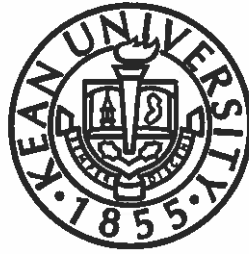


# **POLICY GOVERNING RESEARCH WITH HUMAN SUBJECTS**



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**UNIVERSITY**  
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A handwritten signature in blue ink, likely belonging to the Institutional Signatory Official mentioned in the text.

## Table of Contents

<b>Principles Governing Research with Human Subjects .....</b>	<b>2</b>
<b>Resources .....</b>	<b>4</b>
<b>Common Definitions .....</b>	<b>5</b>
<b>IRB Guidelines .....</b>	<b>7</b>
<b>IRB Exemptions .....</b>	<b>10</b>
<b>IRB Expedited Review .....</b>	<b>15</b>
<b>IRB Processes.....</b>	<b>21</b>
<b>Informed Consent Process.....</b>	<b>23</b>
<b>Debriefing Information .....</b>	<b>27</b>
<b>Submission .....</b>	<b>28</b>
<b>Applicant Duties and Responsibilities.....</b>	<b>29</b>
<b>Appendices.....</b>	<b>30</b>

# **POLICY GOVERNING RESEARCH WITH HUMAN SUBJECTS**

**Kean University**

**REVISED – October 15, 2015**

## **PRINCIPLES GOVERNING RESEARCH WITH HUMAN SUBJECTS**

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 regulations and guidelines. Such practices include research involving human subjects.

In all research projects involving human subjects, Kean University researchers from among the faculty, students or staff will follow ethical standards established by the Belmont Report.

Institutional approval for conducting research with human subjects, whether by a student, a member of the faculty or staff, must be received before embarking on the research. The Institutional Review Board, an appointed group of researchers from across the disciplines will review the research applications according to federal regulations for the protection of human subjects. This Kean University 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.

There are listed exemptions and procedures are in place for expedited review.

***Rights of Subjects.*** Human subjects invited to participate in the research should do so voluntarily and fully informed. Parents will give their consent when their children are involved, and children five years or older will give their assent to participate. The risk and level of risk that the study may cause the subjects should be fully disclosed and they should expect to learn about strategies adopted by the researchers to minimize the risks. The privacy of the subjects' privacy will not be infringed upon and should be protected, as they will be informed of ways in which the researchers will assure their confidentiality. Furthermore, the reason for the research, how the subjects will be engaged in the study and its potential benefits should be fully disclosed and shared with the subjects before the research proceeds.

***Ethical Obligations of Researchers.*** In planning and executing their study, Kean University researchers have the following ethical obligations:

- To inform subjects of all features of the research that may have an effect on their willingness to participate in a research project.

- To respect the freedom of subjects to decline participation or to withdraw from participation in research at any time.
- To honor all commitments and responsibilities that they make to subjects in the research project.
- To protect subjects from physical or mental discomfort, distress, harm or danger. If there is anticipated risk to the subjects, even when considered minimum, their written informed consent must be obtained.
- To protect the confidentiality of subjects to the extent possible and practical. Researchers at Kean University will not disclose personally identifiable information that has been collected during the conduct of research projects.
- To ensure that their research is methodologically sound and capable of answering the questions it is intended to answer and to deal honestly with data collected as part of the research project.
- To inform members of a control group, when applicable, of the results of the study and any benefits they may reap from it.
- If concealment or deception is necessary as part of the administration of a research project, to inform subjects, at the conclusion of the research project, that they have been deceived. Researchers must also explain why concealment and/or deception was necessary to ensure the validity of the research project.

The IRB review process and procedures are devised to support these principles.

## RESOURCES

There are two key documents that deal with the protection of human subjects:

a- The Belmont Report, Ethical Principles and Guidelines for the Protection of Human Subjects, presents the philosophical underpinnings for current federal laws pertinent to research involving human subjects

(<http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>).

b- Code of Federal Regulations, Title 45 (Public Welfare), Part 46 (Protection of Human Subjects), or 45 CFR Part 46, lists and describes the regulations. This is referred to as the Common Rule, adopted in 1991 by seventeen Federal Departments and Agencies.

The above code represents the U.S. Department of Health and Human Services' policy (DHHS) regarding the protection of human subjects in research

(<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>).

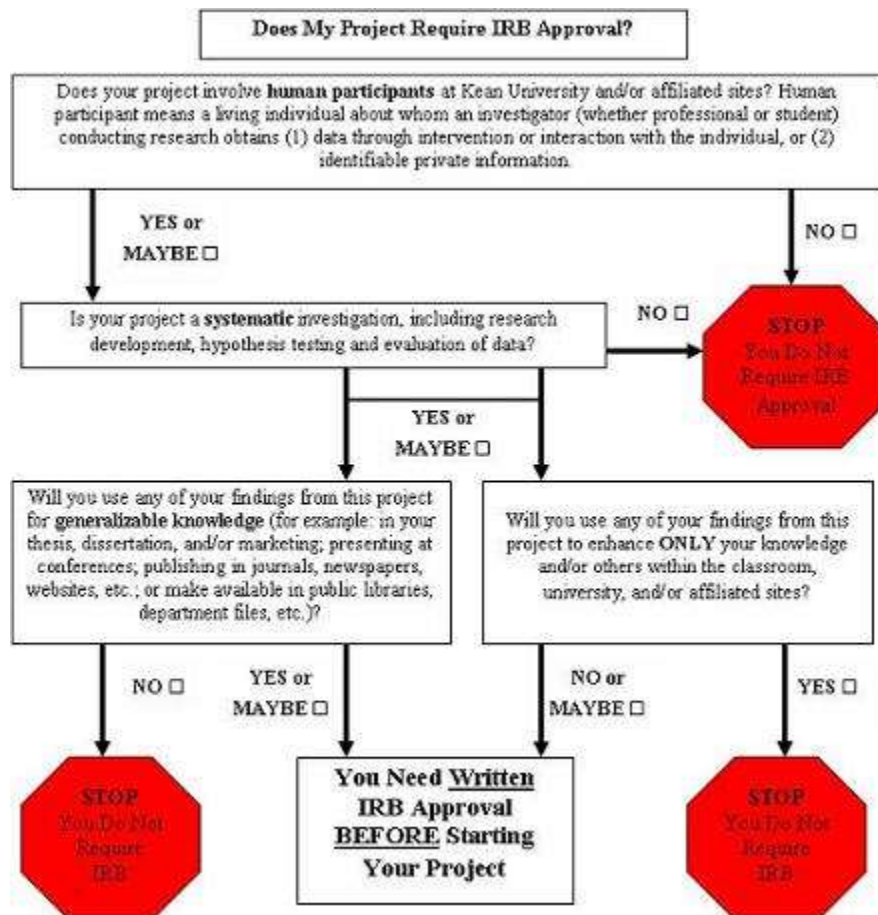
Note that the Federal Policy is codified at different departments and agencies, including the Food and Drug Administration, the National Science Foundation, the Department of Education, the Environmental Protection Agency. Their policies appear under different titles of the Code and referred to through the DHHS' Website.

## COMMON DEFINITIONS

According to the above documents, the following common definitions are of significance:

**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. Please consult the chart below if you have questions about whether or not your project requires IRB approval



In many cases, the educational experiences of student projects mimic actual research activities without reaching the regulatory definition of research. Thus, it is the nature of the activity that determines whether it constitutes research involving human subjects, not the credentials of the person. The important question is “Is the activity a systematic investigation designed to develop or contribute to general knowledge through publication or presented as new knowledge?”

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

**Human Subjects** – Living individuals about whom an investigator obtains data or identifiable private information through interaction or intervention.

**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).

**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).

## **IRB GUIDELINES**

The review of research with human subjects is conducted by the Institutional Review Board (IRB), a body of peer researchers and observers from across the university representing diverse academic disciplines, including psychology, nursing, counseling education, biology, early childhood education, occupational therapy, and social work, among other areas.

The Institutional Signatory Official (IO) appoints the IRB chairs and members, which includes a member external to Kean University, convenes it and registers its membership with the federal Office for Human Research Protections.

In line with federal guidelines, the IRB is a body of peer researchers and observers charged with reviewing any research involving living individuals to evaluate several factors:

- Criterion a. level of anticipated risks to subjects that may result from the project, physical, psychological, sociological, etc., and the extent to which benefits outweigh the risks;
- Criterion b. ways to reduce or prevent these risks and the extent to which the welfare of the subjects is adequately protected;
- Criterion c. assurances that the privacy and rights of participation subjects are fully protected;
- Criterion d. assurances that informed consent is obtained by the subject in an adequate and appropriate manner; and
- Criterion e. adequacy of protocols used and their relevance to desired outcomes.

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:

- Studies that may be exempt from IRB review. (See list of the exempt categories, XM 1-6). For those, an exempt application must be sent to IRB describing the research and stating why it is exempt.
- Studies that could be reviewed through the expedited IRB review process. (See list of the expedited categories, EXP 1-9.) For these, a full application will be submitted to be reviewed by an assigned member of IRB and reported to IRB. If concerns are raised during these reviews about the viability of an application, it will be transferred to the full convened IRB.



- Studies that must be reviewed by a convened IRB.

**Responsibilities.** 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. The researcher bears full responsibility for the way the research is conducted, for following closely the methods and approaches described in the IRB application, and for following the IRB-established procedures. If the researcher is a student, he/she and his/her faculty research advisor bears the responsibility for conducting the research as stated, for minimizing the risks to the participating human subjects, for maintaining confidentiality and for protecting the institutional integrity in the process.

All researchers are urged to act on the side of caution when embarking upon research. This is especially important today considering “potentially invasive” advances in molecular/cellular and psycho-analytical research. Even for “seemingly non-invasive” psychological clinical and therapeutic projects or surveys that on the surface appear to be harmless, IRB review is imperative.

**IRB Deliberations.** The Institutional Review Board convenes monthly as needed to review applications.

**Notification.** Upon IRB review, applicants will receive formal notification from the IRB stating whether approval was granted and what conditions if any attached. When provisions are issued, researchers must address them, resubmit and await approval before proceeding. Resubmitted applications that have been provisionally-approved are reviewed by the IRB Chair. All IRB approvals are valid for a period of one year from the date of notification. Any planned changes in the process of the one-year study or extension beyond the one year may necessitate new IRB approvals (see section on exemptions and expedited reviews).

**Appeal.** In case an applicant disagrees with the decision, a formal letter of appeal addressed to the IRB Chair must be submitted to the IRB, which the full body reviews and decides to reconsider. IRB may opt to reconsider, invite the applicant to present his/her case to the full body at its next meeting (or a specially scheduled meeting), or maintain its original decision. The applicant may opt after this step to appeal to the Institutional Signatory Official, who can form a separate ad-hoc group to review the case for a binding decision.

**Online Tutorial.** All applicants (faculty and students) must complete the tutorial offered as an educational service by the National Institutes of Health (NIH) prior to applying for IRB approval. Upon completion of the tutorial, certificates are available online. This certificate must be attached to their paper application. Instructors of research methods

classes or supervisors of senior these during which experiences research may be conducted that involves human subjects are urged to require their students to complete the tutorial early on in the semester to be certified in preparation for IRB submission.

- URL for training site: <http://phrp.nihtraining.com/users/login.php>

## ***IRB EXEMPTIONS***

*The policy and provisions are closely based on DHHS regulations (45 CFR 46.101-b).*

The following research categories are exempt from full IRB review. Researchers must file an application requesting that the IRB determine exempt status for a project.

IRB review policy requires that, at least two weeks before the research is to be conducted, the researcher must submit an Exempt Application form including the reason (XM) for the exemption and a brief description of the nature of the research.

If there are issues with the research being exempt, IRB will notify the researcher and request a full IRB application.

Researchers are expected to abide by informed consent requirements as adequate for ethical treatment and protection of participating human subjects. In all cases, the documents shared with the human subjects must state that the research is certified exempt from IRB review and the exemption must be listed. Do not include a statement that the Kean University IRB has reviewed and approved the study.

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

### **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 educational practices.

- 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

**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) 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 powder, creatine, and glucosamine chondroitin sulfate should not qualify for exempt status.

## ***IRB 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:

1. 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
  2. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.
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 the IRB Chair or members of the IRB as assigned by the Chair. Expedited reviewers will either “approve” or “approve with provisions”. If the review decision would be to deny, the application will be reviewed by the IRB committee at the next monthly meeting. 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:**

1. Research on drugs for which an investigational new drug application is not required.

or

2. Research on medical devices for which an investigational medical device exemption application is not required, or the medical device 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.

or

- (b) 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 gumbase or wax by applying a dilute citric solution to the tongue
- (f) Placenta removal at delivery
- (g) Amniotic fluid obtained at time of rupture of the membrane before or during labor
- (h) Supragingival and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques
- (i) Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings
- (j) 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) 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 or 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.**

## **IRB PROCESSES**

### **- REVIEW BY CONVENED 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 both electronically and in print with appropriate signatures.

### **- 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 identity 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 or a legally

authorized representative must be informed and sign the consent form permitting the child to participate in the study.

### **- IRB APPLICATION PROCESS**

The IRB Application (see Appendix) must be comprehensive 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.

## 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, you have to describe the duration of the study (how long it will take subjects to participate). You have to describe the 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.** You 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.** You 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 you are using “control groups” as part of your research design, make it clear that the subjects will be entitled to the results.
  - **Compensation/Treatment Statement.** When there is greater than minimal risk involved in your study, you must inform prospective participants whether they will receive any compensation and/or medical treatments if injury should occur. If there is compensation or treatment, it must be described in detail and subjects must be told where they should obtain further information. If there is compensation, will the compensation be in the form of educational benefits (e.g. extra credit points in a class)? If so what is the value to the participant? If there is no compensation, researchers should state stating that no payment or cost will be associated with participation.
  - **Confidentiality Statement.** You 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.** You must explicitly state that participation is voluntary, that refusal to participate involves no penalty or loss of benefits to which the person is otherwise entitled, 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, loss of income or any other relevant issues that would be of importance to the study subjects.
  - **Contact Information Statement.** You 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.
    - You 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.** You should conclude with a statement affirming that they have read the form, understand its contents, and agree to participate in the study.
- **Signature Statement.** You need 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.** You should state that the study treatment or procedures may have risks for the prospective participant that you cannot currently foresee.
- **Termination of Participation Without Consent Statement.** You should explain anticipated circumstances under which the investigator may terminate the participant's further involvement without regard to the person's consent.
- **Additional Cost Statement.** You should describe any additional costs to prospective participants that may result from participation in the study.
- **Consequences and Process of Withdrawal Statement.** You should explain how participants can leave the study and what may happen if they choose to withdraw.
- **Impact of Significant New Findings Statement.** You 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.** You should tell prospective participants the approximate number of persons involved in the study.
- **Statement on Video or Audio-Taping Policies and Procedures.** You 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.

Below is a checklist which allows you to cover all of the required elements of an informed consent document.

- Describe the purpose and scope of the study
- What are the planned procedures
- Risk Statement
- Benefit Statement
- Compensation/Treatment Statement
- Confidentiality Statement
- Voluntary Participation, Refusal, and Withdrawal Statement
- Contact Information Statement
- Affirmation Statement

- Signature Statement (Signature Lines, Approval Boxes, Witness Signature Lines, and Designations)

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.

### **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.

## 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.

## **SUBMISSION**

### **Documents to include**

*Survey or Measurement Instrument.* The instrument, the survey protocol and/or the interview or measurement protocol must be submitted with the application, along with a detailed description of its validity and reliability. A survey that is not well thought out may not lead to desired outcomes and will not meet Criterion c (p4).

*Host Institution IRB Approval or Permission.* If the researcher is a non-Kean student or employee, proof of IRB approval from his/her institution must accompany the Kean IRB application.

*Permission to use copy written material.* Permission to use any materials (e.g. scales/measures) or stimulus materials not created by the researcher is required of all applicants. This can take the form of a permission letter or email from the original authors or copyright holders.

Please remember that an electronic copy of your application must be submitted through the online system found at: <http://irb.kean.edu> IN ADDITION TO a signed hard copy to "IRB," Townsend 130. Non-submittal of an electronic copy may result with a delay in the review process.

### **EXTERNAL RESEARCHERS**

All external researchers will have to submit an application to the Kean Institutional Review Board. 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 must get a Kean faculty member to sponsor their project. Sponsorship in this instance will consist of the Kean faculty member serving as either the faculty sponsor (if the external researcher is an 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 NIH sponsored tutorial on human participant protections and submit proof of completion (the course provides certificate upon completion) with their application.

## **APPLICANT DUTIES AND RESPONSIBILITIES**

Below is a checklist of duties and responsibilities that must be completed by the applicant.

1. Correctly complete IRB application (Provide any and all necessary documents for review to the IRB)
2. Complete online tutorial offered by the National Institutes of Health (<http://phrp.nihtraining.com/users/login.php>) and obtain a Certificate of Tutorial Completion.
3. Design and conduct ethical research
4. Obtain IRB approval prior to initiation of research
5. Comply with IRB requirements and federal regulations
6. Implement research as approved and obtain prior approval for modifications
7. Obtain informed consent from research participants and other required parties
8. Document informed consent by providing subject with a copy and keeping copy for your own records.
9. Report adverse events and any non compliance immediately to IRB
10. Retain records for five (5) years under lock and key

## **APPENDICES**

- A. Exempt Review Application Form
- B. Expedited Review Application Form
- C. Full Review Application Form
- D. Model Consent Form
- E. Model Debriefing Form
- F. Sample Approval Letter
- G. Sample Approval Letter with Provisions
- H. Sample Rejection Letter

## Appendix A: Exempt Review Application Form





**KEAN UNIVERSITY  
INSTITUTIONAL REVIEW BOARD**

APPLICATION FORM TO REQUEST **EXEMPT** REVIEW OF A RESEARCH PROTOCOL  
INVOLVING HUMAN SUBJECTS

**FOR IRB USE ONLY:**

IRB #: \_\_\_\_\_

Received: \_\_\_\_\_ Reviewed: \_\_\_\_\_

\_\_\_\_\_ Approved; \_\_\_\_\_ Approved with Provisions; \_\_\_\_\_ Denied.

**This form should be prepared by the Principal Investigator (P.I.) and attached to a description of the research, referring to the reason (XM) for the exemption**

IRB REVIEW TYPE REQUESTED \_\_\_\_\_ Exempt review – specify category(s): \_\_\_\_\_  
**(XM1-XM6)**

**PROJECT TITLE:**

*Anticipated Start Date:*

*Project End Date:*

**PRINCIPAL INVESTIGATOR**

**Name:**

**Department:** (DO NOT ABBREVIATE):

**E-mail:**

**Home phone:**

**Home mailing address:**

**Position or Title:** .\_\_\_\_ Faculty; \_\_\_\_ Graduate Student; \_\_\_\_ Undergraduate Student; \_\_\_\_ Staff.

**Date of successful completion of the Human Subjects Certification Program:** \_\_\_\_\_

I will not begin this study until receipt of a Notice of Approval, or Exemption, from the IRB. Once approved or exempted, I will conduct this study according to the recommendations of the Kean University Institutional Review Board. I will report any serious adverse events or emergent problems to the IRB, will obtain IRB approval before implementing modifications of protocol, and will request continuing review/approval required beyond the study end date.

\_\_\_\_\_  
(Signature of PI)

Date: \_\_\_\_\_

**CO-PI(s)**

**Name:**

**Department:** (DO NOT ABBREVIATE):

**E-mail:**

**Home phone:**

**Home mailing address:**

**Position or Title:** . \_\_\_ Faculty; \_\_\_ Graduate Student; \_\_\_ Undergraduate Student; \_\_\_ Staff.

**Date of successful completion of the Human Subjects Certification Program:** \_\_\_\_\_

**FACULTY SPONSOR INFORMATION** (if PI is a student)

**Name:**

**Department:** (DO NOT ABBREVIATE):

**E-mail:**

**Office phone:**

**Campus mailing address:**

Indicate the date that the **Faculty Advisor** successfully completed the Human Subjects Certification Program:

Date: \_\_\_\_\_

As faculty advisor/course instructor for the above named student, I have read/reviewed this application for quality, completeness, and accuracy. I certify that I am familiar with Kean University policies and federal regulations regarding the protection of human subjects in research. This study meets the guidelines and requirements of the IRB and has my endorsement.

\_\_\_\_\_  
(Signature)

Date: \_\_\_\_\_

**REQUESTS RECEIVED WITHOUT THE APPROPRIATE SIGNATURE(S) WILL NOT RECEIVE REVIEW.**

**Is this project for a class? Yes/No**

**If yes, please enter:**

Course ID: \_\_\_\_\_

Course Name: \_\_\_\_\_

## PROTOCOL DESCRIPTION

1. State the nature of the research and the reason (XM1-XM6) for the exemption. If you are applying for the exemption status, please include copies of your questionnaire or survey instrument as well as copies of the consent form and debriefing statement.
  
2. Are you using any scales or instruments you did not create yourself? If so, you must demonstrate that you have permission to use the scale. List the names of these scales and provide a copy of the permission to use the instrument. If it is in the public domain, please indicate below. If you purchased the scale, provide proof of purchase.

***NOTE: Please complete this form and send it, along with all the necessary electronic documents (such as consent form, debriefing form, surveys, questionnaires), as a Word or PDF attachment to [irb@kean.edu](mailto:irb@kean.edu) with the subject heading "IRB." Also send an original signed set to: "Attention: IRB," Office of Research and Sponsored Programs, T130.***

## Appendix B: Expedited Review Application Form



**KEAN UNIVERSITY  
INSTITUTIONAL REVIEW BOARD**

APPLICATION FORM TO REQUEST **EXPEDITED** REVIEW OF A RESEARCH PROTOCOL  
INVOLVING HUMAN SUBJECTS

**FOR IRB USE ONLY:**

IRB #: \_\_\_\_\_

Received: \_\_\_\_\_ Reviewed: \_\_\_\_\_

\_\_\_\_\_ Approved; \_\_\_\_\_ Approved with Provisions; \_\_\_\_\_ Denied.

**This form should be prepared by the Principal Investigator (P.I.) and attached to any project proposal involving human experimental subjects, including all grant applications and Released Time for Research and UFRI applications.**

All applicants **must** submit the following items to Townsend 130 by the deadline date:

- A signed hard copy of the application
- NIH certificate
- Consent Form
- Debriefing Form
- Any additional information that cannot be scanned and attached to web application

*Full details must be given and all necessary documentation submitted. Handwritten and/or incomplete forms will be returned to the investigator(s) without review.*

**IRB REVIEW TYPE REQUESTED** \_\_\_\_\_ **Expedited review - specify category(s):** \_\_\_\_\_  
**(EXP1-EXP9)**

*Please refer to the categories of IRB review in the policy guidelines for an explanation of the categories.*

**IF PROJECT WAS INITIALLY DENIED APPROVAL AND THIS IS A RESUBMISSION,  
PLEASE CHECK HERE** \_\_\_\_\_

**PROJECT TITLE:**

*Anticipated Start Date:*

*Project End Date:*

**PRINCIPAL INVESTIGATOR**

**Name:**

**Department: (DO NOT ABBREVIATE):**

**E-mail:**

**Home phone:**

**Home mailing address:**

**Position or Title:** . \_\_\_ Faculty; \_\_\_ Graduate Student; \_\_\_ Undergraduate Student; \_\_\_ Staff.

**Date of successful completion of the Human Subjects Certification Program:** \_\_\_\_\_

I will not begin this study until receipt of a Notice of Approval, or Exemption, from the IRB. Once approved or exempted, I will conduct this study according to the recommendations of the Kean University Institutional Review Board. I will report any serious adverse events or emergent problems to the IRB, will obtain IRB approval before implementing modifications of protocol, and will request continuing review/approval required beyond the study end date.

\_\_\_\_\_  
(Signature of PI)

Date: \_\_\_\_\_

**CO-PI(s)**

**Name:**

**Department:** (DO NOT ABBREVIATE):

**E-mail:**

**Home phone:**

**Home mailing address:**

**Position or Title:** . \_\_\_ Faculty; \_\_\_ Graduate Student; \_\_\_ Undergraduate Student; \_\_\_ Staff.

**Date of successful completion of the Human Subjects Certification Program:** \_\_\_\_\_

**FACULTY SPONSOR INFORMATION** (if applicable)

**Name:**

**Department:** (DO NOT ABBREVIATE):

**E-mail:**

**Office phone:**

**Campus mailing address:**

Indicate the date that the **Faculty Advisor** successfully completed the Human Subjects Certification Program:

Date: \_\_\_\_\_

As faculty advisor/course instructor for the above named student, I have read/reviewed this application for quality, completeness, and accuracy. I certify that I am familiar with Kean University policies and federal regulations regarding the protection of human subjects in research. This study meets the guidelines and requirements of the IRB and has my endorsement.

\_\_\_\_\_  
(Signature)

Date: \_\_\_\_\_

**REQUESTS RECEIVED WITHOUT THE APPROPRIATE SIGNATURE(S) WILL NOT RECEIVE REVIEW.**

**For students to complete**

1. Is this research/student project required to fulfill the requirements of a course?

\_\_\_ Yes

\_\_\_ No

2. If yes, please name the course ID and title \_\_\_\_\_

3. Will this research/student project be published?

\_\_\_ Yes

\_\_\_ No

**A. PROTOCOL DESCRIPTION**

1. Briefly describe the context and goals of your research project. What you hope to accomplish and why? What is the background of this project?
2. Describe the involvement of the human subjects in this project. What will they be doing? Who are the subjects? How many subjects will be involved in the project?
3. Specify how subjects will be recruited (e.g. advertisements, announcements in class, e-mail, internet, etc.).
4. Indicate the duration of anticipated research as applicable (the length of each session and the number of sessions).
5. Describe where the research will be conducted. (NOTE: *If the research is to be conducted in another institution (e.g. a school, hospital, agency, place of business, etc.) a signed copy of the IRB approval or a permission letter from that institution must be attached*).
6. State in detail your plans for obtaining each subject's informed consent to participate in this project (attach copies of any "informed consent" forms or

agreements). Describe how this information will be conveyed to subjects. BE SPECIFIC! (NOTE: *At least 2 copies of the forms should be handed out to participants, with one for them to sign, date and hand back and one for them to keep for their records.*)

7. What expected benefits will accrue to each human subject to humankind in general, as a result of this project? List out all possible or expected benefits.
8. One of the key elements of an expedited project is that there are minimal risks to the participants. Please demonstrate below how there are minimal risks to participants for taking part in your study.
9. In the utilization of the results of your project, are humans protected from possible risks, such as embarrassment or invasion of privacy? Describe in detail how confidentiality will be maintained.
10. Specify how you will keep your data secure, and maintain confidentiality during the research. Be specific and describe how data will be stored throughout the duration of the project and upon its completion.  
PLEASE NOTE THAT ALL CONSENT FORMS AND DATA MUST BE KEPT UNDER LOCK AND KEY FOR 5 YEARS.
11. Describe how you will ultimately dispose of your data after you have completed your research (e.g. shredding, burning). PLEASE NOTE THAT ALL RESEARCH RECORDS MUST BE MAINTAINED FOR AT LEAST FIVE YEARS AFTER THE COMPLETION OF THE RESEARCH.
12. Are you using any scales or instruments you did not create yourself? If so, you must demonstrate that you have permission to use the scale. List out the names of these scales and provide a copy of the permission to use the instrument. If it is in the public domain, please indicate below. If you purchased the scale, provide proof of purchase.

**B. SUPPORTING DOCUMENTS – The following 3 types of documents must be included. If they are not included, you will not receive IRB approval.**

1. **CONSENT FORM** (Please copy and paste your consent form below). Please see informed consent instruction sheet for details on what to include.



2. **DEBRIEFING FORM** (Please copy and paste your debriefing form below). Please see debriefing instruction sheet for details on what to include.

3. **Human Subjects (NIH) Certificate**

**ADDITIONAL DOCUMENTS** (Please insert additional documents, such as surveys/questionnaires below, if applicable)

**INVESTIGATOR CHECKLIST** (This checklist is to be completed as applicable, by the PI and submitted with the IRB application)

- Consent Form(s)
- Debriefing Form
- Questionnaire(s), Survey(s), Interview Questions
- Authorization to Use Data
- IRB Approval Notice from Participating Institutions
- Certification of completion of the online tutorial

***NOTE: Please complete this form and send it, along with all the necessary electronic documents (such as consent form, debriefing form, surveys, questionnaires), as a Word or PDF attachment to [irb@kean.edu](mailto:irb@kean.edu) with the subject heading "IRB." Also send an original signed set to: "IRB," the Office of Research and Sponsored Programs, T130.***

## Appendix C: Full Review Application Form



**KEAN UNIVERSITY  
INSTITUTIONAL REVIEW BOARD**

APPLICATION FORM TO REQUEST REVIEW OF A RESEARCH PROTOCOL  
INVOLVING HUMAN SUBJECTS

**FOR IRB USE ONLY:**

IRB #: \_\_\_\_\_

Received: \_\_\_\_\_ Reviewed: \_\_\_\_\_

\_\_\_\_\_ Approved; \_\_\_\_\_ Approved with Provisions; \_\_\_\_\_ Denied.

**This form should be prepared by the Principal Investigator (P.I.) and attached to any project proposal involving human experimental subjects, including all grant applications and Released Time for Research and UFRI applications.**

All applicants **must** submit the following items to Townsend 130 by the deadline date:

- A signed hard copy of the application
- NIH certificate
- Consent Form
- Debriefing Form
- Any additional information that cannot be scanned and attached to web application

*Full details must be given and all necessary documentation submitted. Handwritten and/or incomplete forms will be returned to the investigator(s) without review.*

**IRB REVIEW TYPE REQUESTED** \_\_\_\_\_ **Full IRB panel review**

*Please refer to the categories of IRB review in the policy guidelines for an explanation of the categories.*

**IF PROJECT WAS INITIALLY DENIED APPROVAL AND THIS IS A RESUBMISSION,  
PLEASE CHECK HERE** \_\_\_\_\_

**PROJECT TITLE:**

*Anticipated Start Date:*

*Project End Date:*

**PRINCIPAL INVESTIGATOR**

**Name:**

**Department:** (DO NOT ABBREVIATE):

**E-mail:**

**Home phone:**

**Home mailing address:**

**Position or Title:** . \_\_\_ Faculty; \_\_\_ Graduate Student; \_\_\_ Undergraduate Student; \_\_\_ Staff.

**Date of successful completion of the Human Subjects Certification Program:** \_\_\_\_\_

I will not begin this study until receipt of a Notice of Approval, or Exemption, from the IRB. Once approved or exempted, I will conduct this study according to the recommendations of the Kean University Institutional Review Board. I will report any serious adverse events or emergent problems to the IRB, will obtain IRB approval before implementing modifications of protocol, and will request continuing review/approval required beyond the study end date.

\_\_\_\_\_  
(Signature of PI)

Date: \_\_\_\_\_

**CO-PI(s)**

**Name:**

**Department:** (DO NOT ABBREVIATE):

**E-mail:**

**Home phone:**

**Home mailing address:**

**Position or Title:** . \_\_\_ Faculty; \_\_\_ Graduate Student; \_\_\_ Undergraduate Student; \_\_\_ Staff.

**Date of successful completion of the Human Subjects Certification Program:** \_\_\_\_\_

**FACULTY SPONSOR INFORMATION** (if applicable)

**Name:**

**Department:** (DO NOT ABBREVIATE):

**E-mail:**

**Office phone:**

**Campus mailing address:**

Indicate the date that the **Faculty Advisor** successfully completed the Human Subjects Certification Program:

Date: \_\_\_\_\_

As faculty advisor/course instructor for the above named student, I have read/reviewed this application for quality, completeness, and accuracy. I certify that I am familiar with Kean University policies and federal regulations regarding the protection of human subjects in research. This study meets the guidelines and requirements of the IRB and has my endorsement.

\_\_\_\_\_  
(Signature)

Date: \_\_\_\_\_

**REQUESTS RECEIVED WITHOUT THE APPROPRIATE SIGNATURE(S) WILL NOT RECEIVE REVIEW.**

**For students to complete**

2. Is this research/student project required to fulfill the requirements of a course?

\_\_\_ Yes

\_\_\_ No

2. If yes, please name the course ID and title \_\_\_\_\_

3. Will this research/student project be published?

\_\_\_ Yes

\_\_\_ No

**A. PROTOCOL DESCRIPTION**

1. Briefly describe the context and goals of your research project. What you hope to accomplish and why? What is the background of this project?
2. Describe the involvement of the human subjects in this project. What will they be doing? Who are the subjects? How many subjects will be involved in the project?
3. Specify how subjects will be recruited (e.g. advertisements, announcements in class, e-mail, internet, etc.).
4. Indicate the duration of anticipated research as applicable (the length of each session and the number of sessions).
5. Describe where the research will be conducted. (NOTE: *If the research is to be conducted in another institution (e.g. a school, hospital, agency, place of business, etc.) a signed copy of the IRB approval or a permission letter from that institution must be attached.*)
6. State in detail your plans for obtaining each subject's informed consent to participate in this project (attach copies of any "informed consent" forms or agreements). Describe how this information will be conveyed to subjects. **BE SPECIFIC!** (NOTE: *At least 2 copies of the forms should be handed out to participants, with one for them to sign, date and hand back and one for them to keep for their records.*)

7. What expected benefits will accrue to each human subject to humankind in general, as a result of this project? List out all possible or expected benefits.
  
8. There are 3 parts to this section, please make sure you answer all 3 parts.
  - 8a. What do you believe are all the possible risks (physical, psychological, sociological, legal, financial, or other) to humans that can result from participation in or assistance to this project? Please list and describe all of them below:
  
  - 8b. Please indicate whether or not the risk(s) you described is considered "high, moderate, low"
  
  - 8c. Describe in detail procedures to protect the human participants involved from each of the risks.
  
9. In the utilization of the results of your project, are humans protected from possible risks, such as embarrassment or invasion of privacy? Describe in detail how confidentiality will be maintained.
  
10. Specify how you will keep your data secure, and maintain confidentiality during the research. Be specific and describe how data will be stored throughout the duration of the project and upon its completion **PLEASE NOTE THAT ALL CONSENT FORMS AND DATA MUST BE KEPT UNDER LOCK AND KEY FOR 5 YEARS.**
  
11. Describe how you will ultimately dispose of your data after you have completed your research (e.g. shredding, burning). **PLEASE NOTE THAT ALL RESEARCH RECORDS MUST BE MAINTAINED FOR AT LEAST FIVE YEARS AFTER THE COMPLETION OF THE RESEARCH.**
  
12. Are you using any scales or instruments you did not create yourself? If so, you must demonstrate that you have permission to use the scale. List out the names of these scales and provide a copy of the permission to use the instrument. If it is in the public domain, please indicate below. If you purchased the scale, provide proof of purchase.

**B. SUPPORTING DOCUMENTS – The following 3 types of documents must be included. If they are not included, you will not receive IRB approval.**

**1. CONSENT FORM** (Please copy and paste your consent form below). Please see informed consent instruction sheet for details on what to include.

**2. DEBRIEFING FORM** (Please copy and paste your debriefing form below). Please see debriefing instruction sheet for details on what to include.

### **3. Human Subjects (NIH) Certificate**

**ADDITIONAL DOCUMENTS** (Please insert additional documents, such as surveys/questionnaires below, if applicable)

**INVESTIGATOR CHECKLIST** (This checklist is to be completed as applicable, by the PI and submitted with the IRB application)

- Consent Form(s)
- Debriefing Form
- Questionnaire(s), Survey(s), Interview Questions
- Authorization to Use Data
- IRB Approval Notice from Participating Institutions
- Certification of completion of the online tutorial

***NOTE: Please complete this form and send it, along with all the necessary electronic documents (such as consent form, debriefing form, surveys, questionnaires), as a Word or PDF attachment to [irb@kean.edu](mailto:irb@kean.edu) with the subject heading "IRB." Also send an original signed set to: "IRB," the Office of Research and Sponsored Programs, T130.***

## Appendix D: Model Consent Form

**Please note that this consent form is meant to be used as a guide when putting together your own informed consent form. It is not meant to be copied verbatim. There are elements of the informed consent form that are not included here because they were not necessary (i.e. numbers for counseling centers). This info may be needed on your form and should be included. It is the responsibility of the researcher to be sure that the form includes the necessary pieces of information.**



## **Informed Consent**

**Title of Project:** The Effect of Using Preferred Versus Neutral Objects to Teach the Acquisition of Prepositions in a Child with Autism

**Researcher:** XXXX, Graduate Student/Primary Investigator  
Department: Communication Disorders and Deafness  
Contact Information: Telephone (XXX) XXX-XXXX Email XXXX@XXX.XXX

**Faculty Advisor:** XXXXX  
Department: Communication Disorders and Deafness  
Contact Information: Telephone (XXX) XXX-XXXX Email XXX@XXX.XXX

### **Invitation to Participate:**

Your son is being invited to participate in a research study. This study will determine if using preferred objects of a child with an autism spectrum disorder to teach prepositions is more effective than using neutral objects.

### **Subject Selection:**

Your son is being invited to participate in this research study because he has been diagnosed with an autism spectrum disorder and is of school age.

### **Purpose of Study:**

The purpose of this study will be to teach the participant two prepositions, one using preferred objects of the participant, and one using neutral objects. This will determine if using preferred objects is more effective. Through testing, two prepositions that the participant demonstrates a deficit in use will be identified. The researcher will then teach one preposition using preferred objects and one preposition using neutral objects. The participant's use of each preposition taught will be reassessed and it will be determined if using preferred objects to teach prepositions to a child with an autism spectrum disorder is more effective than using neutral objects.

### **Procedures:**

The subject for this study will be one 7-year old male whom has been diagnosed with an autism spectrum disorder. The study will be composed of four phases. During the first phase, preferred objects of the participant will be determined through a checklist filled out by the parents, and through an assessment of preferred objects. In the second phase, discrete trial training will be used to determine the participant's use of prepositions. Two prepositions that the participant demonstrates a deficit in use will be identified. During the third phase, using discrete trial training one of the prepositions will be taught with preferred objects, and the other will be taught with neutral objects. During the fourth phase, using discrete trial training the participant's use of the two prepositions will be reassessed. The results of this assessment will be analyzed, and it will be determined if using preferred objects as opposed to neutral objects is more effective when teaching prepositions to a child with an autism spectrum disorder.

Participation in this research study is completely voluntary. If at any time you decide that you do not want your son to participate in this study, his participation will be withdrawn without penalty.

### **Potential Risks:**

The participant should not experience any risks from participating in this study.

**Potential Benefits:**

By participating in this study, the participant may have a better understanding and use of prepositions. In addition, the results of this study may result in more effective teaching of children with an autism spectrum disorder.

**Financial Obligation:**

There will be no financial obligation to the participant or his family.

**Confidentiality:**

All of the information obtained over the course of this study will remain confidential and be contained under lock and key in the primary investigator’s office. All of the data collected will be reported anonymously. The participant’s name will not be written on any forms of saved data. In addition, if you are interested in reviewing the results of this study, you may contact the primary investigator, XXXX XXXX, at (XXX) XXX-XXXX or [XXXX@XXXX.XXX](mailto:XXXX@XXXX.XXX), or the faculty advisor, XXXX XXXX, at (XXX) XXX-XXXX or [XXXX@XXXX.XXX](mailto:XXXX@XXXX.XXX), after the study is completed.

**Questions/Comments:**

If at any time you have any questions or concerns, feel free to contact the primary investigator or faculty advisor at any time.

**Primary investigator/Graduate student:** XXXX (XXX) XXX-XXXX or [XXXX@XXXX.XXX](mailto:XXXX@XXXX.XXX)

**Faculty Advisor:** XXXX (XXX) XXX-XXXX or [XXXX@XXXX.XXX](mailto:XXXX@XXXX.XXX)

The Institutional Review Board of Kean University should be contacted if you have questions about your rights as a research participant. Use either of the contact numbers below:

**Kean University Institutional Review Board:** (908) 737-3461 or [IRB@kean.edu](mailto:IRB@kean.edu)

**Agreement to Participate:**

If you agree to the participation of your son in this study, please sign and print your name where designated below. Your signature indicates that you have read and understood the information provided in this document, and that you agreed to let your son participate in this study. If at any time you have questions or concerns regarding this study, feel free to contact the primary investigator or faculty advisor at the telephone numbers or email addresses provided in this document.

\_\_\_\_\_  
Signature of Parent/Guardian Date

\_\_\_\_\_  
Printed Name of Parent/Guardian Date

\_\_\_\_\_  
Signature of Primary Investigator Date

\_\_\_\_\_  
Signature of Faculty Advisor Date

## Appendix E: Model Debriefing Form

## Debriefing Form

**Title of Project:** The Effect of Using Preferred Versus Neutral Objects to Teach the Acquisition of Prepositions in a Child with Autism

**Researcher:**

Primary Investigator/Graduate Student: XXXX

Contact Information: Telephone (XXX) XXX-XXXX Email [XXXX@XXXX.XXX](mailto:XXXX@XXXX.XXX)

Faculty Advisor: XXXX

Contact Information: Telephone (XXX) XXX-XXXX Email [XXXX@XXXX.XXX](mailto:XXXX@XXXX.XXX)

Thank you for your participation. This study is concerned with determining if using preferred versus neutral objects of a child with an autism spectrum disorder when teaching affects the child's acquisition of prepositions. The investigator hypothesized that using preferred objects as teaching tools will aid in the acquisition of prepositions in a child with an autism spectrum disorder.

A checklist and a preferred stimuli assessment determined objects that the participant prefers. Two prepositions that the participant demonstrated a deficit in use were then identified by an assessment using discrete trial training. Next, one preposition was taught using discrete trial training with preferred objects, and the other was taught with neutral objects. Finally, the participant's acquisition of each preposition taught under the two conditions was assessed. The practical application for this research is to search for more effective practices to teach children with autism.

Participation in this study is strictly voluntary and very much appreciated. If at any time you have any questions, concerns, or if you would like a copy of the results, feel free to contact the primary investigator, XXXXX, at (XXX) XXX-XXXX or by email at [XXXX@XXXX.XXX](mailto:XXXX@XXXX.XXX), or the faculty advisor, , XXXXX, at (XXX) XXX-XXXX or by email at [XXXX@XXXX.XXX](mailto:XXXX@XXXX.XXX). The Institutional Review Board of Kean University should be contacted if you have questions about your rights as a research participant, feel free to contact them at (908) 737-3461 or IRB@kean.edu

## Appendix F: Sample Approval Letter



**KEAN UNIVERSITY  
INSTITUTIONAL REVIEW BOARD  
NOTIFICATION OF REVIEW**

**Federal Registration #** IORG 0003969

**IRB #** 08-022151

**P.I. Name:** XXX

**Research Advisor:** XXXXX

**Project Title:** “The Effect of Using Preferred Versus Neutral Objects to Teach the Acquisition of Prepositions in a Child with Autism”

The project identified above has been reviewed and **approved by the IRB committee**. The approval is only effective for this research study as described and for the duration of one year from the date of this letter.

This decision is based on the following assumptions:

1. The application you submitted to the Office of Research and Sponsored Programs (ORSP) provide a complete and accurate account of how human subjects are involved in your project.
2. You will carry on your research according to the procedures described in this application.
3. If any substantive changes are made, you will resubmit the project for IRB review.
4. You will immediately report to the ORSP any problems that you encounter while using human subjects.

On behalf of the IRB,

Date: March 13, 2008

## Appendix G: Sample Approval Letter with Provisions



**KEAN UNIVERSITY  
INSTITUTIONAL REVIEW BOARD  
NOTIFICATION OF REVIEW**

**Federal Registration #** IORG 0003969

**IRB #** 08-052318

**P.I. Name:** XXXX

**Research Advisor:** XXXXXX

**Project Title:** “The Relationship between Self-Awareness and Executive Functioning in Learning Disabled College Students”

The project identified above has been reviewed and **approved with provisions by the IRB** at its meeting of May 23, 2008. This provisional approval is only effective for this research study as described in your application and for the duration of one month from the date of this notice. For approval of the application by the IRB you will need to resubmit a modified application addressing the provisions below.

**Provisions**

You are required to make the following modifications:

1. Applicant’s successful completion of the certificate is outdated. Must be within one year of application. Submit new certificate of updated completion of tutorial.
2. Please provide proof of permission to use these copyrighted instruments being using for this study.
3. Recruitment Flyer for Participants has discipline specific terminology that is not common knowledge, such as executive deficits, executive dys/functioning, and neuropsychological. As such the consent is not truly informed. These terms needs to be explained in layman’s language.
4. Recruitment Flyer for Participants: Anonymity is not an issue since you will have participant identity in the consent forms; however, unless all instruments are to be stapled, some type of tracking number is needed for the various instruments. Also, last sentence in the Anonymity section ignores the fact that participants sign a consent form. This is confidential, not anonymous. Please clarify this fact.
5. Where will the researcher and participant meet? This needs to be in a private location.
6. Kean Counseling Center contact information needs to be included in the Debriefing form.



You must use the Provisional Form to address these issues.

On behalf of the IRB,

Date: May 24, 2008

## Appendix H: Sample Rejection Letter



**KEAN UNIVERSITY  
INSTITUTIONAL REVIEW BOARD  
NOTIFICATION OF REVIEW**

**Federal Registration #** IORG 0003969

**IRB #** 08-012305

**P.I. Name:** XXXX

**Research Advisor:** XXXXX

**Project Title:** “Does Expressive Language Improve in Children with Autism When Precision Teaching is Implemented in Speech-Language Therapy?”

The project identified above was **not approved by the IRB committee** at its meeting of January 23, 2008 (IRB identification number 0000706). The reasons are stated below:

1. Provide IRB approval from both schools where research is to be conducted.
2. How will the children be selected? Will all the children at these schools have an opportunity to participate in the study?
3. What will the PI do with the other children who were not selected for the study?
4. What are the other potential benefits of this study? What are the potential benefits for the parents who are agreeing to let their children participate in this study?
5. Where exactly is this research to be conducted? It is not clear.
6. What will the PI do if the child becomes upset during the study? There are more risks than the ones described in the application form. This is a vulnerable population.
7. Consent form is not written properly. Needs to be redone. Please refer to the ORSP example on the website. Also, do not use the word “subject” when referring to a parent’s child. Who is conducting the testing? The PI or the Speech Pathologist?
8. Does the researcher have written approval to use these standardized tests for research purposes? If so, must be submitted to ORSP.
9. Must enclose ROWPT and EOWPVT with your application.
10. Consent forms should be coded and codes, not names, used on the actual assessment data.

You must resubmit your application to be reviewed by the IRB.

On behalf of the IRB,

Date: January 24, 2008