INSTITUTIONAL REVIEW BOARD (IRB) HANDBOOK

Revised and Updated August 2017

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The *Institutional Review Board (IRB) Handbook* is designed to assist students, faculty, and staff who are seeking approval to conduct research while affiliated with Ashford University. This includes all research involving human and vertebrate participants (including but not limited to all mammals, reptiles, birds, fish, etc.), dissertations, and other related research projects.

Definitions related to the IRB process are provided in Appendix A. All students are encouraged to consult the chair of the IRB Committee with any questions.

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SECTION I: PRINCIPLES OF RESEARCH INVOLVING HUMAN PARTICIPANTS

Ashford University is committed to the highest ethical standards in the conduct of research. For projects involving humans as participants, Ashford University is guided by the ethical principles set forth in the Declaration of Helsinki, the National Commission for the Protection of Human Participants of Biomedical and Behavioral Research's Ethical Principles, and Guidelines for the Protection of Human Participants of Research: The Belmont Report. In addition, Ashford University is committed to ensuring that all human participant research, regardless of funding source, follows the requirements set forth in Title 45, Part 46 of the Code of Federal Regulations (https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html).

The IRB Policies and Procedures apply to all research involving human and vertebrate participants (including but not limited to all mammals, reptiles, birds, fish, etc.), funded or non-funded, sponsored or not sponsored, and carried out by Ashford University students, faculty, and staff, on or off campus.

STATEMENT OF ETHICAL PRINCIPLES

The following broad principles are the basis for Ashford University policy concerning review of research involving humans:

- Whereas the participation of humans in research projects may raise fundamental ethical and civil rights questions, all such research, funded and unfunded projects, sponsored and not sponsored, which is carried out by Ashford University students, faculty, and staff, on or off campus, shall be covered by the Ashford University Institutional Review Board (hereinafter referred to as IRB) for the Protection of Human Participants in Research Policies and Procedures covered by this document.
- All activities involving human participants must provide for the rights, safety, health, and welfare of each individual participant.
- The direct or potential benefit to the participant and the importance of the knowledge gained must outweigh any inherent risk to the individual.
- Participation in research must be voluntary and informed consent procedures must conform to the IRB Policies and Procedures.
- An individual does not abdicate any rights by consenting to be a research participant. A participant has the right to refuse to participate or may withdraw from research at any time without penalty or loss of benefits to which the participant would otherwise be entitled.
- Safeguarding information about an individual that has been obtained in the course of an

investigation is a primary obligation of the principal investigator.

- The primary responsibility for protection of human participants rests with the principal investigator and with support, approval, and monitoring by Ashford University as set forth in the IRB Policies and Procedures.

SECTION II: INSTITUTIONAL REVIEW BOARD GENERAL INFORMATION

The purpose of the Ashford University IRB is to ensure ethical research practices among its students, faculty, and staff. Individuals affiliated with Ashford University who are conducting research projects must receive approval from the Ashford University IRB before commencing the study.

MEMBERSHIP

The IRB shall have one chair and at least five members, including representatives from each of the four primary colleges (Forbes School of Business and Technology, College of Education, College of Health, Human Services, and Science, College of Liberal Arts), with varying backgrounds, to promote complete and adequate review of research activities. The Senior Vice President of Academic Affairs (SVPAA) in conjunction with the chair shall appoint members of the IRB. The chair is a voting member of the IRB and will be appointed by the SVPAA. The IRB shall be sufficiently qualified through the experience and expertise of its members; their diversity, including consideration of race, gender, and cultural backgrounds; sensitivity to issues such as community attitudes; and promoting respect for its advice and counsel in safeguarding the rights and welfare of human participants. Members must also possess the necessary professional competence to review specific institutional commitments and regulations, applicable law, and standards of professional conduct and practice. IRB members shall be full-time faculty and identified consultants with expertise in the field. Every effort will be made to ensure that the members of the IRB represent diverse backgrounds. The IRB shall not consist of members of a single profession or discipline. In order to comply with requirements for National Institute of Health or other funded proposals, the IRB may agree to add additional permanent or temporary members or consultants to review funded proposals.

TERMS OF SERVICE

The IRB chair shall be appointed by the SVPAA, and is a voting member of the IRB. Members of the IRB shall be appointed by a joint effort between the chair and the SVPAA for terms of service of two years. Members may serve consecutive terms as determined by the SVPAA. Terms start the first of appointment and end two years later.

TRAINING IN HUMAN PARTICIPANTS' PROTECTION

All IRB members, faculty, sponsors and primary investigators planning to submit or sponsor a proposal to the IRB are required to complete the NIH online training in human participant's protection, which can be accessed electronically at: http://phrp.nihtraining.com. A Completion Certificate, obtained at the conclusion of this training, must be included in the Request for Review and must not be older than three years, otherwise recertification will be required.

RESPONSIBILITIES OF IRB CHAIR

The chair shall:

- Schedule and lead all meetings of the IRB
- Notify members of meetings
- Assign cases for review as appropriate
- Arrange for subject matter experts as needed
- Ensure the timely disposition of all requests
- Appoint a secretary who will be responsible for meeting minutes and maintaining records

MEETING DATES AND TIMES

The IRB meetings are held when deemed necessary by the chair. Contact the IRB chair for a current schedule. The IRB chair may convene additional meetings as necessary to handle business. Members must be notified at least 72 hours in advance of any such meetings. The chair may cancel meetings when there are no proposals to be reviewed.

MEETING PROCEDURES

Evaluation Quorum

No risk or minimal risk proposals may be evaluated by a majority of the IRB, the IRB chair, or a committee member appointed by the chair. Whenever possible, the appointed committee member will have competence in the research area of the proposal. When moderate or higher risk proposals are considered, a majority of IRB members must evaluate the proposal prior to obtaining approval. The chair may appoint outside reviewers to evaluate a proposal as needed. Outside reviewers must have a doctorate from an accredited institution in a field related to the proposal, and submit a curriculum vitae (CV) and supporting documents to the chair. Members present may, by simple majority vote, defer agenda items if they believe requisite members of the IRB are not present.

Order of Business

The agenda for IRB meetings shall be determined by the chair, and may include the following:

- Review of and action on minutes of previous meetings.
- Old and new business related to IRB functioning.
- Review and discussion of, and action, on (a) new proposals (in order of submission), (b) continuing proposals, and (c) substantive changes to previously approved proposals.
- Other business.

Actions

Proposals shall be approved, approved with revisions, disapproved, or tabled until a specified future date by majority vote of those members present.

Closed Meetings

To preserve the autonomy of the IRB and its decisions, IRB meetings are typically closed, as long as such closure is not in conflict with 45 CFR Part 46 or other applicable Federal, State, or local law and regulations.

- Anyone may speak for or against a proposal, but remarks must be based only on the Criteria for Approval as stated for each criterion of the IRB paperwork.
    - The chair may limit the duration of comments or the number of speakers for and against a proposal to serve the best interest of committee functioning.
    - Written comments received by the chair prior to the meeting will be read into the minutes or distributed and appended to the minutes, insofar as they address the Criteria for Approval.
- The IRB chair may invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that represented by the regular IRB members.

Voting

Only IRB members may vote.

Conflict of Interest

IRB members, and persons speaking or submitting written comments, must declare any potential conflict(s) of interest in advance. Members may speak for, but may not vote on their own proposals, proposals of students they are sponsoring, or any proposal in which an IRB member is or is likely to be a participant. Written comments shall explicitly address any conflict of interest or its absence (in the event of a perceived conflict of interest that could be addressed for clarity).

Minutes

The secretary of the IRB will keep minutes of the proceedings. The minutes must show attendance; actions taken by 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 controversial issues and their resolution.

IRB RECORDS

The secretary of the IRB shall keep the following documentation of IRB activities on file for at least three years:

- Written procedures for the IRB.
- A list of IRB members including name, earned degrees, representative capacity, indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations, and employment or other relationship between each member and the institution.
- Minutes of IRB meetings.
- Copies of all proposals received, scientific evaluations (if any) that accompany the proposals, copies of all internal and external correspondence related to each submitted proposal, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to participants (if any).
- Copies of all correspondence between the IRB and the primary investigator for any study.
- Records of continuing review activities.
- Updating and maintaining the IRB repository
- Statements of significant new findings provided to participants as required by the consent documents.

SECTION III: SUBMISSION PROCEDURES

All proposals to conduct research must be submitted to the Ashford University IRB. If the research involves Ashford University students, faculty, or staff, approval from the college dean as well as the Office of Research and Creative Scholarship (ORCS) may be required. The investigator must obtain IRB approval before undertaking the research and beginning data collection, to do so without approval would constitute research misconduct. Following successful completion of NIH training, proposals must be submitted to the chair, or to a person appointed by the chair to receive proposals. As noted previously, all principal investigators submitting proposals must undergo training, and submit the appropriate documentation of successful training along with each proposal. Proposals should be submitted electronically in word .doc or .docx format, and sent to IRB@Ashford.edu.

CRITERIA FOR REVIEW (HHS §46.102 DEFINITIONS)

Research proposals submitted to the IRB are evaluated with respect to the safety and protection of subjects according to the following levels of risk or danger to study participants. The primary task of the IRB is to weigh the actual or potential risks posed to participants against the possible benefits of the proposed research to the scientific community.

1-No Risk

Research participants face no physical or psychological stressors. An example of a no risk study would be a proposal to collect and analyze existing data sources with no human subject interaction.

2-Minimal Risk

Minimal risk (most common) means that the probability and magnitude of harm or discomfort anticipated 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.

3-Moderate Risk

Research participants face moderate physical or psychological stressors beyond those encountered in daily life. The potential benefits of the research must outweigh potential risks to study participants.

4-High Risk

Research participants face severe physical or psychological stressors beyond those encountered in daily life, which may have sustained, lasting effects. The potential benefits of the research must outweigh potential risks to study participants.

LEVELS OF IRB REVIEW

Exempt Research

Although the category is called "exempt," this type of research does require IRB review and registration. The exempt registration process is much less rigorous than an expedited or full-committee review. To qualify, research must fall into six federally-defined exempt categories. These categories present the lowest amount of risk to potential subjects because they generally involve either collection of anonymous or publicly-available data, or conduct of the least potentially-harmful research experiments. Examples include the following:

- Anonymous surveys or interviews
- Passive observation of public behavior without collection of identifiers
- Retrospective chart reviews with no recording of identifiers
- Analyses of discarded pathological specimens without identifiers

Expedited Research

To qualify for an expedited review, research must be no more than minimal risk and fall into nine federally-defined expedited categories. These categories involve collection of samples and data in a manner that is not anonymous and that involves no more than minimal risk to subjects. Examples include the following:

- Surveys and interviews with collection of identifiers
- Collection of biological specimens (e.g., hair, saliva) for research by noninvasive means
- Collection of blood samples from healthy volunteers
- Studies of existing pathological specimens with identifiers

Full Board Research

Proposed human subject research that does not fall into either the exempt or expedited review categories must be submitted for full committee review. This is the most rigorous level of review and, accordingly, is used for research projects that present greater than minimal risk to subjects. The majority of biomedical protocols submitted to the IRB require full committee review. Examples include the following:

- Clinical investigations of drugs and devices
- Studies involving invasive medical procedures or diagnostics
- Longitudinal interviews about illegal behavior or drug abuse
- Treatment interventions for suicidal ideation and behavior

REGULATIONS AND REFERENCES

- Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research: DHHS 45 CFR 46.110
- Criteria for IRB approval of research: DHHS 45 CFR 46.111(a)(1-2)
- Code of Federal Regulations Title 21, Section 56.110: FDA 21 CFR 56.110
- Code of Federal Regulations Title 21, Section 56.111: FDA 21 CFR 56.111(a)(1-2)

DOCUMENTATION REQUIRED FOR IRB REVIEW

IRB Forms and sample documents are available on the Ashford University website: https://www.ashford.edu/about/institutional-review-board-forms. Submit electronic copies of the following to the IRB chair or appointed IRB representative:

- ORCS approval sheet (if using **any** Ashford data)
- Dean approval form/email (If using Ashford student data)
- If requesting exempt status (Appendix J)
- A Completed Research Proposal Application (Cover sheet in Appendix B)
- A Research Summary (Appendix C)
- Consent document (sample in Appendix G) and if minors are participants, assent document (sample in Appendix I).
- If applying for "No Risk" (sample in Appendix H)
- Copies of any and all data collection surveys or instruments
- Copies of approvals from any other IRB or proposed data collection site, such as a school or business
- All other relevant material

Researchers may not collect data or proceed with their research until they have received written IRB approval. Collecting data without IRB approval is research misconduct and may result in dismissal from the institution.

GENERAL CRITERIA FOR APPROVAL

The IRB uses eight review criteria when reviewing proposals:

1. Risks to participants are minimized. This is made possible in the following ways:
    - by using procedures that are consistent with sound research design;

- by not exposing participants to unnecessary risk; and
- by using procedures already being performed on the participants for diagnostic or treatment purposes, whenever appropriate.

2. Risks to participants are reasonable in relation to anticipated benefits and the importance of the knowledge that may reasonably be expected to result.

    - In evaluating risks and benefits, the IRB considers only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies participants would receive even if not participating in the research).
    - The IRB does not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as a research risk that falls within its purview.

3. Selection of participants is equitable.

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

4. Informed consent will be sought from each prospective participant or the participant's legally authorized representative.

    - Except as provided elsewhere in this policy, no investigator may involve a human being as a participant in research unless the investigator has obtained the legally effective informed consent of the participant or the participant's legally authorized representative.
    - An investigator must seek consent under circumstances that provide the prospective participant or the participant's representative sufficient opportunity to consider whether or not to participate and that minimizes the possibility of coercion or undue influence.
    - The information given to the participant or the representative must be in language understandable to the participant or the participant's representative.
    - No informed consent, whether oral or written, may include any exculpatory language through which the participant or the representative is made to waive or appear to waive any of the participant's legal rights, or releases or that appears to release the investigator, the sponsor, the institution or its agent from liability for

negligence.

5. Required elements of informed consent are present.
    - The IRB may waive or modify this requirement under certain circumstances. Any modification to informed consent procedures must be fully justified in writing.
6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants.
7. Whenever appropriate, there are provisions to protect the privacy of participants and to maintain the confidentiality of data.
8. When some or all of the participants are likely to be vulnerable to coercion or undue influence (e.g., children, prisoners, pregnant women, mentally disabled persons), additional safeguards have been included in the study to protect the rights and welfare of these participants.

MEETING WITH THE IRB

The IRB may request a Full Board Review of any proposal. In the case of a Full Board Review, the IRB will set up an additional meeting after reviewing the proposal. During this meeting, the researcher(s) is encouraged to present a brief overview of the proposed study. The IRB Committee may ask a variety of questions during this meeting. After all questions have been answered, the IRB Committee, will be asked to leave the meeting space so that a vote can take place. Within 24 hours one of the following decisions regarding the proposal will be made: "approved," "approved with specific changes," or "rejected," in which case suggestions for major revisions will be given to the researcher(s).

A meeting between the IRB Committee and the researcher(s) may be required in the case of a Full Board Review.

ACTIONS BY THE IRB

The primary investigator may proceed only after written notification of approval from the IRB. Proposals approved subject to revisions require that revisions and/or clarification be submitted in writing to the IRB chair. The IRB may give the chair authority to act on revisions.

Written notification of approval after revisions are made must be received by the primary investigator prior to proceeding with data collection.

No research proposal will be rejected until it has been reviewed in accordance with the full review procedures set forth in this document. If the IRB rejects a research proposal, a written statement of the reasons for its decision will be given to the principal investigator. The

investigator will have an opportunity to respond in person or in writing.

CONTINUING REVIEW

Federal regulations require reevaluation of approved research at intervals that are appropriate to the degree of risk. At the time of its initial review, the IRB will determine the renewal date. If the project is to continue past the expiration date, then the investigator must submit a Request for Renewal Form (Appendix D) to the IRB chair. The investigator must submit the Request for Renewal in time for review and approval by the one-year anniversary date of the previous approval. If an investigator has failed to provide continuing review information to the IRB or the IRB has not reviewed and approved a research study by the continuing review date specified by the IRB, then the research may not continue. Enrollment of new participants cannot occur after the expiration of IRB approval.

The IRB may require continuing review of any research at more frequent intervals than 12 months whenever the degree of risk justifies such review. Additionally, IRB has the authority to observe or have a third party observe the consent process and the research. Such individuals are required to comply with confidentiality standards governing the ongoing research.

CHANGES TO APPROVED RESEARCH

Minor changes in previously approved research that do not increase risk to participants during the period for which the research is approved need not be submitted for additional IRB approval. Any changes that affect the risks to participants must be approved by IRB prior to implementing the changes. In addition, the IRB must be notified of any changes in principal investigator(s) or faculty sponsorship. Investigators must submit changes in writing to the IRB chair on the Report of Change Form (Appendix E).

SECTION IV: DATA COLLECTION

This section is only applicable to those studies in which data is being collected. Data for any study may only commence **after** the primary investigator has been approved by the IRB. When conducting research, the participants must agree to be a part of the research and the privacy and security of their information must be ensured.

Researchers may not collect data or proceed with their research until they have received written IRB approval. Collecting data without IRB approval is research misconduct and may result in dismissal from the institution.

INFORMED CONSENT

A Consent Form signed by each participant (sample provided in Appendix G), or the parent/guardian of each participant, is normally required for protocols submitted for either expedited or full reviews. It is also required when participants include vulnerable populations.

For any study in which children up to 17 years (unless emancipated) will be participating, informed consent must be obtained from their parents/legal guardians (sample provided in Appendix H). Informed assent must be obtained from minor participants if they are between ages 7 to 17 (see sample provided in Appendix I). An assent form is a written document used to inform the child of the study using age-appropriate language so he/she can determine whether or not to participate in the research. An assent form is generally presented to children over six years of age. If the child is not yet able to read, procedures may be used to present the information verbally to obtain verbal assent. Certain studies may be exempt from the permission requirement (e.g., if the research is designed for conditions or for a participant population for which parental or guardian permission is not a reasonable requirement to protect the participants (e.g., neglected or abused children; Source 45 CFR 46.408). Proposals of research to be conducted in an educational or other institution must include a letter of approval from the school district, hospital, or other institution.

Informed consent or assent must be obtained **before** any data can be collected. The informed consent and/or assent document must contain the following elements:

- Identification of investigator's name, department, institution, status, mailing address, and telephone number. If the researcher is a student, the name, address, and telephone number of the faculty advisor must be included.
- A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the participant's participation, a description of the procedures to be followed, and identification of any procedures that are experimental. The informed consent form should tell the potential participant all s/he will encounter,

how long it will take, where it will take place, etc. It should be written at a reading level appropriate for the particular participant. Consent forms should provide a description of the types of questions to be asked (e.g., "In this study we are exploring whether some people are 'at their best' at different times of the day.We will be asking you questions about your daily activities, your personality, and some basic demographic characteristics, such as your age, gender, and race.")

- A description of any reasonably foreseeable risks or discomforts to the participant. The following risks, if foreseeable, must be thoroughly explained:
    - When sensitive questions are to be asked, either examples of the most sensitive questions or an explicit description of these questions should be given (e.g., "We will be asking you questions, the most sensitive of which might be: Have you ever considered committing suicide? Have you ever made yourself throw up after a meal? Do you enjoy looking at people of the same sex?")
    - When research gathers information about a participant's involvement in illegal activities and no Certificate of Confidentiality is held by the researcher, the researcher must provide a statement that questions regarding illegal activities will be asked as part of the research study. The researcher must state in the consent form that the possibility exists, although it is not probable, that the researcher's data could be subpoenaed and used against the participant.
    - Suspected child abuse/neglect: When applicable, a statement should be included in the consent form that the researcher may report to appropriate legal authorities known or suspected child abuse or neglect, and circumstances or conditions which might reasonably result in abuse or neglect that become apparent as a result of a parent's participation or their child's participation in a research study.
    - If the participant incurs or may incur expenses as a result of participating in the project (e.g., medical or transportation expenses), the researcher must clearly state whether the participant will be reimbursed for those expenses or if there will be no reimbursement for participating in the research.
    - In a situation where a participant could be injured while participating in a project, the researcher must clearly explain any limitations of liability on the part of the researcher.
- A description of any benefits to the participant or to others that may reasonably be expected from the research. The following benefits, if mentioned, must be accurately described:
    - Possible benefits to society: Societal benefits should not be overstated. There may

be no direct benefit to the participant, other than a sense of helping the public at large.

  - Payment of participants: Only include information on payment if payment is available. Any conditions for receiving the payment must be included in the consent form (e.g., if only partial payment will be made to a participant who withdraws from the study, the researcher must clearly explain the formula for partial payment). If payment is given to defray the incurred expense of participation, it must not be coercive in amount or method of distribution.

- A disclosure of appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the participant. For example, in drug studies the medication(s) may be available through a family doctor or clinic without the need to volunteer for the research activity.

- A statement describing the extent to which confidentiality of records identifying the participant will be maintained. Federal Regulations stipulate that, where appropriate, proposals should include adequate provisions to protect the privacy of participants and to maintaining the confidentiality of data. When a proposal does not explain if and how privacy will be maintained, participants cannot know the future status of their contributions to the study and so they cannot provide truly informed consent. The section on privacy and confidentiality should include the following statements:

  - Explaining how the participant's participation will either be known, kept confidential, or anonymous. Anonymity means that there is no way to identify an individual participant's responses. Confidentiality implies participants' identities are known, but will be protected by the investigator (to the best of his/her ability). For example, if participants sign a consent form and their names are tied to their responses through a master list of names and code numbers, and in addition the coded responses are kept in a secure location, the participants' responses may be considered confidential, but are not anonymous.

  - How individual privacy will be maintained in publications or presentations.

  - Explaining what the disposition of audio- or video-tapes will be at the conclusion of the study (e.g., destroyed, erased, given to participants, used for other purposes, such as advertising a product or procedure).

  - Explaining what the disposition of master lists (linking participants' names with data) will be at the conclusion of the study.

- For research involving more than minimal risk, an explanation as to whether any compensation will be given, whether medical treatments are available if injury occurs

and, if so, what they consist of, or where further information may be obtained. Note that the federal regulations (see CFR 46.102[g]) do not limit injury to "physical injury."

- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled, and that the participant has the right to refuse to answer questions.

- An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury to the participant. The name and telephone number of the IRB chairperson should be included should the potential participant wish to contact the IRB, should s/he have questions or concerns.

- All studies funded by federal agencies which require demographic information about gender and race/ethnicity must include the following statement: "This study is being funded by a federal agency which requires that data be collected in a form that may be analyzed for differences between men and women and races or ethnic groups."

When appropriate, one or more of the following elements of information shall also be provided to each participant:

- a statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant) which are currently unforeseeable;

- anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent;

- any additional costs to the participant that may result from participation in the research;

- the consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation;

- a statement that significant new findings developed during the course of the research which may relate to the participant's willingness to continue participation will be provided to the participant; and

- the approximate number of participants involved in the study.

An investigator shall seek such consent only under circumstances that provide the prospective participant or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to

the participant or the representative shall be in language understandable to the participant or the participant's representative.

No informed consent, whether oral or written, may include any exculpatory language through which the participant or the representative is made to waive or appear to waive any of the participant's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agent from liability for negligence.

The IRB may approve waiver of the requirement of a signed consent form in the following cases:

- The only record that links the participant to the research is the signed consent form, and the principal risk to the participant would be a breach of confidentiality. In this case, participants must be asked if they want to sign a consent form that links them to the research.
- The research presents no more than minimal risk of harm to the participants and the research involves no procedures for which written consent would be required outside of the research context. If the research involves more than "minimal risk," then no waiver or alteration of informed consent is allowed.
- The research could not practicably be carried out with the waiver or alteration

In these cases, the IRB may require the investigator to provide participants with information sheets to retain (e.g., an information letter that contains the information normally included in a consent form, but with no signature line).

CULTURAL CONSIDERATIONS

In some cultures, an investigator may enter a community to conduct research or approach prospective participants for their individual consent only after obtaining permission from a community leader, a council of elders, or another designated authority. Such customs must be respected. In no case, however, may the permission of a community leader or other authority substitute for individual informed consent. In some populations, the use of a number of local languages may complicate the communication of information to potential participants and the ability of an investigator to ensure that they truly understand it. Investigators should develop culturally appropriate ways to communicate information that is necessary for adherence to the standard required in the informed consent process. They should describe and justify in the research protocol the procedure they plan to use in communicating information to participants. When consent forms need to be translated into different languages, the IRB will need to see copies of those translated forms, along with evidence (through back translation) that the pertinent information has been included.