Institutional Review Board (IRB) Guidelines

I. The Institution Authority Under Which the IRB is Established and Empowered

Policy

The Institution Authority under which this IRB is established and empowered is Benedictine College. The authorized institutional official for this IRB is the Dean of the College.

II. The Purpose of the Institutional Review Board (IRB)

Policy

The purpose of this IRB is to protect the rights, well-being, and personal privacy of individuals; to assure a favorable climate for the conduct of scientific inquiry; and to protect the interests of Benedictine College.

The IRB will ensure that all requirements of Title 45, Part 46, of the Code of Federal Regulations (45 CFR 46) will be met for all human subject research regardless of sponsorship. 45 CFR 46 is the set of regulations under which the Benedictine College IRB operates. Regardless of source, no funds for which this Assurance applies may be expended for research involving human subjects unless the requirements of this Assurance have been satisfied.

The Policy and Procedures manual provides the framework for the ethical and scientifically sound conduct of human research. This manual will be reviewed by the IRB committee annually and updated to reflect current policies and procedures.

III. The authority of the IRB

This Policy applies to all research involving human subjects, and all other activities which even in part involve such research, regardless of sponsorship, if one or more of the following apply:

1. The research is sponsored by this institution, or
2. The research is conducted by or under the direction of any employee or agent of this institution in connection with his or her institutional responsibilities, or
3. The research is conducted by or under the direction of any employee or agent of this institution using any property or facility of this institution, or
4. The research involves the use of this institution's non-public information to identify or contact human research subjects or prospective subjects.

The term, "research" means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition may be funded or unfunded, or may be conducted as a component of another program not usually considered research. For example, demonstration and service programs may include evaluation components, which constitute research activities under this definition.

Precedent and practice have established the principle that certain kinds of activities that might be called "human subjects research" do not require review for the protection of human subjects. The following kinds of activities do not require such review: (a) accepted and established service relationships between professionals and clients where the activity is designed solely to meet the needs of the client; (b) research using only historical documents; and (c) research using only archaeological materials or other historical or pre-historical artifacts. Pilot studies, pre-tests, and other "preliminary" investigations are considered research, and must be reviewed unless they fall into one of the excluded categories listed above.

Classroom activities may include instructing students in research methodologies and techniques. If the sole purpose of the activity is to teach students research techniques or methodology and not to develop or contribute to generalizable knowledge, it is not considered to be research. However, if students will practice research methodologies on human beings, they should be instructed in the ethical conduct of such activities and should be advised to obtain informed consent from their practice subjects.

Quality improvement and quality assurance activities conducted solely for the intent of maintaining or improving quality of services provided by an institution, likewise, are not considered research activities. However, if the data collected are generalizable and are to be shared outside of the institution through discussion, presentation, or publication, the activity qualifies as research. Sometimes, data from a quality improvement or quality assurance activity become of interest to the external community after they have been analyzed. In these cases, the research use of the data collected for another purpose must be reviewed.

IV. Membership of the IRB

The IRB shall consist of at least five regular voting members of varying backgrounds. In order to promote complete and adequate review of research activities commonly conducted at Benedictine College, members of the IRB shall be appointed with consideration of expertise, race, gender, cultural background, and sensitivity to community attitudes.

There shall be at least one member whose primary concerns are in scientific areas relevant to research reviewed by the IRB. There shall also be at least one member whose primary concerns are in nonscientific areas. Finally, there shall be one member who has no affiliation with Benedictine College, and who is not part of the immediate family of a person who is affiliated with the College. This individual should be knowledgeable about the local community, and invulnerable to intimidation by the other members of the IRB or by College administrators. Consideration should be given to those who are able to speak on behalf of communities from which Benedictine College research subjects are likely to be drawn.

The IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond that possessed by the membership of the IRB. These are not voting members of the IRB, but contribute only through their consultation.

The Chair of the IRB is appointed by the Dean of the College. The Chair serves for a renewable three-year term, conducts the monthly meetings of the IRB, develops IRB policy in collaboration with the Board, and serves as the point of contact for applicants. The Chair, as do all other IRB members, recuses himself or herself from consideration and voting on projects in which he or she has a conflicting interest.

V. Recruitment and Term of Service of IRB Members

Regular IRB members and the Chair are expected to commit to a 3-year term and will be appointed on a rotating basis to ensure continuity and, during that time, to fulfill certain duties. These duties will be described prior to appointment and each IRB member is expected to fully understand the duties of IRB members prior to accepting appointment as an IRB member.

IRB members are recruited by the Dean of the College and the IRB Chair and serve for a three-year renewable term. IRB membership is staggered so that the board always has more experienced members serving to advise newer members. Board members are expected to attend once-monthly meetings and provide written documentation of their review of assigned research project applications. Board members may be asked to resign if they are unable or unwilling to meet their attendance and project application review responsibilities. When replacement is called for, the IRB Chair works to ensure continued diversity while at the same time maintaining standards of knowledge and experience necessary to adequately and fairly evaluate applications for human participant research.

VI. Training of Board Members

New members of the IRB receive a copy of the IRB's Policies and Procedures, the *Instructions for Submitting Applications to the Benedictine College IRB*, all other Benedictine College IRB documents, a copy of the *Belmont Report*, and a copy of *45 CFR 46, Protection of Human Subjects*. Members are also given a copy of the OHRP video, *PROTECTING HUMAN SUBJECTS*.

Members are encouraged to attend IRB-relevant workshops; Benedictine College will support such activities to the extent possible and as appropriate to the responsibilities of members and staff. In order to assist new members to understand the review process, the IRB Chair also provides sample applications and a suggested model to use when reviewing applications to facilitate new members' familiarization with the review process. Training and continuing education shall be documented and added to the records of the IRB.

VII. Conflict of Interest (CoI)

Department of Health and Human Services regulations at 45 CFR 46.107(e) stipulate that no Institutional Review Board (IRB) member may participate in the IRB’s initial or continuing review of research in which the member has a conflicting interest, except to provide information requested by the IRB. A conflict of interest exists when the member is involved as an investigator on the research, is listed as a supervising faculty member, or possesses a professional association or significant financial interest with potential to bias the design, conduct, reporting or reviewing of the research.

Members of the IRB must disclose potential conflicts of interest with research submitted for review, and must exempt themselves from the meeting room when the IRB reviews research in which they have a conflicting interest.

VIII. Liability

See Appendix A.

IX. Distribution of Materials

All complete applications will be submitted to the IRB Chair. If a submission meets expedited review criteria, the review will be performed as described in section XIII (Expedited Review). All other applications will be placed on the agenda for the next meeting of the full IRB. A complete application must be received at least five business days prior to an upcoming meeting of the full IRB in order to be reviewed at that meeting.

Copies of application materials for consideration at a meeting will be distributed to all IRB members at least three days prior to that meeting. Each member of the IRB will receive a copy of the initial application material. Consultants will receive only copies of material that pertain to their requested input.

X. IRB Meeting Administration

The IRB will meet on the last working Thursday of each month during the academic year. Except when an expedited review procedure is used, the IRB will review proposed research at convened meetings at which a majority of the voting members are present, including at least one member whose primary concerns are in nonscientific areas and one member whose primary concerns are in scientific areas.

At least three working days prior to each meeting, all voting members will receive a copy of the meeting agenda and a complete copy of each application submitted for review, including appendices. The agenda will remind members to declare any potential conflict of interest they may have with the research scheduled for review.

Prior to the meeting, each member will complete an Evaluation Form for Reviewers for each application submitted for review. In order for research to be approved by the Board, it must receive the approval of a majority of those members present at the meeting.

In accordance with 45 CFR 46.115(a)(2), "Minutes of IRB meetings… shall be in sufficient detail to show attendance at the meeting; 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 controverted issues and their resolution."

Therefore, the minutes must include the following:

1. the names of those present at the meeting;

2. any conflicts of interest and recusals;

3. the title of each research application discussed at the meeting, actions taken for each, and details of all votes, including the number voting for, against, and abstaining;

4. the reason for approving, requiring modifications in, or disapproving research; and

5. a summary of the discussion of controversial issues and the resolution of those issues.

A copy of the minutes will be presented to the members for approval at the next meeting. Corrections will be made by the IRB Chair or designee and the Chair will sign and date a final copy of the minutes, to be filed with the IRB's records.

XI. Research submission requirements

There are two kinds of IRB review: the *initial review* occurs when a research application is first submitted for approval, before any data has been collected. All approved research is required to also undergo *continuing review* on at least an annual basis. The submission requirements for each type of review are as follows:

Submission Requirements for Initial Review

Applications are submitted using the IRB Application for Project Approval. The form is available from the IRB Chair, the office of the Dean of the College, or at campus.benedictine.edu/irb.

Part I: The IRB application consists of four pages (a face page, a checklist page, a description page, and an abstract page).

Part II: Appendices should also be submitted with the application. Appendices contain supplementary information regarding the application, which usually include (but are not limited to) a copy of the written Informed Consent form (if applicable) to be used in the conduct of the research, and copies of any additional supplementary materials (surveys, questionnaires, recruiting materials, etc.) that will be used in the conduct of the research. The Principal Investigator (PI) should feel free to include any materials that (s)he believes will assist the committee in evaluating the application.

Submission Requirements for Continuing Review

During the approval period, investigators must submit documentation to inform the IRB about changes in the status of the study including, but not necessarily limited to: reports of serious or unexpected adverse events, change to the status of Principal Investigator or other researchers, and revisions and/or amendments to the research protocol.

Approximately thirty days prior to the IRB approval expiration date, the PI will receive a notice from the IRB requesting submission of a completed Project Status Report. Research not reapproved by the anniversary date will be designated as Inactive and approval will be withdrawn. Researchers who have completed their research will be asked to indicate that on the same form so that so that their research can be designated Inactive.

The two-page Project Status Report requires that researchers provide information regarding project status, withdrawals and complaints, summary of findings, adverse events, risks and benefits, and a copy of the investigator's current consent form.

XII. Criteria for Initial IRB Approval

By law, the IRB can only grant approval to projects that satisfy certain requirements. PIs who anticipate evaluation on these requirements and attend to them in their applications will encounter markedly fewer problems during the IRB approval process. The requirements for approval (as paraphrased from the Code of Federal Regulations), include the following:

Risks to subjects are minimized. This is the first and foremost concern in the review of application by the IRB. What potential risks, stresses, or discomforts (if any) will be incurred by participation in this project? Has the PI taken steps in the design or procedures of the study to reduce the possibility of these risks or discomforts?

Risks to subjects are reasonable in relation to anticipated benefits. Do the benefits, if any, to be derived from this research outweigh the risks posed by this research to the subjects? In evaluating risks and benefits, the IRB will consider only those risks and benefits that may result from the research. The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

Selection of subjects is equitable. In making this assessment, the IRB should take into account the purposes of the research, and the setting in which the research will be conducted. The IRB should be especially cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

Informed consent will be sought from each subject (or the subject's legal representative) and documented in a manner consistent with 45 CFR 46.116 and 46.117. Subjects must be fully informed of the risks and benefits of participation in the research and of their basic rights in participating (e.g., withdrawal without penalty). All of the appropriate aspects of informed consent must be included; if not, the omissions must have been adequately justified (see Deception Research). If audio or video taping is part of the research procedure the participants must be given the option of not being taped or having taping stopped at any time. A copy of the informed consent form must be given to the person signing the form. An IRB may waive the requirement for the investigator to obtain a signed Informed Consent form if it finds either:

1. that the only record 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. In that case, each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.
2. that the research presents no more than minimal risk of harm to subjects, and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the researcher to provide subjects with a written statement regarding the research.

Adequate provisions for monitoring data to ensure the safety of subjects. When appropriate, the research plan must make adequate provision for monitoring the data collected to ensure the safety of subjects. This includes the monitoring of data in the case that individual subjects are identified as being at risk for medical or psychological problems.

Adequate provisions to protect the privacy of subjects and maintain confidentiality of the data. To what degree are subjects' responses protected with respect to confidentiality and anonymity? Will subjects' names be associated with their data? Who will have access to materials (e.g., data sheets, audio recordings or videotapes) through which subjects might be identified? Will response sheets be kept in a safe place? What are the plans for disposition of materials through which subjects might be identified when the study is finished?

Appropriate additional safeguards for subjects who are especially vulnerable. Have adequate additional provisions been made to protect the rights of those subjects who might be especially vulnerable to coercion or undue influence? Federal law specifically mentions children, those with physical illness or psychological disorders, or those who are economically or educationally disadvantaged, as being members of this class. Are there any circumstances in the proposed research under which subjects might feel coerced to participate?

IRB Policy on Experiments Involving Deception of Subjects

The IRB acknowledges that it is occasionally necessary to use deception in a research design in order to protect or strengthen the scientific integrity of an investigation. However, because participants are deliberately misinformed concerning the actual purposes or procedures of the research in such cases, the IRB considers such research to not meet the general requirement for informed consent as stated in the Code of Federal Regulations (45 CFR 46.116.a.1). This part of the law delineates the basic elements of informed consent, and states that in seeking informed consent, the following information shall be provided to each subject:

...an explanation of the purposes of the research and...a description of the procedures to be followed...

Please note that federal law does not necessarily restrict the concept of "informed consent" to the consent form that subjects sign at the start of a study. The Code of Federal Regulations, however, does provide for instances in which informed consent can be altered or waived. Under this federal law (45 CFR 46.116.d.1-4), this can occur only if all of the following conditions are met: (1) The research involves no more than minimal risk to the subjects; (2) The waiver or alteration [of consent] will not adversely affect the rights and welfare of the subjects; (3) The research could not practicably be carried out without the waiver or alteration [of consent]; and (4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Therefore, investigators proposing research to the IRB in which participants are misinformed concerning the study's procedures or purposes during the course of data collection must address how their applications meet these conditions. This requirement may be met in a number of ways. However, in order to address these issues and facilitate review of such applications, the IRB recommends that applications for research involving deception include the following elements:

a. Justification for the Deception. The justification should address condition 3 listed above. Investigators should provide specific and cogent reasons why fully informed consent is not appropriate for this study, and/or the manner in which fully informed consent threatens the integrity of the research.

b. Explicit Statement of No Risk/Minimal Risk. This statement should address conditions 1 and 2. Investigators should provide a statement affirming that the proposed research presents no more than minimal risk to the participants.

Federal law (45 CFR 46.102.g) defines "minimal risk" as follows:

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

c. Description of Debriefing. Procedures for debriefing should address condition 4, listed above. Subjects should be informed that deception took place, and should be appropriately informed as to the actual purpose of the research, and the role of the deception in protecting the integrity of the research. Finally, subjects should also be reminded of their right to withdraw from the study at this time; this can be accomplished through a range of various procedures, extending from the inclusion of a simple statement to that effect in the debriefing, to having the participant sign a second informed consent form at the end of the study.

It is noted that the text of the Code of Federal Regulations allows for the possibility that circumstances may arise in which debriefing may not be judged to be "appropriate." The IRB allows for this possibility, but PIs should note that requests to omit such debriefing in research involving deception should be strongly justified.

Although applications involving deception must meet the conditions for alteration of informed consent, signed informed consent is still required to meet the requirements described in 45 CFR 46.116.a.2-8. Note that the informed consent form may not contain misinformation, may not be used as part of the deception, and may not be used as a means for manipulating subjects' behavior.

XIII. Expedited Review

Due to the confusion that the Exempt category 45 CFR 46.101 (b) is likely to cause researchers, and to the relatively low volume of research conducted at Benedictine College, this IRB uses only Expedited and Full Board Review. Projects that would have been included as Exempt are now given Expedited review.

Research projects that meet the criteria for Expedited review must fall under those designated as exempt in the Federal Regulations or a set of descriptions found in a list of categories published by the Office for Human Research Protections, effective as of November 9, 1998. Even if the research activities fall under one of the categories for Expedited review, the research procedures must present no more than minimal risk to participants, or must represent minor changes in previously approved research.

Federal law (45 CFR 46.102.g) defines "minimal risk" as follows:

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

An expedited review procedure consists of a review of research involving human subjects by the IRB Chair or by one or more experienced reviewers designated by the Chair from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB, except that they may not disapprove the research. A research activity may be disapproved only after review by the full IRB. When a proposal is approved using the expedited procedure, that information must be provided to the full Board at its next meeting and must be reflected in the minutes.

The expedited category list below includes those research activities identified as "exempt" in the Federal Regulations:

46.101 (b) (1)
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 on the comparison among instructional techniques, curricula, or classroom management methods.

The purpose of this category is to exempt research on educational practices, in an educational setting. This category does not extend to research conducted in a school setting but not related to the instruction in that institution. For example, an evaluation of two methods of fourth grade classroom instruction in a local school district would qualify as exempt research. A sociometric survey of children's preferences for playmates in the same school, involving the same children, would not qualify as exempt research. As the example indicates, research on minor students can be exempt if it is educational research in the sense intended here.

46.101 (b) (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 the human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the 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."

"Existing" means that the data are "on the shelf" at the time the researcher develops a proposal for their use. Use of data not already on the shelf is not regarded as belonging to this category. State and federal laws preclude the use of certain kinds of existing data (including health care information, records of drug and alcohol treatment, and records of psychiatric care) from use by researchers without human subjects review, regardless of whether they are "existing" or recorded by the investigator in such a way that subjects cannot be identified.

46.101 (b) (3)
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 paragraph (b)(2) of this section, 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.

46.101 (b) (4)
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.

46.101 (b) (5)
Research and demonstration projects which are conducted by or subject to the approval of the 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.

The "department or agency heads" referred to are federal, not state, local, or university. This category of exempt research refers to activities sponsored by federal agencies to evaluate their own benefit or service programs.

46.101 (b) (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 of and for a use 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.

The expedited category list below includes those identified as "expedited" in the Federal Regulations; only those categories of research that are likely to be conducted by researchers at Benedictine College. A complete list of categories can be found at 46 FR 8392, and is provided as an addendum to 45 CFR 46.

(1) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, nonpregnant adults who weigh at least 110 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.

(2) Prospective collection of biological specimens for research purposes by noninvasive means. Examples:

(a) hair and nail clippings in a non-disfiguring manner;

(d) excreta and external secretions (including sweat);

(e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;

(i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings.

(3) Recording of data form subjects 18 years of age and older, using noninvasive procedures routinely employed in clinical practice.

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) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

(4) The study of existing data, documents, records, pathological specimens, or diagnostic specimens.

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

(6) 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 where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects.

(7) 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.

The following categories of research are not eligible for expedited review, and always require review by the full IRB: 1) research involving prisoners; 2) research on minor children unless the research qualifies as educational research in the sense of 46.101 (b) (1), above, or where the research does not involve direct interaction with the child, and 3) research using non-public records.

XIV. Categories of Action

As a result of its review, the IRB may decide to approve or disapprove the proposed research activity, or to specify modifications required to secure IRB approval of the research activity. Except when the expedited review procedure is used, these actions will be taken by a vote of a majority of the members present, except for those members present but unable to vote in accordance with the IRB's conflict of interest policies. When reviewed via expedited review, the Chair can take any of the following actions except to disapprove a study.

The IRB may make one of the following determinations as a result of its review of research submitted for initial review or for continuing review:

A. **Approval:** The protocol and accompanying documents are approved as submitted. Approval will commence on the day the study is approved by the full IRB (or Chair or designee, in the case of expedited review) and expire within one year of the approval date.

The IRB approval and expiration dates must be included on all informed consent/assent forms.

Approvals are always considered conditional. The conditions for continued approval, and the time frame (if any) within which they must be met will be clearly stated in the approval letter. If the conditions of the approval are not met, approval may be withdrawn.

B. **Contingent Approval:** This designation is reserved for projects whose proposals require minor changes or clarification prior to approval. Researchers are informed in the Contingent Approval Letter of the contingencies named by the Board. Researchers are instructed that they may not begin data collection until they have responded in writing to the contingencies and have received final approval. The IRB Chair has the authority to determine whether the contingencies have been met; the researcher's response need not be reviewed by the full IRB. If the researcher fails to respond within 90 days, he or she must begin the application process anew.

In the case of contingent approval, the expiration date of IRB approval will be based on the anniversary date of the initial IRB review. However, subjects may not be recruited into the study until final approval has been issued.

C. **No Decision:** This designation is reserved for projects whose proposals lack clarity or are missing significant required information or documents such as a consent form, questionnaire, or complete application form. Researchers are informed in the No Decision Letter of the concerns named by the Board, and are given the opportunity to respond in writing to those concerns in time for the response to be considered at the next meeting of the full IRB. If the researcher fails to respond within 90 days, he or she must begin the application process anew.

D. **Disapproval:** This designation is reserved for projects for which the IRB believes there may be unacceptable risk to the participants in the research. Researchers are informed in the Disapproval Letter of the concerns named by the Board, and are given the opportunity to respond in writing to those concerns in time for the response to be considered at the next meeting of the full IRB. If the researcher fails to respond within 90 days, he or she must begin the application process anew.

Notification to Investigators

The IRB Chair will notify the Principal Investigator in writing of the IRB's decision within one week. If the research is being conducted by students, the lead student researcher will also be notified in writing. In the case of IRB approval, the notification will include the following instructions to researchers:

1. You must provide the IRB with an annual status report to maintain approval.
2. Any significant change in the experimental procedure as described must be reviewed by the IRB prior to altering the research.
3. Notify the IRB about any new investigators not named in the original application.
4. Any injury to a subject because of the research procedure must be reported to the IRB immediately.
5. When signed consent documents are required, the Principal Investigator must retain the signed consent documents for at least three years past completion of the research activity. If you use a signed Informed Consent form, provide a copy to subjects at the time of consent.
6. IRB approval and expiration dates must be included on all Informed Consent forms.
7. If this is funded research, keep a copy of this approval letter with your proposal/grant file.

XV. Review by institution

Research covered by this policy that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by the IRB.

XVI. Continuing Review

The IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year. The IRB's continuing review of research is conducted through a two-page Project Status Report in which the investigator must provide information regarding project status, withdrawals and complaints, summary of findings, adverse events, risks and benefits, and a copy of the investigator's current consent form.

Principal Investigators should be notified no less than 30 days prior to their approval expiration date, and should submit a completed Project Status Report no less than five working days prior to the next meeting of the full IRB in order to request approval for an additional twelve-month period. A protocol that was originally reviewed using the expedited review procedure may receive its continuing review on an expedited basis. Additionally, a full Board review protocol, that had no changes during the previous period, or which has not been awarded funding, or which remains open only to data analysis may be reviewed using an expedited review.

If the Project Status Report is satisfactory, the IRB sends a letter to the PI that indicates approval for another twelve-month period, based upon the approval anniversary date. As an outcome of continuing review, the IRB may require that the research be modified or halted altogether. The IRB may need to impose special precautions or relax special requirements it had previously imposed on the research protocol.

The IRB may determine that certain projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review. The IRB may randomly select projects, or may decide that complex projects involving unusual levels or types of risk to subjects should receive an extra measure of scrutiny. Also, the IRB may engage in full Board discussion of continued approval for projects conducted by investigators who previously have failed to comply with the requirements of the HHS regulations or the requirements or determinations of the IRB. The IRB may seek information from research participants where concern about possible material changes occurring without IRB approval have been raised based upon information provided in continuing review reports or from other sources.

Serious or Unexpected Adverse Events

Subject safety is of the greatest importance for both the individual subject and the goals of the research. If the event is serious or unexpected, prompt reporting to the IRB Chair is mandatory. All Unexpected Adverse Events should be reported within 24 hours.

Reports will be reviewed by the IRB Chair. If the Chair determines that action may be needed to protect the safety of research subjects due to the nature or frequency of reported adverse events, he/she may take such action or utilize the full IRB to review the adverse events and study in question to determine action, if any, by the IRB. Summaries of all such events will be presented as soon as possible at a convened meeting.

Amendments

Changes in approved research, during the period for which approval has already been given, may not be initiated without prior IRB review (full or expedited review, as appropriate) and approval, except where necessary to eliminate apparent immediate hazards to human subjects.

Investigators must submit requests for changes to the IRB in writing. Upon receipt of the protocol change, the Chair will determine if the revision meets the criteria for minimal risk. If the change represents more than a minimal risk to subjects, it must be reviewed and approved by the full IRB at a convened meeting. Minor changes, involving no more than minimal risk to the subject, will be reviewed by the expedited review procedure.

Other Information and Reports

It is the responsibility of the IRB staff and members to act on information or reports received from any source that indicate a study being conducted at any facility under the jurisdiction of the IRB could adversely affect the rights and welfare of research subjects.

All credible reports of inappropriate involvement of human subjects in research must be investigated by the IRB. The results of the investigation will be reported to the appropriate institutional official(s). Regulatory authorities or Sponsors may also be notified. Such reports of noncompliance may come from any source including IRB members, Investigators, subjects, institutional personnel, the media, anonymous sources or the public.

The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB policies, is not in compliance with federal regulations, or

has been associated with unexpected serious harm to subjects. All such suspension and or terminations will be reported by the IRB chair to the Dean of the College within one week.

Authority to Suspend or Terminate Approval of a Study

The IRB has authority to suspend or terminate 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. Any suspension or termination or approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, and appropriate institutional officials, and the department or agency head.

Flow path for the IRB's Processing of Complaints and Allegations Against Researchers

I. Complaint/Allegation is received by IRB Chair.

A. Receipt of the complaint is noted to the IRB members and the Dean of the College.

B. Acknowledgement of receipt of complaint is sent to complainant, with an indication that the matter has been taken under inquiry.

II. The complaint is checked against the existence of any approved IRB protocol.

A. If no approved protocol exists, the Dean of the College is notified of the matter as a possible instance of noncompliance. The PI, student researcher, and the chair of the department from which the project originated are advised by the IRB Chair of this noncompliance, and the Dean of the College shall make formal allegations of academic misconduct (in the case of a student) or scholarly/scientific misconduct (in the case of a faculty member).

B. If an approved protocol exists, proceed to step III below.

III. The complaint is checked against the existing IRB protocol.

A. If the procedures carried out by the researcher were not approved by IRB, or if there is a violation of the approved protocol, then the complaint is forwarded to the Dean of the College as an instance of noncompliance. The PI, student researcher, and the chair of the department from which the project originated are advised by the IRB Chair of this noncompliance, and the Dean of the College shall make formal allegations of academic misconduct (in the case of a student) or scholarly/scientific misconduct (in the case of a faculty member).

B. If there is no obvious violation of the approved protocol, proceed to step IV.

IV. By definition, in reaching this step it should have been determined that the project had been approved by the IRB, and that there is no obvious violation of the approved protocol.

A. The IRB Chair sends a copy of the complaint to the PI, student researcher, and chair of the department from which the project originated. The PI and student researcher are directed to respond to the charges in writing within 5 days.

XVII. IRB Records

The IRB shall prepare and maintain adequate documentation of IRB activities, including the following:

A. Copies of all research proposals reviewed, along with their appendices;
B. Project Status Reports submitted by investigators;
C. Reports of injuries to subjects;
D. Minutes of IRB meetings, which include attendance at the meetings, actions taken by the IRB, the vote on these actions, including 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 controverted issues and their resolution;
E. Records of continuing review activities;
F. Copies of all correspondence between the IRB and investigators;
G. A list of IRB members, identified by name, earned degrees, representative capacity, indications of experience sufficient to describe each member's chief anticipated contributions to IRB deliberations, and any relationship of each member to the institution;
H. Written procedures for the IRB; and
I. Statements of significant new findings provided to subjects.

The records required by this policy shall be retained for at least three years, and records relating to research which is conducted shall be retained for at least three years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the sponsor, funding agency, regulatory agencies and institutional auditors at reasonable times and in a reasonable manner.