

POLICIES AND PROCEDURES FOR RESEARCH INVOLVING HUMAN PARTICIPANTS

LOYOLA UNIVERSITY MARYLAND

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I. STATEMENT OF PRINCIPLES

Loyola University Maryland is dedicated to the protection of the rights and welfare of all human subjects participating in research sponsored by the University. The University is guided by the ethical principles regarding research involving human participants as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, entitled *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (the "*Belmont Report*"). All research involving human participants will be conducted in accordance with federal, state, and local law utilizing the guidelines established in Title 45, Part 46 of the *Code of Federal Regulations*.

II. DEFINITIONS

- A. **Research** means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities. For the purpose 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 the specific individuals about whom the information is collected.**
 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.
- B. **Human subject** means a living individual about whom an investigator (whether professional or student) conducting research (i) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens or (ii) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no

observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

For purposes of this policy, the terms human subject and human participant are used interchangeably. This acknowledges the terminology used by federal agencies in their regulations, the traditions of various academic disciplines, and the role of a potential participant in consenting to be a part of a research study.

- C. **Clinical trial** means a research study in which one or more human subjects 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.
- D. **Minimal risk** means that the probability and magnitude of harm or discomfort anticipated in the 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.
- E. **Informed consent** means the knowing, legally effective consent of an individual or the individual's legally authorized representative. Such consent can be obtained only under circumstances that provide the prospective subject or representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.
- F. **Assent** means the affirmative agreement of a minor to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as consent.
- G. **Legally authorized representative** means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective participant to the subject's participation in the research procedure(s). If there is no applicable law addressing this issue, legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the nonresearch context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.
- H. **Written, or in writing** refers to writing on a tangible medium (e.g., paper) or in an electronic format.

III. INSTITUTIONAL POLICY

Loyola University Maryland bears full responsibility for complying with the requirements set forth in Title 45, Part 46 of the *Code of Federal Regulations* for all research involving human subjects, without regard to funding source, if

- the research is sponsored by this institution, or
- the research is conducted by or under the direction of any employee or agent of this institution in connection with his or her institutional responsibilities, or
- the research is conducted by or under the direction of any employee or agent of this

- institution using any property or facility of this institution, or
- the research involves the use of this institution's nonpublic information to identify or contact human research participants or prospective participants.

This institution will comply with all federal, state, or local laws as they may relate to research covered by this policy.

In accord with 45 CFR 46, Loyola University Maryland has established and will maintain the Institutional Review Board on Human Subjects Research (IRB), which has the responsibility and authority to review, approve, disapprove, or require changes in research activities involving human participants.

All research covered by this policy will be reviewed by the IRB. Research involving human participants will not be permitted until the IRB has reviewed and approved the research protocol. Furthermore, some projects lasting longer than one year will be subject to annual review by the IRB.

Unless informed consent has been specifically waived by the IRB in accord with 45 CFR 46.116, no research investigator shall involve any human being as a participant in non-exempt research unless the research investigator has obtained the legally effective informed consent of the participant or the participant's legally authorized representative. Furthermore, unless the requirement for documentation of informed consent has been waived by the IRB in accordance with 45 CFR 46.117, informed consent shall be documented by use of a written consent form signed (in writing or electronically) by the participant or the participant's legally authorized representative.

This institution also accepts responsibility for safeguarding the rights and welfare of human participants participating in cooperative research projects. When research covered by this policy is conducted at or in cooperation with another entity, all provisions of this policy remain in effect for that research, however, Loyola may accept, for the purpose of meeting the IRB review requirements, the review of an Institutional Review Board established at another institution provided it has approved and signed off on a reliance agreement. The reliance agreement will document the institution's reliance on the IRB for oversight of the research and responsibilities that each entity will undertake to ensure compliance with the requirements.

This institution accepts responsibility for complying with human subjects education requirements as required by federal, state, and/or local funding agencies.

This institution encourages and promotes constructive communication among research administrators, department heads, research investigators, members of the IRB, other institutional officials, and human participants as a means of maintaining a high level of awareness regarding the safeguarding of the rights and welfare of the participants.

To help ensure awareness of this policy, all relevant approval documents will contain the webpage address for the *Policies and Procedures for Research Involving Human Participants*. A statement directing investigators to acquaint themselves with these policies and procedures will be included on the approval form. Investigators will be provided with alternative means of obtaining a copy of the human participants policy and procedures if internet access is not available to an investigator.

IV. STRUCTURE OF THE INSTITUTIONAL REVIEW BOARD

The IRB shall be comprised of a minimum of five Loyola faculty members and one outside member, including an elected chair, from diverse backgrounds to promote complete and adequate review of research activities covered by this policy and shall have the professional competence necessary to review the specific research activities assigned to it. The IRB shall be sufficiently qualified through the experience and expertise of its members and the diversity of the members' backgrounds including consideration of the race, gender and cultural backgrounds of members and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human participants.

IRB membership may not consist entirely of men or women, or entirely of members of one profession. The Loyola faculty members assigned to the IRB shall include at least one member from the Social Sciences, one member from the School of Education, and three (3) at large members at least one of whom is not a member of the Social Sciences or Natural & Applied Sciences or School of Education. The outside member may not be affiliated with Loyola in any way or be a part of the immediate family of a person affiliated with Loyola. The chair of the IRB will be elected by the Loyola faculty members serving on the committee. Normally, the chair will be elected to a two-year term during the spring in which the incumbent chair's term will expire.

When research is reviewed involving a category of vulnerable participants (e.g., prisoners, children, individuals institutionalized as mentally disabled), the IRB shall include in its reviewing body one or more persons who have as a primary concern the welfare of these participants.

With the exception of the outside member, all members of the IRB will be selected by the Faculty Affairs Committee and approved by the Academic Senate. Members will be appointed for three year terms except for the Director of Research and Sponsored Programs who serves *ex officio* on the IRB. The Assistant Director of Research and Sponsored Programs also may be assigned as an *ex officio* member of the IRB. The Office of Research and Sponsored Programs (ORSP) will provide administrative support to identify an unaffiliated member to serve on the IRB. Upon identification of suitable candidate(s), resumes will be forwarded to the IRB and the Faculty Affairs Committee. The IRB will vote to approve or disapprove appointment of the unaffiliated member. The unaffiliated member will serve a three year term, which may be renewed.

Convened meetings of the IRB shall occur:

- A. Once each semester; and
- B. At the call of the chairperson when the chairperson judges the meeting to be necessary or advantageous; or
- C. At the call of the chairperson upon the receipt of a joint written request of three or more members; or
- D. At the call of the ORSP for the full review of protocols; or
- E. At the call of the ORSP for requests for reconsideration.

V. TYPES OF REVIEW

- A. **Exempt Review** means the research project involving human participants that falls

outside the oversight of the Institutional Review Board on Human Subjects Research (IRB). Exempt status may only be designated by the ORSP or the IRB. However, ***exempt designation does not release investigators from upholding the ethical standards required by this policy in the conduct of their research.***

For projects that include human participants who are minors (Subpart D) exempt category 1, 4, 5, 6, 7, and 8, may be applied. Paragraphs 2 (i) and 2 (ii) may only apply if educational tests or the observation of public behavior do not include investigator participation in activities being observed. These exemption categories never apply to prisoners (Subpart C) except for research aimed at involving a broader subject population that only incidentally includes prisoners. In all other cases, the following types of research will be considered exempt:

1. Research conducted in established or commonly accepted educational settings that specifically involve normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special educational instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Please note: Loyola IRB has determined that project involving minors will not be reviewed using the exempt procedures.

2. Research that only includes interactions involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:
 - i. the information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects;
 - ii. any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation; or
 - iii. the information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination regarding confidentiality.
3.
 - i. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:
 - A. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
 - B. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

- C. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination regarding confidentiality.
- ii. For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.
- iii. If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.
- 4. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:
 - i. The identifiable private information or identifiable biospecimens are publicly available;
 - ii. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
 - iii. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or
 - iv. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.
- 5. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of any federal department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and

demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended

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, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.
7. **NOT CURRENTLY IMPLEMENTED AT LOYOLA** Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8).
8. **NOT CURRENTLY IMPLEMENTED AT LOYOLA** Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:
 - i. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d);
 - ii. Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117;
 - iii. An IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and
 - iv. The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

B. **Expedited Review:** Research that involves one or more of the following categories and is evaluated to be no more than minimal risk may be reviewed by the IRB through the expedited review procedure. A study is presumed to be minimal risk and thus eligible for expedited review if the study only involves categories described in this document, unless the reviewer determines and it is documented why the study involves more than minimal risk.

The criteria for IRB approval of research as stipulated in 45 CFR 46.111 and 21 CFR 56.111, including but not limited to requirements for informed consent and documentation of informed consent, as applicable, apply when expedited review procedures are used by the IRB.

Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB.

Evaluating if Proposed Activities are No More than Minimal Risk

Most research falling within one or more of the categories below will, ordinarily, present no more than minimal risk to subjects and will be eligible for review through the expedited review procedure. However, the IRB reviewer is required to evaluate all proposed research and consider whether the proposed research is more than minimal risk.

In evaluating if the proposed research presents no more than minimal risk, an IRB reviewer should consider the nature of the study procedures, the implications of study findings for the subject (e.g., the results of genetic testing of blood samples), other study characteristics, and steps taken to minimize risk. The IRB reviewer should also consider the characteristics of the subject population, including but not limited to age, health conditions, social or economic circumstances and experience in relation to the anticipated harms and discomforts.

The expedited review procedure may not be used, for example, when identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, educational advancement, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal. In evaluating the risks, the IRB reviewer should consider only those risks that may result from the research (as distinguished from the risks of therapies subjects would receive even if not participating in the research).

Applicability

1. Categories one (1) through fourteen (14) apply to initial IRB review of research that has been determined to be no more than minimal risk.
2. Category fifteen (15) applies to continuing review of research previously approved by the convened IRB that does not otherwise qualify for expedited review.
3. The categories in this document apply regardless of the age of subjects, except as noted.
4. Research eligible for expedited review under §__110(b)(1)(i) must fit within one or more of the categories below.
5. Examples are intended to suggest the types of research activities and procedures that pose no more than minimal risk and may be approved using expedited procedures. However the applicability of the category is not limited to the specific examples provided.
6. The expedited review procedure may not be used for classified research involving human subjects.
7. Unless an IRB determines otherwise, continuing review of research is not required for research eligible for and approved by expedited review in accordance with §__.109(f)(1)(i).

Research Categories

1. Research involving the use of drugs and medical devices only when condition (a) or (b) is met.
 - a. Research involving use of “over-the-counter” drugs, when used within their approved indications and dosages, and exempt from the IND requirements of 21 CFR 312.
 - b. Research involving use of medical devices exempt from the IDE requirements of 21 CFR 812.1
2. The collection of blood specimens for research purposes using techniques consistent with routine clinical practice to minimize pain and risk of infection and within the following limits: (a) from adults whose health will not be adversely affected by the blood draws who weigh at least 50 kg, the amounts collected should not exceed 550 ml in an 8-week period; or (b) from children² and other adults whose health will not be adversely affected by the blood draws, the amounts collected should not exceed the lesser of 150 ml or 3 ml per kg in an 8-week period. Examples: Finger stick, heel stick, ear stick, venipuncture, collection of blood from an indwelling peripheral venous catheter (not including a PICC line) placed for research purposes, or collection of blood from an indwelling catheter already in place for clinical purposes.
3. Prospective collection of biological specimens, excluding blood, for research purposes by noninvasive means and not requiring sedation for research purposes. Examples: (a) tissues and fluids that the body produces continuously or sheds as a normal process (including hair, nails), which are collected in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation; (c) excreta and external secretions (including sweat, urine, stool); (d) uncannulated saliva; (e) placenta removed at delivery; (f) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (g) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (h) mucosal and skin cells collected by buccal scraping or mouth washings; (i) sputum collected after saline mist nebulization
4. Prospective collection of biological specimens, excluding blood, for research purposes by minimally invasive means and not requiring sedation for research purposes. Examples: (a) tissues from non-facial, non-genital skin punch biopsy with allowable local anesthesia and limited to 2mm in diameter and not requiring sutures; (b) Specimens collected by swab (nasal, oral, urethral, vaginal, rectal); (c) teeth if routine patient care indicates a need for extraction.
5. Collection of additional information or biological specimens, excluding blood, for research purposes during procedures already being performed for clinical purposes, provided the additional collection does not introduce more than a minimal increase in risk, pain or discomfort over that imposed by the underlying procedure. When extension of general anesthesia is required, it must meet the criteria for minimal risk. Examples: (a) collection of additional bodily fluids and tissues (e.g., peritoneal fluid, bone marrow or cerebrospinal fluid); (b) tissue collected from pap smears; (c) collection of additional clinical information (e.g., vital signs, electroencephalography or echocardiography).
6. Collection of information for research purposes through noninvasive procedures and interventions routinely employed in clinical practice and not requiring general anesthesia or sedation. Examples: (a) physical sensors that are applied either to the surface of the body or

used at a distance; (b) testing sensory acuity; (c) magnetic resonance imaging without use of contrast agent and using magnet and sequence parameters within accepted clinical use guidelines; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and transthoracic echocardiography; (e) measures of cognitive functioning; (f) exposure to ionizing radiation with a total effective dose not exceeding 0.1 mSv (the amount typically associated with a single chest x-ray) provided appropriate shielding techniques are employed.⁴

7. Collection of information for research purposes through activities performed by persons in daily life in individuals and groups whose health will not be adversely affected by the activities.
Examples: (a) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing; (b) measures of symptoms, mobility, range of motion, quality of life and activities of daily living in patient and non-patient populations by clinical or other trained personnel (e.g., nurses, physicians, social workers, physical and occupational therapists); (c) manipulations of diet and lifestyle; (d) measuring height, weight, circumference; (e) assessment of reading levels.
8. Activities at statistical and data coordinating centers or biospecimen repositories that are not responsible for the primary oversight of the primary data collection activities and are not involved in the primary collection of information or specimens, which may be ongoing at other sites.
9. Collection of information from voice, video, digital, or image recordings made for research purposes that are not exempt under §__.104(d).
10. Research that only includes interaction involving (1) educational tests (cognitive, diagnostic, aptitude, achievement); (2) survey procedures, interview procedures, or observation of public behavior (including visual and auditory recording) not eligible for exemption under §__.104(d)(2) either because there are risks to subjects other than informational risks, or because the informational risks are not addressed as specified under §__104(d)(2)(i) through (iii); (3) other data collection procedures (e.g., written or computer-assisted interactions or assessments) where the subject provides self-reports for the purposes of the research and/or may choose what data to provide; (4) non-invasive physical or behavioral tasks or manipulation of the subject's environment; and (5) observations of individual group behavior where the subject is a voluntary participant in the behavior and is aware that data are being collected.
11. Benign behavioral interventions that are not eligible for exemption under §__.104(d)(3) because they (a) involve children as subjects; (b) involve individuals with impaired decision-making capacity; (c) are conducted without the prospective agreement of the subject, including interventions involving deception; (d) are not brief in duration, or; (e) are not limited to verbal or written responses by the subject, data entry by the subject, or observation of the subject.
12. Creation and maintenance of subject databases to which subjects have provided prospective informed consent or informed consent has been waived by an IRB and does not qualify for exemption under §__.104(d)(7). Examples: (a) collection of identifiable information for the purpose of establishing subject pools; (b) disease-specific patient registries; (c) screening protocols including interviews, questionnaires and minimally invasive physical assessments, when performed for

research purposes, that could not be expedited under one of the categories listed above.

13. Secondary research uses of identifiable private information or identifiable biospecimens that are not exempt under §___.104(d)(4) because (a) the identifiable private information or identifiable biospecimens are not publicly available; (b) information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of human subjects can be readily ascertained directly or through identifiers linked to the subjects, or the investigator intends to contact the subjects or will re-identify subjects; (c) research use of identifiable health information not regulated under 45 CFR parts 160 and 164, subparts A and E.
14. Research involving the use of identifiable private information or identifiable biospecimens for secondary research use that is not exempt under §___.104(d)(8) because the investigator includes returning individual research results to subjects as part of the study plan.

Continuing Review of Previously Approved Research

15. Research previously approved by the convened IRB and not otherwise eligible for expedited review under categories (1) through (13) above, where one of the following conditions apply:
 - a. the research remains active only for long-term follow-up of subjects;5 or
 - b. no subjects have been enrolled at sites under the purview of the reviewing IRB and no additional risks have been identified; or
 - c. the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk (including, when applicable, a non-significant risk (NSR) determination was initially made by a convened IRB for research involving investigational medical devices), and no additional risks have been identified. In such cases, the exemption from further continuing review at §109(f)(1)(i) does not apply.

- C. **Full Review** means the research project involving human participants involves more than minimal risk. These type of reviews must be reviewed by the full (or quorum—more than half) IRB committee.

VI. INFORMED CONSENT

A. General Requirements of Informed Consent:

General requirements for informed consent, whether written or oral, are set forth below. Broad consent may be obtained in lieu of informed consent obtained only with respect to the storage, maintenance, and secondary research uses of identifiable private information and identifiable biospecimens. Waiver or alteration of consent is described on p. 14, E. Waiver or Alteration of Consent. Informed consent shall conform with the following:

1. Before involving a participant in research covered by this policy an investigator will obtain the legally effective informed consent of the participant or the participant's legally authorized representative.
2. Consent must be obtained under circumstances that offer sufficient opportunity for the participant or the participant's legally authorized representative to discuss and freely consider whether or not to participate;

3. The information given to the participant, or to the participant's legally authorized representative, must be in a language understandable to the participant or the legally authorized representative;
4. **NOT CURRENTLY IMPLEMENTED AT LOYOLA** Except for broad consent (see Elements of Broad Consent):
 - i. Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in research. This must be presented in a way that facilitates comprehension.
 - ii. Informed consent must present information in sufficient detail relating to the research and facilitates the prospective participant's or legally authorized representative's understanding of the reasons why one might or might not want to participate.
5. Consent must not include exculpatory language through which the participant or the legally authorized representative is made to waive or appear to waive any of the participant's legal rights, or releases or appears to release the research investigator, the sponsor, the University or its agents from liability for negligence.

B. **Basic Elements of Informed Consent:** Unless waived by the IRB, research investigators shall provide the following information to each participant or the participant's legally authorized representative:

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 (if the risk potential is currently unknown or immeasurable, a statement to that effect will be required);
3. A description of any benefits to the subject or to others that may reasonably be expected from the research;
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
6. For research involving more than minimal risk, an explanation as to whether any compensation and/or medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
7. Identification of the responsible investigator and the investigator's sponsoring institution, and an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;
8. A statement that participation is voluntary and that refusal to participate or a subsequent decision to discontinue participation will not result in penalty or loss of benefits to which the subject is otherwise entitled;
9. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
 - i. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the

information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional information consent from the subject or the legally authorized representative, if this might be a possibility; or

- ii. A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

10. The following statement will be included in ALL written informed consents (including letters): THIS PROTOCOL HAS BEEN REVIEWED AND APPROVED BY THE LOYOLA UNIVERSITY MARYLAND INSTITUTIONAL REVIEW BOARD ON HUMAN SUBJECTS RESEARCH.

C. **Additional Elements of Informed Consent:** Except when broad consent is used or there is an approved waiver or alteration of consent, the research investigator shall provide one or more of the following additional elements of information, when appropriate, to each subject or the subject's legally authorized representative:

1. A statement that the particular 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 currently unforeseeable;
2. Anticipated circumstances under which the subject's participation may be terminated by the research investigator without regard to the subject's or legally authorized representative's consent;
3. Any additional costs to the subject that may result from participation in the research;
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
5. A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;
6. The approximate number of subjects involved in the study;
7. A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
8. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
9. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

D. **NOT CURRENTLY IMPLEMENTED AT LOYOLA Elements of Broad Consent:** Broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or nonresearch purpose) is permitted as an alternative to the informed consent requirements. If subject or the legally authorized representative is asked to provide broad consent, the following shall be provided to each subject or the subject's legally authorized representative:

1. The *basic elements of informed consent* (b), (c), (e), and (h) and, when appropriate,

additional elements of informed consent (g) and (i);

2. A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted;
3. A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens;
4. A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite);
5. Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies;
6. Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject; and
7. An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm.

E. **Waiver or Alteration of Consent** in research involving public benefit and service programs conducted by or subject to the approval of state or local officials:

1. Waiver. An IRB may waive the requirement to obtain informed consent provided the IRB satisfies the requirements listed below. If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements of *elements of broad consent*, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.
2. Alteration. An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth in *basic elements of consent* and *additional elements of consent* provided the IRB satisfies the requirements listed below. An IRB may not omit or alter any of the requirements under *general informed consent*. If a broad consent procedure is used, an IRB may not omit or alter any of the elements required under *broad consent elements*.
3. Requirements for waiver and alteration. In order for an IRB to waive or alter consent, the IRB must find and document that:
 - i. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
 - A. Public benefit or service programs;

- B. Procedures for obtaining benefits or services under those programs;
 - C. Possible changes in or alternatives to those programs or procedures; or
 - D. Possible changes in methods or levels of payment for benefits or services under those programs; and
- ii. The research could not practicably be carried out without the waiver or alteration.

F. General Waiver or Alteration of Consent

1. Waiver. An IRB may waive the requirement to obtain informed consent for research provided the IRB satisfies the requirements listed below. If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements of *elements of broad consent*, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.
2. Alteration. An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth in basic elements of consent and additional elements of consent provided the IRB satisfies the requirements listed below. An IRB may not omit or alter any of the requirements described in general informed consent. If a broad consent procedure is used, an IRB may not omit or alter any of the elements required under elements of broad consent.
3. Requirements for waiver and alteration. In order for an IRB to waive or alter consent as described in this subsection, the IRB must find and document that:
 - i. The research involves no more than minimal risk to the subjects;
 - ii. The research could not practicably be carried out without the requested waiver or alteration;
 - iii. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
 - iv. The waiver or alteration will not adversely affect the rights and welfare of the subjects; and,
 - v. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

G. Screening, Recruiting, or Determining Eligibility An IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject's legally authorized representative, if either of the following conditions are met:

1. The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or
2. The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

H. Posting of Clinical Trial Consent Form

1. For each clinical trial conducted or supported by a Federal department or agency, one IRB-approved informed consent form used to enroll subjects must be posted by the awardee or the Federal department or agency component conducting the trial on a

publicly available Federal website that will be established as a repository for such informed consent forms.

2. If the Federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a Federal website (e.g. confidential commercial information), such Federal department or agency may permit or require redactions to the information posted.
3. The informed consent form must be posted on the Federal website after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol.

- I. **Documentation of Informed Consent**: Research investigators shall be responsible for insuring that informed consent is documented by the use of a written informed consent form approved by the IRB and signed (including in an electronic format) by the participant or the participant's legally authorized representative, unless this requirement is specifically waived by the IRB. A copy of the consent form shall be supplied to each person signing the form.

Research investigators may use a consent form that is either:

1. A written informed consent form that meets the requirements of 45 CFR 46.116. The research investigator shall give either the participant or the legally authorized representative adequate opportunity to read the informed consent form before signing it; alternately, this form may be read to the participant or the participant's legally authorized representative.
2. A "short form" written consent form stating that the elements of informed consent required by 45 CFR 46.116 have been presented orally to the participant or the participant's legally authorized representative and key information was presented to the subject before other information was provided. The IRB shall approve a written summary of what is to be said to the subject or legally authorized representative. When the "short form" is used, research investigators shall insure that:
 - i. The written summary presents key information first before other information, if any, is provided;
 - ii. The written summary of what is to be said to the participant or the representative receives the prior approval of the IRB Committee;
 - iii. a witness is present at the oral presentation;
 - iv. the short form is signed by the participant or the legally authorized representative; the witness signs both the short form and a copy of the written summary of the oral presentation;
 - v. the person obtaining consent signs a copy of the summary; and
 - vi. a copy of both the short form and summary is given to the participant or the legally authorized representative.

An IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds **any** of the following:

1. That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;

2. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or
 3. If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.
- J. **Assent:** In addition to procedures for obtaining informed consent from parents and legal guardians, verbal or written assent shall be obtained from minors when, in the judgment of the IRB, the minor is capable of providing assent. As a guideline, minors age 12 and over generally are capable to give written assent, and minors between seven and age 12 generally are able to give verbal assent. Even where the IRB determines that the participants are capable of assenting, the IRB may waive the assent requirements in accordance with guidelines for the waiver of consent contained herein.

VII. PROCEDURES

- A. **Responsibilities of Research Investigators:** Research investigators shall make provisions for the adequate protection of the rights and welfare of prospective research participants and insure that all pertinent laws and regulations are observed. Additionally, investigators shall be responsible for complying with all IRB decisions, conditions, and requirements. These requirements are applicable even in cases where the research is exempt under 45 CFR 46.104.

Research investigators are responsible for ensuring that all research involving human participants is submitted to the Office of Research and Sponsored Programs (ORSP) for review by the IRB. Investigators shall use the definitions of “research” and “human subject” provided on page 2 of this document under II. Definitions, items A and B and in 45 CFR 46.102 to determine whether the project is subject to the policies and procedures herein outlined. A table can also be found on the ORSP website that outlines which projects require IRB review: [\[insert link\]](#). In the case of research conducted by students, the determination shall be made by the faculty member sponsoring the research project. When it is not clear whether the research involves human subjects as defined in 45 CFR 46.102, research investigators should seek assistance from the ORSP and the IRB in making this determination.

If it is determined that the research does involve human participants, the investigator shall complete the Application for Approval of Investigation Involving the Use of Human Participants (IRB Application), giving a complete protocol of the proposed research.

The research investigator or faculty sponsor shall make the preliminary determination on the IRB Application of whether the research is exempt from coverage under 45 CFR 46.104. However, if the project involves human participants that are under the age of 18 or prisoners, the project may not be deemed exempt. Section V. Types of Review, A. Exempt Reviews for more information.

Research investigators shall include the proposed informed consent and/or assent forms with the protocol, along with recruitment materials, surveys, interview questions, or any other research instruments.

If research requires use or disclosure of protected health information for which a participant's authorization or a waiver is required under the Health Information Portability and Accountability Act (HIPAA), an investigator must provide a copy of such authorization or waiver request as an attachment to the Application for Approval of Investigation Involving the Use of Human Participants. Investigator requests for waivers or alterations of the patient authorization requirements under HIPAA will be reviewed by the IRB using these procedures, as modified to reflect the applicable HIPAA regulations.

1. Informed Consent: Research investigators are responsible for obtaining the participant's informed consent and for insuring that no human subject will be involved in the research prior to obtaining consent. See Section VI. Informed Consent for more information.
2. Retention of records: Research investigators shall retain copies of documents related to the use of human participants in any research project approved by the IRB including but not limited to all signed consent and assent documents and complete records of any adverse incidents that occurred during the research as well as any follow-up correspondence or actions taken in response to the adverse incident. Research investigators are responsible for maintenance and retention of such records for a minimum of three years after the completion of the research. If the principal investigator is a student and the application is submitted for an independent research project, thesis or dissertation, the faculty sponsor is responsible for maintenance of these records. If the principal investigator leaves the institution within this period, all records must be provided to the department so that they can be retained for the required three-year period.
3. Reporting changes in the research: Research investigators are responsible for prompt reporting of proposed changes in a research activity to the ORSP. When research is ongoing, the research investigator may not institute changes until IRB review and approval has been obtained, except when necessary to eliminate apparent immediate hazards to the participant. If steps must be taken to eliminate a hazard after approval has been given, documentation of the hazard eliminated and the steps taken to eliminate the hazard must be forwarded to the ORSP.
4. Submission of amendments to the ORSP: Research investigators shall be responsible for submitting a supplement and the original protocol to the ORSP when:
 - i. it is proposed to involve human participants, and the activity previously had only indefinite plans for the involvement of human participants, or
 - ii. it is proposed to involve human participants, and the activity previously had no plans for the involvement of human participants, or
 - iii. it is proposed to change the involvement of human participants and that involvement is significantly different from that which was initially approved by the IRB.
5. Submission of injury reports and reports of unanticipated problems involving risks: Research investigators are responsible for reporting promptly to their department heads and to the ORSP any injuries to human participants and any unanticipated problems that involve risks to the human research participants or others.
6. Reporting of noncompliance: Research investigators and department heads are responsible for reporting promptly to the ORSP and the IRB any protocol violations, or serious or continuing noncompliance with this policy and/or the determinations of the IRB.

7. Attending IRB meetings: To facilitate the review of research and the protection of the rights and welfare of human participants, research investigators and department heads are encouraged to attend IRB meetings when invited by the IRB.
8. Notifying the ORSP concerning investigational new drugs: Research investigators shall be responsible for notifying the Food and Drug Administration (FDA) and the ORSP whenever it is anticipated that an investigational new drug or device exemption will be required.

B. **Responsibilities of the Office of Research and Sponsored Programs:** The ORSP shall provide administrative support to the IRB.

The ORSP shall receive all protocols and ensure that all applicable questions have been completed. For protocols submitted under the exempt category the ORSP shall verify exempt status that do not require limited review. The ORSP shall forward all protocols that are non-exempt research or exempt research requiring limited review to the IRB for review. The ORSP shall keep research investigators aware of decisions and administrative processing affecting their prospective protocols and shall return all disapproved protocols to the research investigators. As appropriate, the IRB or the ORSP may negotiate protocol modifications with the research investigator.

For cooperative projects already approved by an Institutional Review Board of another institution, Loyola's IRB may approve the research upon receipt of a signed authorization agreement signed by the appropriate officials at the cooperating institutions for that specific protocol. Alternatively, Loyola's IRB may require that the researcher submit a separate application for review to Loyola before work can proceed.

1. Requests for Reconsideration: The ORSP shall receive all requests for reconsideration of IRB decisions with attached protocols from the research investigators. Upon receipt of a written request for reconsideration, the ORSP shall convene a meeting of the IRB for full review of the protocol.
2. Investigational New Drug or Device Certification Requirements: When the proposal involves a test article (i.e., drug biologic or device) which requires certification to the HHS, the ORSP shall identify the test article in the certification to HHS and state whether the 30-day interval required for test articles has elapsed or was waived by the FDA.
 - i. If the 30-day interval has expired, the ORSP shall state in the certification to HHS whether the FDA has requested that the sponsor continue to withhold or restrict the use of the test article for application in human participants.
 - ii. If the 30-day interval has not expired and a waiver has not been issued, the ORSP shall send a statement to HHS upon expiration of the interval.
3. Supplements to Research Protocols: When required by the funding agency, the ORSP is responsible for submitting a certification to the funding agency and a supplement to an original protocol when:
 - i. It is proposed to involve human participants, and the activity previously had only indefinite plans for the involvement of human participants, or
 - ii. It is proposed to involve human participants, and the activity previously had no plans for the involvement of human participants, or
 - iii. It is proposed to change the involvement of human participants and that involvement is significantly different from that which was initially approved by

the IRB.

In addition, the IRB will takes steps to ensure that no human participants are involved in research projects for which the filing of a supplement is required by HHS, prior to review of the submitted supplement and approval by appropriate HHS officials.

4. **Reporting Requirements:** The ORSP shall be responsible for promptly reporting information, as appropriate, to the IRB, the appropriate institutional authorities, the federal Office for Human Research Protections (OHRP), research investigators and department heads.

Information may flow from sources such as human participants, research investigators, the IRB, or other institutional staff. Specifically, the ORSP shall:

- i. Report promptly to appropriate institutional authorities or to the OHRP any instances of injuries to participants and unanticipated problems involving risks to participants or others;
- ii. Report to the IRB information received concerning noncompliance by research investigators, injuries to participants, unanticipated problems involving risks, changes proposed in research activities and the progress of the research;
- iii. Maintain information concerning the IRB's reasons for the termination or suspension of IRB approval; and
- iv. Report promptly any changes in IRB membership to the OHRP, when required.

The ORSP will be responsible for maintaining documentation of human participants education completed by investigators and forwarding said documentation to granting agencies as required.

The ORSP will remain abreast of policy changes made by OHRP, federal, state and local agencies and make recommendations, as needed, to the IRB so as to ensure compliance with regulatory requirements. The ORSP will ensure that necessary educational and administrative activities are completed so as to be able to provide federal assurances regarding human subjects protections.

- C. **Investigator Noncompliance:** The Loyola University Maryland (Loyola) has granted the responsibility for review of all human subjects research to Loyola's Institutional Review Board (IRB). The IRB may approve applications that meet the criteria set forth in government regulations, institutional policies, and other federal, state, and local laws and regulations. IRB approval notices to the Principal Investigator (PI) detail any special conditions or requirements for conduct of the research and provide a time limit on the approval period. The PI is responsible for conducting the approved research in accord with the IRB's requirements, as well as in accord with all ethical standards, institutional policies, and federal or state laws or regulations applicable to the research study. It is the obligation of the PI and study team to submit a written report to the IRB if non-compliance occurs during the conduct of the research.

Loyola defines non-compliance to be:

- Failure on the part of the PI, any member of the study team, or any other individual involved in research's review or oversight to follow the terms of IRB's approval; or

- Failure of the PI, any member of the study team, or any other individual involved in research's review or oversight to abide by applicable laws or regulations or Organization policies, including failure to submit human subjects research or changes to the approved research for IRB review and approval prior to commencing the research or changes to it.

Non-compliance varies in nature, severity, and frequency. The IRB must review written reports of non-compliance. The IRB will determine whether each report represents either: a) an instance of minor non-compliance with the IRB's approval determinations; b) an instance that is serious non-compliance; or c) a pattern of continuing non-compliance with the IRB's determinations.

Minor non-compliance is defined by the IRB to be reported incidents or events which are not serious or continuing non-compliance.

Serious non-compliance is defined by the IRB to be failure to comply with laws or regulations, institutional policies, or the requirements or determinations of the IRB when that failure actually or potentially increases risk to participants or adversely affects the rights and welfare of the participants. A single instance of non-compliance may be determined by the IRB to be serious non-compliance.

Continuing non-compliance is defined by the IRB to be a pattern of behavior or minor non-compliance issues that, if unaddressed, may compromise the integrity of human research protections applicable to the study.

Written reports of non-compliance may originate from a PI, study team, monitoring staff, other Loyola staff or offices, sponsors, or collaborators. All written reports, regardless of origin, will be reviewed by the IRB at a convened session.

The Institutional Official (IO), IRB, or other Loyola offices or staff may be notified informally or may receive a non-written allegation of non-compliance. An allegation of non-compliance is defined by the IRB as an assertion by a second party of an incident of non-compliance that should be reviewed. The IO or IRB may authorize senior staff or monitoring staff to conduct a fact finding effort to determine whether the allegation has a basis in fact. An allegation determined to have a basis in fact and to meet the IRB definition of non-compliance must be forwarded to the IRB for review. An allegation determined not to have a basis in fact will be forwarded to the IO for response to the source of the allegation.

The IRB will review written reports of non-compliance or allegations of non-compliance that have a basis in fact. The IRB is authorized to collect additional information before making a determination. The IRB may collect information using a variety of methods, such as, but not limited to, communicating directly with the PI and study team, or requiring the PI and study team to meet with the IRB.

The IRB may determine the non-compliance reported is: minor non-compliance, serious non-compliance, or continuing non-compliance. An IRB finding of non-compliance may include a determination of what appropriate corrective action, if any, should be implemented by the PI and study team.

The IRB may require a range of actions to correct minor, major, or continuing non-

compliance. The table below describes actions the IRB can and cannot take with respect to unanticipated problems or non-compliance in a human subjects research study and is based on the IRB Policies and Procedure Guide. It is intended to be used as a reference tool and is not completed or retained in the IRB file. The IRB Committee can be consulted about any actions that are not listed here.

Actions the IRB cannot take

Note: The IRB can take action on human research under its purview and impose limitations on individual projects. The IRB does not have the authority to take action against or impose sanctions on the researcher. Nevertheless, the IRB can require that the IRB Committee communicate concerns about the researcher or forward recommendations to the appropriate institutional office or authority.

1.	Retroactively approve use of data collected without Loyola University Maryland IRB approval (including secondary use of the data).
2.	Require that data not be published.
3.	Require that data be destroyed.
4.	Require that data not be used for a dissertation or thesis.
5.	Take away a researcher's privilege of conducting research with human subjects.

Actions the IRB can take

1.	Approve the investigator's proposed corrective/preventive action plan.
2.	Require modifications to some or all parts of the research, and/or the corrective/preventive action plan.
3.	Require additional information from the investigator.
4.	Require additional information/consultation from others (e.g. subject matter experts).
5.	Require training or education for the investigator and/or other individuals involved in the research (IRB identifies issues and topics; method and type of education).
6.	Increase the frequency of continuing review.
7.	Require reports after specific milestones.
8.	Require the investigator to provide information to subjects or others, in coordination with other applicable laws, regulations, and Loyola policies (e.g. HIPAA breach notification requirements).
9.	Require re-consenting of subjects.

10.	Require verification of information from sources other than the investigator [subject to the limitation that the Institutional Officer (IO) retains the authority to determine how to fulfill the IRB's request when it involves site visits, investigations, or audits].
11.	Require additional monitoring of research procedures or outcomes.
12.	Require the destruction of subject identifiers (or the link between data and identifiers), if those identifiers were collected or relevant research procedures were performed without prior Loyola IRB approval.
13.	Suspend IRB approval for some or all parts of the research activity, until remediation is complete.
14.	Terminate IRB approval for some or all parts of the research activity
15.	Report a problem or concern to other Loyola offices, co-investigators, collaborators, collaborating institutions and/or funding agencies/sponsors.
16.	Request the IRB's Institutional Officer to consider one of the actions listed below (for which the IRB itself does <u>not</u> have authority). (a) requiring that data not be published or presented; (b) requiring that data not be used for a thesis or dissertation; (c) requiring that data be destroyed; and/or (d) any other actions for which the institutional office has authority.
18.	Additional supervision of the PI and the PI's research studies.
19.	A limit on the number of research activities conducted by the PI.
20.	A limit on the number of participants who may be enrolled by the PI.

D. **Authorities and Responsibilities of the Institutional Review Board:** The IRB shall have the responsibility to review and the authority to approve, require modification of, or disapprove all research activities or proposed changes to previously approved research activities covered by this policy. However, no IRB member may participate in the IRB's initial or continuing review of any project in which that member has a conflicting interest, except to provide information requested by the IRB.

1. **IRB approval:** shall be based on the determination that the following requirements are satisfied.
 - i. Risks to participants are minimized, by using procedures consistent with sound research design that do not unnecessarily expose participants to risk and, whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.
 - ii. Risks to participants are reasonable in relation to anticipated benefits, if any, to participants and the importance of knowledge that may reasonably be expected to result. In evaluating risks and benefits that may result from the research (as distinguished from risks and benefits of therapies participants would receive even if not participating in the research), the IRB shall not consider long-range effects of applying knowledge gained in the research as among those research risks that fall within the purview of its responsibility.

- iii. Selection of participants is equitable. In making this assessment the IRB shall take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations and/or economically or educationally disadvantaged persons.
 - iv. Unless otherwise provided for in this policy, informed consent shall be sought from each participant or the participant's legally authorized representative and documented by the use of a written consent form approved by the IRB and signed by the participant or the participant's legally authorized representative.
2. Observation of the consent process and the research: The IRB shall have the authority to observe or have a third party observe the consent process and the research.
 3. Frequency of review: The IRB shall determine, in its review of research protocols, which projects will require IRB review more often than annually.
 4. Continuing review: The IRB shall conduct continuing review of research at intervals appropriate to the degree of risk, but not less than once per year, except as described below:

Unless an IRB determines otherwise, continuing review of research is not required in the following circumstances:

- i. Research eligible for expedited review;
 - ii. Research reviewed by the IRB in accordance with the limited IRB review;
 - iii. Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:
 - a) Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
 - b) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.
5. Verification of change: The IRB shall determine which projects need verification from sources other than the research investigators that no material changes have occurred since previous IRB review.
 6. Authority to suspend or terminate approval of research: The IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's decisions, conditions and requirements or that has been associated with unexpected serious harm to participants.
 7. Information dissemination and reporting requirements: The IRB shall have the authority and be responsible for promptly reporting information to the ORSP and, when appropriate, the OHRP on a variety of issues. In conjunction with this requirement the IRB must be prepared to receive and act on information received from a variety of sources, such as human participants, research investigators, the ORSP or other institutional staff.

For reporting purposes, the IRB will follow the procedures described below:

- i. Any serious or continuing noncompliance by research investigators with the requirements of the IRB—this information shall be reported promptly to the ORSP and, when required, the ORSP will report it to the OHRP.
- ii. Injuries to human participants—information received by the IRB concerning injuries to participants shall be reported promptly to the ORSP. The ORSP is responsible for reporting to the appropriate institutional officials and, when required, to the OHRP.

- iii. Unanticipated problems—information received by the IRB concerning unanticipated problems involving the risks to participants or others shall be reported promptly to the ORSP. The ORSP is responsible for reporting to the appropriate institutional officials and, when required, to the OHRP.
 - iv. Suspension or termination of IRB approval—the suspension or termination of approval of research protocols shall be reported promptly to the research investigator, the ORSP, and, when required, to the OHRP. Such reports shall include a statement of the reasons for the IRB's action.
8. **IRB Records:** The IRB shall prepare and maintain adequate documentation of IRB activities, including the following:
- i. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent forms, progress reports submitted by research investigators and reports of injuries to participants.
 - ii. Minutes of IRB meetings shall be in sufficient detail to show the names of attendees at the meetings; actions taken by the IRB; the vote of these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; a written summary of the discussion of controverted issues and their resolution; and dissenting reports with opinions. If a member in attendance has a conflicting interest regarding any project and therefore did not participate in a review, minutes shall show that this member did not participate in the review, except to provide information requested by the IRB.
 - iii. Records of continuing review activities including rationale for conducting continuing review of research that would otherwise not require continuing review.
 - iv. Copies of all correspondence between the IRB and the research investigators.
 - v. A list of IRB members.
 - vi. Written procedures for the IRB.
 - vii. Statements of significant new findings provided to participants.
 - viii. The rationale for an expedited reviewer's determination that research appearing on the expedited review list is more than minimal risk.
 - ix. Documentation specifying the responsibilities that an institution and an organization operating an IRB each will undertake to ensure compliance with the requirements of this policy.

The IRB shall provide for the maintenance of records relating to a specific research activity for at least three years after completion of the research.

IRB records of research funded by federal agencies or departments shall be accessible for inspection and copying by authorized federal representatives at reasonable times and in a reasonable manner, or shall be copied and forwarded to the appropriate federal agency or department when requested by authorized representatives.

E. **Institutional Review Board Procedures:** The following procedures are followed when reviewing the different types of research projects.

- 1. **Exemptions:** The ORSP receives all applications that are submitted to the IRB. The ORSP will review all projects that are submitted under the exempt category to determine whether they meet the requirements for exemption. The ORSP also will review student classroom projects that meet the criteria for exemption. At the

discretion of the ORSP, such projects also may be sent to other IRB members for review.

2. Expedited review: The eligibility of some research for review through the expedited procedure is in no way intended to negate or modify the policies of this institution or the other requirements of 45 CFR 46.

Expedited review shall be conducted by two IRB members with the exception, generally, of any *ex officio* members. The IRB members conducting the expedited review may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. The reviewers shall refer any research protocols that are not approved through the expedited process to the full IRB for a full review. The reviewers also may refer other research protocols to the entire IRB whenever either reviewer believes that full review is warranted.

When the expedited review procedure is used, the IRB members conducting the review shall inform IRB members in writing of research protocols which have been approved under the procedure.

At a convened IRB meeting, any member may request that an activity that has been approved under the expedited procedure be reviewed by the IRB in accordance with non-expedited procedures. A vote of the members shall be taken concerning the request and the majority shall decide the issue.

3. Full review: Research protocols scheduled for review by the entire IRB shall be distributed to all members of the IRB prior to the meeting, along with all relevant correspondence pertaining to the application. Additionally, the Principal Investigator will be invited to appear before the IRB during the discussion of the application.

When it is determined that consultants or experts will be required to advise the IRB in its review of a protocol, the research protocol shall also be distributed to the consultants or experts prior to the meeting.

All IRB initial review and continuing review shall be conducted at convened meetings and at timely intervals.

A majority of the membership of the IRB, including at least one member whose expertise is in non-scientific areas, constitutes a quorum and is required in order to convene a meeting for full review of research protocols.

For a research protocol to be approved, the protocol must receive the approval of a majority of those members present at the convened meeting.

No member of the IRB may participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

In cases where research activities were initially approved under expedited procedures and subsequently reviewed by non-expedited procedures, the decisions reached at the convened meeting shall supersede any decisions made through the expedited review.

4. IRB notification to research investigators and the ORSP: The IRB shall notify the research investigators and the ORSP in writing of the IRB's decisions, conditions and requirements.

The IRB shall also provide to the research investigator reasons for the IRB's decision to disapprove a research protocol and an opportunity for the research investigator to respond. Reasons for disapproval shall also be transmitted to the ORSP by the IRB.

5. Reconsideration: When a research investigator chooses to question a decision made by the IRB, the investigator shall submit a request for reconsideration, complete with justification or revised research protocol, in writing to the ORSP. The ORSP shall convene a meeting of the IRB within 15 business days of receipt of the request for the purpose of reconsideration of the protocol. The research investigator shall have the right to be present at a meeting convened for the reconsideration of his/her proposal.