Principal Investigator Responsibilities

I. Purpose
   The purpose of this policy is to identify the responsibilities of Principal Investigators (PIs) performing Human Subject Research within Ochsner Health Systems (OHS).

II. Scope
   This policy applies to all individuals at OHS whom are engaged in human subject research including but not limited to any person paid by, under the control of or affiliated with the institution such as scientists, investigators, research coordinators, fellows, residents, guest researchers and collaborators.

III. Policy Statements
   A. The PI is the ultimate protector of the subjects’ rights and safety.
   B. The PI is responsible for ensuring compliance with the following:
      1. All federal and state regulations;
      2. Sponsor requirements;
      3. Institutional Review Board/institutional policies in conducting human subject research.

IV. Procedures/Standards and Roles & Responsibilities
   A. Human Subject Protection
      1. Subjects are consented for research studies only under the conditions of effective informed consent, as a voluntary act, free from coercion or undue influence from the investigator or members of the study staff.
      2. The PI or designee informs subjects of new information regarding the trial, including but not limited to new adverse events, Food and Drug Administration (FDA) alerts, and warnings. Accordingly, subjects are allowed to make an informed decision about continuation in the trial.
      3. The PI verifies clinical research protocols are written and/or implemented to maximize possible benefits to the subject or to society. This is an ongoing process, spanning from study feasibility through trial execution and closure.
      4. The PI minimizes the risk of psychological, physical, legal, social and economic harm by:
         a. Ensuring study staff are qualified to perform their delegated tasks under the state and federal regulations, sponsor and institutional requirements.
         b. Following the institutional policy on Protected Health Information (PHI)
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c. Monitoring protocol deviations and amending processes to prevent recurrences
d. Reviewing adverse events and ensure appropriate medical care is obtained for the events.

B. Principal Investigator (PI) Qualifications:
1. Only Ochsner scientific staff (in the generic sense of the term, e.g., physicians, nurses, Ph.D., etc.) may serve as PIs on protocols.
2. The investigator meets the required Human Subject Research education as outlined in the institutional policy of “Educational Requirements of Study Staff”.

C. Supervision and Oversight of the Research Process:
1. The PI is obligated to ensure research is not initiated until the following approvals are obtained:
   a. The IRB,
   b. Appropriate institutional committee/departments, and
   c. the Office of Grants Management (OGM)
2. The PI is responsible to ensure subjects or their legally authorized representative has signed an IRB approved informed consent prior to subject participation in the research, unless the requirements have been waived by the IRB.
3. The PI ensures protocol training of study staff throughout the trial, adherence to the protocol, and regularly reviews the research process, addressing any deficiencies identified.
4. The PI must maintain a list of appropriately qualified persons to whom they have delegated significant clinical trial-related duties.
5. The PI is responsible for the procurement and use of the investigational drug/device throughout the trial.

D. Recordkeeping and record retention:
4. The PI is to maintain adequate and accurate case histories for the time prescribed by the sponsor, and by federal, state, and institutional requirements.
5. Research records, including regulatory documents and case histories, must be accessible for inspection by authorized agents of the institution, the sponsor and federal authorities.
   a. Further information can be found in Ochsner’s Guidance: Research Data Retention.

E. Confidentiality:
Principal Investigator Responsibilities

1. The PI must adhere to all regulatory and institutional requirements related to confidentiality of information obtained in the course of the conduct of clinical trials to include protected health information and proprietary scientific information.

F. Reports:
   1. It is the responsibility of the PI to guarantee all required reporting are completed and submitted in time frames which are defined by the sponsor, and the IRB, in accordance with institutional, and federal requirements.
   2. The PI reports adverse events, deviations, and unanticipated problems to the IRB and sponsor according to their requirements.
   3. The PI submits progress reports and requests for continuing review to the IRB in accordance with federal, institutional and IRB policies.
   4. The PI is responsible to obtain required approvals/acknowledgment from the sponsor, institution, and federal agencies as appropriate, and in accordance with their requirements.

V. Enforcement and Exceptions
Failure to comply with this policy may result in disciplinary action up to and including termination of employment for employees or termination of contract or service for third-party personnel, students or volunteers.

VI. Definitions:
[Section intentionally left blank]

VII. Internal References
IRB Written Procedures at https://ersa.ochsner.org
OHS.RES.004 Human Subject Research
OHS.RES.005 Human Subject Protection
OHS.RES.003 Educational Requirements for Personnel in Clinical Research
OHS.ACR.014 Source Documentation in Clinical Research
OHS.RES.008 External Safety Reporting
OHS.RES.009 Adverse Event Reporting – Internal Events
OHS.RES.001 HIPAA
OHS Guidance for Principal Investigator Responsibilities
OHS Guidance for Unanticipated Problems
Principal Investigator Responsibilities

OHS Guidance: Research Data Retention

VIII. External References
Guidance for Industry: Investigator Responsibilities – Protecting the Rights, Safety, and Welfare of Study Subjects
45 CFR 46
21 CFR 50.3
21CFR 56.102

IX. Approved
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X. Policy History
8042-18 Principal Investigator