POLICY ON THE USE OF HUMAN SUBJECTS

I. Statement of Purpose

Goucher College maintains an Institutional Review Board on the Use of Human Subjects in Research (hereafter referred to as the IRB) comprised of at least five members. The members of the IRB are appointed by the Provost of the College. They are selected both from within and from outside Goucher College and from different disciplines, to provide a range of perspectives. All members of the IRB are aware of issues relating to individual civil liberties. Since the members of the IRB represent a range of backgrounds, the board is competent to review a variety of projects and ensure that the rights of research subjects are protected. The board reviews proposed projects in terms this policy, which is based on the guidelines on human protection put forth by the Office of Human Research Protections of the Department of Health and Human Services (45 C.F.R. 46 "Protection of Human Subjects") as well as in terms of applicable standards of professional conduct and practice, modern ethical principles, and the consensus of contemporary community standards.

In their evaluations, the members of the IRB shall attempt in all cases to assure that inherent and potential risks to subjects are reasonable in relation to anticipated benefits, if any, to the subjects and/or humanity. It is the role of the Goucher College Institutional Review Board to minimize inherent and potential risks to subjects as much as is feasible, regardless of projected benefits to individuals or to society.

II. Membership of the Institutional Review Board

A. The IRB of Goucher College shall have no less than five members, with varying backgrounds, to promote complete review of research activities commonly conducted by the College. The IRB shall be sufficiently qualified through the expertise and diversity of the members, including consideration of their race, gender and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its decisions in safeguarding the welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct. The IRB shall therefore include persons knowledgeable in these areas.

B. The IRB may not consist entirely of members of one profession or one gender. However, selection must be made on the basis of qualified expertise, not solely on the basis of gender.

C. The IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in

nonscientific areas (e.g. lawyers, ethicists, members of the clergy).

D. The IRB shall include at least one member who is not otherwise affiliated with Goucher College and who is not part of the immediate family of a person who is affiliated with Goucher College.

E. The members of the IRB must all complete the NIH-sponsored online training, Protecting Human Research Participants before reviewing proposals and within 5 years of their service on the IRB. They must submit a certificate attesting to their completion of the training to the IRB Chair.

III. Definitions

A. "Human subject" means a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual, or obtains identifiable private information.

B. "Minimal Risk" means that the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater than those encountered in daily life, or during the performance of routine physical or psychological examinations or tests.

C. "Research" means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

IV. General Review Procedures

A. All College research projects and activities that involve human subjects, and that meet the definition of research in the Code of Federal Regulations (45 CFR 46(d)), regardless of the risk foreseen, require review and approval by the IRB, prior to the initiation of the project or activity. IRB review is required for projects or activities involving human subjects that are conducted on the College premises or elsewhere by faculty, students, or employees. Each project and activity involving human subjects will be referred to the IRB, following the procedures outlined below. In case of full reviews, the research proposal will be reviewed by the IRB at the scheduled meeting closest to the time the proposal is received.

B. Except when a project is excluded or exempt from review or when an expedited review procedure is used (see Sections V and VI), the IRB shall review proposed research at convened meetings at which a majority of the members are present, including at least one member whose primary concerns are in non-scientific areas. Decisions of the IRB are rendered by a majority of all members present. Where any questions of significance arise, Board members absent from a meeting are apprised and their views solicited so that participation to the fullest degree is possible. Minutes of each IRB meeting are circulated to the Provost, to all IRB members, and are on file in the office of the IRB Chair.

C. No members of the IRB will be involved in the review of any project in which the member has a direct professional responsibility or some conflicting interest, except to provide information requested by the IRB.

D. The IRB may in its discretion consult with outside sources of expertise beyond or in addition to that available on the IRB. Such sources could include additional legal counsel or members of the Institutional Review Boards of other institutions. The outside sources may not vote on matters before the IRB.

E. Each IRB member is encouraged to exercise independent judgment, so that reviews may be conducted in the most objective manner possible.

F. The IRB has the authority to make decisions involving projects or activities that involve human subjects including:

1. determination of whether the project is exempt from IRB review;
2. determination of whether the project is eligible for expedited review;
3. determination of the level of risk to which human subjects may be exposed;
4. approval of the project or activity and procedures as submitted;
5. specification of modifications in the protocol necessary to obtain IRB approval;
6. disapproval of the project or activity; or
7. suspension or termination of IRB approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects.

G. Application to the various categories of review shall be made on the forms developed by the IRB. The forms are available in the Office of the Provost and online on the IRB website.

H. The IRB shall notify investigators and the Provost in writing, and, normally, within two weeks of receipt of the proposal, of its decision to approve or disapprove the research, or of modifications required to secure its approval. If the IRB decides to disapprove a research project or activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

I. All research projects and activities approved by the IRB shall be subject to continuing review at appropriate intervals. Research that is conducted, supported or otherwise subject to regulation by any federal department or agency shall be reviewed at least annually.

J. Researchers seeking approval for projects approved by other IRBs (that also adhere to the regulations set forth in 45 C.F.R. 46) must submit documentation of that IRB approval, along with whatever materials were originally submitted to that IRB (proposal, instruments, etc.), in both hard copy and electronic copy. The Goucher College IRB Chair or designee may determine if these materials are sufficient for the Goucher IRB to give its approval (secondary

concurrence), or if more information (e.g., a proposal on the appropriate Goucher IRB forms) is required, in which case the submission will be reviewed according to the procedures outlined below. If the project is approved based on the materials submitted to another IRB (and that IRB's approval), the Goucher College IRB must be kept apprised of all continuing reviews and addenda submitted to the primary IRB (at the other institution), and may request further information to continue its approval at any time.

V. Projects Excluded from Review (for which no submission to the IRB is necessary)

A. Data collection conducted by an instructor, in a classroom setting, as part of a course curriculum does not need to be presented to the IRB in any form. These activities include those designed for demonstration purposes as part of the educational experience for students. If the instructor plans to disseminate research findings beyond the classroom, s/he should submit the appropriate proposal (EXEMPT, EXPEDITED, FULL).

B. Oral History projects are not required to be presented to the IRB in any form. As guided by statements of the Oral History Association, the Goucher College IRB defines oral history as gathering, preserving, and interpreting the voices and memories of people and communities through recorded interviews with participants in past events and ways of life. It is the IRB's position that oral history projects do not constitute "research" as defined by the OHRP, as they are not intended to contribute to generalizable knowledge, but rather are intended to enhance understanding of historical periods, contexts, and events. Those using oral history must conform to the principles and practices for oral history developed by the Oral History Association.

VI. Projects Exempt from Review

A. Broad categories of research that do not use living human subjects or that normally present little or no risk of harm to subjects may be exempt from formal review by the Board. In these cases, researchers must submit an IRB-EXEMPT form to the IRB, so that the IRB chair (or designee) may review the study and make the determination of whether or not the project is indeed exempt. In general most social, economic and educational research is exempt if the only involvement of human subjects is in one or more of the following categories:

1. the use of survey and interview procedures;
2. the observation of public behavior; or
3. the study of existing data, documents, records, or specimens.

B. Specifically, the following categories of research are exempt from review (based on 45 C.F.R. 46.101(b)):

1. Research undertaken without the intention of involving living human subjects.

2. Research in which the only involvement of human subjects will be in one or more of the following categories:

a. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as

(1) research on regular and special education instructional strategies; or
(2) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

b. Research involving survey procedures, interview procedures, educational testing, or observation of public behavior unless:

(1) information obtained will be recorded in such a manner that the human subjects can be identified, either directly or through identifiers linked to the subjects, and

(2) the subject's responses, if they became 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, employability, or reputation (e.g. when the research deals with the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol).

c. Research involving survey procedures, interview procedures, educational testing, or observation of public behavior, and the human subjects are elected or appointed public officials or candidates for public office, or when federal statutes require without exception, maintenance of confidentiality of personally identifiable information, throughout the research and thereafter.

d. 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 will be recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

C. An investigator who believes that his/her project qualifies for exemption must submit one hard copy and one electronic copy of the IRB-EXEMPT form to the IRB

Chair, describing the project and explaining why the investigator believes the proposed project qualifies for exemption.

D. The Chair will notify the investigator within two weeks whether the proposed research qualifies for exemption. If the research does not qualify, the Chair will advise the investigator in writing concerning the submission of the appropriate forms for request for review. If the proposal qualifies, the Chair will notify the investigator and file the signed copy of the form.

VII. Research Qualifying for Expedited Review

A. Research activities qualify for expedited review if they involve no more than minimal risk, as defined in III.B above, AND are included in the categories suitable for expedited review as determined by the Department of Health and Human Services (DHHS), listed in B below. In addition, minor changes to a previously approved research protocol may be acceptable for expedited review during the period for which approval is authorized.

B. The following categories of research are currently determined to be eligible for expedited review, based on OHRP guidelines:

1. Clinical studies of drugs and medical devices, only when a) the research is on drugs for which an investigational new drug application is not required, or b) the research is on medical devices for which an investigational 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;

2. Collections of blood samples by finger stick, heel stick, ear stick or venipuncture, under the conditions described by DHHS;

3. Prospective collection of biological specimens for research by noninvasive means (e.g. hair and nail clippings, teeth, saliva);

~~4.~~ Collection of data through noninvasive procedures routinely employed in clinical practice, excluding procedures involving x-rays or microwaves (e.g. physical sensors, muscular strength testing);

5. Research involving materials (data, documents, records or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis);

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

6. Research on individual or group characteristics or behavior (such as studies

of perception, cognition, motivation, communication, social behavior), or research employing survey, interview, focus group, program evaluation, human factors evaluation, or quality assurance methodologies;

7. Continuing review of research previously approved by the convened IRB, where the research is permanently closed to the enrollment of new subjects, all subjects have completed all research-related interventions and the research remains active only for long-term follow-up of subjects; or where no subjects have been enrolled and no additional risks have been identified; or where the remaining research activities are limited to data analysis;

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories 2 through
8 above 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;

C. Investigators who believe that their projects qualify for expedited review must submit to the IRB Chair one hard copy and one electronic copy of the IRB-EXPEDITED form. The forms will be reviewed by the Chair or an IRB member designated by the Chair. At their discretion, the investigator may be required to discuss the project with the Chair or the designated member. A research activity may be disapproved only under the full review procedure (Section VII below).

D. The Chair will notify the investigator within two weeks whether the proposed research qualifies for expedited review. If the proposal does not qualify, the Chair will advise the investigator in writing concerning the submission of the appropriate forms for request for full review. If the proposal qualifies and is approved, the Chair will notify the investigator and file the signed copy of the form. The remaining members of the Board will be advised of research proposals that have been approved under the expedited procedure.

VIII. Research that Requires Full IRB Review

A. All projects that are not subject to exemption or expedited review are subject to full IRB review. The investigator must submit one hard copy and one electronic copy of the IRB-FULL form and a copy of his/her project or activity proposal. In order to approve the project, the IRB must determine that all of the following requirements are satisfied:

1. Risks to subjects are minimized (a) by using procedures that are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (b) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes;

2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be

expected to result;

3. Selection of subjects is equitable, taking into account the purpose of the research and the setting in which the research will be conducted;

4. Informed consent will be obtained from each prospective subject or the subject's legally authorized representative, according to the Guidelines for Consent in IX below, and will be appropriately documented. The prospective subject or representative must be given sufficient opportunity to consider whether or not to participate. Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

5. Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

6. Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as persons with acute or severe physical or mental illness, children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, appropriate additional safeguards have been included in the study to protect the rights and welfare of these subjects.

B. In each case, the IRB requires that the research activity be performed by scientifically or otherwise qualified persons with adequate supervision by professional personnel and that the general procedures employed are legal and acceptable by both national and local standards of practice.

C. Investigators who believe that their projects qualify for Full Board review must submit to the IRB Chair one hard copy and one electronic copy of the IRB-FULL form. The Chair then assesses the completeness and compliance of the application with these regulations and policies. After this initial review, the forms may be returned to the investigator with a request for more details or suggestions for change. Upon acceptance by the Chair, the application is put on the agenda for the next scheduled IRB meeting. In certain cases, the investigator may be requested to attend the meeting to clarify the proposal and to respond to questions by members of the IRB.

D. If the proposal is approved, the Chair will notify the investigator and the original of form IRB-FULL will be signed by three members of the IRB. If the proposal is not approved, reasons for denial will be provided in writing to the researcher. All records of review are public information once the IRB has ascertained that no data pertaining to individual subjects is present in those records.

IX. Human Subjects Data Collected by Goucher College Students to Fulfill Classroom Assignments

Many class-assigned projects using humans as subjects do not meet the definition of research in 45 CFR 46(d) (i.e., "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge"). In some of these cases, classroom projects may not require an IRB application.

To minimize administrative burdens on instructors and students, the IRB offers instructors an alternative to requiring each student to submit an IRB application, provided none of the conditions in A below are met, and the instructor agrees to fulfill all responsibilities in B.

A. An IRB application is required when the classroom research project meets one or more of the following conditions:

1. *Use of vulnerable populations or minors.* The project involves minors (under 18 years of age), prisoners, persons lacking the capacity to give informed consent, pregnant women, or other vulnerable populations as defined by 45 CFR 46.

2. *Publication or presentation outside of Goucher College*. Data obtained from the class project will be used for publication, presentation outside of Goucher College, thesis research, dissemination to media outlets, or any other type of public dissemination.

3. *The project involves sensitive topics or confidential information that could place a subject at risk if disclosed*. Any interview, survey or questionnaire that proposes to investigate opinions, behaviors, and/or experiences regarding, but not limited to, any of the following sensitive topics requires IRB approval:

- sexual orientation, incest, rape, sexual molestation, deviant sexual behaviors or attitudes regarding sexual conduct (pedophilia, bestiality, etc.), practices of contraception, abortion, and/or pregnancy.
- substance use and/or abuse including, but not limited to, alcohol, marijuana, steroids, amphetamines, narcotics and any prescription medication legally or illegally obtained.
- mental health of the subject or of others (e.g., suicide, depression, or obsessive compulsive behaviors including, but not limited to, gambling, smoking, eating, etc.).
- traumatic experiences of a subject, including war or combat experiences of veterans.
- any activity that could put the subject or others at risk of criminal or civil liability.

4. *The project involves more than minimal risk.* "Minimal risk" exists when "the probability and magnitude of harm or discomfort in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." 45 CFR 46.102(i).

5. *The project involves the use of any kind of deception.* Deception means that

subjects will not be fully informed of the nature of the project, its risks, and benefits before giving consent to participate.

6. *The project involves video recording or photography of subjects.* Use of audio recording does not trigger the requirement for IRB review if the recording will be erased by the end of the semester.

B. Instructors whose students are conducting research that does not require IRB approval must accept primary responsibility for ensuring the rights and welfare of the human subjects. Instructors must also:

1. *Submit an IRB application if the instructor will use data collected by students in his or her own research.* If the instructor is either collecting data from the students in the class, or will be using data students have collected from other subjects, he or she must submit an IRB application.

2. *Train students in the proper conduct of research and the protection of human subjects.* To supplement classroom instruction on research ethics, instructors must have students complete the NIH "Protecting Human Research Participants" online training program prior to beginning the classroom research project. The program is at http://phrp.nihtraining.com/

3. *Review student class project applications and determine if each project requires IRB review.* Some projects will not require IRB review. Instructors are responsible for keeping all paperwork associated with the course for a period consistent with federal and college guidelines.

4. Ensure that all recruitment materials and consent forms contain the following points:

- The student identifies him/herself as a Goucher College student who is performing the activity to fulfill a course requirement, and the course is specifically identified.
- The name and contact information of the student and the supervising faculty member are provided.
- The persons who have access to the individual data and/or summarized results are specified.
- Respondents are informed that their participation is completely voluntary and confidential.
- The term "IRB" or "IRB-approved" is removed. Instead, the College recommends including a statement on the consent form such as, "This project is conducted as a requirement for [class name here]. This project has been reviewed and approved by the instructor, Professor [X]."

5. *Ensure that students obtain informed consent from all human subjects. Informed consent processes must include all information that may be relevant to an individual in deciding whether or not to participate in research, including the nature of the research activities, anticipated risks and compensation, etc. See IX for more information about*

informed consent.

C. Goucher College may designate individuals within the institution to evaluate whether or not specific projects qualify for EXEMPT status, in cases where particular programs or courses generate many projects of this sort. For example, projects to be conducted by students in the Graduate Programs in Education may submit summaries of their projects to the Program Director for verification of EXEMPT status. Other programs wishing to establish an arrangement of this sort must contact the IRB and to designate such an individual. It is the responsibility of the designee to keep the IRB apprised of the topics of projects that have been deemed exempt by the designee.

X. Requirements for Consent

A. The requirements for informed consent, or its waiver, alteration, or exception apply regardless of the type of review—expedited or full—utilized by the IRB.

B. The investigator must provide the Board with assurance that truly informed and free consent of subjects at risk will be obtained by methods that are adequate and appropriate, and that carry the least possibility of coercion, undue influence, omission, error, or misunderstanding. The informed consent procedure and documents employed for this purpose shall contain no exculpatory language through which the subject or the subject's legally authorized representative is made to waive or appear to waive any of his or her legal rights, or to release or appear to release the researcher, Goucher College or any of its personnel from any liability for negligence.

C. In many cases, research may involve children, persons with restricted educational backgrounds, or persons for whom English is not their native tongue. Consent is not "informed" if the person concerned cannot understand the consent form. The language used in the consent form must be appropriate for the age, education and intellectual levels of the persons who are to be subjects.

D. In some cases, Goucher students under age 18 may wish to participate in research projects. In order for these students to consent to participate in research, they must get written permission of a parent to do so (using the appropriate form on the IRB website), submit the original signed parent form to the Provost's Office, and submit copies of both the signed parent form and their own signed consent form to the researcher at the time of participation.

E. To obtain informed consent, the investigator must provide prospective subjects with the following information:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are

experimental. *NOTE: This statement may be provided to the subject following the research project in cases where the "deception" is a material part of the project.*

2. A description of any reasonably foreseeable risks or discomforts to the subject.

3. A description of any benefits to the subject or to others which may reasonably be expected from the research.

4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.

6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained. Such injury may consist of physical, psychological, emotional, financial, or other harm.

7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.

8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

9. A statement informing subjects of their right to withdraw any consent given and, at the point of withdrawal, to require that their own data, including records, be eliminated from use after withdrawal.

F. When appropriate, the investigator must also provide prospective subjects with one or more of the following:

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable.

2. Anticipated circumstances under which the subject's participation

may be terminated by the investigator without regard to the subject's consent.

3. Any additional costs to the subject that may result from participation in the research.

4. The potential consequences of a subject's decision to withdraw from
the research and procedures for orderly termination of participation by the subject.

5. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.

6. The approximate number of subjects involved in the study.

7. Plans for protecting the confidentiality of personally identifiable information.

[NOTE: These requirements for informed consent are not intended to preempt any applicable federal, state, or local laws.]

G. In most cases, the investigator should document informed consent by use of a written document that incorporates appropriate parts of the above requirements. This document must be approved by the IRB. The form may be read to or read by subjects or their legally authorized representatives, and must be signed by the subject or the representative. The person signing the form must be given a copy of it. Under certain limited circumstances (as defined in 45 CFR 46.117(c)) the IRB may waive the requirement for a signed consent form.

H. In some instances, the investigator may prepare a "short form" written consent document which states that all elements required above were read to the subject or to a legally authorized representative. Short form consent requires that:

1. there must be a witness to the oral presentation;
2. the IRB must approve a written summary of the oral statement;
3. the consent form will be signed by the subject or representative;
4. the witness will sign the short form and a copy of the summary;
5. the person obtaining consent will sign a copy of the summary; and
6. a copy of the short form and the summary will be given to the subject or representative.

I. In no case shall an investigator propose, or the IRB approve, an informed consent procedure in which any possible or potential risk is knowingly or purposely minimized, misrepresented, or otherwise distorted.

J. All approved consent procedures will be retained by the IRB Chair, and all signed consent forms will be retained by the principal researcher.

XI. Confidentiality

A. All personnel associated with each project or activity involving the use of human subjects will ensure that confidentiality will be maintained with respect to individuals in the collection, storage, security, use, and ultimate destruction of all primary data.

B. Measures taken to assure confidentiality should be described to the IRB in writing by the investigator in each case, regardless of risks to subjects involved or of consent procedures used.

C. Exceptions to the confidentiality of data associated with individual human subjects are made only when disclosure is required by statutory or judicial authority or when the subject has given prior written approval for disclosure.

D. General information such as descriptions of consent procedures and outcomes of the review process and minutes of IRB meetings are public information.

XII. IRB Records

A. The IRB shall prepare and retain documentation of its activities, including the following:

1. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

2. Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of disputed issues and their resolution.

3. Records of continuing review activities.

4. Copies of all correspondence between the IRB and investigators.

5. A list of IRB members, including name, earned degrees, representative capacity, indications of experience sufficient to describe anticipated contributions to IRB deliberations, and any employment or other relationship with the College.

6. Statements of significant new findings regarding risk factors for subjects that appear during the course of the research.

All such records and minutes shall be retained for at least three years

after completion of the research, and the records shall be accessible for inspection and
copying by authorized persons, including representatives of the Department of Health and Human Services, at a reasonable time, place and manner.

XIII. Research Undertaken Without the Intention of Involving Human Subjects

In the event research is undertaken without the intention of involving human subjects but it is later proposed to involve human subjects, the research shall first be reviewed and approved by the IRB according to these procedures, before any such involvement occurs.

XIV. Proposed Changes to a Project

In the event an investigator proposes to make changes to an IRB-approved research project or activity, the changes may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subjects. Investigators proposing changes should submit a detailed description in writing **of any substantive changes to the project as well as those modifications that change the risk to the subject**, referring specifically to appropriate sections of the Research Proposal submitted with the original IRB form. Such reviews by the IRB will be undertaken at the closest scheduled meeting of the IRB.

XV. Procedure for Reporting Unanticipated Problems Involving Risks

In the event of any unanticipated problems or serious noncompliance with protocols that involve risks to human subjects or others, the investigator or research subject must promptly report the matter to the IRB Chair *and* the Office of the Provost.

XVI. Certain Categories of Research

In research involving prisoners, pregnant women, fetuses, neonates and children, the IRB will follow the guidelines established in the Code of Federal Regulations at 45 CFR 46, and any future amendments.

XVII. Additional Issues to be Treated on a Case-by-Case Basis

A. LONGITUDINAL RESEARCH: The IRB may request the investigator in any project or activity extending over a period of time exceeding one year to obtain consent from subjects on a yearly basis.

B. CONCEALMENT OR DECEPTION:

1. The IRB recognizes that it may be impossible to study some

psychological processes without withholding information about the true object of the study
or deliberately misleading the subjects. However, for any research project or activity that involves the use of deception or concealment, the investigator must demonstrate to the satisfaction of the IRB that:

a. the potential benefits of the experiment exceed the risks to the subjects of using deception or concealment;

b. alternative procedures avoiding concealment or deception are not available; and

c. the investigator has considered the effects on the subjects of the way that the withholding of information or deliberate deception will be received.

2. Normally, it is expected that those who have been subjects in a project involving concealment or deception be so informed at the completion of the subject's participation in the study. In studies where the subjects are aware that they have taken part in an investigation in which the data have been collected using concealment or deception, the IRB may require the investigator to:

a. provide the subjects with any necessary information to complete their understanding of the nature of the research; and

b. discuss with the subjects their experience of the research in order to monitor any unforeseen negative effects or misconceptions.

C. OBSERVATIONAL RESEARCH:

1. Studies based upon observation must respect the privacy and psychological well-being of the individuals studied. The IRB may require that those observed give their consent to being observed and be made aware that they may be observed by strangers (unless the research project entails deception or concealment as a material condition of the project, in which case the investigator is required to comply with the guidelines set forth in Section XVI.B and C).

2. Additionally, the IRB may require assurance that particular account is taken of local cultural values and of the possibility of intruding upon the privacy of individuals who, even while in a normally public space, may believe they are unobserved.

XVIII. Audio and Video Recording

Audio and video recording of human subjects is a form of research that does not

protect the anonymity of the subject. Therefore, certain precautions must be taken whether or not the project is exempted from review under Section V:

1. Subjects should be informed that they will be recorded by audio or video for research purposes only. That is, the investigator and/or department may not use these recordings for purposes other than those specified in the research project.

2. The recording must be stored in a password-protected folder on a password-protected computer.

    a. In some cases, the IRB may require encryption of the file, as a further protection.

    b. In some cases, the IRB may prohibit use of recording devices that are connected to the Internet (e.g., cell phones, laptops). Such recordings may not be stored on devices connected to the Internet until after the appropriate password-protection/ encryption has taken place.

3. Only the investigator and, where appropriate, the investigator's advisor(s) or supervisor(s) may listen to or view the recording.

4. The recording must be destroyed or erased as soon as possible (e.g., upon transcription), but in no case later than the completion of the project.