IRB Guidelines

These general principles are presented to aid the researcher in the preparation of the research protocol. The researcher should provide information in his/her protocol addressing each of these topics, if applicable.

1. There are two levels of anonymity to be considered in research with human participants; (1) in no case should names or identifying data be used in reporting results, (2) design considerations (such as a double-blind study) may require that research participants are anonymous to the investigator(s) also. The type or types of anonymity for a study's participants must be explicitly stated in the Consent Form.

2. All data should be recorded anonymously or identifying information deleted at the end of the study. The coding system to protect subjects' identity should not use subjects' initials, Social Security numbers, addresses, etc., in place of name. Such information could readily be used to identify specific individuals. Instead, assignment of unique or random numbers to subjects is recommended. In cases where follow-up is important, a master key could be maintained with the subject's name and number in a separate place from the data. The master key, as well as the data, should be secured in a locked drawer or file cabinet. When the final analyses are completed and no follow-up is planned, this key is then destroyed.

3. When required, subject/parental permission must always be written permission that is returned to the researcher. There should be a separate Assent Form for subjects under age 18, along with parental/legal guardian Consent Form. For children under age 12, there should be an Oral Assent Procedure or Script.

4. Subjects should be given a copy of the signed Assent/Consent Forms for their records. It should be stated in the form that a copy will be provided.

5. If a control group is used as part of the treatment-type study, the advantages derived from the research should be made available to the control group or the control group told of the advantages.

6. Subjects should be given the office address and phone number of the researcher in order to request details of the research study. If the researcher is a student, subjects should be told to contact him/her through the department in which the student is studying. Home addresses and phone numbers should never be given out. In the Informed Consent and in the Solicitation/ Recruitment Letter, the researcher should specify his/her institutional affiliation with Keystone College by identifying the department and college/school.

7. If requested, results generally should be given to the subjects in aggregate or group form. As a rule, individual results, especially those which could require professional interpretation, should not be reported back to the subjects.

8. Explain discipline specific terms when used in the application.

9. Services, class standing, etc. are not to be terminated or negatively affected if the subject refuses to participate or withdraw from the study.

10. Letters of authorization/permission from IRBs of cooperating institutions, school districts, hospitals, clinics, etc. must be on that institution's letterhead and included in the IRB proposal.

11. The researcher must provide all cover letters, scripts, instructions to the subjects, introductory remarks, etc .to the IRB for review.

12. Protocols not typed and properly collated as previously outlined, or with multiple grammatical and spelling errors, or missing a substantial amount of information will be returned to researcher without review.

13. Total class projects should not be attached as the description of methodology, etc. Rather, the researcher should provide concise answers to the questions on the application.

14. Approval to conduct research: (1) Outside the College - permission on letterhead from appropriate administrative authority. (2) within the College - letter of approval from faculty or staff member who oversees the subjects who are anticipated to participate in research.

15. When there is minimal risk in mailed surveys, the Letter of Solicitation can replace the Informed Consent. In that event, the Letter of Solicitation must contain all points of the Informed Consent except the signature.

16. If the study is carried out outside the college (e.g. hospitals, clinics, schools, etc.), approval of the site institution needs to be added to the material submitted to the IRB. If the institutions have a local IRB (e.g. hospitals, colleges, universities), its approval of the study is also required.

17. Federal regulations require that all state laws also be followed in conducting research. Thus, researchers wishing to use lotteries, raffles, etc. need to abide by the regulations of the state in which they wish to conduct the research. In New Jersey, this means a state license is required.

Required Materials for IRB Report Submission

- The signed/approved pre-IRB form (as a cover sheet for each packet) (Pre-IRB Requirements)
- The signed IRB Request for Approval form
- The IRB Review Sheets with typed responses
- The Solicitation/Recruitment Letter/Recruitment Flyers, Oral Script, etc.
- The Informed Consent Form/Assent Form/Oral Assent Procedure or Script covering all 15 points in separate paragraphs and with paragraph headings on department letterhead
- Approval to Conduct Research Letters/Performance Site's IRB Approval(s)
- Special Populations Concerns
- Equipment utilized in research (testing instruments, questionnaires, etc.)
- Certificate indicating completion of Human Subjects Tutorial (Certificate Requirements)
- Completed IRB Review Checklist

In materials, such as the Informed Consent form, given to prospective subjects, the names of the tests to be administered should be specified and a brief description given unless the purpose and/or subject matter are obvious from the title of the instrument. The IRB reserves the right to request additional copies of all materials provided for the review of the project activities.

NO RESEARCH INVOLVING HUMAN SUBJECTS
SHOULD BE CONDUCTED PRIOR TO RECEIPT OF FINAL APPROVAL.

If the research has been conducted without formal approval, the IRB cannot consider the proposal, and the materials will be returned. Appropriate college and government offices will be informed of this unauthorized activity.

Materials will be returned un-reviewed: (1) if the materials are not typed, collated and stapled; (2) if a substantial amount of information is missing; (3) or if there are multiple grammatical and spelling errors.

Certificate Tutorial

All investigators are required to attach a certificate indicating completion of the tutorial on the protection of human research subjects when a protocol is submitted to the IRB for review. This training can be accessed at http://cme.cancer.gov/c01/nih_intro_04.htm. Under Course Accreditation, click on Option 3 - "Completion Certificate only, no continuing education credits" *(no charge).*

Upon completion of the tutorial, print the completion certificate and attach a copy of it to your IRB application. Documentation of completion of an approved education program must be on file with the IRB before protocols can be reviewed and research on human subjects can be conducted.

The Review Process

Federal Guidelines

For Federal regulations governing human subject research, go to
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm

In accordance with the College's Assurance Agreement, when appropriate, the following will be reported to institutional officials, the federal Office of Human Research Protections, and/or other governmental agencies: any unanticipated problems involving risks to subjects or others; serious or continuing non-compliance with pertinent federal regulations or the requirements of the IRB; and suspension or termination of IRB approval of research protocols.

Non-compliance with IRB requirements will result in withdrawal of IRB approval and in the suspension or termination of the research.

Federal regulations require that all applications submitted to the IRB be screened to determine if the research is exempt from or requires a review. It is the IRB, not the researcher, that makes this decision. Accordingly, all applications are initially reviewed by a subcommittee of members of the IRB to determine whether a proposal will be considered under exempt, expedited or full Board review. The results of this initial review are announced at the first subsequent meeting of the full Board. Any member of the IRB, however, may ask that a proposal be given the consideration of the entire Board. In this event, the decision of the initial review is superseded by the decision of the full Board. The Board's decision is then recorded in the minutes.

A. Exempt

Federal regulations indicate the following research activities are exempt:

1. Research conducted in established or commonly accepted educational settings, involving normal education 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.
2. 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 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 or employability.
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude achievement), survey procedures, interview procedures or observation of public behavior that is exempt under paragraph (2), if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statue(s) requires without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Taste and food quality evaluation studies, if wholesome foods without chemical additive are consumed or if a limited amount of a food is consumed that contains a food additive or agricultural chemical at or below a level approved by the Food and Drug Administration, the Environmental Protection Agency, or the Animal Plant Health Inspection Service of the United States Department of Agriculture.
5. Research involving the observation (including observation by participants) of public behavior, except where all of the following conditions exist: (i) observations are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects, (ii) the observations recorded about the individual, if they become known outside the research could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability, and (iii) the research deals with sensitive aspects of the subject's own behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol.
6. 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 subject.

B. Expedited Review

It is possible for the IRB to review through expedited procedures certain categories of research which recur with some regularity. They include:

1. Collection of: hair and nail clippings, in a non-disfiguring manner; deciduous teeth, and permanent teeth if patient care indicates a need for extraction.
2. Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.
3. Recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subjects privacy. This includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, x rays, microwaves).
4. Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant.
5. Collection of both supra- and subgingival dental plaque, and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.
6. Voice recordings made for research purposes such as investigations of speech defects.
7. Moderate exercise of healthy volunteers.
8. The study of restricted access data, documents, records, pathological specimens, or diagnostic specimens.
9. Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the research investigator does not manipulate subject's behavior and the research will not involve stress to subjects.
10. Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.
11. Any other category specifically added to this list by HHS and published in the Federal Register.

C. Full Committee Review

All other projects not described as exempt or expedited will require full Committee review.

Continuing Review:

Protocols will undergo the federally mandated continuing review no later than 12 months after initial approval has been granted. If risks to subjects are regarded as extraordinary, re-review at more frequent intervals may be required. Please notice that after one year, the proposal is no longer valid and needs to go through such review. An IRB continuing review form needs to be filled out and sent in to the IRB office within 30 days before the existing approval expires. The IRB office will send a letter and the continuing review form within 30 days prior the deadline.

Letter of Solicitation

The following MUST be included in any letter or other correspondence (including flyers, newspaper ads, etc.) to recruit subjects:

1. The researcher's affiliation with Keystone College (college/school, department and program).

2. An explanation of the purpose of the research in lay terms.

3. Expected duration of the subject's participation (estimate of the amount of time involved to participate in the research).

4. A description of the procedures to be followed, and identification of any procedures which are experimental. If questionnaires or survey instruments are used in the research, they should be specifically named and briefly described unless their purpose and subject matter are obvious from their titles.

5. A statement of the voluntary nature of the participation.

6. A statement indicating if anonymity (i.e., no identifying data on subjects to researcher or others) will be preserved. If anonymity will be maintained, then an additional statement must be included saying how this will be achieved.

7. A statement of how the subject's data will be securely stored to maintain confidentiality.

For clarity's sake, each of these above 7 points should be addressed in a separate paragraph. If a Solicitation/Recruitment Letter does not follow these directions, the protocol will be returned to researcher without review for remediation. This will delay the IRB review at least until the next month.

If a **flyer or newspaper advertisement** is to be used, it should include the following:

1. The researcher's affiliation with Keystone College (college/school, department and program). A brief explanation of the purpose of the research and the expected duration of the subject's participation (estimate of the amount of time involved to participate in the research).

2. A brief description of the procedures to be followed, and identification of any procedures which are experimental. If questionnaires or survey instruments are used in the research, they should be specifically named and briefly described unless their purpose and subject matter are obvious from their titles.

3. A statement of the voluntary nature of the project.

4. A statement of how anonymity will be preserved.

5. A statement of how the subject's data will be securely stored to maintain confidentiality.

Informed Consent Form

The Informed Consent Form must be printed on departmental letterhead and must include the following elements stated in terms that the subject can readily understand. To avoid the implication of waiver of rights, use the grammatical 3rd person only in the Informed Consent document.

1. The researcher's affiliation with the College (college/school, department, program).

2. An explanation of the purpose of the research in lay - non technical terms, and the expected duration of the subject's participation (estimate of the amount of time involved to participate in the research).

3. A description of the procedures to be followed in lay terms, and identification of any procedures which are experimental.

4. If questionnaires or survey instruments are used in the research, they should be specifically named and briefly described, with a sample of questions to be asked.

5. A statement of the voluntary nature of the participation, specifying that refusal to participate or discontinuing participation at any time will involve no penalty or loss of benefits to which the subject is otherwise entitled.

6. A statement indicating if anonymity (i.e., no identifying data on subjects to researcher or others) will be recorded, so that no one will ever be able to link the data to any individual.

7. A statement of how the subject's data will be securely stored to maintain confidentiality (i.e. identifying information will be collected but efforts will be made to protect the subjects' identities). If the data will be confidential, include an additional statement specifying the measures that will be used to maintain the subjects' confidentiality and the circumstances, if any, under which identifying data may be used or disclosed without the subjects' express consent.

8. A statement describing to what extent records will be kept confidential, including a description of who may have access to research records.

9. A description of any reasonably foreseeable risks or discomforts to the subjects, an estimate of their likelihood, and a description of what steps will be taken to prevent or minimize them. If there are no anticipated risks, this should be stated.

10. A description of (1) the direct benefits, if any, that subjects may reasonably be expected to receive as a result of participating in the research; and (2) the potential benefits of the knowledge reasonably expected to result from the research. If no direct benefits to subjects are expected, this should be stated. Monetary compensation or other remuneration to subjects is not considered a direct benefit.

11. If subjects are to be paid or given any other type of remuneration, the amount of the payment and/or the nature of the other remuneration should be stated in the consent document.

12. For research involving more than minimal risk, an explanation and description of any compensation and any medical treatments that are available if research subjects are injured, where further information may be obtained, and whom to contact in the event of a research-related injury must be provided. Similarly, if the activity poses the possibility of causing undue stress or psychological harm to the subject, the research must develop a referral mechanism, e.g., suggest to seek medical or psychological help and provide a list of centers that can be contacted for that purpose.

13. A disclosure of appropriate alternative procedures or courses of treatment that might be advantageous to the subject.

14. Contact Information: An explanation of whom (that is, [1] the principal investigator/researcher, [2] the researcher's faculty advisor, [3] the IRB office) to contact for answers to pertinent questions about the research and research subject's rights should be identified. Only office addresses and phone numbers should be given. Do not give out home addresses or phone numbers. If researcher is a student, use the address and phone number of the department in which researcher is studying.

15. If video or audio-tapes are involved, the Consent Form should ask for the subject's written permission for such taping and should indicate how the 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, who will transcribe the tapes, and when the tapes will be erased or destroyed.

16. A Clear Statement must be made that subjects are to be given a copy of the signed and dated Informed Consent Form.

Note: For anonymity's sake, the researcher, instead of asking for a signature, can include the following statement in the Informed Consent form: "Consent to participate is indicated by returning the enclosed (questionnaire, test, etc.) to the researcher."

_____ _____

Subject Date

The following statement MUST be included in the informed consent form only for projects which pose a risk to subjects:

"The Department of Health and Human Services requires that you be advised as to the availability of medical treatment if a physical injury should result from research procedures. No special medical arrangements have been made regarding your participation in this project. If you are a registered student at Keystone College, you are eligible to received medical treatment at the College Health Service. If you are not a registered student at the College, immediate medical treatment is available at usual and customary fees at the local community hospital.

In the event you believe that you have suffered any injury as a result of the participation in the research program, please contact the Chairperson of the IRB who will review the matter with you, and identify any other resources that may be available to you."

The Informed Consent Form must be on department letterhead and must contain all the points listed above in separate paragraphs and under headings specific to the point. This is to ensure clarity to the prospective research subject in a simple, efficient way. If the Form is deficient in this, the protocol will not be forwarded to the IRB for review. Rather, it will be returned to the researcher for remediation, which will delay review by at least one month.

The Informed Consent Form must have a place for the subject's signature and date. Subjects are to be given a copy of the signed and dated Consent Form before their participation begins.

Children over age 12 who sign Assent Forms need to have a parent/legal guardian countersign and date the document. ***Child subjects and their parents/legal guardians are to be given a copy of the signed, countersigned and dated Assent Form before their participation begins***.

Children under age 12 need to have a parent/legal guardian sign and date the Oral Assent Procedure or Script. ***Child subjects and their parents/legal guardians are to be given a copy of the signed, dated Oral Assent Procedure or Script before their participation begins.***

Copies of all completed Consent Forms, Assent Forms, Oral Assent Procedure or Script forms must be retained by the researcher for a period of at least 3 years following termination of the research.