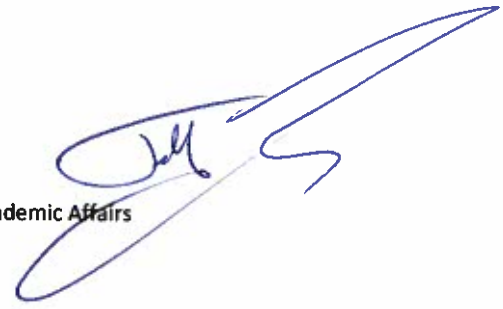
Kean University
Human Research Protection Program
Policy and Procedure Manual



OFFICE OF RESEARCH & SPONSORED PROGRAMS

Approval Authority: Provost and Vice President for Academic Affairs

Originally Issued: August, 2008

Revised/Updated: August, 2012; June, 2017

1. Human Research Protection Program (HRPP)

1.1 Mission:

Kean University supports research as an integral element of its mission to advance and disseminate knowledge. The University's practices and policies in support of research will firmly uphold the highest standards of ethics and integrity and comply with all federal and state regulations and guidelines.

In order to help fulfill this mission, Kean University has established the Institutional Review Board, an appointed group of researchers from across disciplines, who review all research applications according to federal and state regulations and university policies for the protection of human subjects.

The mission of IRB is to safeguard and promote the health and welfare of human research participants by reviewing proposed research protocols to ensure that the rights of human subjects are protected and that risk of harm to subjects is minimized. The IRB accomplishes this through:

- providing timely and high quality education and training for IRB applicants, research advisors, and staff;
- providing initial and continuing review of research studies and responding to reports of adverse events or other research-related problems; and,
- facilitating excellence in human subject research.

The IRB includes mechanisms to:

- Establish a formal process to monitor, evaluate and continually improve the protection of human participants
- Dedicate resources sufficient to do so
- Exercise oversight of research protection
- Educate investigators and research staff about their ethical responsibility to protect research participants
- When appropriate, intervene in research and respond directly to concerns of research participants

1.2 Policy

The Kean University Human Research Protection Policy is in close alignment with that of the U.S. Department of Health and Human Services, Code of Federal Regulations, Title 45 (Public Welfare), Part 46 (Protection of Human Subjects), or 45 CFR Part 46, referred to as the Common Rule, adopted in 1991 by seventeen Federal Departments and Agencies and revised effective January, 2018.

Kean University is committed to promoting the highest standards of research ethics and integrity within its community, across all disciplines and areas of study. Its policies and procedures not only assure compliance with federal laws governing the conduct of research but also foster continual, intellectual and artistic exchange and development. As researchers/scholars/artists, members of the Kean University faculty seek to discover, develop, and communicate new knowledge, in an environment of intellectual honesty and free inquiry. To that end, they commit to developing and continually enhancing their scholarship, cognizant of the special responsibility in their areas of study to seek and state the truth as they see it and of the obligation to exercise critical self-discipline and judgement.

Developing new knowledge and understanding is achieved by building upon the knowledge gained from others and the works created by others; as such, members of the faculty appropriately recognize in their published or exhibited works the published or exhibited works of others, conversations with colleagues, and student efforts as applicable. They present their own data only after thorough verification through standard data gathering techniques. They exercise extreme caution when using data or information reported by others, and they are guided only by the truth when evaluating the works of others.

1.3 Institutional Authority

Kean University Human Research Protection Program operates under the authority of the Provost and Vice President for Academic Affairs, who is the Institutional Official (IO) for the University. The operating procedures in this document serve as the governing procedures for the conduct and review of all human research conducted by faculty, staff and students at Kean University. The HRPP Policy and Procedures are made available to all Kean University investigators and research staff and are posted on the Kean University IRB & Research Compliance website.

1.4 Ethical Principles

Kean University is committed to conducting research with the highest regard for the welfare of human participants. It upholds, and adheres to, the principles of The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research by the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research (1979).These principles are:

1) Respect for Persons, which is ensured by obtaining informed consent, consideration of privacy, confidentiality, and additional protections for vulnerable populations.

2) Beneficence, which is assured by ensuring that possible benefits are maximized and possible risks are minimized to all participants.

3) Justice, the equitable selection of participants.

The Kean University IRB, in partnership with its research community, is responsible for ensuring the ethical and equitable treatment of all human participants in research conducted under its auspices.

1.5 Regulatory Compliance

IRB is responsible for ensuring compliance with federal regulations, state law, and institutional policies. All human research at Kean University is conducted in accordance with the policy and regulations found in 45 CFR 46 and 21 CFR 50 and 56. The actions of Kean University will also conform to all other applicable federal, state, and local laws and regulations.

1.6 Federal wide Assurance (FWA)

All of the Institution's human subjects research activities, regardless of whether the research is subject to the U.S. Federal Policy for the Protection of Human Subjects (also known as the Common Rule), will be guided by a statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution. This statement of principles may include (a) an appropriate existing code, declaration (such as the World Medical Association's Declaration of Helsinki), or statement of ethical principles (such as the

Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research of the U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research), or (b) a statement formulated by the institution itself.

1.7 Institutional Official

The ultimate responsibility of the HRPP resides with the Provost and Vice President of Academic Affairs. The IO is responsible for ensuring the Kean University HRPP has the resources and support necessary to comply with all institutional policies and with federal regulations and guidelines that govern human research. The IO is legally authorized to represent Kean University. He is the signatory of the FWA and assumes the obligations of the FWA. The IO is the point of contact for correspondence addressing human research 1-5 with the DHHS Office for Human Research Protections (OHRP), the Food and Drug Administration (FDA), and any other federal regulatory agencies. The IO also holds ultimate responsibility for oversight of the Institutional Review Board (IRB) and all Kean University investigators; for assuring the IRB members are appropriately knowledgeable in accordance with ethical standards and applicable regulations; for assuring the investigators are appropriately knowledgeable to conduct research in accordance with ethical standards and applicable regulations; and for the development and implementation of an educational plan for IRB members, staff, and investigators.

1.8 Written policies and procedures

Kean University Human Research Protection Program Policy and Procedure Manual details the policies and regulations governing research with human participants and the requirements for submitting research protocols for review by the Kean University IRB. The policies and procedures manual is not a static document. The policies and procedures are reviewed regularly and revised by the Director of the Office of Research and Sponsored Programs (ORSP), the Institutional Review Board, and University counsel, as necessary. The IO (Provost and Vice President of Academic Affairs) will approve all revisions of the policies and procedures. The IRB office will keep the University research community apprised of new information that may affect the human research protection program, including laws, regulations, policies, procedures, and emerging ethical and scientific issues on its website and through campus electronic mailing lists. The policies and procedures will be available on the Kean University IRB website and copies will be available upon request.

2.0 Institutional Review Board (IRB)

Kean University has four IRB committees, appointed by the IO. The IRB prospectively reviews and makes decisions concerning all human research conducted by its students and faculty. The IRB complies with the requirements of the Common Rule, state regulations, the FWA, and institutional policies.

2.1 Purpose

The purpose of Kean IRB is to review all proposed research protocols in order to ensure that the rights of human subjects are protected and that risk of harm to subjects is minimized.

IRB Authority - Under University policy "Human Research Protection Program (HRPP)," the IRB is authorized to:

- Approve, require modifications to secure approval, or disapprove all research activities overseen and conducted in Kean University
- Suspend or terminate approval of research not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to participants;
- Observe, or have a third party observe, the consent process; and
- Observe, or have a third party observe, the conduct of the research.

2.2 Number of IRBs

There is one institution-wide Institutional Review Board. The IRB has four committees under its jurisdiction. The Director of ORSP and the Assistant Director of ORSP/IRB Coordinator will annually review the activity of the IRB and make a determination as to the appropriate number of IRB committees that are needed for the institution.

2.3 Roles and Responsibilities

The Director of ORSP, in consultation with Provost and Vice President of Academic Affairs, appoints Chairs and Members of the IRB committees. Any change in appointment, including reappointment or removal, requires written notification. Appointments have a specified term.

2.4 IRB Guidelines

According to the federal rules, all Kean University researchers (students or faculty) involving human subjects in their research must apply for, and receive, approval from the Institutional Review Board (IRB) before proceeding with their research. Research studies fall into three categories:

1. Studies that may be **exempt from IRB review**. (See list of the exempt categories, XM 1-6). Exempt Applications can be reviewed by one IRB member, sometimes in consultation with others. If the study is considered low-risk and the only involvement of human subjects will be in the categories outlined in **45CFR 46.101 (b).** For those a memo must be sent to IRB describing the research and stating why it is exempt.
2. Studies that could be **reviewed through the expedited IRB review process**. (See list of the expedited categories, EXP 1-9.) "Expedited" means review by the IRB chair and one or more experienced reviewers. In general, research may qualify for expedited review if it is judged to involve only minimal risk, does not include intentional deception, does not employ sensitive populations or topics, and includes appropriate informed consent procedures. If concerns are raised during these reviews about the viability of an application, it will be transferred to the full convened IRB.
3. Studies that are not eligible for exempt or expedited review should be submitted as **full panel review**. In summary, research that is judged to involve more than minimal risk, or involves protected/vulnerable populations such as children, prisoners, or disabled individuals, must undergo a full board review. Researchers intending to conduct research that requires full review should allow ample time to complete the review process.

2.5 Role of Principle Investigators (Researchers) and Faculty Advisors

Kean University students or members of the adjunct faculty must be sponsored by a research advisor/full-time faculty member before proceeding with research involving human or animal subjects. Their IRB

applications must be reviewed and signed by the research advisor/full-time faculty member. Similarly, a member of the external community seeking to conduct research at Kean University must apply for Kean IRB approval.

Researcher Responsibilities

- Education – complete the CITI Training Course (https://www.citiprogram.org) prior to the start of any human subject research activity
- Design and conduct ethical research in accordance with the fundamental ethical principles of Respect for Persons, Beneficence, and Justice outlined in the Belmont Report
- Correctly complete IRB application (Provide ALL necessary documents for review to the IRB)
- Obtain IRB approval prior to initiation of research
- Ensure that recruitment activities are not initiated prior to IRB approval or after the expiration date of IRB approval. Researchers are responsible for enrolling only the number of subjects that were indicated and approved in the protocol.
- Ensure that the research is conducted as approved and obtain prior approval for modifications
- Obtain informed consent from research participants and other required parties
- Document informed consent by providing subject with a copy of the signed form and keeping a copy in the study records
- Report adverse events and any non-compliance immediately to IRB
- Disclose any conflicts of interest of research team members
- Retain research records securely for five (5) years after closure of the IRB approved protocol

Faculty Research Advisor Responsibilities

Preparation of Students for the Role of Researcher – The Faculty Research Advisor is responsible for instructing students in the ethical conduct of research and assisting students in the preparation of IRB applications. The Faculty Research Advisor ensures that their advisees:

- design a study that minimizes the risk to human subjects,
- understand the elements of the consent process,
- develop a readable consent form,
- plan appropriate recruitment strategies for identifying subjects, and
- establish strict guidelines for protecting anonymity and confidentiality.

Scientific Review – The Faculty Research Advisor is responsible for the scientific review of the research study. The Faculty Research Advisor signature on the IRB application serves as the verification that the research design is sound and the study hypothesis is reasonable. Prior to submission of a student protocol to the IRB, the advisor should review the protocol and all supporting documents including consent forms, recruitment materials and study instruments. The faculty research advisor signature affirms that:

- the research uses procedures consistent with sound research design,
- the study design can be reasonably expected to answer the proposed question, and
- the importance of the knowledge expected to result from the research is known.
- The IRB reserves the right to require scientific review on a study-by study basis.

Conduct of Research – The Faculty Research Advisor shares with the student researcher the responsibility for the ethical conduct of research. The Faculty Research Advisor takes an active role in providing supervision for the duration of the project and ensures that their advisees conduct their research in accordance with the IRB approved protocol. The Faculty Research Advisor:

- Reviews all changes to the research, ensures that changes are submitted to the IRB, and that approval is obtained before a change is implemented;
- Reports any adverse events or other research-related problems to the IRB as soon as possible;
- Ensures that continuing review requirements are satisfied when applicable and that the study is properly closed.

2.6 Chairperson of the IRB

The IRB Chair should be a highly respected faculty member, from within the University, fully capable of managing the IRB and the matters brought before it with fairness and impartiality. The IRB committee must be perceived to be fair, impartial, and immune to pressure by the institution's administration, the investigators whose protocols are brought before it, and other professional and nonprofessional sources. The IRB Chair is responsible for conducting the meetings and is a signatory for correspondence generated by the IRB committee. The performance of the IRB Chair will be reviewed on an annual basis by the ORSP Director in consultation with the Assistant Director of ORSP/IRB Coordinator

2.7 IRB Membership

IRB members are selected based on the requirements of HHS for membership/makeup of committee, including consideration of representation by multiple, diverse professions, specific community concerns in addition to knowledge and experience with vulnerable participants, and inclusion of both scientific and non-scientific members. The structure and composition of the IRB must be appropriate to the amount and nature of the research that is reviewed. ORSP makes every effort to have member representation that has an understanding of the areas of specialty that encompass most of the research performed at Kean University. The University has procedures that specifically outline the requirements of protocol review by individuals with appropriate scientific or scholarly expertise. In addition, the IRB will include members who are knowledgeable about, and experienced working with, vulnerable populations that typically participate in Kean University research or have ready access to consultants with appropriate knowledge and experience. The IRB must promote respect for its advice and counsel in safeguarding the rights and welfare of research participants and possess the professional competence necessary to review specific research activities. A member of the IRB may fill multiple membership position requirements for the IRB.

2.8 Composition of the IRB

1. The IRB committees will have at least five members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution.

2. The IRB will be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community 2-4 attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human participants.

3. In addition to possessing the professional competence necessary to review specific research activities, the IRB will be able to determine the acceptability of proposed research in terms of institutional policies and regulations, applicable law, and standards of professional conduct and practice.

4. Consideration will be given to the inclusion of one or more individuals on the IRB, who are knowledgeable about and experienced in working with these participants. When protocols involve vulnerable populations, the review process will include one or more individuals who are knowledgeable about or experienced in working with these participants, either as members of the IRB or as consultants.

5. Every nondiscriminatory effort will be made to ensure that the IRB does not consist entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. The IRB shall not consist entirely of members of one profession.

6. The IRB includes at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

7. The IRB includes at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

8. One member may satisfy more than one membership category.

9. The ORSP Director and administrators may be voting members of the IRB

2.9 Role of IRB Committee Members

IRB committees perform duties, as appropriate, for review, signature authority, and other IRB functions. Duties of a subcommittee may include the following:

1. Serve as designees by the IRB Chair for the expedited review of new or continuing protocols, and/or modifications of continuing protocols. The committee must be experienced in terms of seniority on the IRB.

2. Review and approve the revisions requiring only simple concurrence submitted by investigators for a protocol given provisional approval by the convened IRB.

3. Conduct an inquiry. A committee is appointed consisting of IRB members, and non-members, if appropriate, to conduct an inquiry into allegations of noncompliance the committee is given a charge by the IRB, which can include any or all of the following:

4. Review of protocol(s) in question;

5. Review of any relevant documentation, including consent documents, case report forms, participants' files, as they relate to the investigator's execution of her/his study involving human participants;

6. Interview of appropriate personnel, if necessary;

7. Preparation of either a written or oral report of the findings, which is presented to the full IRB at its next meeting; e. recommend actions, if appropriate.

8. The applications, agenda and other appropriate documents required for review is distributed two weeks prior to the convened meetings at which the research is scheduled. Members received materials for review at least two weeks before each meeting. All information provided are expected to handle with great confidentiality.

2.10 Alternate members

The appointment and function of alternate members is the same as that for primary IRB members, and the alternate's expertise and perspective are comparable to those of the primary member. The role of the alternate member is to serve as a voting member of the IRB when the regular member is unavailable to attend a convened meeting. When an alternate member substitutes for a primary member, the alternate member will receive and review the same materials prior to the IRB meeting that the primary member received or would have received. The IRB roster identifies the primary member(s) for whom each alternate member may substitute. The IRB minutes will document when an alternate member replaces a primary member. If both primary and alternate members are present at the meeting, it will be made clear at the outset which member is there in a voting capacity.

2.11 Use of Consultants

When necessary, the IRB Chair or the ORSP Director may solicit individuals from the University or the community with competence in special areas to assist in the review of issues or protocols which require appropriate expertise beyond or in addition to that available on the IRB. The need for a consultant is determined in advance of the meeting by the Director or the Assistant Director by reviewing the protocols scheduled to be reviewed at the convened meeting. Assistant Director will ensure that all relevant materials are provided to the consultant prior to the convened meeting. Written reviews provided by the consultant, as necessary, will be shared with the full committee. Individuals who have a conflicting interest or whose spouse or family members have a conflicting interest in the sponsor of the research will not be invited to provide consultation. The consultant's findings will be presented to the full board for consideration either in person or in writing. If in attendance, these individuals will provide consultation but may not participate in or observe the vote. Ad hoc or informal consultations requested by individual members (rather than the full board) will be requested in a manner that protects the researcher's confidentiality and is in compliance with the IRB conflict of interest policy.

2.12 Ethical Concerns

No IRB member should participate in IRB's initial review, continuing review/renewal or amendment/modifications of any project in which the member has a conflicting interest except to provide information as per IRB's request. Conflicting interests include, but are not limited to: serving as the faculty advisor for the study under review; or, benefiting in any way in the research project. IRB members with conflicting interest will not be in the room during discussion of the study. Through its policies, IRB makes every effort to maintain the fundamental principle of transparent research and protect personal information.

2.13 Attendance Requirements

Members are required to attend all meeting they are scheduled. All IRB Committees shall meet at least three times each year. The schedule and committee charge is distributed among members in summer. If a member is unable to attend a scheduled meeting due to an emergency, they should inform the IRB Chair

and IRB Coordinator. If the inability to attend will be prolonged, a request for an alternate to be assigned may be submitted to the Chair and the IRB Coordinator.

Any committee member who misses more than half of the meetings in a year will be considered as having resigned from the committee for the next year. Committee Chairs will notify the IRB Coordinator of the need to replace members.

2.14 Training/ Workshops of IRB Committees in regards to Regulations and Procedures

A key segment of a comprehensive human research protection program is a training program for IRB Chair and the IRB members. Kean University is dedicated to providing training and an on-going educational workshops for IRB members and the staff of IRB, related to ethical concerns and regulatory and institutional requirements for the protection of research participants.

To participate in ongoing research activities, the Social& Behavioral Research Basic, Biomedical Investigators Basic, or Data and Specimens module(s) must be renewed every 3 years by taking the corresponding Refresher Course. Initial IRB approvals, modifications, renewals and other mid-research submissions will not be approved without verification of up-to-date researcher training. CITI completion reports are valid for **three years** and then must be renewed.

Orientation

New IRB members, existing members as well as alternate members will meet with the IRB Chair and IRB Coordinator for an informal orientation session. At the session, the new member will be given materials that include:

- Belmont Report
- Federal regulations relevant to the IRB
- Kean University HRPP Policy and Procedures Manual
- IRB committee charge and schedule of meetings

Initial Education

New members are required to complete the initial education requirement for IRB members before they may serve as Primary Reviewer. Initial Education IRB members will complete the following web based training:

• CITI program

Continuing Education

All IRB members will be providing training in regards to updated policies and regulations throughout their service. Examples of activities may include:

- In-service training at IRB meetings
- Workshops presented during Professional Development Days
- Special issues meetings
- Panel presentations
- Guest Speaker

- Dissemination of new information released by HRPP that includes changes/updated on laws, policies, procedures, and emerging ethical issues to all committee members

IRB Member Mentoring Program

Kean University has established a mentoring program for new IRB committee members during their first year of service. Each new member is paired with a senior member and pairs are encouraged to meet before each regularly scheduled committee meeting to discuss the applications under review and the review process. Senior IRB committee members who serve as mentors are encouraged to explain their thinking behind issues rather than to influence the decisions of new members.

2.15 Review of IRB Member Performance

The IRB member's performance will be reviewed at regular intervals by the office of ORSP. Members who are not abiding by the guidelines and regulations aligned with the IRB's mission or who have violated the attendance policy will be removed.

3 IRB Review Categories

3.1 Human Participant Research Determination

The responsibility for initial determination as to whether an activity constitutes human research rests with the investigator. The investigator should make this determination based on the definitions of "human participant" and "research" listed on compliance website. Since the University will hold them responsible if the determination is not correct, investigators may request a confirmation that an activity does not constitute human research from ORSP. The request may be made verbally, by phone contact, by email, or through a formal written communication. All requests must include sufficient documentation of the activity to support the determination. Determinations as to whether an activity constitutes human research will be made according to the definitions in Section Determinations regarding activities that either clearly are, or clearly are not, human research, may be made by the IRB Manager. Determinations regarding less clear-cut activities will be referred to the IRB Chair, who may make the determination or refer the matter to the full IRB.

3.2 IRB Exempt Studies

The policy and provisions are closely based on DHHS regulations (45 CFR 46.101-b). The following research categories (XM1 – XM6) are exempt from IRB review:

NOTE: No research involving children as the primary research participant is eligible for exempt review.

In instances where the investigator believe the study is exempt from IRB review, the university policy requires the researcher to submit, at least two weeks before the research is to be conducted, an exempt application to the IRB briefly stating the nature of the research and referring to the reason (XM) for the exemption. If there are questions with the research being exempt, IRB will notify the researcher and request an expedited or full IRB application. In all cases, however, the documents shared with the human subjects must state that the research is exempt from IRB review according to Kean University's policy on

research with human subjects, and the exemption must be listed. Researchers must still abide by informed consent requirements as adequate for ethical treatment and protection of participating human subjects.

XM1. 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 the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Examples of research exempt through this criteria

- Study of normal educational practices conducted in commonly accepted settings such as elementary, secondary, or post-secondary schools.

Examples of research NOT EXEMPT via this criteria

- Research that involves evaluation of a radically new instructional strategy or use of random assignment of subjects to different instructional methodologies is not exempt because the methods employed deviate from normal education.
- Educational research that involves deception or withholding of information from subjects is not exempt. - Exemptions are not granted for research on physical education that involves exercise if the activity is altered in a significant way for the purposes of the research. Regardless of whether or not the exercise is considered normal educational practice an element of risk may be introduced with physical exercise.

XM2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior unless:

(i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects and
(ii) Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

Examples of research exempt through this criteria

- Research where no questions of a sensitive or private nature are asked AND where the data cannot be linked back to individual subjects.

Examples of research NOT EXEMPT through this criteria

- Surveys or questionnaires that ask invasive questions of a sensitive or private nature that might be deemed to cause the subject some discomfort or distress. This includes but is not limited to questions or inquiries about sexual preferences, sexual behaviors, substance use or abuse, or illegal conduct.
- Research where subjects can be identified as participating in the study. This can be found in the forms of collecting personal info such as name, SS#, or student ID number.

XM3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under exemption 2, if:

(i) The human subjects are elected or appointed public officials or candidates for public office or

(ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

Examples of research exempt through this criteria

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior as long as that research is conducted on an elected or appointed public official. However, their participation in the research has to remain confidential.

Examples of research NOT EXEMPT through this criteria

Research where the public official's participation is revealed or identifiable.

XM4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

Examples of research exempt through this criteria

- Information derived from the use of the data, records or biological specimens collected must be recorded in a manner whereas subjects cannot be identified. This means there must be no direct or indirect subject identifiers such as demographic information that can be linked to the subjects.
- Important to note that not having access to the subjects name does not automatically mean that the research is exempt. The existence of a one-way identifier, such as a code that can be used to identify a subject disqualifies the research.
- All research material must be existent (on-the-shelf) at the time the research begins. Any use of research material collected after the research is initiated constitutes a prospective study and disqualifies the study from exempt status. In order to be exempt under this rule, the research must be retrospective in nature. Examples of research NOT EXEMPT through this criteria - Research where materials will be collected after IRB approval - Research where there are direct or indirect subject identifiers attached to the specimens that can be traced back to the respondent.

Examples of research NOT EXEMPT through this criteria

- Research where materials will be collected after IRB approval.
- Research where there are direct or indirect subject identifiers attached to the specimens that can be traced back to the respondent

XM 5. Research and demonstration projects which are conducted by or subject to the approval of 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.

Examples of research exempt through this criteria

Research that is conducted on public benefit or service programs such as welfare, Medicaid, unemployment, and Social Security.

Examples of research NOT EXEMPT through this criteria

Research where analysis is conducted by individual not associated with the agency

XM 6. Taste and food quality evaluation and consumer acceptance studies

(i) if wholesome foods without additives are consumed or
(ii) (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 Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Examples of research exempt through this criteria

- Research that is limited to taste and food quality evaluation studies that do not involve consumption by the subject of any type of food that has any potential risks such as indigestion or vitamin deficiencies.
- Food consumed by the subject and the time frame in which this is accomplished should constitute reasonable eating behaviors.

Examples of research NOT EXEMPT through this criteria

Studies that involve consumption of alcohol, vitamins, or supplements such as protein power, creatine, and glucosamine chondroitin sulfate should not qualify for exempt status.

3.3 IRB EXPEDITED REVIEW

NOTE: No research involving children as the primary research participant is eligible for expedited review.

The policy and provisions are closely based on DHHS regulations (45 CFR 46.110). When proposed research activities are expected to present no more than minimal risk to participating human subjects, and when they fit within one or more of the categories below, they may be reviewed by the IRB through the expedited review procedure (21 CFR 56.110).

Applicability

The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

The categories in this list apply regardless of the age of subjects, except as noted.

The expedited review procedure may not be used where 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, 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.

Federal and state guidelines dictate that in order for research to be considered eligible for expedited review, certain criteria must be met and maintained. In order to approve research designated as expedited, the IRB must determine that all of the following requirements are satisfied:

1. The proposed procedures must be consistent with sound research design, and when possible, procedures already being performed on subjects should be used.
   → For example, obtaining additional blood at time of routine venipuncture is preferred rather than doing an extra needle stick to obtain the research sample.
2. The risks of the research must be reasonable in relationship to the anticipated benefits, if any, to the subjects and the importance of the knowledge that may be gained.
3. Subject selection must be equitable, with all subjects having an equal opportunity to accept or decline participation.
4. Informed consent should be sought and documented unless a waiver of consent and/or documentation of consent has met the waiver criteria specified by the DHHS (45 CFR 46). DHHS mandates that an IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:
   i) That the only document linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research and the subjects wishes will govern or
   ii) 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.
5. Where appropriate, there is a plan to collect and monitor data to ensure subject safety
6. The privacy of subjects and maintenance of confidentiality of data are protected.
7. Where necessary, additional safeguards have been included to protect valuable subjects.
8. Research that is being conducted does not ask questions of a sensitive nature (e.g. questions or inquiries about sexual preferences, sexual behaviors, substance use or abuse, or illegal conduct.) Research does not allow for subjects to offer responses that could reasonably place them at risk for criminal or civil liability, be damaging to their financial standing, insurability, reputation, or be stigmatizing.

The expedited review procedure may not be used for classified research involving human subjects. Expedited reviews may be conducted for initial as well as continuing IRB applications.

Review Process:

The expedited review process consists of the application being reviewed by members of the IRB as assigned by the Chair. Expedited reviewers will suggest provisions, reject, and/or approve on behalf of the IRB. In the case of serious concerns, such applications will be referred to the full IRB. Reports of expedited reviews will be made to the IRB on a monthly basis.

The applicant will complete for an expedited review the same IRB application and will identify specifically in which "expedited" category (EXP) the research fits.

Standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of IRB review--expedited or convened.

In cases of expedited review, the documents shared with the human subjects must state that the research has received IRB approval by expedited review according to Kean University's policy on research with human subjects, and the exemption must be listed. Kean University's IRB number must be listed.

Research Categories:

EXP1 - Clinical studies of drugs and medical devices only when one of the following 2 conditions are met:

a) Research on drugs for which an investigational new drug application is not required.
    a. or
b) Research on medical devices for which an investigational medical device exemption application is
    a. not required, or the medical devise is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

EXP2 - Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

a) from healthy, non-pregnant adults who weigh at least 150 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week.
b) or
c) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.

EXP3 - Collection of biological specimens for research purposes by noninvasive means. Examples:

a) Hair and nail clippings in a non-disfiguring manner
b) Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction
c) Permanent teeth if routine patient care indicates a need for extraction
d) Excreta and external secretions (including sweat)
e) Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing
f) gumbase or wax by applying a dilute citric solution to the tongue

g) Placenta removal at delivery
h) Aminotic fluid obtained at time of rupture of the membrane before or during labor
i) Supragingival and subgingival dental plaque and calculus, provided the collection procedure is not
j) more invasive than routine prophylactic scaling of the teeth and the process is accomplished
k) accordance with accepted prophylactic techniques
l) Mucosal and skin cells collected by buccal scraping or swab, skin swap, or mouth washings
m) Sputum collected after saline mist nebulization

EXP4 - Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples:

a) Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy
b) Weighing or testing sensory acuity
c) Magnetic resonance imaging
d) (d)Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography
e) Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

→ PLEASE NOTE: These examples assume the research is being conducted with a subject population for whom these tasks would pose no more than a minimal risk. If the tasks are performed on a subject population for whom the tasks would be considered risky, then this research is no longer eligible for expedited review.

EXP5 - 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).

→ PLEASE NOTE: Research using retrospectively of prospectively collected routine medical record information or leftover specimens collected at the time of clinical care would qualify in this category of expedited review, if the information is not considered sensitive and any potential breach of confidentiality would not be damaging to the subject. Research using the medical records of HIV-positive patients is an example of a study that should not be reviewed by the expedited method.

EXP6 - Collection of data from voice, video, digital, or image recordings made for research purposes.

→ PLEASE NOTE: If information included in the recordings is considered sensitive or potentially damaging to the subject's financial standing, employability, insurability, reputation, or if the subject's voice or (still or moving) image could be identified then this research is not eligible for expedited review.

EXP7 - 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.

→ PLEASE NOTE: Research studies on intelligence or other traits involving specific populations require careful analysis because this type of research, depending on the nature of the survey questions, could result in stigmatization of a segment of society.

EXP8 - Continuing review of research previously approved by the convened IRB as follows:

(a) Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects;

or

(b) Where no subjects have been enrolled and no additional risks have been identified;

or

(c) Where the remaining research activities are limited to data analysis.

EXP9 - Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

3.4 CONVENED IRB MEETINGS :

The IRB meets according to a regular schedule, with additional meetings as needed. IRB full committees meet on a monthly basis with the exception of July and August. The schedule can be found on compliance.kean.edu website. Upon IRB review, applicants will receive formal notification from ORSP stating whether approval was granted and what conditions if any attached. The schedule of IRB meetings and deadlines for submission of proposals will be posted on the website of the IRB. All documents submitted for review will be available to IRB members before each scheduled meeting. IRB staff prepare the agenda with input from the IRB Coordinator. The Chairperson will facilitate the meeting according to the following format:

1. Call the meeting to order
2. Announcements
3. Review of Protocols
4. Discuss projects with concerns and voting discrepancy
5. Record the vote
6. Adjourn the meeting

Protocols with concern will be discussed until every member of the IRB has had his/her concerns and questions addressed. The IRB members will refer to the Criteria for IRB Approval of Research as articulated in the Federal Regulations (45 CFR 46.111) in making their determination as to what action to take

regarding each proposed study (see section VIII below). After an adequate period of discussion of the research protocol, the Chairperson may call for a "motion to consider," at which point any IRB member may move for one of the following:

APPROVAL: Protocol and all associated documents are satisfactory as presented, and Investigator may begin research immediately upon receiving notification of approval.

PROVISIONAL APPROVAL: Study is not satisfactory as submitted. Investigator must make modifications and/or alterations to protocol and/or associated documents as directed by the IRB or modify the protocol another way to meet the IRB concerns. In case of a provisional approval, the application would not have to come back for full committee review. Revisions and modifications will be reviewed by IRB Members (acting on behalf of the IRB), who will then determine whether the changes are sufficient for APPROVAL.

DENIED: The protocol places subjects at unacceptable risk relative to benefits. Research project as designed and described is not suitable for involvement of human subjects. Following the "motion to consider" and a second to that motion there will be opportunity for further discussion and clarification. If the motion is for approval or provisional approval with specific directed changes, the motion will also include the length of time for which the protocol will be approved before a continuing review/renewal is required. The motion can then be and voted upon. In order for the reviewed research to be approved, it must receive the approval of a majority of those members present. When there are tie votes, the Chair will facilitate further discussion in an effort to have the committee reach a quorum. If a consensus or majority is not possible, consultation with others, who are not members of the IRB, may be solicited to aid in resolving the issues.

After the full IRB review, the IRB Chairperson or IRB coordinator shall notify the investigator(s) of the findings and actions regarding their protocol within (5) working days of the IRB meeting.

For exempt and expedited reviews, any changes requested by the reviewer will be communicated to the PI within 20 working days after submission of application. If the PI does not address all the changes requested by reviewer, the PI may be required to re-initiate an IRB submission for following month.

3.5 IRB MEETING PROCEDURES:

The IRB Chair will call the meeting to order, once it has been determined that a quorum is in place. The Chair will remind IRB members to recuse themselves from the discussion and vote by leaving the room where there is a conflict. The IRB will review and discuss the IRB minutes from the prior meeting and determine if there are any revisions/corrections to be made. If there are no changes to be made, the minutes will be accepted as presented and considered final. If it is determined that revisions/corrections are necessary, the minutes will be amended and presented at the following IRB meeting, if requested by the IRB. The IRB reviews all submissions for initial and continuing review, as well as requests for amendments. The reviewer(s) presents an overview of the research and leads the IRB through the completion of the regulatory criteria. All members present at a convened meeting have full voting rights, except in the case of a conflict of interest. In order for the research to be approved, it must receive the approval of a majority of those voting members present at the meeting. It is the responsibility of the IRB staff to record the proceedings of the session and to take minutes at each IRB meeting.

3.6 CONFLICT OF INTEREST:

IRB members and consultants will not participate in any IRB action taken, including the initial and continuing review of any project, in which the member has a conflicting interest, except to provide information requested by the IRB. IRB members are expected to self-identify conflicting interests. A full board reviewer or expedited reviewer with a conflict of interest must notify the IRB staff who will re-assign the protocol. Roles that would present a conflict of interest include, but are not limited to, principal investigator, co-investigator, and faculty student advisor. Except when requested by the IRB to be present to provide information, IRB members will absent themselves from the meeting room when the IRB reviews research in which they have a conflicting interest. The Chair will allow for board discussion once the conflicted member has recused him/herself. The absent member is not counted toward quorum and his/her absence during the discussion and vote on the protocol will be noted in the IRB meeting minutes. If the conflict of interest status of an IRB member changes during the course of a study, the IRB member is required to declare this to the IRB Chair and/or IRB Director.

3.7 QUORUM:

A quorum consists of a simple majority of the voting membership, including at least one member whose primary concern is in a non-scientific area. If research involving an FDA-regulated article is involved, a licensed physician must be included in the quorum. The IRB Chair, with the assistance of the IRB staff, will confirm that an appropriate quorum is present before calling the meeting to order. The IRB Chair will be responsible to ensure that the meetings remain appropriately convened. A quorum must be maintained for each vote to occur. IRB staff takes note of arrivals and departures of all members and notifies the chair if a quorum is not present. If a quorum is not maintained, the protocol must be deferred or the meeting must be terminated. Members are considered present and counted towards the quorum if participating through teleconferencing or videoconferencing. In this case the member must have received all pertinent material prior to the meeting and must be able to participate actively and equally in all discussions. Opinions of absent members that are transmitted by mail, telephone, facsimile or e-mail may be considered by the attending IRB members but may not be counted as votes or to satisfy the quorum for convened meetings.

3.8 IRB REVIEW PROCESS

IRB When the research study does not fit within an exemption or an expedited review category, it must be reviewed and approved by a convened IRB. The Institutional Review Board convenes monthly as needed to review applications. Convened IRB decisions are generally made by consensus; where needed, however, a formal vote should be taken with the majority ruling. Subgroups of IRB may on behalf of the full body act on applications. However, such subgroups cannot consist of fewer than 5 members, with the IRB Chair presiding over the monthly review. All applications requesting IRB approval must be complete with attachments and submitted to the Office of Research & Sponsored Programs both electronically and in print with appropriate signatures.

3.9 IRB CONCERNS TO BE ADDRESSED

- RISK Factor – An application must identify all risks involved (personal or professional, psychological, physical or sociological; from low, such as discomfort to high, such as a dangerous situation), and rate them as low, moderate or high. If no risks are anticipated beyond the risks

encountered in normal daily life, then the application and the documents shared with the subject must state that the risks are minimal and are not expected to surpass normal risks encountered daily. Otherwise, the nature of the risk must be disclosed and specific strategies for minimizing the risks must be explicitly described.

- PRIVACY Factor – One of the risks in all studies involving human subjects is the infringement of privacy. Except for special studies where subjects are tied to results (and in which written permission to identify the subject must be sought), and for studies that are anonymous (i.e., no pairing of subject and results is possible) studies with human subjects must maintain confidentiality. Every possible step should be taken so that there are no links between the identities of the subject, and the results of the works and results must be presented in aggregate forms. Furthermore, raw data, along with signed consent forms (and any other data that may reveal identify information) must be stored safely under key for 5 years before being shredded.
- KNOWLEDGE Factor – The human subject has the right, ethically and legally, to be informed about the research study and should provide his or her consent to participate in the study. As such, it is important for the researcher to discuss with the subjects where possible (not only interacting through a piece of paper) the nature of the research, its methods and sought outcomes, along with most importantly the anticipated risks and benefits. The subject must know that his/her participation is completely voluntary (under no coercion or duress), he/she can refuse to participate or withdraw any time from the study without any penalty or loss of benefits to which he/she is otherwise entitled. When the subject is too young to understand his or her involvement, a parent of a legally authorized representative must be informed and sign the consent form permitting the child to participate in the study.

The IRB application must be comprehensive enough to allow the members of IRB to render informed judgment based on criteria a-e above and make meaningful suggestions to help protect human subjects and enhance the proposed study. As such, the application must describe in detail the context and purpose of the study, the methods planned, in particular the way subjects will be recruited and data accrued, and the validity and reliability of instruments or protocols used, as it should discuss the anticipated risks and benefits of the study. Attachments Consent forms and debriefing forms must be included with the IRB Application form, you may view some samples here. Please attach all other relevant documents, including surveys, and letters that accompany surveys etc. where appropriate. Researchers are required to share with the subject consent forms describing the research as detailed below. In most cases, especially when the anticipated risk posed by the research study is more than minimum; a written informed consent must be shared and signed by the participating subject.

3.10 INFORMED CONSENT PROCESS

Consent Form - Informed consent is a crucial element of the IRB application as it pertains to the process in which the participant learns about the study and what their rights are if they elect to take part in the study. No human subject should participate in a research study without receiving full notification of the nature of the research and its goals, risks and how they will be minimized, benefits, and how their privacy will be maintained. (See model consent form in appendix). Every human subject should have their rights explained to them.

For any subjects who are not able to give consent, either because they are minors or because they are legally incompetent, agreement to participate is still required. These individuals must be provided a way to decline participation if they choose to. Agreement to participate by such individuals who cannot otherwise provide "consent" is called "assent." The form that documents this agreement is called an

"assent form". Whenever possible, an assent form should be used to document assent. Like consent, assent is supposed to be "informed" -- that is, subjects should know what they are getting into, and what effects their participation is likely to have. Any information that can affect a subject's decision to take part should be included.

Since assent forms can be used with a very wide range of people, they should be written to suit the population from which you are sampling. In other words, an assent form that is to be used with subjects who are not quite 18 years old, and unable to give consent only because of their ages, should be very different from one used with adult subjects who have been declared incompetent because of severe cognitive deficits, or with children between the ages of 8 and 10 years.

It is, ultimately, the investigator's responsibility to design the appropriate consent/assent forms. It is the IRB's responsibility to decide whether or not the forms are appropriate, but the IRB is not responsible for writing all consent and assent forms. The language used in the consent/assent form should be clear and accessible to the subjects. The form should begin by introducing the researcher (student, status and in what field or faculty and in what department) and the institution (Kean University). It is suggested that the form be divided up in sections, in which a detailed description is provided as relevant:

- ***Describe the purpose and scope of the study-*** It must be stated explicitly in the form that the study involves research as well as describing the purpose of the study.
- ***What are the planned procedures***- Specifically, PI has to describe the duration of the study (how long it will take subjects to participate). Researcher will describe actual procedures they will undertake and tell subjects exactly what they will be doing. If there are any experimental procedures involved, these must be described as well. If these procedures differ from existing, standard procedures, they must be specified as well.
- ***Risk Statement***- PI must describe any reasonably foreseeable risks or discomforts involved and strategies taken to minimize them. When describing risks, it is important to be explicit and describe them in detail.
- ***Benefit Statement***- PI must describe the benefits to the subject or to others which may reasonably be expected from the research. When the subjects are not expected to reap any direct benefits from the study, describe how the study will benefit the larger community, our understanding of science, etc. When using "control groups" as part of the research design, it must be made clear that the subjects will be entitled to the results.
- ***Compensation/Treatment Statement***- When there is greater than minimal risk involved in the study, PI must inform prospective participants whether they will receive any compensation and/or medical treatments if injury should occur. If there is no compensation, researcher should state stating that no payment or cost will be associated with participation.
- ***Confidentiality Statement*** - PI must inform prospective participants how their participation and records/data will be kept confidential. Describe in detail how their records will be kept confidential. Federal regulations dictate that all data be kept under locked key with the principal investigator or research advisor if the researcher is a student for 5 years to be shredded or destroyed beyond that point. This should be explained to all participants.
- ***Voluntary Participation*** - Refusal, and Withdrawal Statement. PI must explicitly state that participation is voluntary, that refusal to participate involves no penalty or loss of benefits to which the person is otherwise entitles, and that the person may discontinue participation at any time without penalty. It should also be stated that deciding to participate will not affect

grades, delivery of services, and loss of income or any other relevant issues that would be of importance to the study subjects.

- ***Contact Information Statement***- PI must provide the names and contact information (mailing addresses, phone numbers and email addresses) of those individuals participants should contact if they have any questions about the study or about their rights as a research participant. This should take the form of contact info for the primary researcher and faculty sponsor (if applicable) as well as contact info for the IRB. PI should also include numbers for participants to contact if material made them uncomfortable or if the material prompted them to consider personal matters. This information can take the form of a university medical counseling center or community/county crisis/help line. This information should be provided if study deals with issues of a personal or private nature or if participants are exposed to stimuli (i.e. survey questions) that might potentially cause them to question their own behavior.
- ***Affirmation Statement***- PI should conclude with a statement affirming that they have read the form, understand its contents, and agree to participate in the study.
- ***Signature Statement***- PI needs to obtain a signature from the potential participant, primary investigator, and reader/translator if such services were required. If potential participant is younger than 18 years of age you should obtain signature of minor and parent or legally authorized representative; and of primary investigator.

Other information to include if applicable –

-***Unforeseeable Risk Statement*** - PI should state that the study treatment or procedures may have risks for the prospective participant that you cannot currently foresee.
-***Consequences and Process of Withdrawal Statement***- PI should explain how participants can leave the study and what may happen if they choose to withdraw.
-***Impact of Significant New Findings Statement***- PI should state that participants will be told of any significant new findings developed during the research which may relate to their willingness to continue in the study.
-***Number of Participants Statement*** –PI should tell prospective participants the approximate number of *persons involved in the study.*
-***Statement on Video or Audio-Taping Policies and Procedures***- PI should ask for subject's written permission for such taping and should indicate how subject will be identified on the tape (by name, by code number, etc.), who will have access to the tapes, who will listen or view the tapes, how the tapes will be stored, and when the tapes will be erased or destroyed.

Furthermore, the consent form must state that the research study was reviewed by and has received IRB approval from Kean University (Federal Registration #IORG 0003969). Any approved consent/assent forms given to participants must be printed on Kean University departmental letterhead.

Note that according to federal law, signed informed consent forms must be retained for a minimum of five years. The researcher (or research advisor in case of a student) is required to file them in a safe storage place under key.

3.11 Policies and Procedures for Oral Administration of the Consent Information

Federal guidelines dictate that those instances where a written informed consent form is not feasible or applicable, the consent information can be read to potential participants. The informed consent form can be read to the subject or their legally authorized representative, but in any event the investigator must give the subject or their representative adequate opportunity to read it before it is signed.

A short form written consent document stating that the elements of informed consent have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or representative. Only the short form itself is to be signed by the subject or representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or representative, in addition to a copy of the short form.

3.12 DEBRIEFING INFORMATION

Debriefing Form- Especially when subjects participate in the study in person, a debriefing form should be issued to them by the researcher thanking them for their participation, summarizing the procedures in which they had just participated, and reminding them of the risks and/or benefits of the study. When referral services are necessary, the debriefing forms should reiterate their availability and provide the full name and contact information for the researcher (and the faculty research advisor when the researcher is a student). The debriefing statement must contain the following pieces of information.

- A statement thanking participants for their participation. You should fully reveal the purpose of the study to participants. Nothing should be kept from them at this point.
- If there was any deception involved in the study, a statement should be included asking them not to reveal the purpose of the study or any deception involved in the study.
- Any and all detail about their compensation or rewards for participation should be addressed in the debriefing.
- A name, contact phone number and e-mail address should be provided that participants can use if they have any questions about the study. This should take the form of contact information for the both principal investigator and the IRB.
- Participants should also be told that they can have access to the results once analysis is completed.
- Contact information should be provided in case participation has caused them to feel uncomfortable in any way. This is important information to provide if the study deals with questions or issues of a sensitive nature. The contact number should be of a place and number participants can call for counseling. Usually this can take the form of a counseling service or health center.

4 EXTERNAL RESEARCHERS

All external researchers must submit an application to the Kean Institutional Review Board for review and approval before commencing research. External researchers are defined as those researchers who come from institutions other than Kean University. Any external researcher must demonstrate that they have

obtained IRB approval at their host institution or the institution of origin for the research project in question prior to obtaining approval from the Kean IRB.

In order to obtain Kean IRB approval, external researchers musthave a Kean faculty member as a sponsor for their project. Sponsorship consists of the Kean faculty member serving as either the faculty advisor (if the external researcher is a undergraduate or graduate student at another academic institution) or as the co-PI (if the external researcher is a fellow-faculty member or a post-doc).

External researchers must also complete the CITI training on human participant protections and submit proof of completion (the course provides certificate upon completion) with their application.

5 Criteria for IRB Approval for Research

5.1 Principle Investigator

The PI must either be a: (1) Kean faculty or staff member or; (2) Kean adjunct faculty member, currently teaching at Kean or under contract to teach this year. The Primary Contact may be: (1) The Principle Investigator (2) A currently enrolled student with their faculty sponsor listed as PI, if this is a student-led research project. - (A faculty sponsor is defined as a full-time Kean faculty member willing to ensure that the study is conducted in accordance with all Kean University's IRB policies, guidelines, and approvals and federal, state, and local laws that relate to research involving human participants); or, (3) Another full-time Kean employee supporting the PI in research activities.

5.2 Submission requirements

In order to review the research, the Principal Investigator, with human subjects' protection straining, must submit the following to the IRB.

- Complete IRB application (Provide signature and all necessary documents for review to the IRB)
- CITI training certificate
- Informed Consent Form
- Digital Recording Consent Form (If Applicable)
- Debriefing Form
- Site Approval Letter(s) -on letterhead (if Applicable)
- Screening and Recruitment materials (e.g., flyers, posters, internet or newspaper ads)

If Applicable, Provide the Additional Documents:

- IRB Approval letters from other institutions
- Participant testing materials (e.g., questionnaires, surveys, tests)
- Scoring instructions for tests (e.g., questionnaires)
- Scripts (i.e., for interviewers)
- Screening materials m. Recruitment materials (e.g., flyers, posters, internet or newspaper ads)
- Pictures/Images/Diagrams of devices that will be used

5.3 Continuing Review/Renewal of Approved Research

IRB approvals are effective for the duration of one year from the date of the approval. The IRB is required to conduct continuing review of all non-exempt research not less than once a year. Researchers must submit a continuing review application not less than 60 days prior to the end date of their approval to avoid the possibility of a lapse in IRB approval.

Any research study that has not received continuing review and approval by the end of its approval period is automatically considered expired and all research and research-related activities must cease.

If IRB approval for the research study has lapsed less than 30 days and the PI provides the required Continuing Review information, the existing protocol may be reviewed for consideration of continued IRB approval. If IRB approval has lapsed for more than 30 days the study is considered closed and the PI must submit a new application as an initial submission for IRB review and approval.

5.4 Changes/Amendments/Modifications in Protocol and/or Consent Forms and/or Personnel

i) Changes/Amendments/Modifications to Protocol or Consent Form Investigators shall file with the IRB any substantive changes in protocol or consent forms using an amendment/modification submission. Any proposed change(s) cannot go into effect until IRB approval has been obtained. EXCEPTION: A protocol may be changed without prior IRB approval where necessary to eliminate apparent immediate hazards to the subjects. However, the IRB Chairperson must be notified via an Incident Report/Adverse Event form of such a change within 72 hours and review is still eventually required.

ii) Addition or Removal of Personnel; Addition or Removal of research sites Investigators shall file with the IRB any addition or removal of personnel from the approved protocol using the appropriate Amendment/Modification Submission. The policy in its entirety to comply with guidelines from the DHHS-OHRP or other federal agencies. In the event of a policy change, a notice will be posted on the IRB website. The new personnel cannot participate in the research until IRB approval has been obtained. Investigators shall file with the IRB any addition or removal of research sites from the approved protocol using the appropriate Amendment/Modification Submission. Research activities at the new site cannot begin until IRB approval has been obtained.

5.5 Risk Benefit Assessment

Risk/Benefit Assessment The goal of the assessment is to ensure that the risks to research participants posed by participation in the research are justified by the anticipated benefits to the participants or society. Toward that end, the IRB must judge whether the anticipated benefit, either of new knowledge or of improved health for the research participants, justifies asking any person to undertake the risks;

Upon review, IRB can also disapprove research in which the risks are judged unreasonable in relation to the anticipated benefits. The assessment of the risks and benefits of proposed research - one of the major responsibilities of the IRB - involves a series of steps:

(i) Identify the risks associated with the research, as distinguished from other risks, such as the risks of therapies the participants would receive even if not participating in research;
(ii) Determine whether the risks will be minimized to the extent possible;
(iii) Identify the probable benefits to be derived from the research;
(iv) Determine whether the risks are reasonable in relation to the benefits to participants, if any, and assess the importance of the knowledge to be gained;
(v) Ensure that potential participants will be provided with an accurate and fair description of the risks or discomforts and the anticipated benefits; Risks to participants are minimized:

5.6 Selection of participants is equitable

The IRB determines by viewing the application, protocol, and other research project materials that the selection of participants is equitable with respect to gender, age, class, etc. The IRB will not approve a study that does not provide adequately for the equitable selection of participants or has not provided an appropriate scientific and ethical justification for excluding classes of persons who might benefit from the research. In making this determination, the IRB evaluates: the purposes of the research; the setting in which the research occurs; scientific and ethical justification for including vulnerable populations such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons; the scientific and ethical justification for excluding classes of persons who might benefit from the research; and the inclusion/exclusion criteria. At the time of the continuing review the IRB will determine that the PI has followed the selection criteria that s/he originally set forth at the time of the initial IRB review and approval.

5.7 Recruitment of Participants

The investigator will provide the IRB with all recruiting materials to be used in identifying participants including recruitment methods, advertisements, and payment arrangements.

5.8 Privacy and Confidentiality

The IRB will determine whether adequate procedures are in place to protect the privacy of participants and to maintain the confidentiality of the data.

Privacy - having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.
Confidentiality – methods used to ensure that information obtained by researchers about their participants is not improperly divulged. Regulations 46.102(f) Human subject means a living individual about whom an investigator... conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.
Private information - information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).
Identifiable information – information where the identity of the participant is or may readily be ascertained by the investigator or associated with the information.

The IRB must determine whether the activities in the research constitute an invasion of privacy. In order to make that determination, the IRB must obtain information regarding how the investigators are getting access to participants or participants' information and the participants expectations of privacy in the situation. Investigators must have appropriate authorization to access the participants or the participants' information.

Confidentiality and anonymity are not the same. If anyone, including the investigator, can readily ascertain the identity of the participants from the data, then the research is not anonymous and the IRB must determine if appropriate protections are in place to minimize the likelihood that the information will be inappropriately divulged. The level of confidentiality protections should be commensurate with the potential of harm from inappropriate disclosure. At the time of initial review, the IRB ensures that the privacy and confidentiality of research participants is protected. The IRB assesses whether there are adequate provisions to protect participant privacy and maintain confidentiality. The IRB does this through the evaluation of the:

- Methods used to obtain information about participants,
- Methods used to obtain information about individuals who may be recruited to participate in studies
- The use of personally identifiable records and
- The methods to protect the confidentiality of research data. In some cases, the IRB may also require that a Certificate of Confidentiality be obtained to additionally protect research data (See Section 4.16.8). The PI will provide the information regarding the privacy and confidentiality of research participants at the time of initial review through the completion of the research protocol. The IRB will review all information received from the PI and determine whether or not the privacy and confidentiality of research participants is sufficiently protected. In reviewing confidentiality protections, the IRB shall consider the nature, probability, and magnitude of harms that would be likely to result from a disclosure of collected information outside the research. It shall evaluate the effectiveness of proposed de-identification techniques, coding systems, encryption methods, storage facilities, access limitations, and other relevant factors in determining the adequacy of confidentiality protections.

5.9 Vulnerable Populations

At the time of initial review the IRB will consider the scientific and ethical reasons for including vulnerable participants in research. The IRB may determine and require that, when appropriate, additional safeguards are put into place for vulnerable participants, such as those without decision-making capacity.

The IRB carefully evaluates each protocol to determine if vulnerable participants are included in the study population and what measures have been taken to protect them.

The IRB is required to consider the scientific and ethical reasons for including vulnerable populations in research. The IRB must pay special attention to specific elements of the research plan when reviewing research involving vulnerable participants. These specific elements may include strategic issues such as inclusion and exclusion criteria for selecting and recruiting participants, informed consent and willingness to volunteer, coercion and undue influence and confidentiality of data.

The IRB carefully considers group characteristics, such as economic, social, physical, and environmental conditions, to ensure that the research incorporates additional safeguards for vulnerable participants. For

example, it is not appropriate to focus on prisoners as research participants merely because they are a readily available "captive" population.

IRB may require additional safeguards to protect potentially vulnerable populations. For instance, the IRB may require that the investigator submit each signed informed consent form to the IRB. The IRB may also require that someone from the IRB oversee the consent process or that a waiting period be established between initial contact and enrollment to allow time for family discussion and questions.

Kean University Policy Governing Research Involving Children

The legal age of adulthood in New Jersey is 18. Federal regulations and Kean University policy require these protections for children and adolescents involved as subjects of research. Note that the IRB may require additional protections on a case-by-case basis.

- No research involving children is eligible for exempt review.
- No research involving children is eligible for expedited review.
- All research studies involving children must be submitted for full review.
- The IRB will only approve research involving not greater than minimal risk to children that also satisfies all the conditions of additional protections for children.
- Parents or guardians must give their permission (consent) for their children to participate in research.
- Protocols for research involving children that use a passive parental consent procedure will not be approved.
- Parental consent forms must not be unduly long, must be written in terms understandable to the general population, and must include all appropriate details about the research that are most relevant to the parent's decision to allow a child to participate in the study.
- Children must give their agreement (assent) to participate in research.
- When reviewing whether adequate provisions have been made for soliciting assent, the IRB will review the procedures and assent form taking into account the age, maturity and psychological state of the children involved

5.10 Advertisements

The IRB must approve all advertisements prior to posting and/or distribution for studies that are conducted under the Kean University IRB. The IRB will review:

- Information contained in the advertisement
- Mode of communication
- Final copy of printed advertisements, when necessary
- Final audio/video taped advertisements, when necessary this information should be submitted to the IRB with the initial application or as an amendment to the protocol.

The IRB reviews the material to assure that the material is accurate and is not coercive or unduly optimistic, creating undue influence to participate which includes but is not limited to:

- Statements implying a certainty of favorable outcome or other benefits beyond what was outlined in the consent document and the protocol
- Emphasis on payment or the amount to be paid, such as bold type or larger font on printed media
- Inclusion of exculpatory language

- Claims, either explicitly or implicitly, that the drug, biologic or device was safe or effective for the purposes under investigation and/or that the test article was known to be equivalent or superior to any other drug, biologic or device

5.11 Compensation

It is the policy of the Kean University Institutional Review Board (IRB) that payments to individual participants, in the form of cash, gift cards, or merchandise, are not allowed. Participants may be entered into a lottery with other participants for the opportunity to win a single gift card, but directly rewarding participants for taking part in a research study will not be approved.

There are several reasons for this. The most pertinent is the issue of coercion. Giving money or a gift card of any value may create a situation where research participants feel influenced to participate when they really do not want to. Research participants should never feel obligation to take part in a research study.

5.12 Waiver of Consent

There is no "Waiver of Consent Form" per se. In the Consent Process section of the protocol, the PI must describe how all of the regulatory criteria are met to qualify for a waiver of informed consent. A request to waive written and verbal informed consent, or any of the required elements of informed consent must be accompanied by a complete explanation in response to the four statements below:

1. The proposed research presents no more than minimal risk of harm to subjects.

2. The waiver or alteration of consent will not adversely affect the rights and welfare of the subjects.

3. The research could not practicably be carried out without the waiver or alteration.

4. Whenever appropriate, the subjects will be provided with additional pertinent information.

Once the PI submits all the information, IRB will decide if the research qualifies for Waiver of Consent.

5.13 International Research (US and Non US Institutions)

For any research to which the Kean University FWA applies, the Institution also will comply with any additional applicable human subjects regulations and policies of the U.S. federal department or agency which conducts or supports the research and any other applicable federal, state, local, or institutional laws, regulations, and policies. When the Institution is engaged in non-exempt human subjects research conducted or supported by HHS, the Institution will comply with the requirements of subparts B, C, D, and E of the HHS regulations at Title 45 Code of Federal Regulations part 46, when applicable, for research involving pregnant women, fetuses, and neonates; prisoners; and children, respectively.

All human subjects' research conducted by Kean University faculty, staff, or students, regardless of funding source or the ***location*** at which the research will be conducted, requires submission to Kean USA IRB. When research is conducted outside the United States, investigators must comply both with the U.S. regulations and with the local policies and regulations governing the international research sites. It is important to investigate early and, if possible, enlist a local collaborator to help address that site's

requirements and assist in identifying who to contact and what is required to obtain ethics reviews and permissions to conduct research at that international site.

Investigators are **strongly** encouraged to collaborate with an individual or organization with expertise in the region. This collaboration will greatly assist in identifying appropriate research sites, navigating the local regulations and policies, understanding culture, local infrastructure, overcoming language barriers & increasing community partnership. Based upon study location and risk level, the IRB may **require** a local site collaborator.

5.14 Recruitment of Non-English speaking participants

When enrolling non-English speaking research subjects, investigators must have a plan to manage communications with participants during ***all phases*** of study participation. Given that participants may have questions or concerns at any time, Investigators must be prepared to manage communication beyond the consent process and data collection.

5.15 Data Retention

Data Retention: All research data must be maintained by the investigator for at least five years after the project is closed out or the results published, whichever occurs last. The investigator may be required to keep the data for a longer time if mandated by the funding agency, publishers, or changes in Kean IRB policy. Examples of research data include (but are not limited to) completed surveys, electronic data files, notebooks, printouts, photographs, slides, negatives, films, scans, images, videotapes, audiotapes, flash memory and electrophysiological recordings. Other documents that you are required to keep are IRB consent documents and documentation of assent. Unless described in the approved protocol, research data may only be altered or destroyed before this period with written permission from the Kean IRB.

5.16 Responsibility to Report Misconduct

All employees or individuals associated with Kean University should report observed, suspected, or apparent research misconduct to the Research Integrity Officer. *See "Research Integrity Policy: Procedures for Responding to Allegations of Research Misconduct"*

APPENDIX

1.4 Definitions

Research- Any systematic investigation designed to develop or contribute to generalizable knowledge. Some student projects meet the regulatory definition of research and some do not. According to federal regulations, research is defined as a systematic investigation designed to develop or contribute to general knowledge, including research development, hypothesis testing and evaluation. For an activity to fit the definition of research, it is not the credentials of the person conducting the investigation, but rather whether the investigation (goals and procedures) reaches a level of sophistication such that it holds reasonable the prospect of producing findings that are new, or that develop or contribute to previously existing general knowledge, and will be published or presented as new knowledge. For example, will the findings from the project be used in a thesis, dissertation, and/or marketing; will the findings be presented at conferences; published in journals, newspapers, or websites; or made available in public libraries, department files, etc.? If so, then the project is research and needs approval from the IRB.

Researcher – Student, member of the faculty or staff, or associate who is leading or engaged in the research.

Human participant- A human participant is a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or through identifiable private information (45 CFR 46.102(f)). The definition provided in the Common Rule includes investigators, technicians, and others assisting investigators, when they serve in a "participant" role by being observed, manipulated, or sampled. As required by 45 CFR 46.102(f) an intervention includes all physical procedures by which data are gathered and all physical, psychological, or environmental manipulations that are performed for research purposes. For research covered by FDA regulations (21 CFR 50 and 56), human participant means an individual who is or becomes a participant in a clinical investigation (as defined below), either as a recipient of the test article or as a control. A participant may be in normal health or may have a medical condition or disease. In the case of a medical device, a human subject/participant also means any individual on whose tissue specimen an investigational device is used or tested. Note: The terms "subject" and "participant" are used interchangeably in this document and have the same definition.

Confidential Information – Information pertinent to the individual or groups of individuals including personal data, or information about attitude, perspective or behavior that is not expected or anticipated to be made public and which the individual has the right and choice to withhold from the public.

Risk – Exposure to harm, be it physical, mental, emotional or psychological. Risk is considered minimal if the exposure does not surpass in probability, scope and intensity that experienced in daily, routine activities. Consent Form – A document designed to give the researcher knowledge that the subject is participating in the research willingly, knowingly and without coercion or influence. The form should describe the research to be undertaken by the researcher and listing and describing in detail the level and scope of anticipated risk involved and how the research plans to protect the confidentiality of the subject. The form, which also contains contact information about the researcher and institution, needs to be signed by the subject before the research can be initiated (but after IRB approval is issued).

Consent Form - An **informed consent document** is used to provide subjects with the information they need to make a decision to volunteer for a research study. This information is most often presented subjects in the form of a written document, but may also be offered verbally by a member of the study team or in some other format understandable to the subject. Regulations and policy require that certain information be provided as part of the consent process.

Assent Form - Agreement to participate by such individuals who cannot otherwise provide "consent" is called "assent." The form that documents this agreement is called an "assent form". Like consent, assent is supposed to be "informed" -- that is, subjects should know what they are getting into, and what effects their participation is likely to have.

Debriefing Form – A document explaining to the prospective human subjects the value and type of research conducted, the level of anticipated risk that it may cause, how subjects' confidentiality is to be protected. The form has to list contact information for the researcher and institution of which the research is a member and must be signed by the researcher. The debriefing form must be shared with the subjects since the interaction with the subjects is completed (but after IRB approval is issued)

Institutional Review Board (IRB) - An IRB is s a body of peer researchers and observers charged with reviewing research involving human subjects to protect the rights and welfare of the people who participate in the research. The role of the IRB is to assure compliance with the Code of Federal Regulations, Title 45 (Public Welfare), Part 46 (Protection of Human Subjects). ***Institutional Official***- The President of Kean University has designated the Provost and Vice President of Academic Affairs as the Institutional Official for carrying out the University's human research protections program. The IO is the Kean University official responsible for ensuring that the HRPP has the resources and support necessary to comply with all federal regulations and guidelines that govern human research. The IO is legally authorized to represent the institution, is the signatory official for all Assurances, and assumes the obligations of the institution's Assurance. The IO is the point of contact for correspondence addressing human research with OHRP, FDA, and other federal regulatory agencies.

Research under the auspices of the University- Research under the auspices of the institution is research conducted by or under the direction of any employee or agent of this institution (including students) in connection with his or her institutional responsibilities.

Protocol- The research protocol includes the complete packet of materials submitted to the IRB for review, including a description of the research design and methodology as well as a complete description of the procedures for the protection of human participants in the research.