-investigators (including residents and fellows) who participate in the research (e.g. administer the study intervention or study-related procedures and follow-up) be listed on this form.**

- Signed, dated, current Curriculum Vitae (CV) for all Investigators listed on the FDA Form 1572 (or Investigator Agreement).

- Copies of the Investigator and Sub-Investigators’ state medical licenses.

- **Financial disclosure forms** signed by everyone listed on the FDA Form 1572 (or Investigator Agreement for device studies).
- Laboratory certifications and normal ranges for the Institution or Laboratory.
- Protocol. Do not discard outdated, older versions of the protocol.
- A protocol signature page signed by the Investigator.
- The stamped, approved Informed Consent form. Do not discard outdated, older versions of the informed consent.
- The IRB approval letter for both the consent form and the protocol.
- Letter of Assurance from the IRB Program Manager in Research Administration should be obtained in lieu of an IRB membership list.
- Clinical Trial Agreement signed by Ochsner Administration. (File separately from the regulatory binder)
- Investigator brochure
- Confidentiality Agreement
- Enrollment Log/Screening Log
- Study Personnel Signature List
- Monitoring Log

**Delegation of Authority Form.** This form describes the role for each researcher listed in the study and denotes who will conduct informed consent, who will document study data, etc.
- Investigational New Drug Application (if applicable)
- Copy of Investigational Device Exemption (if applicable.)
- Safety reports
- Log of Sponsor/Site Correspondence. Correspondence includes written communication, email or telephone communication.
- Drug/Device Accountability Log
- Telephone/Correspondence Logs (includes e-mail). It is advisable to stamp any correspondence with the date received, and when sending correspondence to the sponsor/CRO to send it registered mail and retain copies.
14.3 Source Documentation

Source Documentation is part of the permanent patient chart/medical record and is the original document describing information about the study patient. It can take the form of test results, progress notes, medication records, flow sheets, and nurse’s notes, or any other original document pertaining to the study patient. For clinical trials, it is important that this information be transcribed accurately onto the Case Report Forms by the CRC, or PI, or Sub-Investigator.

Source documents are an important way to show that the protocol was followed and that the study was managed appropriately. The documentation should tell a story of how the study was conducted and carried out. Source documents are the basis of all clinical studies and are of tremendous importance in assuring the validity of the study. They also serve to notify other healthcare providers that a patient is on study and this is extremely important.

Source documents are created by a variety of people who come into contact with the study participant during the study. This can involve therapists, technicians, doctors, nurses, dieticians etc.

Documentation must be in-depth and include all details pertaining to the informed consent process, information about protocol procedure, and information related to the conduct of the study (i.e. each study visit, diagnoses, adverse events, medications, laboratory work, compliance, etc.). A brief and/or illegible note concerning this information is not adequate when the patient participates in a clinical trial. The Principal Investigator is responsible for ensuring that this source documentation is done correctly, along with the Clinical Research Coordinator and Sub-Investigator (if applicable). Both the investigator and study coordinator are responsible for documenting study visits clearly in the medical record if the research or study procedure(s) impacts clinical care.

Information should be entered clearly in blue or black ink, and “white-out” should never be used. If a mistake is made, it should be corrected by a single line through the error and then dated and initialed. No other method is acceptable; do not scribble out the error or blacken the error.

Example of proper method for correcting errors: 

```
rascearch     research
ABC 09/07/2004
```

It is important for the investigator and study coordinator to document a study note in the medical record with every study-related visit. This note must clearly identify the research study involved and the visit number.

Some sponsors now also generate study-specific source documents to be completed by the study staff. For example, a patient diary is a source document. **SOURCE DOCUMENTS PROVIDED BY THE SPONSOR DO NOT REPLACE DOCUMENTATION IN THE MEDICAL RECORD- THEY ARE AN ADDITIONAL STEP. Documentation in a research record or shadow file alone is not allowed!**
Electronic data entry is becoming more popular and involves the CRC or data entry personnel entering information from “source documents” directly into a computer program online. Often this type of system will prompt the data entry staff if a mistake is made and will ask for a clarification. This can be a more cost effective approach for a sponsor, due to eliminating the need for off-site data entry personnel. It does create an additional burden on the investigator/study coordinator as the information entered must also be kept on file in a hard copy version at the site for sponsor and regulatory verification purposes.

**Monitor Visits and Telephone Conversations:** There should be a record in the regulatory binder of every visit and conversation with the study sponsor’s representative. If not recorded, it did not take place. This also applies to emails and telephone conversations.

**Case Reports Forms (CRF)** are provided by the Sponsor, and are pre-printed forms that allow the CRC to transcribe from source documentation the study visits, medications, adverse events and other study landmarks.

Information should be entered clearly in blue or black ink, and “white-out” should never be used. If a mistake is made, it should be corrected by a single line through the error and then dated and initialed. (No other method is acceptable.)

Only those authorized to do so by the sponsor should write on the Case Report Forms (team members listed on the study personnel list). No other persons should have access to the files. The “Delegation of Authority” list in the regulatory binder will list those authorized to enter information in the case report forms and access the study files.

No blank spaces should be left on the CRFs...N/A (not applicable) or N/D (not done) should be entered instead. Ditto marks should not be used; information should be written out fully.

Case report forms can occasionally be source documents also; a source document is the place where information pertaining to the study participant is first recorded. For example on a patient self-administered questionnaire, or in patient diaries)

**Sponsor/ Site/ IRB Correspondence:** Records of any correspondence between these parties must be kept in the Study Binder. Telephone conversations with the sponsor or monitor should be recorded in a log. Any emails or written correspondence should also be recorded. This is all part of the study files and must be kept up to date. This is in an Investigator’s best interest...do not forget to do this.
15.0 PATIENT ENROLLMENT PROCEDURES

15.1 Subject Recruitment

Recruitment time is an important issue for the Sponsor. Recruitment periods can be extended to
enable enrollment targets to be met, but this adds expense to the study and may affect the overall
quality of the data obtained.

Strategies for recruitment include Advertising, Referrals, Oral Presentations, Chart Review,
Posters, Media and Public Service Announcements. These must be approved by IRB. (Refer to
Ochsner’s Marketing Department can be of assistance with publicity for studies if you have
funding available for this.

Challenges to recruitment include a patient’s fear of risks associated with the study, slow
enrollment, deadlines for enrollment, and physician or family member reluctance to consider the
study as an option.

15.2 Enrollment Logs

Enrollment logs may record the patient number, date of screening, randomization, and visit
dates.

15.3 Entering study participants in the OMIS system.

At the time of consent, each subject must be entered into the Ochsner Medical Information
System (OMIS). The OMIS system notifies the Principal Investigator and/or CRC that a
research subject has been admitted to the hospital or the emergency room (ER). This allows the
PI and CRC to follow-up with the study subject to record any adverse events (whether related or
unrelated to the study) that have occurred.

Once a study has been approved, the IRB office will register the protocol in the OMIS system
and assign a protocol number. The OMIS protocol number will be given to the PI/CRC (usually
this number is located on the ORANGE sheet that accompanies the IRB approval letter). For
questions about the OMIS protocol number, please contact the IRB Office at extension 2-3535.

To register a patient, please follow these general steps:

1. Open the Mainframe system
2. Enter your user id and password and hit Enter
3. Hit Enter again
4. Tab down next to OMIS,
5. Type “s” next to OMIS and hit Enter
6. Hit the “Pause/Break” key on the keyboard
7. Type “MRI81” (no spaces in between MRI and 81) and hit Enter
8. Enter the Clinic # and hit Enter
9. Hit the F4 key on the keyboard to add a new patient
10. Enter the OMIS Protocol Number (found in ERSA)
11. Hit Tab
12. Enter the Patient Consent Date (e.g. 01/23/2004) and hit Tab
13. Enter the Patient Stop Date if known, otherwise, leave blank
14. Hit Enter to add the patient into OMIS
15. Hit Enter to Continue
16. Verify that the patient information is correct.

It is imperative that the PI and CRC maintain accurate and reliable information regarding patients in the OMIS System. Not only should study start dates be entered, but also study end dates for each enrolled patient. **When the study patient is taken off the study or completes the study, the date of discontinuation should ALWAYS be entered in OMIS.**

To discontinue a patient, please follow these general steps:
1. Open the Mainframe system
2. Enter your user id and password and hit Enter
3. Hit Enter again
4. Tab down next to OMIS,
5. Type “s” next to OMIS and hit Enter
6. Hit the “Pause/Break” key on the keyboard
7. Type “MRI81” (no spaces in between MRI and 81) and hit Enter
8. Enter the Clinic # and hit Enter
9. Select the line number you wish to update and hit enter
10. Hit the tab key twice
11. Enter the patient stop date and hit enter

Please note that more detailed instructions are available on the Academic Division-Research website and in Research policy # 8042-2.

**16.0 CONDUCTING STUDY VISITS**

The Clinical Research Coordinator/or PI/or Sub-Investigator is responsible for conducting and scheduling study visits with the patient at the timelines required by the protocol. Every effort should be made not to deviate from these timelines. If a patient misses a study visit the reason should be documented, the sponsor should be notified immediately, and the IRB should be notified.

Study visits should be documented in detail in the patient’s chart (source document) and on the CRFs. It is not acceptable to only maintain a research file or “shadow” chart for study purposes; source documentation must be complete in the patient’s official medical record. In addition, the CRFs should be completed in a timely fashion.

During the study visit, it is important for CRCs to assess and document the following as well as any other study-specific items:

- The subject’s ongoing consent to participate in the study
- Adverse Events
- Concomitant Medications
- Compliance with study procedures/medications

It is necessary to assess and document patient compliance at each study visit. Patient compliance with required visits, tests, and medication regimen is critical to the study. If the patient is non-compliant, then this should be discussed with the PI and sponsor’s representative to see if it is appropriate to discontinue the patient from the study.

**17.0 PROTOCOL VIOLATION/ EXEMPTIONS**

Every attempt should be made not to deviate from the protocol. Should protocol violations occur, the sponsor and IRB should be notified. It is important to provide detailed documentation about the deviation and reasons for deviating from the protocol.
If a deviation from the protocol is considered necessary, then attempts should be made to request from the Sponsor and the IRB permission to deviate from the protocol. Permission to deviate should be obtained in writing. This documentation should become part of the research file.

18.0 PAYMENT OF STUDY PARTICIPANTS

A thin line exists between subject coercion and subject compensation. Any subject compensation must be reviewed and approved by the IRB. Moreover, careful consideration must be given for determining payment to vulnerable populations in order to avoid undue influence or coercion.

The amount and schedule of payments should be determined in a way so as not to present an undue influence on the patient. Any payment should accrue as the study progresses and not just be made at study completion. The consent form should include the amount and schedule of the payments.

At screening, attempts should be made to eliminate “professional” research subjects.

Finally, “finders’ fees” to enhance enrollment are not allowed at Ochsner, and sponsors offering this incentive should be informed of this.

Ochsner Research Policy 8042-10, “Payment to Study Subjects” outlines the general information required to process subject payments.

19.0 BILLING PROCEDURES FOR RESEARCH STUDIES

It is important to ensure that procedures and services related to the clinical trial are billed in the appropriate manner. The following is a list of steps, organized by whether the procedures are outpatient or inpatient procedures, to assure that study-related procedures are billed in the proper manner.

19.1 Outpatient Billing Procedures

When final IRB approval is obtained and it has been determined that the investigator and research staff can begin screening participants for the study, it will be imperative that the following steps be taken and in the order listed below:

1. **Obtain Ochsner IRB number**: Each and every research study at Ochsner will be given a unique Ochsner IRB number. This number is assigned by the IRB office and will be in the format of 4 digits for the year of origination of the study followed by a period than a three digit number sequentially issued by the IRB office followed by a period and the letter A, B, C or W (e.g. 2004.125.A). The IRB office (extension 2-3535) should be contacted to obtain the number which has been assigned to the research study.
2. **Obtain Study Activity number:** Each and every research study at Ochsner will be given a unique Activity number. This number is a seven digit number assigned by the Ochsner’s Treasury department upon the request of Research Operations. This number is essential for accounting purposes. Research Operations will provide the assigned Activity number to investigator and/or coordinator via email.

3. **Establish a Guarantor number for the study with Central Registration office:** A guarantor number must be set up by Central Registration so that procedures performed as part of the research study protocol can be billed to the appropriate study. Research Operations requests the Guarantor number after the contract is executed and the Activity Number is established.

4. **Register Patients in the OMIS system:** Begin enrolling patients on study after all approvals for the study are received or documented. Each patient should be entered into the Ochsner Medical Information System (OMIS) at the time of consent. This will allow for the notification of other caregivers concerning the patient’s participation in the study. It will also be needed for notification if the patient experiences an adverse event (i.e. admission to the hospital or an emergency department visit.).

5. **Obtain a Case Number for the Patient:** A case number must be obtained for every patient participating in a research study, whether the study is inpatient or outpatient related, even though the number is only used for CLINIC billing purposes. This number usually is the patient’s clinic number followed by the number 300 (or 301 etc. if the patient has participated in more than one drug study). Case numbers are issued by Central Registration via an on-line request system which can be accessed through the intranet website (Academics > CRC Resources > Case Creation Request). The on-line request system will require the requestor to enter the Study Fund Number, Principal Investigator’s Name, the Patient’s name, the Patient’s clinic number and the Ochsner IRB number. The requestor’s name and correct email address will also need to be entered so that once assignment of the case number has been done, it can be emailed back to the requestor. In an emergency, central registration will be able to be contacted by phone. However, the on-line system will still be required to be used so that the patient can be listed in the on-line case request system database.

6. **Ordering Procedures for Patients:** All outpatient procedures which are part of the study protocol will be ordered using the patient’s case number described in step # 5. When using the on-line order system, it will be necessary to use the “300 case number” for each and every procedure which is part of the protocol so that the study is billed appropriately. Accordingly, procedures which are not part of the study protocol should not be ordered using the “300 case number.” The “300 case number” must also be placed on all study-related test requisitions. Correct usage of the “300 case number” is very important. This is the mechanism that is used to trigger a billing to the drug study or to the patient or other third party payer.

19.2 **Inpatient Billing Procedures:**

- SECTION UNDER CONSTRUCTION
19.3 Charges for Medical Devices and Radiological Health Products

SECTION UNDER CONSTRUCTION

19.4 Medicare National Coverage Decision (NCD)

- SECTION UNDER CONSTRUCTION

20.0 CLINICAL TRIAL SITE VISITS

An audit is a “systematic and independent examination of trial related activities and documents to determine whether the evaluated trial related activities were conducted, and the data were recorded, analyzed and accurately reported according to the protocol, sponsor’s standard operating procedures, Good Clinical Practices, and the applicable regulatory requirements.” (ICH Guideline).

A routine “site visit” is part of the ongoing monitoring process for the study. It is a time for the clinical trial monitor to evaluate a potential study site, ensure the site is ready to begin the study, verify that study documentation is adequate for the purposes of the study and or make certain that Good Clinical Practices are being followed. The various types of monitoring visits are listed below:

- **Pre-Study Qualification Visit**: This visit is an opportunity for the sponsor’s representative to meet with the study team and evaluate their readiness to undertake participation in a study. The sponsor representative review budgeting needs, availability of equipment and staff resources at this time. According to ICH 5.18.4 b the representative’s has the responsibility to verify “that the investigator has adequate qualifications and resources” to conduct the proposed study.

- **Initiation Visit**: This visit is conducted after approvals are obtained and regulatory documents are filed. The agenda should include an inspection of all documents, a review of the protocol and CRFs, and a review of the sponsor and investigator obligations during the course of the study.

- **Routine Monitoring Visits**: According to 21 CFR 312.56 the sponsor is to monitor the progress of all investigations conducted under its IND. The sponsor will set the frequency of the visits. The CRA will inspect all study related documents, CRFs, and source documents to verify accuracy and ensure that the study is being conducted according to GCP guidelines.

- **Close Out Visits**: This visit is conducted at the conclusion of a clinical trial at an investigational site. The CRA will inspect all study documentation to ensure that files are complete and all data are retrieved. The CRA will return unused test articles/supplies at this time to the sponsor and go over any outstanding financial
issues. The investigator will be reminded to submit a final report on the study to the IRB and the sponsor.

20.1 Preparing for a Study Site Visit

Plans should be made in advance with the CRA (clinical trial monitor) for the sponsor to conduct a site visit. The CRA should be given a quiet place to work and access to the study files and source documents necessary to verify the accuracy of the study data.

It is a good idea for the CRC to go over the CRFs prior to the visit to ensure that everything is complete and that no errors have been made. At the end of the site visit it will be necessary for the CRC and/or PI to be available to answer any queries found by the CRA.

20.2 Monitoring Guidelines

Several departments have found it necessary to develop monitoring guidelines to assist with scheduled monitoring visits. Guidelines for the site visit are helpful and can assist the CRC or PI or Sub-Investigator to have time to complete other necessary tasks while the Clinical Research Associate (CRA) is monitoring. A specific time should be allotted to go over queries and make corrections if needed; this could be as simple as meeting with the CRA for 2 hours a day to clarify any issues.

If a PI/CRC encounters difficulties with a site visit, the Research Compliance Officer should be able to assist (extension # 2-4261).

20.3 Query Resolution

The monitor (CRA) has an obligation to go over queries with the CRC/PI and assist them in resolving queries. Queries are requests for clarification about study documentation. Electronic data capture in the form of online case report forms results in real time queries and a decrease in overall query resolution time. This saves a sponsor of a clinical trial both time and money and helps a product gain marketing approval faster.

20.4 Monitoring Log

This is a log signed by the CRA each time they make a site visit and is kept as part of the study file.

20.5 Other types of site visits

The purpose of an audit is to ensure the integrity and reliability of the study data and the protection of the rights and safety of the participants. An audit may be conducted by the sponsor (or sponsor’s representative), by the Ochsner Research Compliance Office, NIH, OHRP or by the FDA. The description of audit procedures in this section refers to an FDA audit of a clinical trial.
20.5.1 Audit Classifications

The FDA Bioresearch Monitoring Program involves site visits to clinical investigators, research sponsors, contract research organizations, IRBs, and animal laboratories. Program procedures vary slightly depending upon the product type (e.g. drug, biologic, medical device, etc.), however, all inspections aim to ensure the protection of human research subjects and to verify data integrity and quality of information that is gathered and submitted to the FDA.

The FDA has three distinct types of clinical investigator inspections:

1. **Study-oriented inspections**: These inspections are conducted on the basis of assignments handed down by headquarters. The assignments are typically based on studies that are important to product evaluation, such as new drug applications and product license applications that are pending FDA approval.

2. **Investigator-oriented inspections**: An investigator-oriented inspection is conducted because an investigator conducted a pivotal study that merits in-depth examination due to its singular importance in product approval or medical practice. An investigator-oriented inspection may also be initiated “for cause” when the FDA is informed about potential concerns with an investigator’s work or where irregularities have been reported to the FDA.

3. **Bioequivalence study inspections**: A bioequivalence study is conducted when only one study may be the sole basis for market approval of a drug. This inspection differs from other types of FDA inspections because it requires participation by an FDA chemist or an investigator knowledgeable about analytical evaluations.

Again, the purpose of a study-oriented or investigator-oriented audit is to:

- Determine the validity, reliability and integrity of the data;
- Assess adherence to federal regulations and guidelines
- Assess compliance with the study protocol
- Evaluate whether the safety and welfare of human subjects were protected

20.5.2 Preparing for an FDA Audit

The best time to prepare for an FDA audit is at the initiation of the study.

The FDA will usually, but not always, contact the Vice President of Academics to schedule the date of the audit for a particular study. Normally, the FDA investigator will want to visit within two weeks. **Immediately after receiving notice of an FDA audit, the Office of Research Administration will contact the following people, departments or organizations:**
- THE PI OF THE STUDY: The PI must meet with the FDA investigator.

- THE STUDY SPONSOR: The sponsor must be informed and usually provides assistance in preparing for the audit.

- THE CORPORATE AUDIT & COMPLIANCE DEPARTMENT: This department can provide guidance in preparing for FDA audits.

- THE INSTITUTIONAL REVIEW BOARD (extension 2-3535).

When the FDA officer calls it is necessary to ask:

- When do the officers plan to come to the facility?
- How long does the officer plan to stay?
- Which study will be reviewed?
- Which subjects will they review?
- Do they plan on a tour of the facility?

It is necessary to gather the following information:

- Locate and review the regulatory binder.
- Locate and review case report forms and medical charts of enrolled subjects
- Locate and review screen failures and dropouts.
- Review the protocol and regulatory documents to understand the course of the study.
- Review the delegation of authority list, which should be located in the regulatory binder.
- Obtain training records and CVs of all individuals involved in the study.
- Obtain a current CV for the Principle Investigator, which includes any recent research projects.
- Acquire records of the clinical trial drug/device storage and dispensation.

20.5.3 FDA Opening Interview

Upon arrival, the FDA inspector will present his/her FDA credentials or a badge to all individuals present at the opening interview (i.e. PI and Ochsner representative). The FDA investigator will issue a completed Form FDA 482 (notice of inspection) to the Principle Investigator.
During the opening interview, the FDA investigator will ask the PI a variety of questions about the study, including the names of sub-investigators and research coordinators, responsibilities of the research team members, IRB approvals, and how the study was conducted at the site. This information provides the FDA investigator with a general background of the study.

20.5.4 FDA Inspection

After the opening interview, the FDA investigator should be provided with a quiet area to work. The site should provide all requested study documentation for review.

Usually the FDA investigator will begin reviewing the regulatory documents. This includes all versions of the protocol and informed consents, sponsor information, lab information, the FDA 1572’s completed throughout the study, enrollment logs, monitoring logs, etc. The FDA investigator uses this information to assess facts surrounding the course of the study.

The FDA investigator will also interview the PI and research staff (if the research staff are still working at the site). The interviews consist of questions surrounding how the study was carried out, how study responsibilities were delegated and to whom, and clarification of study events or documentation that are uncertain to the FDA investigator.

Sponsor oversight will also be examined with a review of monitoring procedures, communication between the sponsor and PI, and training provided by the sponsor to research staff.

After reviewing the regulatory data, the FDA investigator begins auditing the subject data. The inspector will compare the information submitted to the sponsor with source documentation, looking for any discrepancies. The subject records will be evaluated to determine if procedures in the protocol were correctly followed. The FDA investigator will also examine test article accountability, data collection methods, and any monitor queries.

The Principal Investigator must be available throughout the audit.

20.5.5 FDA Exit Interview

The FDA inspector will conduct an exit interview with the PI to review audit findings and clarify any issues found. A Form 483 may be issued (Notice of Observations) if there are significant findings of noncompliance. The inspector will submit a report to FDA headquarters following the inspection. Upon review and consideration of the report provided, FDA Headquarters will send the investigator one of the following types of communication:

1. **No significant deviations**: The FDA investigator did not find any significant deviations, therefore, a response from the PI does is not required.

2. **Informational letter**: The informational letter identifies deviations from the code of federal regulations. This may or may not require a response from the PI.
3. **A warning letter**. A warning letter identifies deviations and noncompliance issues, which requires prompt action. A response from the PI is required. Sanctions may be taken against the sponsor and/or the PI in addition to receiving this letter.

4. **A Notice of Disqualification Proceeding and Opportunity to Explain (NIDPOE) Letter**. This resolute FDA notice is issued for the most serious deviations from the code of federal regulations. The PI is not allowed to enroll any further subjects until an adequate explanation is provided to the FDA.

### 20.5.6 Consequences of an FDA Audit

Depending on the severity of the findings, the following consequences can result from an FDA audit:

- Restrictions may be placed on the investigator for severe noncompliance
- The investigator may be disqualified from doing further studies involving investigational drugs, devices or biologics.
- The investigator may be debarred from practicing medicine or working for a pharmaceutical firm.
- Criminal prosecution may be taken against the investigator and/or researchers.

#### 21.0 OCHSNER PHARMACY

Unless the principal investigator has a current dispensing license issued by the Louisiana State Board of Medical Examiners, all investigational drugs must be dispensed by either the Inpatient or Outpatient Pharmacy (*OCF Research Policy #8042-5, Management of Test Articles*).

As early as possible in the research study planning process and prior to dispensing any study medication, the following documents must be provided to the pharmacy:

- the research protocol
- the Investigator’s Brochure (IB)

This information assists the pharmacy in estimating costs associated with investigational drug dispensation, storage and disposal, which should be included into the clinical trial budget.

Pharmacy procedures for investigational drugs depend upon whether the drug will be administered on an outpatient or inpatient basis. Below is some helpful information on pharmacy procedures. For complete information, please refer to the Ochsner Pharmacy Policies, or contact the pertinent Ochsner Pharmacist.
21.1 Pharmacy Definitions

The following is a brief list of terms as defined by the Louisiana Board of Pharmacy Laws & Regulations:

- **Administer or administration**: the direct application of a drug to the body of a patient or research subject by injection, inhalation, ingestion, or any other means.

- **Dispense or dispensing**: the interpretation, evaluation, and implementation of a prescription drug order, including the preparation and delivery of a drug or device to a patient or patient’s agent in a suitable container appropriately labeled for subsequent administration to, or use by, a patient. “Dispense” necessarily includes a transfer of possession of a drug or device to the patient or the patient’s agent.

- **Labeling**: the process of preparing and affixing a label to any drug container exclusive, however, of the labeling by a manufacturer, packer, or distributor of a non-prescription drug or commercially packaged legend drug or device. Any such label shall include all information required by federal and state law or regulation.

21.2 Outpatient Clinical Trials

In the State of Louisiana, a CRC or physician **without a dispensing license** is not allowed to **dispense a test product**. At Ochsner main campus the outpatient pharmacy dispenses study medication. The CRC/PI may be responsible for drug administration (see definition in section 21.1), however, a Pharmacist must dispense the drug unless the physician has a drug dispensing license from the Louisiana State Board of Medical Examiners or has written notification that a dispensing license is not required.

To inquire about a drug dispensing license, please contact the Louisiana State Board of Medical Examiners. If a physician obtains a drug dispensing license, the physician is required by law to maintain all essential documentation and reports required by the Louisiana State Board of Medical Examiners.

21.2.1 Outpatient Pharmacy Contact

For information on outpatient pharmacy procedures, please contact an Investigational Pharmacist at extension 63503.

21.2.2 Outpatient Investigational Drug Procedure:

The required pharmacy forms may be found in Appendix C.

Prior to dispensing any drug, the Investigational Pharmacist must receive the following documents:

- The IRB approval letter
In addition, the CRC for the study should provide the Investigational Pharmacist with the CRC’s name, email, telephone number and pager number.

Every study will have an identifying folder prepared by the pharmacist. It will contain the documents listed above along with a Perpetual Inventory Log Sheet.

In order to have drug dispensed by the pharmacy, the following procedures must be followed:

1. The designated research staff member (e.g. CRC, Principal Investigator or Sub-Investigator) for the study must complete the Patient Enrollment Form for each patient (see Appendix C for a copy of the Patient Enrollment Form). The Patient Enrollment Form must be faxed to the Investigational Pharmacy at 842-6338 to expedite filling of the prescription.

2. The researcher must bring the prescription and drug (if stored by the research team) to the Pharmacy for filling. The researcher may wish to notify the pharmacy that he/she will bring a specified amount of the drug and the prescription to the pharmacy to decrease the wait time for the patient.

3. The prescription must include the following information:
   - patient’s name
   - date
   - clinic number
   - patient’s randomization number and initials
   - The drug study name and number
   - drug name
   - the quantity and number of pills to be dispensed
   - directions for use
   - research physician’s name and signature
   - Study medication should be labeled by the sponsor with the drug code number. Pharmacy will label the medication when dispensing the drug, but the pharmacy label will not prevent the drug code number and/or patient number from being seen. The prescription should state the specific daily dose to be taken by the patient with clear directions. “Take as directed” is not sufficient indication of dosing for research dispensing purposes.
4. The pharmacist will log the medication into inventory and fill the prescription for the patient.

5. The pharmacist will transfer the prescription to the CRC, or call the CRC to pick up the medication for delivery to the patient. For stat orders, arrangements can be made to deliver the medication as quickly as possible.

6. The CRC must educate the patient about the medication according to the protocol. This teaching must be documented in the medical record. The pharmacist may need to be in-serviced about the study drug by the sponsor and this training should also be documented.

7. The patient will return unused study drug to the CRC. The CRC should count the medication as a measure of compliance, and check with the study monitor. The medication must be disposed according to protocol or according to sponsor instructions. The Ochsner Pharmacy uses a Pharmaceutical Return & Waste Disposal Service to dispose of unused medications when requested to dispose of drug.

8. Dosage adjustments should be made by the physician in accordance with protocol, and pharmacy notified of any changes made.

9. Study medication should be kept in a locked refrigerator or cabinet, with limited access (as specified by the protocol). In this scenario, Drug Accountability Records must be kept by the CRC.

10. If drug is stored in the pharmacy, the study must furnish any storage requirements for the pharmacy (e.g. refrigerator, freezer, locked cabinets)

11. A new prescription is required every time the medication is dispensed.

12. There will be no re-dispensing of medication to a different patient. If a patient returns the medication, it will not be dispensed to a different patient, but must be returned to the sponsor or destroyed according to protocol.

13. At the conclusion of study, the PI/CRC must send a memo notifying the pharmacy of the date that the study was closed. The memo must include:
   - Study Name
   - IRB number
   - Notice that the study has been closed
   - Date the study closed

### 21.2.3 Storage of Investigational Drugs

Investigational Pharmacist or study coordinator must inventory investigational drugs following protocol guidelines (person completing this task is dependent on whether drugs are stored in pharmacy or stored by investigator/coordinator)
Verify the code numbers of the drugs received and the quantity shipped

Sign and date the packing slip/invoice

Acknowledge receipt of drugs/supplies by completing inventory sheets

- Fax a copy of signed and dated invoice to sponsor
- Mail original to sponsor or designee after photocopying and storing information
- Investigational Pharmacist/study coordinator must store investigational drugs in locked, secured cabinet
- A perpetual inventory of investigational drugs and supplies must be maintained to tally/check quantity stored.
- A weekly check of investigational drugs and supplies must be made to tally/check quantity stored.
- All investigational drug records must be reviewed with study monitor for accuracy and completeness at each monitoring visit.
- Drug accountability records will be available for in-house, sponsor, and/or FDA audits (as applicable).
- Any transfer of drugs from one source to another must be documented by the coordinator, pharmacist, or investigator to ensure that the drug count and transfer are correct. (Applies to transfer of drugs to patient, monitor, or another site within or outside Ochsner, etc.)
- Records concerning investigational drugs will be stored for a minimum of 10 years after study closure
- All unused drug supplies must be returned to the sponsor at the close of the study and after inventory is completed or disposed of according to protocol.
- Copies of final inventory logs will be given to the investigational pharmacist, study coordinator and study monitor.
- For additional information, please refer to Research Policy 8042-5, “Management of Test Articles”.

This handbook is designed as a guide and reference for clinical research and is not intended to be a comprehensive statement of the knowledge, policies, and procedures of Ochsner Clinic Foundation. Updates to the Handbook are available on the Ochsner intranet. Use of the materials in this handbook is limited solely and exclusively to Ochsner Clinic Foundation personnel. Use by any other party is strictly prohibited. Copyright © 2004 by Ochsner Clinic Foundation. All rights reserved.
21.3 Inpatient Clinical Trials

Inpatient Investigational Drug Dispensing Policies are outlined in Ochsner Policy 7710-28 (Investigational Drugs) and Policy 7710-43 (Investigational Drugs for Studies Without Approved Protocols Through Nursing/Pharmacy).

The following is a summary only of the information contained in the Ochsner pharmacy policies pertaining to investigational drugs; refer to the Ochsner policies themselves for complete information.

21.3.1 For Hospitalized Patients on Inpatient Studies

Investigational drugs brought to the hospital by patients participating in outpatient clinical research studies can be dispensed either by the outpatient pharmacy, or may be kept at the patient’s bedside and the patient will self administer them according to Investigator instructions. (The physician will need to write an order for this).

The Investigational Pharmacist will prepare an Investigational Drug Inventory Sheet for each investigational drug for the patient, and this will be kept in the patient profile binder along with information about the drug.

Pharmacy will dispense a 24-hour supply of investigational drug at a time, and will document this amount dispensed each day on the inventory sheet.

The drug will appear on the patient’s MAR (Medication Administration Record).

Investigational Pharmacist will prepare a Drug Fact Sheet and send it to the appropriate Nurse Manager.

The Nurse Manager will then prepare a Nursing Activity Sheet and a Nursing Sign-in Sheet for nurses to read about the study drug. This will ensure that nurses working with the hospitalized study participant will be informed about the study and about the investigational drug prior to its administration.

Nursing will verify that an informed consent was obtained before administering the investigational drug except if this is an emergency use of the drug and consent has been waived.

Upon discharge, study medications are returned to the physician responsible for the study.

For additional information, please refer to Ochsner Policy 77-10-43, “Investigational Drugs for Studies Without Approved Protocols Through Nursing/Pharmacy”.
21.4 Committee on Drug Administration in Nursing (CDAN)

21.4.1 General Information about Drug Trials

Inpatient clinical trials may not begin until all nursing personnel involved in the administration of investigational medication have been appropriately in-serviced on both the protocol and the study medication.

Prior to obtaining IRB approval, it is necessary to contact the CDAN Committee for information about negotiating this process, so that there will be no delay in implementing the protocol once it’s approved. The CDAN Committee can be contacted by calling:

After IRB approval is obtained, for an inpatient clinical trial, in-services must be set up in collaboration with a Hospital Clinical Educator (Ext: 2-1891) and the CDAN Committee Chairperson. The CRC/Investigator/Sub-Investigator must present the study to the CDAN Committee for review and arrange for the required paperwork and in-services to be completed.

Nurse Managers of involved nursing units must receive a copy of the protocol, drug fact sheet, and study summary. Pharmacy must also be supplied with this information. A copy of the forms can be found either on the Ochsner Intranet (Academic Division → CRC Resources → C-DAN Policies and Forms) or at the following web address: [http://ochweb/documents/Academics/Word/C-DAN_Policies_and_Forms.doc](http://ochweb/documents/Academics/Word/C-DAN_Policies_and_Forms.doc) A copy of the forms may also be found in Appendix D.

21.4.2 Steps to Follow for C-DAN Approval of Investigational Drugs

1. The IRB application and C-DAN packet may be obtained from Academic-Division Research Web site on the intranet. The C-DAN packet must be completed for any investigational drug that is to be utilized on a patient that has the potential to be hospitalized.

2. Prior to approval by the IRB, the Clinical Research Coordinator (CRC) may choose to come to a CDAN meeting for a preliminary review of the study. The committee may then advise the CRC on any specifics necessary for the study. Contact Pharmacy to assist with development of Drug Fact Sheet (DFS), budget, and dispensing procedure. *Minimum of 2 weeks needed.*

3. Contact Nursing Education (ext 2-1892) to consult in development of Nursing Activity Sheet (NAS) and instructions on the completion of the inservice report form. *Minimum of 2 weeks needed.* Nursing Education to recommend an educational plan.

4. CRC or investigator will present to CDAN the final Educational plan, which would include completed packet.
5. CRC/Investigational Pharmacist will perform appropriate education for Nursing and Pharmacy.

6. CRC will develop the mailbox inservice. The CRC will complete all mailbox inservice information and fill out the necessary paperwork in the copy center. The CRC will notify the appropriate Clinical Educator who will then send email to notify all involved nursing units that MBI is ready to be picked up at the copy center.

7. The Completed Drug Study Packet including Nursing Activity Sheet, Drug Fact Sheet, MBI (if applicable), sign-in sheet will be distributed to appropriate nursing units to be placed in CDAN manual in the investigational drug studies section.

8. At the completion of the study the CDAN representative of each unit will remove the study information from the CDAN manual and forward to the Nursing Education Department for proper filing.

9. Investigational Pharmacist will disseminate information to Pharmacy Staff.

The necessary forms (drug fact sheet, study summary) for this process may be accessed on the Ochsner Academic Division-Research Intranet Website, Resources Section.

21.4.3 Device Trials

Clinical Educators must be consulted at Ext: 2-1891 concerning device trial in-services for nursing personnel. All nurses involved in the clinical trial must be in-serviced about investigational devices prior to beginning an investigational device study. This is the responsibility of the Investigator and/or his Clinical Research Coordinator, but the Clinical Educators may facilitate this process. Written information about the device should be made available for nurses who are unable to attend the in-service.

22.0 HIPAA AND RESEARCH

22.1 The Privacy Rule

In the mid 1990’s, congress mandated the Health Insurance Portability and Accountability Act (HIPAA) of 1996. In response to this Act, the Department of Health & Human Services (DHHS) issued regulations entitled, “Standards for Privacy of Individually Identifiable Health Information” which is referred to as the “Privacy Rule.” For most covered entities, compliance with the Privacy Rule was required as of April 14, 2003.

The Privacy Rule is a response to public concern about the privacy of health information. The purpose of the Privacy Rule is to establish minimum federal standards for safeguarding the
privacy of individually identifiable health information, and yet allow the flow of health information to provide and promote high quality healthcare and protect the public’s health. The Privacy Rule addresses how organizations (covered entities) use and disclose individuals’ protected health information (PHI), as well as how individuals may control how their health information is used.

The Privacy Rule recognizes that the research community has legitimate needs to use, access, and disclose individually identifiable health information to carry out a wide range of clinical research protocols and projects. In the course of conducting research, researchers are allowed to create, use or disclose individually identifiable health information. The Privacy Rule protects the privacy of such information, but also provides various ways in which researchers can access and use the information for research (NIH publication number 03-5388).

A few definitions that will help in understanding the language of HIPAA:

- **Covered Entity**: A health plan, a health care clearing house, or a health care provider who transmits health information in electronic form in connection with a transaction for which HHS has adopted a standard. **Ochsner Clinic Foundation is a covered entity.**

- **Protected Health Information (PHI)**: is individually identifiable health information held or transmitted by a covered entity or its business associate, in any form or media, whether electronic, paper, or oral.

- **Individually Identified Health Information**: Any information, whether oral or recorded in any form or medium that (1) is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearing house; and 2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or past, present, or future payment for the provision of health care to an individual; and (a) that identifies the individual; or (b) with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

- **De-Identified Health Information**: Neither identifies nor provides a reasonable basis to identify an individual. The two methods for de-identifying information is: (1) formal determination by a qualified statistician; or (2) the removal of specific identifiers of the individual and of the individual’s relatives, household members, and employers, and the covered entity has no knowledge that the remaining information could be used to identify the individual. There are no restrictions on the disclosure of de-identified health information.

- **Research**: A systematic investigation designed to develop or contribute to generalizable knowledge.
22.2 HIPAA & Research

The Privacy Rule permits a covered entity to use and disclose PHI for research purposes without an individual’s authorization if the covered entity obtains one of the following:

- **Research Use or Disclosure of PHI with Authorization (45 CFR 164.508):** A researcher must obtain Authorization from all participants in research prior to internal use or external disclosure of PHI. A HIPAA Authorization has been incorporated into the Ochsner informed consent template, and is available on the IRB intranet site. HIPAA authorization must be obtained in addition to attaining informed consent from subjects for participation in the clinical trial.

- **Accessing PHI preparatory to research [45 CFR 164.512 (i)(1)(iii)]:** The IRB must be notified of the intent to access PHI for the preparation of a research protocol, provided the researcher documents that the disclosure is solely to prepare for research, or identify prospective research participants for the purpose of seeking authorization, the researcher must not record or remove the PHI obtained from OCF and only the minimum necessary information is to be used.

- **Research on decedents:** Researchers must notify one of the following groups/individuals of any research at Ochsner that involves decedents: Pathology Department Chair or his designee, IRB, Information Services, Health Information Management, or Medical Informatics. The notification must document that the following criteria are met: that the use or disclosure of protected health information (PHI) is solely for research on decedents; that the research is necessary; and the researchers can provide documentation of the death of the individual.

- **Waiver of Authorization:** Research Authorizations may be waived or altered by the IRB of record, provided the specific criteria are satisfied and documented. Please see Ochsner Research Policy 8042-9.

For more information on Ochsner HIPAA rules and policies related to disclosure of PHI is available in the OCF Policy 8042-9 (HIPAA Privacy Research Policy).

22.3 De-identified Data Sets

To achieve a de-identified data set (45 CFR 164.514 (b)), the following 18 direct identifiers of the individual or of relatives, employers, or household members of the individual must be removed:

- Names

- All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code and their equivalent geocodes (except for the initial 3 digits of a zip code under certain circumstances)
- All elements of dates (except year) for dates directly related to the individual, including:
  - Birth dates
  - Admission and discharge dates
  - Date of death
  - All ages over 89 and all elements of dates (including year) indicative of such age except if the ages are aggregated into a category of age 90 or older.
- Telephone numbers
- Fax numbers
- Electronic mail addresses (email)
- Social Security numbers
- Medical record numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate or license numbers
- Vehicle identifiers and serial numbers, including license plate numbers
- Device identifiers and serial numbers
- Web URLs
- IP addresses
- Biometric identifiers, including finger and voice prints
- Full face photographic images and any comparable images
- Any other unique identifying number, characteristic or code except as permitted for re-identification purposes provided certain conditions are met

There are no restrictions on the use or disclosure of de-identified health information. For more information on de-identified data sets, please refer to 45 CFR 164.514 (b).
22.4 Limited Data Set (45 CFR 164.514 (e))

A limited data set is PHI that does not include certain specified direct identifiers of individuals or their relatives, household members or employers. A limited data set may be used and disclosed for research and public health purposes provide the recipient enters into a data use agreement promising specific safeguards for the PHI within the limited data set.

For more information on limited data sets, please refer to 45 CFR 164.514 (e) (2).

A limited data set excludes the following direct identifiers of the individual or relatives, employers, or household members of the individual:

- Name
- Address information other than town or city, State and zip code
- Telephone numbers
- Fax numbers
- Electronic mail addresses (Email)
- Social Security numbers
- Medical record numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- Vehicle identifiers and serial numbers including license plate numbers
- Device identifiers and serial numbers
- Web Universal Resource Locators (URLs) or Internet Protocol (IP) numbers
- Biometric identifiers including finger and voice prints
- Full face photographic images and any comparable images

23.0 PATIENT CONFIDENTIALITY

“The right of research subjects to safeguard their integrity must always be respected. Every precaution should be taken to respect the privacy of the subject, the confidentiality of the
patient’s information, and to minimize the impact of the study on the subject’s physical and mental integrity and on the personality of the subject” (Declaration of Helsinki, 2000).

For additional information on confidentiality issues, please refer to Ochsner Research Policy # 8720-42 and 8700-3.

23.1 Protecting Patient Confidentiality

- The research subject’s identity, any identifying indicators (e.g. Social Security number), clinic and hospital records, administrative data, and information that is obtained under the auspices of clinical research are confidential.

- The subject’s identity and study documents should not be revealed to any person except personnel directly involved in the study (the sponsor’s monitors, the FDA, other regulatory authorities, IRB, and/or the compliance office). Express written consent must be obtained from the subject prior to divulging the subject’s identity.

- The subject’s identity, any identifying indicators, administrative data, or medical record should never leave the facility. All records that are copied for the study should have the patient’s name and identifiers obliterated in order to protect the subject’s confidentiality (a black marker can be used to obliterate the identifying information).

- A study number or other code should identify the subject, thereby ensuring that the subject’s identity remains unknown to the sponsor.

- Only required fields should be extracted.

- When results of the study are published, the subject’s identity must remain confidential.

- For protocols involving particularly sensitive data, the investigator may obtain a federal certificate of confidentiality. This is a legal mechanism (PHS Act, section 301(d)) designed to protect certain types of sensitive data from subpoena.

23.2 Maintaining Confidentiality of the Research Project

- Sponsors typically require signed confidentiality agreements prior to sharing any confidential or proprietary information regarding the study protocol.

- Sometimes it may be necessary for the sponsor to disclose proprietary, trade secret, or confidential information. This information should be shared only on a need to know basis with others who are legitimately connected with the study (e.g. the compliance officers and study personnel).

- All proprietary information should be kept in limited access areas.
Proprietary information includes but is not limited to:

- Investigator’s Brochure
- Protocol
- Case Report Forms (CRFs)

24.0 ELECTRONIC DATA SECURITY: RESEARCH DATABASES.

Large amounts of medical data for research and health care systems are stored electronically. This information can be sent around the world at the click of a mouse. This creates issues of concern regarding privacy of medical information. The HIPAA Regulations address some aspects of this issue, but more may need to be done to protect personal health information and to limit its disclosure. Research practitioners need to be sensitive to this issue in their dealings with study participants. Any questions in this regard should be discussed with the Director of Research at Ochsner and with the study sponsor.

Some possible data safeguards might include:

- Reporting aggregated data only without any patient identifiers, so it will not be possible to identify any specific patients from the summary reports. It may be insightful to report on individual cases, seen either as outliers or as typical cases in an analysis—then some data perturbation, for example of dates, numbers of events, and quantities, may be necessary.

- When working data files that include patient identifiers such as clinic numbers to link different tables, they should be stored, accessed and analyzed within the security of the Ochsner IS system. Data should be de-identified at the earliest possible time within the study. If data is sent outside the Ochsner firewall, it should be data without patient identifiers, such as primary aggregate data.

- Computers containing patient data files should be password protected for access to the computer, default in a number of minutes of non-use to a screensaver that requires a password for re-entry, and have a password protected hard disk. Thus, even if the computer or its hard disk were stolen, any information or data on it would be difficult to access. Folders on a hard drive that contain patient data should be set as “not shared” so others on a network connected computer will be excluded from access. Some will use a non-networked computer for greater safety.

- Once the data has been transformed or aggregated into useable flat files for analysis, the patient clinic number and name, along with any other unique identifying codes should be deleted, if it was not able to be deleted earlier in the process. Various encoding systems to transform clinic numbers or alternative identifying numbers
might be used if linkage back to the original databases may be needed to reference original data on occasion.

Please refer to Ochsner Policy #8042-6 (Electronic Data Capture). Additional information about computer security can be obtained from:

- The Institute of Medicine report, “Protecting Data Privacy in Health Services Research” (AHRQ publication No. OM-01-0008) can be accessed at http://www.nap.edu/books/0309071879/html. The full 192-page book is available for review from the Compliance Office.

25.0 RESEARCH MISCONDUCT

25.1 Definition

The Public Health Service established the definition of “misconduct in science” through federal regulation in 1989:

“Fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data” [42 C.F.R. Part 50, Subpart A].

New definition: “Research misconduct is defined as “fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results” [65 Fed. Reg. 76260-76264 (December 6, 2000)].

25.2 Types of Research Misconduct

(Refer to Ochsner Research Division Policy # 8042-8, Research Misconduct; available on the Ochsner Academic Division-Research Website, Policy and Procedures Section.)

25.2.1 Plagiarism

The appropriation of another’s ideas, processes, results, or words without giving appropriate credit.
25.2.2 Conflict of Interest

Having a financial or other interest in a company for whom one is conducting a clinical trial and not disclosing this information. This can give an impression of dishonesty, and give rise to ethical and legal problems. (See Ochsner Policy “Conflict of Interest”). If an IRB member has a conflict of interest with a protocol under review, they must leave the room during the discussion and may not vote on that protocol.

25.2.3 Fraud (Falsification)

Anyone involved in the research study can commit fraud. Fraud is the deliberate reporting of false or misleading data, or the withholding of reportable data, with the intent to mislead the sponsor. This misconduct should be reported to IRB and either the FDA or the Office of Research Integrity (ORI, a branch of the OHRP) as applicable.

Falsification is defined as a process of “manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.”

25.2.4 Investigator Misconduct

This can involve violations of the Code of Federal Regulations, manipulation of research data, or fabrication of research data.

25.2.5 Negligence

Occurs when the Investigator fails to exercise sufficient control over the data leading to compromised data that must be removed from the study database and cannot be included in the statistical analysis of the clinical trial.

25.3 Implications of Research Misconduct

25.3.1 Criminal Liability

Violation of the regulations concerning clinical trials can lead to criminal penalties, and result in state or federal criminal prosecution.

Examples of actions resulting in this type of penalty could be the intentional creation of false or misleading data, or assistance with covering up attempts to do this.

25.3.2 Civil Liability

Deliberate actions may result in liability for monetary damages. This may involve the CRC, Investigator, Institution, and Sponsor. An Investigator who does not adequately supervise his study staff with resulting harm to a patient can be found liable.
In the event that research misconduct is occurring at Ochsner it should be reported it to the Vice President and Director of Research. He/she will then establish a committee to investigate this. The Research Compliance Officers can also be consulted if research misconduct is witnessed.

Ochsner policy # 8042-8 (Research Misconduct) provides a detailed description of research misconduct and can be accessed on the Academic Division-Research website.

26.0 OTHER RESEARCH RESOURCES

Some additional research resources available to the Ochsner research community include

26.1 Ochsner Academic Division Research Website

The Academic Research Division Research Website includes information on policies and procedures, educational programs, IRB forms and information, pharmacy procedures for dispensing and storing medications, contact information, and other resources.

26.2 Clinical Research Department & Resource Center

The Clinical Research Department is located on the 2nd floor of the New Research Building. The Clinical Research Department provides CRC support and protocol assistance. For more details on these services, please contact the Director of Clinical Research Support at extension 2-4685 to schedule an appointment.

Contained within the Clinical Research Department is the Research Resource Center. The Resource Center contains a library of videos and paperback publications related to the conduct of clinical research.

The Clinical Research Department also provides research education support for all researchers at Ochsner. This assistance is for investigators, CRCs, and residents. The department provides assistance and guidance about the research process. For more details, please contact the Director of Clinical Research Support at extension 2-4685.

26.3 In-house Statistician

Please contact Marie Krousel-Wood, M.D. at extension 2-3680 for statistician assistance with study design and statistical analysis. Marie Krousel-Wood, M.D is located on the 2nd floor of the New Research Building.

26.4 Clinical Research Orientation Sessions

Clinical research orientation modules are held on a regular basis. All new clinical research staff are invited to attend, as well as any staff who are interested in a refresher of research at Ochsner. For more information and a list of upcoming workshops or modules, please contact the Clinical Research Support Department at extension 2-4680.
26.5 Physician-Investigator Orientation Sessions

Physician-Investigator Orientation Sessions have been designed to give physicians new to research at Ochsner a concise overview of responsibilities, resources and requirements. Please contact the Clinical/Outcomes Research Department at extension 2-3680 for information.

26.6 RCR Core Lecture Series

The Responsible Conduct in Research (RCR) Core Lecture Series aims to educate healthcare professionals about the latest information and regulatory issues that are related to conducting research. The lecture series furthers Ochsner’s commitment to educating its researchers about the responsible conduct of research. Each year, between the months of September & November, there are approximately 6 lectures held on a weekly basis.

For more information about the RCR Core Lecture Series, please contact the Clinical Research Support Department (ext. 2-4680).

26.7 Clinical Research Coordinator (CRC) Monthly Meetings

Clinical Research Coordinators (CRC), nurses, and other staff engaged in clinical research are encouraged to attend these monthly meetings. Continuing education credits are provided. Please contact the Clinical Research Support Department (ext. 2-4680) for additional information.

26.8 Medical Staff Quarterly Research Open Forums

The purpose of the forum is increase communication regarding clinical and basic science research at Ochsner. For information and dates of the forums, please contact the Clinical/Outcomes Research Department at extension 2-3680.

26.9 On-line Contracts Tracking System

SECTION UNDER CONSTRUCTION

27.0 REFERENCES

The following resources were utilized in preparing this Clinical Research Handbook:


Indiana University Clinical Trials Program. On the web at: http://clinicaltrials.iupui.edu/inv_internal.htm


28.0 APPENDIX A: SCHEMA OF THE CLINICAL TRIAL PROCESS

SECTION UNDER CONSTRUCTION
29.0 APPENDIX B: FEASIBILITY CHECKLIST FOR CLINICAL TRIALS

Study Title:

Study Phase- I □ II □ III □ IV □

PI:

1. Are there time constraints/deadlines that will require short start up time (<6wks)?
   □ YES □ NO

2. Are we an “add on” site for this study? If so, what is the timeframe remaining for accrual activity? □ YES □ NO _____ Weeks _____ Months

3. Anticipated Enrollment: __________

4. Projected “Close to enrollment” date: __________

5. Sponsor Name: ______________________________

6. Device: □ YES □ NO

7. FDA Classification: Category

8. Locations for recruitment:

   □ Main Campus □ Baton Rouge Neighborhood Clinics (List below)
   □ Kenner □ Baptist Metairie
   □ West Bank □ NorthShore
   □ St. Ann

9. Locations for Implementation:

   □ Main Campus □ Baton Rouge Neighborhood Clinics (List below)
   □ Kenner □ Baptist
   □ West Bank □ NorthShore
   □ St. Ann

Financial Considerations:

10. Study start up funds provided: □ YES □ NO unsure, but probably not note that budget still needs to be negotiated

11. Funding for screening cost provided: □ YES □ NO

12. Funding for screen failures provided: □ YES □ NO

13. Does the investigational device need to be purchased: □ YES □ NO If yes, cost $ ________

14. Are required treatments/diagnostic/procedures available at OHS facilities?
   □ YES □ NO

15. Will study scheme/timing of interventions/follow-up create barriers to successful completion? □ YES □ NO If yes, explain:
16. Will anticipated volume or complexity create access issues/bottlenecks in involved clinical depts.? □ YES □ NO

17. Will additional research or clinical staff be required for study implementation/management? □ YES □ NO If yes, are additional positions funded by the sponsor? □ YES □ NO

18. Do we have the required expertise/institutional competence to meet study requirements? □ YES □ NO If no, what’s needed

19. Are there specific equipment requirements that will require purchase prior to the initiation of the study such as; refrigerator, freezer □ YES □ NO If yes, explain

20. If yes, will the sponsor provide funding for purchase? □ YES □ NO

21. Will additional or special storage be required for study materials or investigational product? □ YES □ NO If yes, explain: don’t think so, though the amount & size of study medication containers to be stored are unknown at this time

**Study Population:**
Evidence of required study population may be requested as necessary

22. Subject Health Status: □ Acute □ Chronic □ Healthy
23. Population Age: □ Adults □ Children
24. Are there current active studies involving the same population of patients? □ YES □ NO
25. If yes, are they still open to enrollment? □ YES □ NO
26. Is study initiated in the hospital? □ YES □ NO
27. If yes, where will recruitment/screening occur?
- □ Emergency Room
- □ Intensive Care Unit
- □ Acute Care Unit
- □ Outpatient diagnostic area (i.e., radiology, endoscopy)
28. Anticipated risk participant
- □ High □ Medium □ Low

**Procedures/Clinical Requirements**
If Applicable:

29. If study related procedures/medications administered be performed in the hospital will hospital staff be involved? □ YES □ NO
Procedures/Clinical Requirements cont’d

30. Does the sponsor provide training resources for research and clinical staff?
   □ YES  □ NO

31. Will hospital staff be responsible for additional monitoring/data collection/case report form completion?
   □ YES  □ NO

32. Who will be responsible for after hours study coverage for hospitalized patients?
   □ PI  □ CRC  □ Other  If other, explain:

33. Does the study require cooperation/services/or an investigator from another dept?
   □ YES  □ NO  If yes, Dept Name:

34. Study requires __________ Visits over __________ Months (per subject)

Study Documentation Requirements

35. CRFs electronic?
   □ YES  □ NO

36. If yes:  □ Client based (software installations on existing PC)
   □ Web based

37. Query resolution electronic?
   □ YES  □ NO  unknown at this time

38. If yes:
   □ Client based
   □ Web based

39. Do any study documents (i.e. diaries, questionnaires) require transcription? (Entering information from questionnaire or survey into a computer software or web based program by research staff)
   □ YES  □ NO

40. Are participant questionnaires required?
   □ YES  □ NO  If yes,
   Number __________  Frequency __________
30.0 APPENDIX C: PHARMACY INVESTIGATIONAL DRUG DISPENSATION FORMS

Investigational Drug Fact Sheet

1. Generic and Trade Name:

2. Dosage forms and strengths:

3. Usual dosage range, including dosage schedule and route of administration:

4. Indications pursued in this study:

5. Expected therapeutic effect to be studied:

6. Expected and potential adverse effects, including symptoms of toxicity and their treatment:

7. Drug-drug and drug-food interactions:

8. Contraindications:

9. Storage requirements:

10. Instructions for disposition of unused doses:

11. Names and telephone numbers of principal and authorized sub-investigators and study coordinators from form 1572:
Ochsner Clinic Foundation
Outpatient Pharmacy
Patient Enrollment Form

1. Study name and Protocol Number:

2. Date and time:

3. Patient’s name:

4. Patient’s clinic number:

5. Patient’s study number:

6. Route of administration:

7. Medication and regimen:

8. Date and time medication needed:

9. Other information that may be study specific:

10. If comprod (computer system) is down please provide:
   a. Patient’s address:
   b. Patient’s phone number:
   c. Patient’s date of birth:
APPENDIX D: C-DAN & IN-PATIENT PHARMACY FORMS

OCHSNER CLINIC FOUNDATION
INVESTIGATIONAL DRUG FACT SHEET

I. Generic & Trade Name: ____________________________________________
II. Pharmacological Class: __________________________________________
III. Pharmacological Actions: ________________________________________

IV. Common Adverse Drug Effects: __________________________________

V. Warning and Precautions: _________________________________________

VI. Administration Information: ______________________________________

VII. Special Handling Required: ______________________________________

Approved by: ______________________________________________________
(Pharmacist)
The information contained on this Nursing Activity Sheet is designed to guide the nurse in collecting patient data before and after the administration of an investigational drug. The information listed below must be collected at the intervals indicated, and documented in the patient’s chart. FAILURE TO COLLECT AND DOCUMENT THE INFORMATION LISTED BELOW MAY REQUIRE THAT A PATIENT BE REMOVED FROM THE STUDY.

I. Assessment (includes VS, labs, symptomatology)

II. Reporting (parameters and to whom)

III. Documentation

Note to RN’s administering this drug:
Investigational drug studies require that an informed consent be obtained prior to administration. Visually verify that informed consent was obtained prior to administering this drug.
Ochsner Clinic Foundation
In-service Attendance Record

Title of the Inservice: __________________________________________________________
Date:___________________ Time:_____________ Length: ____________________
Instructor(s): __________________________________________________________
Nursing Education Representative:________________________________________
Location: ________________________
Code: _______________________

<table>
<thead>
<tr>
<th>Print Name</th>
<th>Title</th>
<th>Signature</th>
<th>Unit/Shift</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Print Name</td>
<td>Title</td>
<td>Signature</td>
<td>Unit/Shift</td>
</tr>
<tr>
<td>------------</td>
<td>-------</td>
<td>-----------</td>
<td>------------</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Ochsner Clinic Foundation
Inpatient Investigational Drug Study
NURSING CHARGE

Date: __________

Drug Study Title: _______________________________________________________

Drug Name: ___________________________________________________________

Protocol #: ___________________________________________________________

Physician (Principal Investigator): ________________________________

Drug Study Account #: ______________________________

Nursing Charge:

Hrly nursing rate X # of nursing hrs/ day X # of days = _____ X # of pts per study=

_________________ X ___________ X ________ = ________ X ________ = __________

Comments:

____________________________________

Study coordinator

____________________________________

Approving RN

Routing:
Include this form with “Research Study Payment Authorization” form for pre IRB review by Joan Kateiva.

Note to RN’s administering this drug:
Investigational drug studies require that an informed consent be obtained prior to administration. Visually verify that informed consent was obtained prior to administering this drug.
Below please find a list of terms frequently used in clinical research along with a brief description of each term. The glossary has been adapted from CenterWatch, a division of Thomson Healthcare, Inc, which can be located on the web at: http://www.centerwatch.com/patient/glossary.html

A

**Adverse Drug Reaction (ADR):** An unintended reaction to a drug taken at doses normally used in man for prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function. In clinical trials, an ADR would include any injuries by overdosing, abuse/dependence, and unintended interactions with other medicinal products.

**Adverse Event (AE):** A negative experience encountered by an individual during the course of a clinical trial that is associated with the drug. An AE can include previously undetected symptoms, or the exacerbation of a pre-existing condition. When an AE has been determined to be related to the investigational product, it is considered an Adverse Drug Reaction.

**Adverse Event Reports:** Investigator reports of all serious and adverse events, injury and deaths given to the sponsor, the IRB and the FDA.

**Assurance:** A renewable permit granted by the federal government to an institution or research center to conduct clinical trials.

B

**Biologic:** A virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product applicable to the prevention, treatment or cure of diseases or injuries of man.

**Biotechnology:** Any technique that uses living organisms, or substances from organisms, biological systems, or processes to make or modify a product or process, to change plants or animals, or to develop micro-organisms for specific uses.

**Blinding:** The process through which one or more parties to a clinical trial are unaware of the treatment assignments. In a single-blinded study, usually the subjects are unaware of the treatment assignments. In a double-blinded study, both the subjects and the investigators are unaware of the treatment assignments. Also, in a double-blinded study, the monitors and sometimes the data analysts are unaware. "Blinded" studies are conducted to prevent the unintentional biases that can affect subject data when treatment assignments are known.

C

**Case Report Form (CRF):** A record of pertinent information collected on each subject during a clinical trial, as outlined in the study protocol.

**Certified Research Coordinator (CCRC):** CRC with ≥2 years experience and with certification earned by passing required program and exam through the Association of Clinical Research Professionals (ACRP).
Clinical Investigation: A systematic study designed to evaluate a product (drug, device, or biologic) using human subjects, in the treatment, prevention, or diagnosis of a disease or condition, as determined by the product's benefits relative to its risks. Clinical investigations can only be conducted with the approval of the Food and Drug Administration (FDA).

Clinical Research: Study of drug, biologic or device in human subjects with the intent to discover potential beneficial effects and/or determine its safety and efficacy. Also called clinical study and clinical investigation. Note that in this manual, this term is used in its narrow sense as used by the FDA. Thus, it does not encompass all the research that is carried out in the clinical setting (e.g., health services research).

Clinical Research Associate (CRA): Person employed by the study sponsor or CRO to monitor a clinical study at all participating sites. See also, monitor.

Clinical Research Coordinator (CRC): Site administrator for the clinical study. Duties are delegated by the investigator. Also called research, study or healthcare coordinator, and data manager, research nurse or protocol nurse.

Clinical Study Materials: Study supplies (i.e., study test article, laboratory supplies, case report forms) provided by the study sponsor to the investigator.

Clinical Trial: Any investigation in human subjects intended to determine the clinical pharmacological, pharmacokinetic, and/or other pharmacodynamic effects of an investigational agent, and/or to identify any adverse reactions to an investigational agent to assess the agent's safety and efficacy.

Common Rule: 1991 agreement to cover all federal-sponsored research by a common set of regulations. The Common Rule is the Subpart A of Title 45 CFR part 46, which was initially issued by the Department of Health & Human Services prior to being formally adopted by other federal agencies.

Consent Form: A document explaining all relevant study information to assist the study volunteer in understanding the expectations and requirements of participation in a clinical trial. This document is presented to and signed by the study subject.

Contract Research Organization (CRO): A person or an organization (commercial, academic or other) contracted by the sponsor to perform one or more of a sponsor's study-related duties and functions.

Control Group: A comparison group of study subjects who are not treated with the investigational agent. The subjects in this group may receive no therapy, a different therapy, or a placebo.

Data: This term is legally defined according to the institution. It generally refers to recorded information regardless of form. Most institutions hold title to data while researchers have rights to access the data.

Data Management: The process of handling the data gathered during a clinical trial. May also refer to the department responsible for managing data entry and database generation and/or maintenance.

Deception: Intentionally misleading or withholding information about nature of experiment.

Declaration of Helsinki: A series of guidelines adopted by the 18th World Medical Assembly in Helsinki, Finland in 1964. The Declaration addresses ethical issues for physicians conducting biomedical research involving human subjects. Recommendations include the procedures required to ensure subject safety in clinical trials, including informed consent and Ethics Committee reviews.
Demographic Data: Refers to the characteristics of study participants, including sex, age, family medical history, and other characteristics relevant to the study in which they are enrolled.

Device: An instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent, or other similar or related article, including any component, part or accessory, which is intended for use in the diagnosis, cure, treatment or prevention of disease. A device does not achieve its intended purpose through chemical action in the body and is not dependent upon being metabolized to achieve its purpose.

Documentation: All forms of records that describe or document study methods, conduct and results, including any adverse events and actions taken.

Double-Blind: The design of a study in which neither the investigator nor the subject knows which medication (or placebo) the subject is receiving.

Drug: As defined by the Food, Drug and Cosmetic Act, drugs are "articles (other than food) intended for the use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals, or to affect the structure or any function of the body of man or other animals."

Drug Product: A finished dosage form (e.g. tablet, capsule, or solution) that contains the active drug ingredient usually combined with inactive ingredients.

Drug or Device Accountability Records (DAR): Required documentation for material accountability, quantity used and left over, and date of disposal.

Effective Dose: The dose of an investigational agent that produces the outcome considered "effective," as defined in the study protocol. This could mean a cure of the disease in question or simply the mitigation of symptoms.

Efficacy: A product's ability to produce beneficial effects on the duration or course of a disease. Efficacy is measured by evaluating the clinical and statistical results of clinical tests.

Ethics Committee: An independent group of both medical and non-medical professionals who are responsible for verifying the integrity of a study and ensuring the safety, integrity, and human rights of the study participants.

Exclusion Criteria: Refers to the characteristics that would prevent a subject from participating in a clinical trial, as outlined in the study protocol.

Food and Drug Administration (FDA): An agency within the Department of Health and Human Services that enforces the Food, Drugs and Cosmetics Act and related federal public health laws. Grants IND, IDE, PMA and NDA approvals.

Food Drug and Cosmetic Act (FD & C Act): States only drugs, biologics and devices proven safe and effective can be marketed.
FDA Form 1572: A list of commitments and requirements by the FDA for each investigator performing drug/biologics studies. Also referred to as a statement of the investigator.

Formulation: The mixture of chemicals and/or biological substances and excipients used to prepare dosage forms.

Generic Drug: A medicinal product with the same active ingredient, but not necessarily the same inactive ingredients as a brand-name drug. A generic drug may only be marketed after the original drug's patent has expired.

Good Clinical Practice (GCP): International ethical and scientific quality standard for designing, conducting, monitoring, recording, auditing, analyzing and reporting studies. Insures that the data reported is credible and accurate, and that subject's rights and confidentiality are protected.

Human Subject: A patient or healthy individual participating in a research study. A living individual about whom an investigator obtains private information or data through intervention or interaction.

Inclusion Criteria: A list of criteria that must be met by all study subjects.

Informed Consent: The voluntary verification of a patient's willingness to participate in a clinical trial, along with the documentation thereof. This verification is requested only after complete, objective information has been given about the trial, including an explanation of the study's objectives, potential benefits, risks and inconveniences, alternative therapies available, and of the subject's rights and responsibilities in accordance with the current revision of the Declaration of Helsinki.

Institution: Location of research. Retains ultimate responsibility for human subject regulation compliance.

Institutional Review Board (IRB): An independent group of professionals designated to review and approve the clinical protocol, informed consent forms, study advertisements, and patient brochures, to ensure that the study is safe and effective for human participation. It is also the IRB's responsibility to ensure that the study adheres to the FDA's regulations.

Investigational New Drug Application (IND): The petition through which a drug sponsor requests the FDA to allow human testing of its drug product.

Investigational Device Exemption (IDE): Exemption from FD & C Act to study investigational medical devices.

Investigator: A medical professional, usually a physician but may also be a nurse, pharmacist or other health care professional, under whose direction an investigational drug is administered (or dispensed if the physician has a Louisiana license to dispense drugs). A principal investigator is responsible for the overall conduct of the clinical trial at his/her site, and is 100% accountable for the study.
**Investigator's Brochure (IB):** Relevant clinical and non-clinical data compiled on the investigational drug, biologic or device being studied.

**In Vitro Testing:** Non-clinical testing conducted in an artificial environment such as a test tube or culture medium.

**In Vivo Testing:** Testing conducted in living animal and human systems.

**MedWatch Program:** An FDA program designed to monitor adverse events (AE) from drugs marketed in the U.S. Through the MedWatch program, health professionals may report AEs voluntarily to the FDA. Drug manufacturers are required to report all AEs brought to their attention.

**Monitor:** Person employed by the sponsor or CRO who reviews study records to determine that a study is being conducted in accordance with the protocol. A monitor's duties may include, but are not limited to, helping to plan and initiate a study, and assessing the conduct of studies. Monitors work with the clinical research coordinator to check all data and documentation from the study. See also CRA.

**Monitoring:** Reviewing a clinical study, ensuring conduct, proper records and reports are performed as stated in the clinical protocol, standard operating procedures, GCP and by regulatory requirements.

**Multiple Project Assurance:** Permit given to institution for multiple federally funded research grants for a specified period of time. States institution retains responsibility for all research involving humans and that the institution must have an established IRB.

**National Research Act:** Act created by the National Commission for Protection of Human Subjects of Biomedical and Behavioral Research in 1974 and mandated review of studies by institutional review boards and subject protection by informed consent.

**National Institutes of Health (NIH):** Agency within DHHS that provides funding for research, conducts studies and funds multi-site national studies.

**New Drug Application (NDA):** The compilation of all non-clinical, clinical, pharmacological, pharmacokinetic and stability information required about a drug by the FDA in order to approve the drug for marketing in the U.S.

**Nuremberg Code:** As a result of the medical experimentation conducted by Nazis during World War II, the U.S. Military Tribunal in Nuremberg in 1947 set forth a code of medical ethics for researchers conducting clinical trials. The code is designed to protect the safety and integrity of study participants.

**Off Label:** The unauthorized use of a drug for a purpose other than that approved of by the FDA.
Office for Human Research Protection (OHRP): A federal government agency that issues Assurances and overseas compliance of regulatory guidelines by research institutions.

Open-Label Study: A study in which all parties, (patient, physician and study coordinator) are informed of the drug and dose being administered. In an open-label study, none of the participants are given placebos. These are usually conducted with Phase I & II studies.

Orphan Drug: A designation of the FDA to indicate a therapy developed to treat a rare disease (one which afflicts a U.S. population of less than 200,000 people). Because there are few financial incentives for drug companies to develop therapies for diseases that afflict so few people, the U.S. government offers additional incentives to drug companies (i.e. tax advantages and extended marketing exclusivity) that develop these drugs.

Over-the-Counter (OTC): Drugs available for purchase without a physician's prescription.

Patient: Individual seeking medical care.

Pharmacoeconomics: The study of cost-benefit ratios of drugs with other therapies or with similar drugs. Pharmacoeconomic studies compare various treatment options in terms of their cost, both financial and quality-of-life. Also referred to as "outcomes research".

Phase I Study: The first of four phases of clinical trials, Phase I studies are designed to establish the effects of a new drug in humans. These studies are usually conducted on small populations of healthy humans to specifically determine a drug's toxicity, absorption, distribution and metabolism.

Phase II Study: After the successful completion of phase I trials, a drug is then tested for safety and efficacy in a slightly larger population of individuals who are afflicted with the disease or condition for which the drug was developed.

Phase III Study: The third and last pre-approval round of testing of a drug is conducted on large populations of afflicted patients. Phase III studies usually test the new drug in comparison with the standard therapy currently being used for the disease in question. The results of these trials usually provide the information that is included in the package insert and labeling.

Phase IV Study: After a drug has been approved by the FDA, phase IV studies are conducted to compare the drug to a competitor, explore additional patient populations, or to further study any adverse events.

Pivotal Study: Usually a phase III study which presents the data that the FDA uses to decide whether or not to approve a drug. A pivotal study will generally be well-controlled, randomized, of adequate size, and whenever possible, double-blind.

Placebo: An inactive substance designed to resemble the drug being tested. It is used as a control to rule out any psychological effects testing may present. Most well-designed studies include a control group which is unwittingly taking a placebo.

Pre-Clinical Testing: Before a drug may be tested on humans, pre-clinical studies must be conducted either in vitro but usually in vivo on animals to determine that the drug is safe.

Protocol: A detailed plan that sets forth the objectives, study design, and methodology for a clinical trial. A study protocol must be approved by an IRB before investigational drugs may be administered to humans.
Protocol Amendment: Changes or clarifications made in writing to the original protocol.

Q

Quality Assurance: Systems and procedures designed to ensure that a study is being performed in compliance with Good Clinical Practice (GCP) guidelines and that the data being generated is accurate.

R

Randomization: Study participants are usually assigned to groups in such a way that each participant has an equal chance of being assigned to each treatment (or control) group. Since randomization ensures that no specific criteria are used to assign any patients to a particular group, all the groups will be equally comparable.

Recruitment: Act of enrolling subjects with the proper inclusion criteria.

Recruitment Period: Time allowed to recruit all subjects for a study.

Regulatory Affairs: In clinical trials, the department or function that is responsible for ensuring compliance with government regulations and interacts with the regulatory agencies. Each drug sponsor has a regulatory affairs department that manages the entire drug approval process.

Research: Systematic investigation designed to develop or contribute to generalizable knowledge. Includes Clinical Research.

Research Team: The team of researchers, which may include the Principle Investigator (PI), sub-investigator(s), clinical research coordinator, research assistants, and office staff involved in a research study.

Risk-Benefit Ratio: Risk to individual subject vs. potential benefits. Also called Risk-Benefit Analysis.

S

Safety Reports: FDA report required by investigator for any serious and unexpected adverse experience.

Serious Adverse Event (SAE): Any adverse event (AE) that is fatal, life-threatening, permanently disabling, or which results in hospitalization, initial or prolonged.

Single Project Assurance: Permit given to institution for single grant in compliance with government standards. See "assurance."

Source Data: All information contained in original records and certified copies of results, observations or other facets required for the reconstruction and evaluation of the study that is contained in source documents.

Source Documentation: Location where information is first recorded including original documents, data and records.

Sponsor: Individual, company, institution or organization taking responsibility for initiation, management and financing of study.
**Standard Operating Procedure (SOP):** Official, detailed, written instructions for the management of clinical trials. SOPs ensure that all the functions and activities of a clinical trial are carried out in a consistent and efficient manner.

**Standard Treatment:** The currently accepted treatment or intervention considered to be effective in the treatment of a specific disease or condition.

**Sub-investigator:** Helps conduct investigation at a study site.

**Subject/Study Subject:** Participant in a study. See "Human Subject."

---

**Telephone Report:** Notification via telephone to the FDA of unexpected fatal or life threatening advent associated with a clinical study.

**Treatment IND:** A method through which the FDA allows seriously ill patients with no acceptable therapeutic alternative to access promising investigational drugs still in clinical development. The drug must show "sufficient evidence of safety and effectiveness." In recent decades many patients with AIDS have been able to access unapproved therapies through this program.

---

**Unexpected Adverse Drug Reaction:** A reaction that is not consistent in nature or severity with study application.

---

**Vulnerable Subjects:** Group/individual that cannot give informed consent because of limited autonomy (e.g., children, mentally ill and prisoners). Also refers to subjects who may be unduly influenced to participate (e.g., students, subordinates and patients).

---

**Well-being:** Subject's physical and mental soundness.

**Withdrawal Application:** Investigator/sponsor letter to FDA requesting application withdrawal when no additional work is envisioned.
OCHSNER CLINIC FOUNDATION
TRAVEL AUTHORIZATION FORM
(TRIP APPROVAL)

TO: ___________________________ Date: __________
I would like to request approval for the following trip:

Name of Meeting:______________________________

Location of Meeting: __________________________

Meeting starts _______ at _______ A.M. and ends _______ A.M./P.M.

Number of days in attendance

Employee to attend (ONE EMPLOYEE PER FORM):

Name ________________________________________ Social Security #

What are the Benefits to OCF and Employee Traveling?

Is it required travel? If yes, By Whom?

Employee’s extension Co. #/Center # to be charged

1. Prefers to travel by airplane _______, automobile _______, and would leave New Orleans on _______ and return on _______.

2. Would like a single room at the _______________________

Hotel/motel on the nights of _______________________________________________________

Note: Original receipts must be submitted to support travel/meeting expenses.

Employee Signature ___________ Date ___________ Approval Dept. Manager ___________ Date ___________

TOTAL ESTIMATED COST MUST BE COMPLETED

Budgeted _______ Unbudgeted _______ Total Estimated Cost _______

Trip Approved _______ Disapproved _______ Registration _______

Hotel _______

Transportation _______

Meals/Misc _______

Total _______

________________________________________________________

SIGNATURE OF VICE PRESIDENT

Original to Accounts Payable with Check Request
Copy Retained By Department General Accounting Policy #8516-4

2/02

- 106 -
APPENDIX G: PATHOLOGY AND LABORATORY STUDY APPROVAL

DEPARTMENT OF PATHOLOGY AND LABORATORY MEDICINE

PROCESS FOR DRUG STUDY APPROVAL

I. ______ Drug Study Lab Manual submitted 2-3 weeks prior to start of study.
   a) ______ Date/initials submitted to Sendout Supervisor
   b) ______ Date/initials received by Sendout Supervisor

II. ______ Is Study approved by the IRB?
    a) ______ yes
    b) ______ no

III. Name of Study ________________________________

IV. Name of Contact Person _____________________________

V. Extension/Beep of Contact Person ______________________

VI. Cost information required?
    a) ______ no
    b) ______ yes >>> 1. Validate Pricing __________________________ LIS Manager
        (date/initials)
    2. Date routed/received ___________________________ Sendout Supv.
       (date/initials)

VII. Lab Venipuncture Required?
    a) ______ no
    b) ______ yes >>> 1. Collection validation ___________________________ VP Manager
        (date/initials)
    2. Date routed/received ___________________________ Sendout Supv.
       (date/initials)

VIII. AP/Cytology Required?
    a) ______ no
    b) ______ yes >>> 1. Specimen Validation ___________________________ AP/Cytology Supv.
       (date/initials)
       Physician Supv.
       (date/initials)
    2. Date routed/received ___________________________ Sendout Supv.
       (date/initials)

IX. Freezer Storage Box needed?
    a) ______ no
    b) ______ yes >>> 1. Storage Box Validation ___________________________ Sendout Supv.
        (date/initials)

XII. Type of Patient?
    a) ______ Clinic
    b) ______ Hospital

XII. Study Acceptance:
    a) Contact person notification ___________________________ Sendout Supv.
b) Drug Study folder/QSE provided ______________________ Sendout Supv.  
(date/initials)

XIII. Study Denial  
  a) ________________ Physician Supv.  
    (date/initials)  
  b) Contact person notification ______________________ Sendout Supv.  
    (date/initials)

XIV. Closing of Study  
  Sendout Supv. Notified ______________________ (date)