The University of Louisiana at Lafayette
The Institutional Review Board

APPLICATION GUIDELINES

GENERAL GUIDELINES

The University of Louisiana at Lafayette Institutional Review Board (UL Lafayette IRB) functions to assure that research involving human participants is carried out in an ethical manner. The principles and applications discussed in The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research are applied to guide investigators in formulating informed consent, assessing risks and benefits, and selecting participants. The principles of respect for persons, beneficence, and justice will prevail in IRB review of research involving human participants. This document can be found by clicking on the title above or linked to the IRB home page http://vpresearch.louisiana.edu/research-compliance/institutional-review-board.

The University adheres to the 1991 Federal Policies for the Protection of Human Subjects adopted by the Federal government and set forth in 45 CFR Part 46 , and revised in 2017 and further amended in 2018 (83 FR 28497). Subpart A is known as the Common Rule because it was adopted by many federal agencies. Subparts B-D contain regulations pertaining to special protections for certain populations: pregnant women, human fetuses and neonates; prisoners; and children. These guidelines apply to all research involving human participants

All investigators involved in human participant research at the University of Louisiana Lafayette are required to be trained in the protection of human research participants. The University uses the Collaborative Institutional Training Initiative (CITI) to provide research ethics and compliance training. A shorter version of the full training is available for undergraduate researchers. Faculty may contact the IRB Chair or Director of Office of Research Integrity to discuss options for creating IRB training specific for classes that they teach.

All individuals conducting research involving human subjects are required to have their research proposal reviewed by the UL Lafayette Institutional Review Board (IRB) with the following modification:

> For undergraduate and graduate **class research projects that are part of the required assessed work for class credit** (this does not include capstone projects) and that involve human subjects, there is an abbreviated review process. The faculty member for the class is required to complete the CITI Basic Human Subject Research training for faculty once every five years. The faculty member will have the students complete a brief form (Student Class Project Information Page) describing their research and human subject protections. The students will submit their forms to the supervising faculty, who will review the projects to ensure that they all qualify for Exempt review category. Note that Exempt DOES NOT mean the study is Exempt from IRB review. The faculty will counsel any

students about needed modifications and have the student describe such modifications in a revised student form in order to ensure projects qualify for Exempt review category. Upon completion of the review, the faculty member will submit to either the Departmental IRB member (IRB Delegate) or irb@louisiana.edu (if there is no IRB Delegate) all the project information for the class projects and a summary form listing the class projects and certifying that all the projects qualify for Exempt review category, present minimal risk, are unfunded, and will not be published (in the form of a dissertation/thesis/conference presentation/journal publication). The IRB Delegate will review the project information and confirm the Exempt review status, prior to the class projects beginning.

Forms for the Delegated Review can be downloaded from:
https://vpresearch.louisiana.edu/node/400
Departmental IRB Delegates can be found at:
https://vpresearch.louisiana.edu/research-compliance/institutional-review-board/irb-members-available-delegated-review-approval

Class research projects that are **externally funded**, expose human participants to **greater than minimal risk**, or involve **vulnerable populations** as participants must be reviewed by the UL Lafayette IRB by submitting a regular IRB application for IRB regular review.

For undergraduate Honors theses, the IRB Delegate(s) will submit the record of the review and approval to the IRB Chair and the Director, Honors Program.

Any UL Lafayette faculty member, unclassified staff person, or other personnel performing, advising, or supervising research involving human participants must comply with UL Lafayette IRB guidelines. For assistance in determining the need for review and the type of review, please contact the IRB Chair (irb@louisiana.edu) or utilize the Office of Human Subject Protections Decision Charts.

IRB REVIEW PROCEDURES

The IRB has Four Guiding Principles for the review process

1) Assure the rights of the human participants are safeguarded
2) Assure the University meets relevant Federal Guidelines
3) Assure the procedures selected cause the least amount of risk necessary
4) Assure the procedures and design are sufficiently effective to justify the involvement of human subjects

Each proposal must detail the measures to be taken to protect the confidentiality and privacy of the participants. The depth to which proposals are examined depends on the nature of the research question, participants, and/or methods. Work with individuals at special risk or

unusually invasive procedures require more extensive justification and the scrutiny of the Full Board.

The Federal Government Recognizes Four Categories for Review:

1) Full Board Reviews
2) Expedited Reviews
3) Limited Review of some Exempt Projects
4) Exempt Reviews

All application materials are to be e-mailed as attachments to the IRB Chair as MS Word files (or MS Word compatible formats). The IRB Chair will disseminate the documents to the IRB Committee for review. Upon approval of a proposal, the IRB Chair will send approval documentation to the investigators. IRB approval documentation for theses, dissertations and capstone projects will also be sent to the Graduate Dean.

IRB approval is for one year, unless the risk level, participant population or research protocol changes or needs to be changed during the course of the study. When a project, needs to have changes made in the participant population or procedures, the changes must be reviewed and approved by the IRB prior to implementation. For any project requiring continuing review, the investigator must apply for renewal one month before the expiration date by completing the Continuing Review Form. The consent form that is in current use must be submitted along with the Continuing Review Form. Continuing review of proposals that initially were reviewed by the full IRB will go through Expedited review, if:

(1) The human participants protocol is the same as in previous studies;
(2) There have been no ill effects suffered by the participants due to their participation in the study;
(3) There have been no complaints by the participants or their representatives related to their participation in the study;
(4) There has been neither a change in the research environment nor new information which would indicate greater risk to human participants than that assumed when the protocol was initially reviewed and approved.

In the event of complaints or ill effects during human participants research, the investigator must file a detailed report with the IRB, as soon as possible.

SPECIFIC GUIDELINES

The guidelines below are keyed to each item in the application form. Those items that are self-explanatory are not discussed.

IRB Application Checklist.

The checklist on the first page of the application is a tool to assist in gathering the information needed by the IRB for review of the research proposal. Some items that are frequently missing

or incomplete are the data collection tools and the letter from the supervising faculty member for student proposals. It is not sufficient that the supervising professor merely sign the form. Finally, investigators do not always attach a full and complete proposal, which is important for understanding the project and how the data will be collected and protected.

The signature page of the IRB application: Signatures must be obtained. The presence of the signatures of all the researches on the IRB application signifies that they understand the provisions of the applications.. They should be considered in any revisions to the document as well.

5. TYPE OF REVIEW:

When reviewing applications submitted for either Exempt or Expedited review, the IRB first assesses whether there is risk to human participants and whether the research protocol is eligible for Exempt or Expedited status under the federal guidelines listed below. Special attention is given to adequate protection of the rights and welfare of certain vulnerable populations: children; prisoners or other institutionalized populations; pregnant women, fetuses, and neonates; individuals with impaired decision-making capacity, and economically or educationally disadvantaged persons.

In responding to this item, you first determine under what criterion your study qualifies for Exempt or Expedited review (see definitions below) and check the appropriate box on the application. Then provide a rationale or justify your decision. Investigators often fail to justify their requests for Exempt or Expedited status. Paragraph(s) from these guidelines (see the definitions for Expedited and Exempt) or the federal regulations may be used for this justification.

7. PARTICIPANT POPULATION:

Not all categories listed in this section are considered vulnerable populations by the Common Rule, but the University IRB has determined that closer attention to review may be needed when these populations are the primary participants in research.

NOTE - PRISONERS: The Federal Guidelines are specific and restrictive about the type of research projects that may use prison populations as participants. Investigators should be aware that some types of projects may be forbidden by law and others may be approved only after intent has been published in the Federal Register. Specific information on these restrictions is available in 45 CFR 46, Subpart C.

NOTE - UL Lafayette STUDENTS: Although the UL Lafayette IRB has not identified UL Lafayette students as a vulnerable population, the IRB is especially concerned that the anonymity or confidentiality of UL Lafayette student data is maintained and that the voluntary nature of student participation is protected.

e. Recruitment materials guidelines

Information should include:

(1) Contact information (UL phone number, UL email);

(2) The purpose of the research and, in summary form, the eligibility criteria that will be used to admit participants into the study;

(3) A straightforward and truthful description of the benefits (e.g. payments or free treatment) to the participant from participation in the study; and

(4) The location of the research and the person to contact for further information.

Items 1 and 2 are the minimum. No claims should be made, either explicitly or implicitly, that any drug, device, treatment, or procedure is safe or effective for the purposes under investigation, or that it is in any way equivalent or superior to any other. Investigators may not advertise that they have IRB approval of their research protocol.

h. Confidentiality and Anonymity

Detail the methods used to insure confidentiality **or** anonymity. Consider the definitions of anonymity and confidentiality, the requirements of Louisiana Law (Revised Statute 44, Section 7(F)(1-4) and LAC Title 48:I, Public Health-General (Book 1 of 2), Section 509.C.) prior to writing this section.

Anonymity means that no one, including the principal investigator, is able to associate responses or other data with individual participants. Investigators may promise anonymity only under this condition.

Confidentiality means that although participants' identities may be known to the principal investigator and a limited research staff, participants' identities will be kept confidential and that reports of research findings will not permit associating participants with specific responses or findings. For confidentiality, investigators must provide adequate procedures to protect confidentiality, including security for data which contains participant identifiers. Investigators should be cognizant that non-traditional identifiers may occur, such as diagnosis of a low incidence disease or condition.

Louisiana Law (Revised Statute 44, Section 7(F) and LAC Title 48:I, Public Health-General (Book 1 of 2), Section 509.C.) specifies that confidential data pertaining to public health epidemiological information may be used only in the aggregate and only for statistical, scientific and medical research purposes relating to the cause or condition of health. The law provides civil penalties for violations of this confidentiality. This confidential data is protected from subpoena.

Investigators should also be aware that the Federal government permits application for Certificates of Confidentiality to protect the identity of participants in alcohol

abuse and alcoholism research, in drug abuse research, in mental health research, and in other research areas where participants may be exposed to legal liability. Each application is assessed individually, and the Certificate, if granted, allows the investigator to withhold, from all persons not connected with the conduct of such research, the names or other identifying characteristics of [individuals who are the participant of such research] (42 USC Section 241 (d)). This protection includes federal, state or local civil, criminal, administrative, legislative or other proceedings unless the participant waives these confidentiality rights in writing. Individual agencies handle requests in each area. Specific information is on file in the offices of the Vice President for Research and the Director of Research and Sponsored Programs.

The Department of Justice and the National Center for Educational Statistics also protect certain data by statute. The Department of Justice adheres to 42 U.S.C. 3789g(a) and 28 CFR Part 22. There are 4 laws that affect confidentiality of the National Center for Educational Statistics (see the website for a detailed discussion).

8. INFORMED CONSENT and VOLUNTARY PARTICIPATION:
Where consent is required, a sample of each consent form to be used must be attached to the application. Example consent forms can be found on the IRB website. Please contact the IRB Chair (irb@louisiana.edu) if you are unsure whether your study requires signed consent forms.

The following documentation about informed consent should be included on (or with) the IRB Application for Review form:

(1) Explanation of how participants are told about the project and how they are invited to participate;

(2) Written statement of the oral information or a copy of the written information given to the participants and/or their representatives to enlist their voluntary participation in the study (especially important in securing the assent of minors);

(3) Copies of the written consent form and/or parental consent form (if one is used).

The methods used to obtain consent may vary. They should be designed to fit the research setting -- the nature of the research; the magnitude of the risks involved; the nature of the participants who will participate; and the requirements of applicable policies, laws, and regulations. In most cases a written consent form is used. A signed consent is necessary for most research which requires Expedited or Full review. In some types of research, where the participants' identity must be protected, a letter of information alone should be given to the participants, in lieu of collecting signed consent forms. In many Exempt-from-Full-review proposals, the consent to participate is understood when the participant accepts and completes the instrument, but a letter of information about the study should be made available to the participant. In all cases, written or oral, the basic elements necessary for legally effective consent include:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the participant's participation, a description of the

procedures (identifying any that are experimental, ie. not standard of care or traditional teaching strategies);

(2) A description of any possible risks or discomforts (both physical and emotional);

(3) A description of any benefits to be expected, either for the participant or for society;

(4) A disclosure of any appropriate alternative procedures that might be advantageous for the participant (normally applicable only in therapeutic research);

(5) A statement describing how confidentiality of records will be maintained;

(6) For more than minimal risk research, an explanation about any compensation that will be provided and whether any medical treatments will be available if injury occurs, what the treatments will be and where to get further information.

(7) Telephone numbers and e-mail addresses of individuals who will be available to answer inquiries from participants:

(a) UL telephone number, e-mail address and title and name of I.R.B. Chair for inquiries regarding protection of human participants of research.

(b) UL telephone number(s), e-mail address(es) title(s) and name(s) of investigator(s).

(8) An explanation that (a) participation is voluntary and (b) the individual is free to withdraw his or her consent and to discontinue participation in the project or activity at any time without penalty or loss of benefits to the participant.

(9) When identifiable information will be collected (with or without biospecimens), a statement similar to one of the following statements MUST be included:

Personal identifiers may be removed from the information or biospecimens (note specific tissues or samples may be identified) we obtained from you so that the information or biospecimens may be used for future research without additional consent from you or your legally authorized representative.

Personal identifiers may be removed from the data or biospecimens (note specific tissues or samples may be identified) we obtained from you but your information will NOT be used, shared or distributed for any other studies in the future.

When appropriate these statements may also be needed in the Consent Form:

(1) A statement that a particular treatment or procedure may involve unforeseen risks to the person and any fetus.

(2) A statement about why an investigator might end a participant's participation in the study even if they have consented.

(3) A statement about costs the participant may incur while participating.

(4) The consequences for withdrawing and what procedures will need to be taken. e.g. certain drug studies may require a person to be weaned off the drug or a study on alcohol consumption may require the person to "sober up" or get a ride home.

(5) A statement that significant new findings during the study that might affect a participant's desire to continue in the study will be shared with them.

(6) The approximate number of participants.

(7) A statement that the person’s biospecimens, even with identifiers removed, may be used for commercial profit and whether the person will share in the profit.

(8) A statement about whether clinically research relevant results will be shared with the participant and under what conditions they would be shared.

(9) When biospecimens are collected, a statement about whether whole genome sequencing will occur.

If a participant is a minor, provisions should be made for obtaining a parent's or legal guardian's informed consent signature, and the minor's verbal assent will also be obtained when feasible (see below).Broad Consent (45 CFR 46 .116(d)) is the type of consent obtained for data and biospecimens collected without a specific research project purpose. These items may be collected during regular clinical care or to generate a data or biospecimen bank to be available for secondary use. When Broad Consent will be obtained consult with the Office of Research Integrity and/or the IRB Chair to ensure the consent form contains appropriately worded elements.

The consent form should not include any exculpatory language whereby the participant waives, or appears to waive, any of his/her legal rights, including any release of the institution or its agents from liability for negligence. **A copy of each consent form that the participants have signed should be given to them to keep for their records.**

As a general rule, the IRB does not approve research that makes use of minors or those with impaired decision-making capacity if the research and its objectives can be met by using adults and/or those without impaired decision-making capacity. When the research can only appropriately be conducted using minors or those with impaired decision-making capacity, special considerations are given to risk and to consent procedures. In determining whether children or those with impaired decision-making capacity are capable of assenting, UL Lafayette IRB will take into account the ages, maturity, and psychological state of the participants.

Investigators should be aware that there are several options for obtaining consent for the participation of children. These options are:

(1) Representative consent only (that is, consent by the participant's representative in an institutional setting, e.g. nursery school, school, hospital, park district);

(2) Representative consent plus information to parents or legal guardians;

(3) Information to parents plus consent of parents or legal guardians (oral or signed).

Investigators should not assume that it is best to go the full route toward parent or legal guardians information plus consent in all cases. With the intention of making projects less cumbersome for the investigator, the parents or legal guardians, and the institutional representatives, the IRB supports the simplification of consent procedure whenever justified.

The more unusual the research procedures for a given setting in comparison to the usual and expected activity in which the child engages, the more information needs to be conveyed to

parents or legal guardians and the greater the formality needed in the consent process. The more similar the research procedures are to experiences usually encountered by participants in designated settings (school, hospital, park district) the more likely the IRB will accept a less elaborate consent procedure.

9. RISK/BENEFIT RATIO:
The RISK/BENEFIT concept is discussed on the application form, but the following information should be noted:

> **RISK**: Investigators should not assume that a survey which involves no physical activity for the participant is risk free. At the least, the participant is inconvenienced, commits time to the project, and may reveal private information to the investigator. Violation of confidentiality is a risk.

As part of its overall risk assessment, the IRB will review survey-instruments and other data-gathering tools to determine whether answering or contemplating answers to the questions could cause psychological discomfort to the participant (renewal of painful memories, admission of socially unacceptable feelings or behavior, etc.). These psychological effects are considered a risk to the participant.

> **BENEFITS**: The investigator should consider benefits of the research project both to the individual participant and to society as a whole.

DEFINITIONS

Assent means a child's affirmative agreement to participate in research. Failure to object (absent affirmative agreement) should not be construed as assent.

Benign behavioral intervention means something of short duration that is harmless, painless, not physically invasive and will not have a lasting significant adverse impact. It should not be offensive or embarrassing.

Children are persons who have not attained the legal age for consent to treatments or procedures involved in the research under the applicable law of jurisdiction in which the research will be conducted. Generally, the law considers any person under 18 years old to be a child.

Cinical Trial means a research study in which one or more human participants are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes. Note – not all research identified as a clinical trial meets the requirements for posting consent forms on clinical trials.gov. Consult with Office of Research Integrity to determine if your study meets the requirements.

Confidentiality means that although participants' identities may be known to the principal investigator and a limited research staff, participants' identities will be kept confidential and that reports of research findings will not permit associating participants with specific responses or findings. For confidentiality, investigators must provide adequate procedures to guarantee confidentiality, including security for data which contains participant identifiers.

Exempt Reviews are conducted by the IRB Chair or one other specially appointed IRB member rather than by the full board. Specific designations are found in 45CFR 46.104(d). In general, the following types of research are considered exempt by UL Lafayette policy (see Expedited review for studies utilizing UL Lafayette Students):

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on comparison of instructional techniques (Note: this does NOT include interventions where the investigator interacts with minors).

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual and audio recording), where the participant cannot be identified or disclosure of responses cannot place a participant at risk of civil or criminal liability. If identity can be determined, then limited IRB review is needed to review privacy and confidentiality protections.

(3) Research involving benign behavioral interventions and collection of information from adult, if one of the following is true: identity cannot be determined or disclosure of responses cannot place a participant at risk of civil or criminal liability. If identity can be determined, then limited IRB review is needed to review privacy and confidentiality protections. This exemption cannot be used if deception is involved unless the participant consents to being deceived.

(4) Secondary research where consent is not required because the identifiable data or biospecimens are publically available, data is de-identified by the investigator when it is recorded, information collected and analyzed is for health care operations, or the research is conducted for the Federal government using government collected information.

(5) Research and demonstration projects which are conducted by or participant to the approval of a Federal department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe.

(7) Storage or maintenance for secondary research when broad consent is required. i.e tissue and data banks

(8) Secondary research for which broad consent is required. Research using data and tissue collected for other purposes under broad consent, which allows a wide array of research to be performed.

Expedited Reviews are conducted by a two-person subcommittee instead of the Full IRB. They are used for the annual review of proposals originally reviewed by the Full IRB, where no changes are made to the methods or procedures. Expedited review may also be requested for research activities that (1) present no more than minimal risk to human participants, and (2) involve procedures listed in one or more of the following categories (Note - these categories may change according to 45CFR46.110(a) because the Secretary of HHS must evaluate the categories for Expedited review once every 8 years. See the OHRP Expedited Review Categories for up to date guidance on acceptable categories.) :

(1) Clinical studies where an Investigational New Drug (IND) application or Investigational Device Exemption (IDE) are not required.

(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from healthy non-pregnant adults weighing at least 110 pounds (up to 2x/week and not more than 550 ml in 8 weeks). Or other adults and children (up to 2x/week and the lesser of 50 ml or 3ml/kg in 8 weeks)

(3) Non-invasive biological specimens – e.g. hair, nails, sweat, saliva, mucosal cells

(4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.

(5) 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).

(6) Collection of data from voice, video, digital, or image recordings made for research purposes.

(7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or

quality assurance methodologies.

Full IRB Review includes a quorum of the IRB meeting to ask questions of the investigator(s) and discuss the human participant protections in the research proposal. All proposals that do not qualify for exempt or Expedited status will go through Full IRB Review. Proposals where identification of the participants and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, insurability, reputation, or be stigmatizing should expect Full IRB Review.

Guardian means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care. A child's "guardian" may provide legally effective informed consent for participation in research

High Risk research involves the potential for harm or discomfort, including psychological; vulnerable populations (i.e. children, pregnant women, prisoners); or may place participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, insurability, reputation, or be stigmatizing.

The definition of **Minimal Risk** (45 CFR 46.102(j)) is that the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Parent means a child's biological or adoptive parent.

Permission means the agreement of parent(s) or guardian(s) to the participation of their child or ward in research.

Quorum is a majority of the review board.

Research is defined in 45 CFR 46.102(l) as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalized knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the **following activities are deemed NOT to be research:**

(1) **Scholarly and journalistic activities** (*e.g.*, oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that **focus directly on a specific individual**

(2**) Public health surveillance activities**, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of

disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

(3) **Collection and analysis** of information, biospecimens, or records **by or for a criminal justice agency for activities authorized by law or court order** solely for criminal justice or criminal investigative purposes.

(4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

Voluntary Participation requires that the participant understand that there is no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

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