UNIVERSITY of LOUISIANA LAFAYETTE

POLICY FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH

Policy #	RE.006.1
Responsible Executive:	Vice President for Research, Innovation, & Economic Development
Responsible Office:	Office of Research Integrity
Originally Issued:	2/21/2024
Latest Revision:	2/21/2024

I. Policy Statement

The University of Louisiana at Lafayette ("University") conducts its teaching and Research activities involving Human Subjects Research in compliance with the Common Rule, also known as the Federal Policy for the Protection of Human Subjects (45 C.F.R. 46). In order to protect Human Subjects participating in Research, all members of a Research team are required to conduct Human Subject Research in accordance with the protocol approved by the Institutional Review Board ("IRB") and in accordance with federal regulations, state law, and University policy. Failure to do so may lead to Noncompliance that must be corrected or rectified to restore and maintain appropriate Human Subject protection.

II. Purpose of Policy

This Policy provides the framework for the review and approval of Human Subjects Research and the resolution of Noncompliance with this Policy and the federal regulations. As required by 45 C.F.R. 46, the University established the IRB to review, approve, and oversee the conduct of Human Subject Research. The IRB has the authority to approve, require modifications (to secure approval), disapprove, and suspend or terminate approval of Research activities not being conducted in accordance with IRB requirements**.** The IRB has the authority to observe or authorize the observation of the Informed Consent process and the conduct of the Research. The University has designated the IRB as responsible for conducting initial and continuing reviews and providing oversight for all Research activities involving the use of Human Subjects performed by employees, students, and staff of the University.

The President of the University has appointed the Vice President for Research, Innovation, and Economic Development ("VPRIED") as the Institutional Official ("IO") responsible for the protection

of Human Subjects in Research. The VPRIED has created the Office of Research Integrity ("ORI") to assist the IRB with its oversight duties by assisting with policy development, reviewing training opportunities, and processing applications for IRB review.

A. Minimum Standard for the Review of Human Subject Research

The 45 C.F.R. 46 provides a minimum standard for the review of Human Subject Research. In accordance with federal regulations, the University is required to develop policies and procedures meeting or exceeding the minimum standard as appropriate. This Policy requires all Research involving Human Subjects or their information to be reviewed and approved by the IRB prior to the initiation of data collection. This requirement applies to all Human Subjects Research conducted by faculty, staff, and students in furtherance of their capacity at the University, regardless of the funding support for any particular project or endeavor.

Additionally, the IRB reviews all Human Subjects Research initiated from outside the University and which utilizes University faculty, staff, students, or alumni that has not been reviewed by a collaborator's IRB, including:

1. Research conducted on or off campus by University faculty, students, alumni, or staff in the furtherance of their capacity at the University; or

2. Research conducted on the University campus by non-University personnel when the collaborator's IRB does not have a Federalwide Assurance ("FWA") with the Office of Human Research Protections ("OHRP").

B. Human Subjects Research Reviewed and Approved at Another Institution

Human Subjects Research reviewed and approved at another institution may not require additional review if the external reviewing institution is covered by an FWA. Human Subjects Research reviewed and approved at international institutions without FWA must be reviewed and approved by that institution's ethics committee. Collaborators must first provide evidence of an institution's approval and a project description to the IRB office (via irb@louisiana.edu), who will then determine whether research can begin or if further review is required.

C. Role of the Investigator

The Investigator is responsible for the following:

1. Ensuring Human Subject Research is reviewed by the IRB, who determines it to be exempt from the federal regulations (45 C.F.R. 46.104) or approves it according to the standards outlined in the regulations (45 C.F.R. 46);

2. Conducting Human Subjects Research according to the requirements of the IRB and this Policy;

3. Ensuring the Research is conducted according to the IRB-approved application archived in IRBManager;

4. Collecting and retaining Informed Consent from all Human Subjects, as required by the IRB, in accordance with this Policy;

5. Protecting the privacy of the Human Subjects and the confidentiality of their data;

6. Ensuring the safety of the Human Subjects;

7. Meeting the terms of the grant, contract, or signed funding agreements, as appropriate;
8. Abiding by all applicable laws and regulations pertaining to the location of the Research;
9. Reporting any Noncompliance in accordance with this Policy as soon as they become aware of it;
10. Working with the IRB to remedy identified Noncompliance; and
11. Providing a proposed corrective action plan to prevent further Noncompliance, addressing, as appropriate:
    a) Safety of Human Subjects and others;
    b) Future compliance with the approved protocol; and
    c) Prevention of re-occurrence.

D. Role of the Director of ORI

The Director of ORI is responsible for the following:

1. Providing advice about submitting applications to the IRB;
2. Assisting the IRB Chair and IRB, as needed, including but not limited to:
    a) Drafting policy;
    b) Drafting guidelines;
    c) Maintaining the IRBManager system;
    d) Gathering and forwarding information as needed for the IRB;
    e) Providing Human Subjects Research training as needed; and
    f) Addressing questions about potential Noncompliance.

E. Role of the IRB

The IRB is responsible for the following:

1. IRB coordinators shall conduct pre-reviews of all applications.
    a) Applications are returned to the Investigator for modification as needed.
    b) Applications are sent to the IRB Chair and/or Vice Chair once sufficient revisions (if needed) are applied.
2. The IRB Chair and/or Vice Chair perform a final review of the application.
    a) Applications may be returned to the Investigator for further revisions.

b) The IRB Chair or Vice Chair may assign an additional IRB member to review an application, as needed.

c) The IRB Chair or Vice Chair or any IRB member reviewer may call for a full board review of the application, as needed.

d) The IRB Chair, Vice Chair, or full board, as needed, will adjudicate on the outcome of the application.

3. The IRB shall inform Investigators of the review outcome for each application.

a) The review level, according to the criteria in 45 C.F.R 46.104 and 110, will be determined to be one of the following:

i. Exempt;

ii. Exempt with limited review;

iii. Expedited;

iv. Full board; or

v. Not Human Subjects Research.

b) The review outcome will be one of the following:

i. Approved;

ii. Approved with continuing review;

iii. Disapproved; or

iv. Not Human Subjects Research.

c) All projects approved via full board review will have annual continuing review. Projects approved via expedited review may be required to have continuing review if higher risk for the participants is perceived.

F. Role of the IO

The IO is responsible for the following:

1. Ensuring that meeting space and staffing resources are available to the IRB;

2. Appointing a subcommittee to investigate allegations of Noncompliance by the IRB or IRB office staff; and

3. Review substantiated reports from the IRB of Serious or Continuing Noncompliance and convey the report to the appropriate federal agencies and institutional offices.

G. Unanticipated Problems and Noncompliance

1. The federal regulations also require the IRB to have written procedures to ensure prompt reporting of Unanticipated Problems and Serious or Continuing Noncompliance (45 C.F.R.

46.108(a)(4)(i)). This Policy defines Unanticipated Problems and Noncompliance and establishes procedures for processing reports of Unanticipated Problems and Noncompliance.

2. Examples of Unanticipated Problems that require reporting to the IRB include but are not limited to the following:

    a) Adverse or other events which meet the criteria of the definition of Unanticipated Problems in Section IV (12) below;

    b) New information about a Research study (e.g., a publication in the literature, interim findings, safety information released by the sponsor or regulatory agency, or safety monitoring report) that indicates a possible increase in the risks of the Research;

    c) Changes in approved Research initiated without IRB review and approval;

    d) Incarceration of a Human Subject;

    e) A sponsor-imposed suspension of a protocol due to possible increased risk;

    f) A complaint from a Human Subject when the complaint indicates potential increased risk or when the complaint cannot be resolved by the Investigator; and

    g) A Protocol Deviation that places one or more Human Subjects at increased risk or has the potential to occur again.

3. Examples of Noncompliance that require reporting to the IRB include but are not limited to the following:

    a) Conducting Research without IRB approval;

    b) Use of unapproved recruitment materials and/or informed consent/assent form(s);

    c) Use of unapproved data collection tools (e.g., interview protocols, surveys/questionnaires, technology, and/or procedures);

    d) Failure to secure data; and

    e) Use of an unapproved data collection site and/or population.

4. Note that Noncompliance differs from Research misconduct (42 C.F.R. 93.103) in that Research misconduct involves:

    a) Fabrication – making up data or results and recording or reporting them;

    b) Falsification – 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; or

    c) Plagiarism – appropriating another person’s ideas, processes, results, or words without giving appropriate credit.

        i. The IRB will review all reports of Noncompliance in order to:

        ii. Determine if Noncompliance occurred;

iii. Determine the type of Noncompliance;

iv. Determine whether Human Subjects' rights were protected;

v. Determine if the data gathered during Noncompliance can be used; and

vi. Determine how to bring the project in compliance with this Policy and Human Subjects Research review requirements.

5. The IRB Chair will provide the IRB committee a list of the types of Noncompliance handled by the Chair at each meeting in order to determine if patterns of Noncompliance can be prevented by additional training, modification to policies, or additional oversight measures.

H. Categories of Noncompliance

1. Minor Noncompliance. Minor Noncompliance is the failure to adhere to this Policy without affecting the rights of or increasing the risk to Human Subjects. These events can be resolved administratively to bring a project into compliance. Examples of Minor Noncompliance include but are not limited to the following:

   a) Increasing the number of Human Subjects unknowingly;

   b) Changes in the Research site that do not increase the risk; or

   c) Inadvertently using an unapproved informed consent/assent form.

2. Continuing Noncompliance. Continuing Noncompliance is a pattern of Noncompliance that, in the judgment of a quorum of the convened IRB:

   a) Indicates a lack of understanding or a disregard for the regulations or institutional requirements that protect the rights and welfare of Human Subjects;

   b) Suggests a likelihood that Noncompliance will continue without intervention; or

   c) May involve frequent instances of Minor Noncompliance, such as repetitive protocol deviations.

3. Serious Noncompliance. Serious Noncompliance is the failure to comply with applicable laws, regulations, or institutional policies pertaining to the protection of Human Subjects or with the requirements or determinations of an IRB that has a significant adverse impact either on the rights or welfare of Human Subjects or on the integrity of the data. Serious Noncompliance will be determined by a quorum of the convened IRB and may include but is not limited to those actions which may:

   a) Increase risk to Human Subjects or others;

   b) Have adverse effects on the rights, welfare, and safety of the Human Subjects;

   c) Have adverse effects on the scientific integrity of the Research;

   d) **Reflect failure** to adhere to the federal regulations governing the use of Human Subjects in Research;

e) **Reflect failure** to obtain IRB approval for projects requiring exempt with limited, expedited, or full IRB review prior to initiation of Research procedures that involve Human Subjects;

f) **Reflect failure** to notify the IRB of significant changes that impact the welfare, privacy, or confidentiality of Human Subjects in approved procedures;

g) **Reflect failure** to obtain informed consent when required by the regulations or the IRB;

h) **Reflect failure** to document informed consent when required by the regulations or the IRB.

Noncompliance may also be deemed Serious when it involves fraud and/or scientific misconduct, even in Research posing minimal risk to Human Subjects.

I. System of Record

This Policy also establishes IRBManager (https://ull.my.irbmanager.com/Login.aspx) as the electronic system of record used for the submission and management of all records of Human Subjects Research protocols. Submission of Human Subjects Research protocols by any other means will not be accepted. The purpose of IRBManager is to increase efficiency with compliance tasks, thereby allowing Investigators to focus on their Research while helping the University manage risk associated with Research protocols. IRBManager facilitates the following:

1. Online submission;
2. Transparency of the review process;
3. Audit trails;
4. Electronic routing;
5. Security of documents;
6. Continuing review of studies when required;
7. Training verification with the Collaborative Institutional Training Initiative ("CITI") program;
8. Electronic signatures of the Investigator and Faculty Advisor (when the Investigator is a student) and routing;
9. Email notifications; and
10. Ease use for Investigators and IRB committee members.

Faculty, staff, and students who wish to conduct Human Subjects Research are required to create submissions via IRBManaager for Human Subjects Research protocols. IRBManager also allows for collaboration between Investigators when completing the IRB application, as well as collaboration between the IRB and Investigators during the protocol review process.

III. Applicability

This Policy is applicable to and enforceable against all employees, students, visitors, and individuals affiliated with the University by contract or otherwise (including, but not limited to, non-Employees, such as vendors and independent contractors, volunteers, student organization advisors, and retirees) who conduct Research involving Human Subjects in furtherance of their capacity at the University or as University designees responsible for the oversight of Human Subjects Research.

IV. Definitions

1. **Continuing Noncompliance:** a pattern of repeated Noncompliance that if continued will likely, in the IRB's judgment, materially adversely affect the rights, welfare, or safety of Human Subjects Research participants, the integrity or validity of the related Research, or the work of the IRB. Continuing Noncompliance may involve repeated occurrence of the same type of event(s) or a series of different events.
2. **Human Subject:** a living individual about whom an Investigator (1) obtains data through intervention or interaction with the individual, or (2) uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. Also referred to as Human Participant (45 C.F.R. 46.102(e)(1)).
3. **Human Subjects Research:** Research that requires the use of Human Subjects or the information of or from Human Subjects.
4. **Informed Consent:** the knowing consent of an individual or their legally authorized representative, so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion.
5. **Investigator:** any individual who conducts Human Subjects Research studies for the purposes of this Policy and Department of Health and Human Services ("HHS") Regulations.
6. **Institutional Official ("IO"):** the Vice President for Research, Innovation, and Economic Development ("VPRIED").
7. **Institutional Review Board ("IRB"):** a federally mandated body established under HHS regulations for the Protection of Human Subjects (45 CFR 46 which is comprised of a diverse group of scientific and non-scientific individuals who conduct the initial and ongoing review of Human Subjects Research studies. Its purpose is to protect the rights and welfare of Human Subjects recruited to participate in Research activities conducted under the auspices of the University. (45 C.F.R. 46.107 and 108).
8. **Noncompliance:** failure to comply with applicable laws, regulations, or institutional policies pertaining to the protection of Human Subjects or with the requirements or determinations of an IRB.
9. **Protocol Deviation:** a deviation from IRB-approved activities related to a Research study. This means that the Investigator(s) has performed activities that are different than those described in the protocol, that procedures not previously described in the protocol were performed, or that procedures described in the protocol were not performed.
10. **Research:** a systematic investigation, including Research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 46.102 (l)).
11. **Serious Noncompliance:** Noncompliance that materially increases risks, that results in substantial harm to Human Subjects or others, or that materially compromises the rights or welfare of Research participants.
12. **Unanticipated Problems**: any incident, experience, or outcome that meets all of the following criteria:
    a) Unexpected (in terms of nature, severity, or frequency) given (a) the Research procedures that are described in the protocol-related documents, such as the IRB-approved Research protocol and Informed Consent document; and (b) the characteristics of the Human Subject population being studied;

b) Related or possibly related to participation in the Research (possibly related means that there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the Research); and

c) Suggests that the Research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

V. Policy Procedure

A. Submissions to the IRB

All Human Subjects Research IRB applications must be electronically submitted within IRBManager (https://ull.my.irbmanager.com/Login.aspx) using UL Lafayette login credentials prior to initiating any Human Subjects Research.

ORI and the IRB will oversee all protocols submitted via IRBManager. ORI provides pre-review for the Investigator prior to submitting the application to the IRB Chair for review and assessment. Depending on the clarity of the submission and responsiveness of the Investigator, protocol review requires one – four (1 – 4) months.

Submission of Human Subjects Research protocols by any other means will not be accepted. Additionally, it is the responsibility of the Investigator to submit IRB applications and required revisions in a timely manner – failure to do so may result in delays in the IRB review process.

B. Role of the IRB Upon Protocol Submission

The IRB will review all Research involving the collection of information from or about Human Subjects. The IRB will use this review to determine if the activity is Research or not according to (45 CFR 46.102(l)). The IRB has the authority and responsibility to formally review, approve, monitor (45 C.F.R. 46.109), or curtail any Research involving Human Subjects. The IRB has the authority to suspend or terminate approval of Research that is not being conducted in accordance with IRB requirements. The IRB annually reviews all Research protocols which have been reviewed and approved by the convened IRB (quorum of convened members). The IRB plays a primary role in the protection of Human Subjects by ensuring that all Research involving Human Subjects meets approval criteria outlined in 45 C.F.R. 46.111, including:

1. Risks to Human Subjects are minimized and reasonable considering any expected benefits;
2. The selection of Human Subjects is equitable;
3. Informed Consent is sought and documented as required by 45 C.F.R. 46.116 and 46.117, particularly as to its description of the risks and benefits;
4. Data monitoring is provided to ensure the safety of Human Subjects when appropriate;
5. Privacy of Human Subjects and confidentiality of data are maintained when appropriate; and
6. Safeguards are in place to prevent coercion or undue influence of vulnerable populations of Human Subjects such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

C. Reporting Noncompliance

When a Protocol Deviation that meets the criteria for an Unanticipated Problem or incident of Noncompliance becomes known to an individual, said individual has a duty to and is responsible for reporting the information to any member of the IRB or the Director of ORI in person, via email, or via

written document, which they may do anonymously. It is expected that Investigators and Research staff promptly self-report events that may meet the criteria for an Unanticipated Problem or Noncompliance.

Anyone cognizant of a possible Noncompliance committed by the IRB or the IRB office staff is responsible for reporting the information to the IO in person, via email, or via written document, which they may do anonymously on the Research Integrity compliance website.

Reports and allegations of Serious or Continuing Noncompliance, involving nonexempt Human Subjects Research conducted or supported by HHS or any federal agency which has adopted the Common Rule or is covered by a FWA regardless of funding will be reported to OHRP (or the U.S. Food and Drug Administration ("FDA"), as appropriate) by the IO following the investigation. The OHRP's guide provides more information regarding reporting Noncompliance incidents and is helpful in addition to the information below.

D. Process for Handling Noncompliance Reports

Reports of Noncompliance will be promptly reviewed by the IRB Chair and/or Vice Chair, investigated by the IRB when needed, and resolved in a fair process and in accordance with all applicable regulatory requirements and University policies. Every faculty member, student, and staff member has a duty to cooperate with University and IRB inquiries and investigations.

All reports of Noncompliance will be communicated to the IRB Chair.

The IRB office staff will assist by investigating and gathering information for the Chair, such as relevant approved IRB applications, Informed Consent forms, and Research procedures. The IRB Chair will confidentially consult with individuals, such as collaborators, subject matter experts, research assistants, and affected Human Subjects, as needed to evaluate the report of Noncompliance and determine appropriate steps.

There is a two-step process for handling reports of Noncompliance:

1. **Step 1: IRB Chair and/or Vice-Chair evaluates the allegation:**
    a) Establish whether the report of Noncompliance contains enough information to determine if it is in fact a Noncompliance;
    b) Establish the type of Noncompliance: Minor, Continuing, or Serious;
    c) Refer all Continuing or Serious Noncompliance allegations to a quorum of the convened IRB; and
    d) Schedule an IRB meeting to investigate the allegation.
2. **Step 2: Quorum of the Convened IRB investigates the allegation:**
    a) Determine the actions needed to bring the Research into compliance, which may include but are not limited to:
        i. Filing a modification of the approved IRB application;
        ii. Discarding data collected without approval or Informed Consent/assent; and/or
        iii. Suspending or terminating Research.

E. Potential Findings and IRB Resolution

1. Minor Noncompliance

Should Noncompliance be determined by the IRB Chair to be a Minor Noncompliance, it will be handled administratively to bring the Research into compliance and will not be reviewed at an IRB meeting. The IRB Chair and/or Vice Chair and/or IRB office staff will assist the Investigator with the administrative needs to bring the Research back into compliance.

2. Continuing or Serious Noncompliance

a) Human Subjects At Risk. The IRB will assess whether Human Subjects are at risk. When Human Subjects are at risk, the Research will be suspended until an investigation determines the appropriate mitigating actions to take.

b) Potential Continuing or Serious Noncompliance. When Noncompliance is determined to be a potential Continuing or Serious Noncompliance, the IRB Chair will bring the information concerning the event to the attention of the IRB at a convened meeting. When an Investigator provides a report with corrective actions, the IRB will determine if the corrective actions are appropriate. The IRB will discuss the Noncompliance, the corrective actions (if any) proposed, any changes in risk to the Human Subjects, and consider which actions are appropriate to reduce risk and bring the Research back into compliance. During a convened quorum of the IRB, the IRB will review the evidence and may also determine that suspension or termination of the Research is necessary to protect the Human Subjects. The Investigator will be notified in person and provided a written document explaining the needed corrective actions. The Investigator's immediate supervisor will be notified via email.

c) Substantiated Continuing or Serious Noncompliance. If the allegation of Continuing or Serious Noncompliance is substantiated, the IRB Chair will notify the Investigator of the IRB's decision and any needed corrective actions, which may include suspension or termination of the Research. The IO will be provided a report upon IRB determination of Continuing or Serious Noncompliance. If the Research is funded by a Federal or State agency, the agency will be notified in writing by the IO, which may result in sanctions to the University such as disallowing costs, withholding future awards, or wholly or partially suspending a grant.

3. Unsubstantiated Continuing or Serious Noncompliance.

a) If an allegation of Continuing or Serious Noncompliance is not substantiated, the IRB Chair will provide a report to the Investigator. The IRB may, but is not required to, notify the IO if the allegation is unsubstantiated.

VI. Enforcement

The VPRIED/IO is responsible for enforcement of this Policy.

A. Employee Sanctions

Failure to comply with this Policy may include, but not be limited to, disciplinary action up to termination of employment, as may be determined by the Vice President that an individual reports to upon the recommendation of the IO in consultation with the Office of Human Resources.

B. Student Sanctions

Failure to comply with this Policy may result in sanctions which may include, but not be limited to, disciplinary action up to expulsion, as may be determined by Student Rights and Responsibilities upon the recommendation of the IO.

VII. Policy Management

Upon adoption, the IO shall be the Responsible Executive for this Policy in charge of the management of this Policy. The Director of ORI is the Responsible Officer for this Policy and will assist the IRB with any revisions determined to be necessary. ORI is the Responsible Office for this Policy.

VIII. Exclusions

The IRB is not required to review projects collecting data from people for the purpose of improving a University program, evaluating a University-sponsored conference or event, improving course offerings, or improving University services, where the results will not be shared for publication or conference presentation outside the University for broad application.

IX. Effective Date

This Policy is effective on the date of the University President's approval signature.

X. Adoption

This Policy is hereby adopted on this 2/21/2024.

DocuSigned by:
Joseph Savoie
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Dr. E. Joseph Savoie
President

XI. Appendices, References and Related Materials

- 21 CFR Parts 50 and 56
- 45 CFR Part 46
- Federal Office of Research Integrity
- Guide to Handling Research Misconduct
- Guidance on Reporting Human Subjects Research Noncompliance
- IRB membership
- UL Lafayette Code of Conduct and Ethical Behavior Policy
- UL Lafayette Financial Conflict of Interest Policy
- UL Lafayette Institutional Review Board Guidelines

- UL Lafayette Research Integrity Policy
- Human Subjects Research Training Requirement Policy

XII. Revision History

- Adoption of Policy for the Protection of Human Subjects in Research: 2/21/2024 (RE.006.1).