INSTITUTIONAL REVIEW BOARD (IRB) HANDBOOK

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The *Institutional Review Board (IRB) Handbook* is designed to assist students, faculty, and staff who are seeking approval to conduct human research while affiliated with Harding University. All 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

Harding University is committed to the highest ethical standards in the conduct of research. For projects involving humans as participants, Harding 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 Research: The Belmont Report. In addition, Harding 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.

The IRB Policies and Procedures apply to all research involving human participants, funded or non-funded, sponsored or not sponsored.

STATEMENT OF ETHICAL PRINCIPLES

The following broad principles are the basis for the Harding 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 Harding University students, faculty, and staff, shall be covered by the Harding 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 the protection of human participants rests with the principal investigator with support, approval, and monitoring by Harding University as set forth in the IRB Policies and Procedures.

SECTION II: INSTITUTIONAL REVIEW BOARD GENERAL INFORMATION

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

MEMBERSHIP

The IRB shall have one chair and at least six members, one of which is unaffiliated with Harding University, of the remaining members representatives from each, with varying backgrounds, to promote complete and adequate review of research activities. 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 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. All IRB members maintain active Human Subjects and IRB Member training certificates supported by the NIH and OHRP.

TERMS OF SERVICE

The IRB members (including the Chair) shall be appointed by the Vice-President for Academic Affairs (VPAA), and are voting members of the IRB. Terms start the first of the appointment and end upon termination by the VPAA.

TRAINING IN HUMAN PARTICIPANTS' PROTECTION

All IRB members, faculty, students, staff, sponsors, principal investigators, and supporting investigators planning to submit or sponsor a proposal to the IRB are required to complete relevant training certificate from the OHRP Human Research Protection Training course. A Completion Certificate, obtained at the conclusion of this training, must be included in the Request for IRB Review and must remain active through the entirety of the IRB review and approval, otherwise recertification will be required. More information on the process can be obtained by contacting the IRB at www.harding.edu/irb.

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; and
- 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 and attendance should be seen as mandatory.

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, an IRB meeting will be scheduled and a majority of the IRB members must evaluate the proposal prior to obtaining approval. The chair may appoint outside reviewers to evaluate a proposal as needed. Outside reviewers, except in legal matters, 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. For a vote to pass, a quorum must be achieved (at least 5 IRB Committee Members) a majority 'aye' vote must occur.

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 conditions, disapproved, or tabled until a specified future date by majority vote of those members present.

Class 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 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.

Meeting with the IRB

A meeting between the IRB and the faculty, staff, or student proposing a dissertation may be required only in cases of a Full Board Review, at the discretion of the IRB. The meeting, if required, will take place via teleconference. Exempt and Expedited Reviews do not necessitate that the PI meet with the Board. In cases of an Exempt or Expedited Review, the PI may proceed with solicitation of participants and data collection after receiving the formal IRB Approval Letter from the IRB Chair. Following a Full Board Review, the IRB will take one of the following actions regarding the proposal: "approved," "approved with conditions." "deferred," or "disapproved." Details regarding the possible actions are found below.

ACTIONS BY THE IRB

The following are the possible actions the IRB can take following a review of an IRB proposal.

Approved. The IRB will provide the principal investigator a letter indicating the state date and end date of the approval.

Approved with Conditions. IRB requests that are approved with conditions necessitate that revisions, clarifications, or additional documents that address the issues raised by the IRB be submitted to the IRB. The IRB will also provide a list of documents required for resubmission. The IRB Chair may act on revisions, depending on the extent of them. **The investigator for written notification of approval after revisions are made before proceeding with solicitation of participants and data collection.**

Deferred. A deferred decision is rendered when insufficient information is provided or the meeting fails to meet a quorum.

Disapproved. Applications are disapproved if the research does not meet the criteria for protecting participants and substantial changes would be required. No IRB request will be disapproved until it has been reviewed in accordance with the full review procedures set forth in this document. If the IRB disapproves a request for review of a research study, a written statement of the reasons for its decision will be given to the principal investigator. The principal investigator will have an opportunity to respond in person or in writing. Review of a previously disapproved protocol requires a Full IRB review.

Parallel IRB and Organization Permission. If approval of another IRB is required for a study to proceed, this University's IRB will generally review the proposal first, and when satisfied with the proposal, will "approve with conditions" the study with the only condition being that the researcher secures the necessary permission(s) from the other IRB(s). Once permission from the other IRB(s) has been obtained and submitted to this University's IRB, a full Approval

Letter will be issued. The researcher can share that full approval with the other IRB if the other IRB(s) desires to have a copy of it.

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, OHRP certifications, 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 principal 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 human research must be submitted to Harding University IRB. The investigator is encouraged to use the OHRP decision chart (see www.harding.edu/irb) to identify the type of research proposal that will be submitted (Exemption, Expedited, or Full IRB Review). The investigator should attach the following paperwork to the IRB Chair via email (irb@harding.edu) as instructed on Harding University IRB website (see www.harding.edu/irb):

- The appropriate form found in "Forms for Researchers"
- Synopsis of research protocol (include purpose/design, site, and duration of study, methodology for participation recruitment and data collection, and strategy for ensuring safety and confidentiality)
- Informed consent and/or instructions for participants
- Copy of relevant training certificate from OHRP Human Research Protection Training course [Exempt research does not require documentation of training.]
- Copies of any surveys you plan to use

- Proposals should be submitted electronically in PDF format (Word files can be easily 'Saved As' a PDF file) and sent to irb@harding.edu.
- All files must be saved using the same format for each file (Last Name, First Name, Name of Document).
    - Smith John Research Summary
- File names should not include any special characters (e.g. & #).

The investigator must obtain IRB approval before undertaking the research and beginning data collection. Absolutely no solicitation of human participants or data access or collection may occur prior to IRB approval.

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 risk 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

Research in this category involves risk or stressors that are not greater than those ordinarily encountered in daily life or during performance of routine physical or psychological examinations. The IRB Chair must determine that a research study qualifies for an exempt review. **Researchers must not proceed with the research until written IRB approval has been received. Absolutely no solicitation of human participants or data collection is allowed prior to receipt of IRB approval, including pilot studies.**

Action on Exempt Research is generally taken within 2-4 working days of receipt by the IRB Chair or a Committee Member at their direction. Incomplete requests will be returned.

Research qualified as Exempt if it falls in one of the following six (6) categories (note that not all types of research described below are, or are permitted to be, conducted at Harding University):

1. Research conducted in established or commonly accepted educational settings, involving education practices.

2. Research involving the use of educational tests (e.g., cognitive, diagnostic, aptitude, and achievement tests), survey procedures, or observation of public behavior, unless specific individual human participants can be identified, directly by or through identifiers linked to the participants, and disclosure of their identity could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.

3. Research involving the use of educational tests (e.g., cognitive, diagnostic, aptitude, and achievement tests), survey procedures, or observation of public behavior that is not exempt under category 2 of this section, if the human participants are elected or appointed public officials or candidates for public office, or federal statute(s) require(s), without exception, that the confidentiality of the personally identifiable information will be maintained through the research and thereafter.

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 participants cannot be identified directly or through identifiers linked to the participant.

5. Research and demonstration studies that are conducted by or subjected to the approval of department or agency heads, and that are designed to study, evaluate, or otherwise examine: a) Public benefit or service programs; b) Procedures for obtaining benefits or services under those programs; c) Possible changes in or alternatives to those programs or procedures; or d) Possible changes in methods or levels of services under those programs.

6. Taste and food quality evaluation and consumer acceptance studies, if wholesome foods without additives are consumed or if a food is consumed that contains an ingredient at or below the level 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.

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. Actions on Expedited Research typically take between 4-6 working days to review. Incomplete applications will be returned. Examples of Expedited Research 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 Board 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 and protected population research submitted to the IRB will require Full Board 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.
- Depending upon the research, protected populations can include **(Note, those in bold are the most protected and require additional IRB protection):**
    - Pregnant women
    - **Prisoners**
    - **Children**
    - **Individuals with physical disabilities**
    - **Individuals with mental disabilities or cognitive impairments**
    - Economically disadvantaged
    - Socially disadvantaged
    - Terminally ill or very sick
    - Racial or ethnic minorities
    - **Institutionalized persons (for example, persons in correctional facilities, nursing homes, or mental health facilities)**

Incomplete requests will be halted and returned. Action on Full Board Research requires a meeting of the IRB and generally takes 15 to 25 working days. For most efficient consideration of the Request for Full Review, all forms and materials must be submitted by the 15th of the preceding month. The IRB will review the submission and provide the researcher a list of concerns one (1) week prior to the meeting. At the IRB meeting the IRB Chair will facilitate the review of the issues and the researcher should be prepared to address each one in front of the IRB Committee. The IRB reserves the right to explore other issues besides those provided to the researcher. **Researchers must not proceed with the research until written IRB approval has been received. Absolutely no solicitation of human participants or data collection is allowed prior to receipt of IRB approval, including pilot studies.**

CONTINUING REVIEW

Federal regulations require re-evaluation 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 of the IRB approval. If the research study is going to continue past the expiration date, then the investigator must submit a Request for Renewal form. The principal investigator must submit the request for renewal in time for review and approval by the one-year anniversary date of the previous approval. The researcher should provide all information requested on the form; incomplete requests will be halted. If a researcher fails to provide continuing review information to the IRB or the IRB has not reviewed and approved a request for renewal by the continuing review date specified by the IRB, then the research study may not continue. No enrollment of new participants or data collection is allowed 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, the IRB has the authority to observe or have a third-party observe the consent process and the research process for a given study. These third-party observers are required to comply with confidentiality standards governing the ongoing research.

CHANGES TO APPROVED RESEARCH

Any changes to previously approved research, including, but not limited to, those that may change the risk/benefit ratio, 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. Principal Investigators must submit changes in writing to the IRB Chair. Incomplete requests will be halted.

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)

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 principal investigator has received an IRB Approval Letter. 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 results in dismissal from the institution for faculty, staff, and/or students.

INFORMED CONSENT

An Informed Consent Form signed by each participant, 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 student in which children up to 17 years (unless emancipated) will be participating, informed consent must be obtained from their parents/legal guardians. Informed assent must be obtained from minor participants if they are between ages 7 to 17. 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 Doctoral Research Chair 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 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: Social benefits should not be overstated. There may be no direct benefit to the participant, other than a sense of helping the public.
  - 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 provision 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.
- Within the consent form, researchers must clearly state that all research materials will be held for a period of no more than five years and what will occur with the participant lists, data stored, etc. It must also be noted that collected data for this research will never be shared with any other researcher beyond what is publicly published.

- 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 participants 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 answer questions.
- Identification 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 email address of the IRB Chair (irb@harding.edu) should be included should the potential participant wish to contact the IRB, should he or she 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 whether or not to participate and that minimize the possibility or 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 the 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).

SUBJECT RECRUITMENT

Use of the University Imagery and Logos

Harding University and its IRB do **not** permit the use of its imagery or logo in any recruitment materials. If the researcher has received an IRB Approval Letter, then the use of the University logo is permitted on the consent form and data collection materials.

Recruitment of Students, Employees, Friends, and Family

The federal regulations do not specifically mention the inclusion of students, employees, friends, and family members in research, but their designation as a special population stems from 45 CFR 46.111(b):

"When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects."

As a general rule, the IRB disapproves of recruiting employees, students, friends, or family members as a targeted population, merely for the sake of convenience or because of their easy availability.

Research participants should be recruited through general announcements, bulletin/message board postings or advertisements, rather than individual solicitations. Investigators seeking to target students, friends, and/or employees, including study team members, for enrollment must describe in their IRB application how they will avoid creating the perception that participation in the research by a student, friend, or employee will favorably influence the participant's professional or academic career. Investigators must stress that the student/ employee's performance evaluations, job advancement, relationship, or grades will not be influenced by participation or lack of participation in the research study. As appropriate, the IRB may require language to that effect in the informed consent document.

Any investigator wishing to enroll one of the groups discussed in this policy must obtain specific IRB approval for their inclusion. The following elements must be discussed in the research summary, for initial reviews, or in an amendment for an ongoing study:

- Precise description of the group or individual(s) to be enrolled;
- Relationship of the group or individual(s) to the study team, including supervisory relationships;
- Importance of including this group to individual(s) in the study;
- Who will consent the group or individual(s) and how the possibility of coercion will be minimized; and
- Process for ensuring objective analysis of study results, particularly for friends and family members.

Organizational Permission Forms

Organizational Permission forms allow for permission to access participants or data or use the premises, for recruitment, data collection, or analyses. The fastest growing area of recruitment is via social media. Given the organizational structure of social media this is understandable, but it must be known that groups and organizations on social media are afforded the same protections as any other private entity. If a researcher wishes to recruit from a company, institution, organization, private server, private email list, or social media groups signed Organizational Permission forms are required and the Authorizing Person must be in a position to grant such permissions.

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 has been included.