Minnesota State University, Mankato
Institutional Review Board (IRB) Manual

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Introduction

This manual prescribes the policies and procedures of Minnesota State University, Mankato (hereafter known as the University) for the protection of human participants in research and related activities conducted at, sponsored or co-sponsored by the University. The administrative authority for the protection of human participants at Minnesota State University, Mankato has been delegated to the Associate Vice President of Research and Dean of Graduate Studies (IRB Administrator). The Institutional Review Board for the Protection of Human Subjects (IRB) is a standing committee of the University and is administratively responsible to the IRB Administrator.

The IRB serves to implement the Department of Health and Human Services' (DHHS) assurance of compliance with federal and state of Minnesota policies, regulations and laws relating to the protection of human participants in research as defined in 45 CFR 46.102(l).

The policies and procedures described herein apply to all research and research-related activities involving human participants regardless of the source of funding or whether there is funding. In some cases, the regulations at the University are more stringent than federal guidelines.

In order to meet this institutional responsibility, it is the policy of this University that no research activity involving human participants shall be undertaken unless the IRB has reviewed and approved.

The IRB may refer questions regarding the applicability of policies and procedures to legal counsel.

General Information

Minnesota State University, Mankato is guided by the ethical principles regarding all research involving humans as participants as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled Ethical Principles and Guidelines for the Protection of Human Subjects of Research (The Belmont Report). In addition, the requirements set forth in Title 45, Part 46 of the Code of Federal Regulations (45 CFR 46) are upheld. Minnesota State University, Mankato has chosen to require that all research under its auspices be conducted in accordance with the requirements of 45 CFR 46, regardless of the source of funding. Additionally, some University requirements are more stringent than those found in the federal regulations are.

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Underlying the policy of the University are the following basic principles embodied in the policy statement contained in 45 CFR 46. These principles will serve to assist the University in discharging its responsibilities, through its authorized representatives IRB, to protect the rights and welfare of human participants, as well as to assist faculty engaged in relevant research from unknowingly committing unethical acts. The University bears full responsibility for the oversight of all research involving human participants covered by this set of policies and procedures.

Research involving human participants is an important and necessary activity of the University and must be conducted in an ethical manner. Such research has the encouragement of the University when the rights and welfare of human participants are protected.

1. Before any research project which uses human participants can be started and conducted at the University (or under its auspices), the project must be submitted for review to the IRB. Researchers may begin their projects upon receiving formal, written approval from the IRB Director and Chair or Co-chairs. All proposals must comply with DHHS Policies and Regulations on Protection of Human Subjects and this document.
2. Supplemental to DHHS regulations and applicable law are ethical codes developed and adopted by various professional associations which will assist and guide investigators in various disciplines in protecting the rights of human participants. They do not supplant or substitute for DHHS regulations or this document.
3. Principal investigators (PI) are responsible to assure compliance by co-researchers and students with all current policies and procedures governing the participation of humans as research subjects in the research. If the researcher is a student, then the supervisory Minnesota State University, Mankato faculty member is considered the principal investigator and consequently the responsible person. Students at Minnesota State Mankato who also are faculty at Minnesota State Mankato cannot be principal investigator on research required for completion of their degree.
4. Students, research assistants or others performing IRB approved research activities which exceed minimal risk to research participants, under the supervision of a faculty advisor may be considered "agents" of the University for risk-management purposes. In such cases, the faculty advisor should formally request the services of students/research assistants in a memorandum which outlines their anticipated activities to be performed in the study. A copy of that memorandum must be forwarded to the IRB and may need to be reviewed by other University administrators.

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5. The University may rely upon the review of another qualified IRB, or act as the IRB of record by entering into a Reliance Agreement as outlined in 45 CFR 46.114, cooperative research projects with federal funding will be required to have a single IRB of record (sIRB).
6. Whenever medical, psychological, or physical intervention is used, or whenever the participant's environment is likely to be changed beyond normal limits, the research must be performed in conformity with established standards of healthcare practice under proper healthcare supervision.
7. Research involving medical devices will be conducted according to the requirements set forth in 21 CFR 812 and 45 CFR 46.
8. Research involving investigational drugs will be conducted according to the requirements set forth in 21 CFR 56 and 45 CFR 46.
9. Research with Human Genomes is subject to precautions prescribed by federal guidelines. Researchers should allow extra time for review of applications for studies involving this population.
10. Any possible breach of human participant protection in research activities conducted at the University of which investigators may become aware must be reported immediately to the IRB Administrator.

IRB Membership

Membership Composition

The IRB membership is determined as outlined in 45 CFR 46.107. The IRB is primarily comprised of faculty members from the colleges and departments most concerned with projects involving human participants. In order to assure diversity of intellectual perspective, the faculty members of the IRB will be selected from more than half the academic colleges in the University. A medical doctor will be a member of the IRB whenever possible. The IRB may include graduate student members chosen at large from the College of Graduate Studies and Research. Graduate Students do not have voting privileges. The IRB Administrator is an ex-officio member of the IRB with no voting privileges. The Director is a voting member of the IRB. If the IRB regularly reviews research that involves classes of vulnerable participants, the IRB shall include one or more individuals who are primarily concerned with the welfare of these participants.

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Total voting membership on the Board will be no more than 15 not including community members or the Director with at lease one member per college. Graduate students are non-voting members.

Method of Appointment

When a position on the IRB becomes available, the Director will place a call for applications in the monthly campus newsletter or elsewhere as deemed appropriate and inform any potential applicants from the college where the vacancy exists. Priority will be given to applicants from any college where no representation exists. Applications will be reviewed by the co-chairs and Director in consultation with the IRB Administrator. The Administrator will make a final recommendation to the President for appointment.

Appointments to the IRB normally are for a period of three (3) years. As much as possible, terms are staggered to ensure continuity within the group. With appropriate approval, a member may be appointed for more than one term.

The IRB Chair or Co-Chairs will normally serve for a period of at least three years, having first served as an IRB member for at least three years. IRB Chairs and Co-Chairs maybe appointed for more than three years.

Removal of IRB Members

An IRB may recommend to the IRB Administrator that a person be removed as a member for cause, by specifying the reasons in writing, and providing a copy to the member. The IRB Administrator will review the recommendation with the Chair or Co-Chairs and Director and come to a decision. If the decision is to remove a member from the Board, the IRB Administrator will provide the member with a letter outlining the decision and reason(s) for the decision. The decision will be based on the member's failure to complete her/his responsibilities as an IRB member.

Membership Responsibilities

1. To review all assigned research protocols in the timeframe requested or advise the Director within 24 hours of being notified of the review assignment that review is not possible,
2. To prepare for and attend all Committee meetings and to notify IRB Director in advance if there is a need to be absent from a scheduled meeting,

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3. Be available to consult with researchers and answer questions related to IRB,
4. To complete required human subject's protection training,
5. To maintain confidentiality regarding reviewed protocols,
6. To participate in Committee discussion of protocols, and
7. To participate actively in continuing education to assure continued excellence in the research review process.

Meetings, Quorum, Voting and Minutes

The IRB will normally meet monthly or as necessary during the academic year. If an emergency meeting is necessary, a meeting may be called by the IRB Chair or Co-Chairs. Proposals may be reviewed during the summer.

Meetings are open to all persons who desire to attend. The public, however, may not participate in meetings, nor examine confidential records or documents, etc., used by the IRB.

Quorum and Voting

In order to review proposed research at a convened meeting, a majority of the members of the IRB must be present, including at least one member whose primary concerns are in nonscientific areas (45 CFR 46.108(b); 21 CFR 56.108(c)). If a majority of the IRB membership is not present, or if a nonscientist is not present, then quorum has not been met.

If the total IRB membership is even, then a majority by using the "half-plus-one". This technique works well for IRBs with an even number of IRB members. If the IRB has an odd number of members, then the majority will be calculated by taking half of the total number of IRB members, and rounding up to the next whole number.

A quorum must be maintained throughout the meeting. If quorum is lost during a meeting, then the IRB may not vote on proposed research (45 CFR 46.108(b); 21 CFR 56.108(c).

The minutes of a convened meeting will record late arrivals, early departures and those who leave the meeting temporarily so it will be clear that a quorum was present when a discussion research being reviewed is conducted.

IRB members may become inactive for a period such as when they are on sabbatical or their

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University duties make participation with the IRB impossible. For a member to become inactive, the member must request moving to inactive status in writing. When in inactive status, the member is no longer considered for purposes of determining a quorum.

Minutes and Other Records

Minutes and Records of the IRB are kept in accordance with 45 CFR 46.115. Minutes of all convened meetings are recorded in the University's IRBNet site and taken in accordance with 45 CFR 46.115(a)(2). In addition, minutes of convened meetings must include at least the following information: date, time and place of meeting, members of the IRB present or absent, an accurate description of all actions proposed, and the names of the members who proposed each motion. The minutes will include a listing of all research (Level I and II) approved by the Chair, or Co-Chairs, and IRB Director since the previous Minutes. All Minutes and records will be stored for a period of at least three (3) years and are available on the IRB web site.

The minutes will show that any Board member with a conflicting interest regarding a project did not participate in a review conducted at a meeting except to provide information requested by the IRB.

The Minutes shall include a list of all applications approved since the previous Minutes. Approval of the Minutes shall constitute Full Board endorsement of those approved applications.

Leadership

Leadership of the IRB consists of the IRB Administrator, an IRB Director, and a Chair or two Co-chairs.

IRB Administrator

The IRB Administrator is the Associate Vice President of Research and Dean of Graduate Studies. The duties and responsibilities of the IRB Administrator are found later in this document.

Director

When the position of Director is vacant, the IRB Administrator will put out a call for applications from faculty at large. A committee of three (3) members of the IRB, one of whom

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shall be the IRB chair or co-chair, and two of whom shall be people selected by the IRB Administrator, shall review applications. The IRB Chair or Co-Chair shall provide the committee's recommendation to the IRB Administrator who then provides the final recommendation to the President. The President shall then make the appointment.

The appointment for the Director is for three (3) years with the option to renew twice times for a total of nine (9) years. The Director is a faculty member who is given reassign time. In their first year, the Director should consider completing the Certified IRB Professional (CIP) training (see https://www.primr.org/certificates/). In addition to the usual five (5) summer duty days, extra summer duty days may be possible so ther training can be completed.

Job Requirements for Director (approved November 2019)

Required:

- At least 3 years' experience on an Institutional Review/Ethics Board.
- Minimum education is a terminal degree determined by the discipline.

Preferred:

- Doctoral degree preferred.
- 3 years' experience on Minnesota State University, Mankato's Institutional Review Board as chair or co-chair.
- CIP certification (see https://www.primr.org/certificates/).
- Evidence of ability to handle sensitive and confidential information.
- Medical group or healthcare compliance experience.
- Ability to interpret and implement institutional, state, and federal laws and policies related to IRB's role in protecting human participants in research (e.g., FERPA, HIPAA, 45CFR46, etc.).
- Demonstrated strong organizational skills, computer literacy, and social media literacy.
- Demonstrated ability to build relationships and collaborations.
- Demonstrated commitment to fostering a diverse working and learning environment.
- Evidence of respect for multiple research paradigms/methodologies (e.g. qualitative and quantitative).

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- Demonstrated effective written, oral communication and/or presentation skills.

Duties of the Director are as follows but are not limited to this list:

Maintain

- the CITI site and correspond with the administrators of that site to solve any problems,
- the IRBNet site and correspond with the administrators of the site when necessary,
- the IRB campus web site, and
- the IRB Manual.

Daily Administrative Duties

- Looks after the IRBNet site and the daily administration duties of the IRB.
  - Assign Level II reviewers and Level III previewers.
  - Review all submissions (Level I, II, III, Continuing Review, and Revisions).
  - Prepare and send all letters related to reviews of research submitted for IRB review.
  - Schedule Board and Executive meetings being sure all meeting dates have been communicated to the Administrative Assistant to IRB Administrator.
  - Coordinate with the Administrative Assistant to the IRB Administrator to be sure meeting rooms are booked and refreshments for the Board meetings are ordered.
  - Inform the Board of meeting dates and times and the availability of the agenda and other documents that will be discussed at a meeting.
  - Respond to all irb@mnsu.edu email.

Communication

- Works with the policy holders in updating and implementing University policies and procedures as they relate to IRB.
- Establish an effective working relationship and builds credibility with faculty staff and students to promote a culture of ethics and compliance.
- Keep the IRB Administrator up to date on IRB activities.
- Disseminate reports as assigned by the IRB Administrator.

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Prepare and Present Training

- Research and develop recommendations in conjunction with other interested parties on how most effectively to address compliance issues related to data confidentiality, data security, privacy, and record retention as they relate to IRB.
- Attend classes and present on topics related to IRB in general and specifically related to Minnesota State Mankato's IRB.
- Meet individually with researchers to provide guidance in submissions.
- Provide guidance, suggestions, and resources for researchers on topics such recruitment, confidentiality, consent, privacy, etc.
- Conduct drop-in sessions at least once a month during the academic year.
- Coordinate with the Director of the Center for Excellence in Teaching and Learning (CETL) and prepare and present the necessary information for an IRB Compliance Certificate.
- Attend graduate student orientation and new faculty orientations and present a brief introduction to IRB.
- Prepare information regarding IRB for the Provost's and the Campus newsletters.

IRB Administration

- Act as a liaison between researchers and the Board.
- Assist in the assessment of compliance readiness as it relates to IRB.
- Oversee the IRB membership as outlined in the IRB manual.
- Mentor new board members and help train them to prepare useful reviews.
- Review IRB documents such as the Manual, review letters, etc. informing the Board if changes are needed.
- Prepare draft documents for review by the co-chairs or IRB as necessary.
- Maintain training records of faculty, staff, and students reminding researchers to renew their training when required.
- Maintain IRB productivity records and construct annual data spreadsheet.
- Hire and supervise the IRB Graduate Assistant whose duties include:
    - Taking minutes of the monthly IRB meetings.

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- Updating the meeting schedules in IRBNet.
- Complete monthly closures.
- Help maintain the IRB web site.
- Other duties as assigned.

Continued Preparation and Study

- Attend appropriate professional development opportunities.
- Keep current on regulatory changes at the federal, state, and institutional level that affect IRB.

Other

- Participate in the Provost's monthly Chairs and Directors meetings, the Provost's workshops, IRB board and IRB executive meetings.
- Perform other duties as assigned by the IRB Administrator.

Chair or Co-chairs

By the last meeting of an IRB chair's or co-chair's expiring term, the committee, by majority vote, will nominate one IRB member to replace the outgoing IRB Chair/Co-Chair. This individual is/must be a Minnesota State University, Mankato faculty member. The nomination is given to the IRB Administrator for final approval.

The IRB Chair/Co-Chairs have the following duties and responsibilities:

1. Serve as chair for the IRB meetings.
2. Serve as a reviewer.
3. Serve as the focal point (along with the IRB Administrator and Director) for interaction of the IRB with the university community.
4. Oversee (along with the IRB Administrator) the development and execution of the educational efforts of the IRB on campus.
5. Monitor (along with the IRB Administrator and Director) changes in federal regulations and institutional policy for the protection of human subjects in research.
6. Assist the Director in ensuring that all IRB procedures are appropriately documented. This includes, but is not limited to, reporting of IRB actions to the IRB Administrator, liaison with the staff support, and liaison with faculty in general.

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Replacement of Chair or a Co-Chair under Extraordinary Conditions

If for any reason either the Chair or Co-Chair should not be able or is unwilling to complete her or his term of office, notification in writing will be given to the IRB Director who will share the information with the IRB Administrator. The IRB Director will also notify the Board by e-mail or at a regular or special meeting. The Board will nominate an appropriate replacement as described above.

Application

The process begins with identification of those projects or activities which involve human participants. Applicants should use the DHHS decision tree to determine if a project is human participant research. Ultimate verification as to whether any project or activity is human participants research is the responsibility of the IRB. Researchers are advised not to decide if their research does or does not require IRB approval. Consult with the Director.

The University's IRB uses IRBNet to manage its human research documentation and reviews. Application forms utilized by the IRB are available in the Forms and Templates section of IRBNet. The completed application packet is submitted using IRBNet. Preliminary review will take place in the order that applications are received.

All proposals must include a faculty (not adjunct) or staff member as defined below under the heading Principal Investigator (PI) as the PI of the research study. Graduate and undergraduate students cannot be the PI.

Principal investigators will be notified through the IRBNet system when their proposals are approved or if modifications are required. Any changes to approved proposals must be submitted to the IRB for approval. Approvals will be kept on file in IRBNet for at least three (3) years after the research is closed.

Researchers including student researchers must ensure that their current CITI completion reports are uploaded for storage in IRBNet.

Principal Investigators

Principal investigators are ultimately responsible for the protection of humans participating in their research. For IRB purposes, the following employees can serve as principal investigators:

- All faculty, excluding adjunct faculty, and

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- All full-time unclassified employees.

Principal Investigators Working with Student Co-Investigators

1. Principal investigators who supervise student researchers must take an active part in preparing student researchers for the role of researcher, instructing them in the ethical conduct of research and sharing responsibility for the preparation of applications for IRB approval. Primary investigators shall take an active role in ensuring that the conduct of the research meets the highest ethical standards. It is important to remember that researchers could be legally liable for issues that arise regarding the research.
2. Principal investigators shall ensure that their student co-investigators use appropriate research design and conduct their research in accordance with the policies and procedures of the IRB.
3. The principal investigator's electronic signature is required when submitting the IRB application form, providing documentation that the principal investigator verifies that the application is accurately completed and consistent with all IRB policies and procedures. The principal investigator is ethically and legally responsible for the protection of human participants in any research for which they are PI including research in which they are mentoring student researchers.

Equipment Description

Any research in which electrical, electronic or mechanical equipment will be in physical contact with the participant, researcher may be required to describe the equipment in the application form suppling:

1. Trade Name, Manufacturer, Model Number
2. Schematic diagram, picture or other representation of the equipment including a demonstration or other means of showing the IRB the machine's normal operation;
3. Verification of safety including UL certification or other certification;
4. For old equipment, equipment that has been out of usage, equipment that has been moved, or equipment of local fabrication and/or not available from commercial vendors, the researchers must provide evidence of recent inspection and certification for safety.

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Review Process

General Policy Statement

All research involving the use of human participants conducted at or sponsored by this University, including both funded as well as non-funded research, must be reviewed by the University's IRB. The criteria for review are outlined in 45 CFR 46.109 and if relevant, as required the Food and Drug Administration (FDA) 21 CFR 56, the Federal Educational Rights and Privacy Act (FERPA), the Health Insurance Portability and Accountability Act (HIPAA), state and federal privacy laws, Minnesota State University's system policies and the University's policies. In order to approve research, the IRB shall determine that all of the requirements of 45 CFR 46.111 are satisfied.

The IRB may not have a member participating in the review of any application in which the member has a conflicting interest, except to provide information requested by the IRB.

Classroom Research Assignments

A project is only research for IRB purposes if it is meant to generate generalizable knowledge. Accordingly, graduate and undergraduate course research assignments that are conducted under the supervision of course faculty and not shared outside of the course may not need to be submitted to the IRB for approval. Consultation with the IRB Director, Chair or a Co-Chair is strongly advised.

Research for master's theses, doctoral dissertations, research that will be publicly presented, and independent research studies are not considered course assignments and must comply with the usual IRB review procedures. Capstone courses may require IRB approval. Consult with the IRB Director, Chair or a Co-Chair. More information can be found at this link.

Initial Review Process

The IRB Director will determine the Level of Review. If the Director is unsure, the co-chairs or at least two board members will be consulted.

The IRB Director will conduct a preliminary review of each proposal and related documents to determine whether the materials submitted are sufficiently informative and complete to constitute a basis for a fair review by the IRB. If the Director determines the submitted material is not ready for review, the PI will be sent information about what needs to be done to qualify for review.

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The documents that IRB will need for review are the CITI completion report, application form, consent form, data collection documents, and any other documents that potential participants and participants will see. This might include an assent form, surveys, recruitment documents, etc.

If the IRB Director determines that consultants or experts will be required to advise the IRB in its review, the research application shall also be distributed to the consultants or experts prior to any meeting. The consultants or experts may attend the convened meeting at which the research will be reviewed, or they may provide written comments. Consultants and experts attending convened meetings of the IRB do not vote.

Levels of IRB Review

A review timeline is provided on the IRB web pages. There are three levels of review:

Level I

Proposals eligible for Level I review (Exempt) may be reviewed by the Director and must fall under certain categories of activities outlined in 45 CFR 46.104 involving minimal risk (45 CFR 46.102(j)). Categories 7 and 8 are new with the 2018 Common Rule and are not being implemented at Mankato. They may be implemented in future if we can meet the technical and regulator requirements.

Level II

Proposals eligible for Level II review (Expedited) will be reviewed by the Director and at least one other Board member who might be a co-chair.

Level III

Consistent with 45 CFR 46.108(b) proposals involving more than minimal risk must be reviewed at convened meetings at which a quorum is present.

Once it is established that a proposal is Level III, two Board Members will be assigned to review the submission. The Director and reviewers will determine when the submission is ready for full board review.

Once the pre-review is complete and the submission ready for full board review, all documents related to the research shall be made available through IRBNet to all members of the IRB at least 10 days prior to the convened meeting of the full board.

After review of a Level III proposal, the Board may stipulate that the Director and one other

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Board Member may review any resubmission and, at least on the Board's behalf, decide if the resubmission will be approved. If the resubmission contains substantial changes, the revised documents will be brought to the next Board meeting for review. The reviewers will provide the Board with advice on what requested modifications were not made or what additional modifications need to be requested.

Notification of Decision Resulting from Review of an Application

The IRB Director, Chair, or Co-Chair shall notify the research investigators in writing of the IRB's decisions and required modifications needed for the research to be approved. The IRB may approve or require modifications. The IRB does not disapprove any research. Suggestions are provided for what must be changed for IRB approval.

The IRB Director may consult with the IRB Chair or Co-Chair as to the accuracy of the information communicated to the investigator. Copies of the decision letters will be made available to the investigator(s) in IRBNet. The PI will be provided an opportunity to respond.

Approval of Research

Once the PI has received, on letterhead from IRBNet, an approval letter from the IRB Director and co-Chairs, recruitment may begin. This decision is subject to the monthly review by the full IRB Committee where the Committee will vote to approve the record as found in the IRBNet agenda for the meeting. The Committee may request placement at a different Level than in the approval letter.

At a convened IRB meeting, any member may request that an activity which has been approved under these procedures be reviewed by the Full Board. A vote of the members shall be taken concerning the request and the majority shall decide the issue.

The decisions reached at the convened meeting shall supersede any decisions made through any other normal review process.

Recruitment Process

Recruitment of participants into a study may not begin prior to IRB approval. The IRB must approve all recruitment methods and material (flyers, letters, brochures, e-mail

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advertisements, radio announcements, etc.) prior to use. The content of recruitment materials and the method for communicating it cannot create undue influence or contain misleading or exculpatory language.

Women and Minorities

The National Institutes of Health (NIH) policy requires that minorities and women be included in clinical research study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study. Special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions that disproportionately affect them. This policy is intended to apply to people of all ages and must be representative of the population at large or that being studied. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale must be provided.

Non-English Speakers

1. Study-related information that is given to a subject or a subject's legally authorized representative must be in a language understandable to the subject or representative.
2. Base the translations on IRB approved English versions.
3. Language and reading level should be culturally sensitive to the population to whom the documents are being presented.
4. The IRB-approved and validated English documents must be translated into the language/dialect of the participant population and/or legally authorized representatives. The translated material should then be back translated into English to confirm that the meaning has not been changed.
5. Submit the following to the IRB for review and approval:

   IRB approved English version

   Forward translation (into foreign language)

   Back translation must be performed by someone other than members of the research team (from foreign language back into English to confirm the translation is accurate). If using a professional translation service, provide a formal letter from the translation service that certifies the translation.

When back-translating, it is important to only use the non-English translated version

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when translating the document back into English. Back-translators should not have access to the approved English version. The IRB Director should then compare the back translation to the approved English version and verify the translation.

Electronic translator applications (such as Google Translate) are not appropriate for generating forward or backward translations.

Translation costs are the responsibility of the researchers.

Recruitment from Other Institutions

In cases where participants are recruited from other institutions (hospitals, community agencies, physicians, etc.), the first contact with potential participants should be made by institutional staff who, after outlining the researcher's interest and obtaining the potential participant's permission, will refer the person to the researcher or vice versa. This may be done by a letter, an email or other approved means from the researcher which is distributed by the appropriate institutional representative at the institution where recruitment is going to occur. This procedure has been implemented to protect privacy rights of potential participants.

Snowball Sampling

IRB will not approve a recruitment method in which a researcher asks a research participant for contact information of potential participants (snowball sampling). This method of recruitment is considered an invasion of privacy. There is a valid exception when IRB will approve this type of snowball sampling. IRB might approve snowball sampling for Investigators who seek to recruit from populations for which adequate sample frames are not available.[1] The protocol must include justification of the use of this method in the context of the study and target population. The risk of violating an individual's privacy should be articulated in the recruitment section of the protocol. Current participants cannot receive incentives or compensation for referrals.[2]

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[1] https://www.nsf.gov/bfa/dias/policy/hsfaqs.jsp#snow (Feb. 2020)

[2] https://research.oregonstate.edu/irb/policies-and-guidance-investigators/guidance/snowball-sampling (Feb. 2020)

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For studies studying sensitive topics, study protocols should adhere to the recommendations for confidentiality. For example, studies of networks of drug users or tracking sex partners of HIV+ cases require extreme caution with information gathered from one subject about another.

Recruiting Family, Friends, Employees, and Students

Recruitment and enrollment of family members of the research team as well as students and employees who may be in a status relationship with the investigators raise special ethical concerns. The existence of a status relationship between the prospective subject and members of the research team may result in a recruitment and consent process that is not free from undue influence. Additionally, enrollment of individuals already known to the research team may heighten the potential for loss of privacy for those subjects and loss of confidentiality of their data. IRB has received complaints from individuals who felt they could not decline participation in a research study because they believed that refusal would lead to adverse consequences for their employment or student careers.

Generally, Minnesota State University, Mankato IRB discourages investigators from enrolling family members of a research team as well as employees or students who are in a status relationship with the researcher(s). Students are in a status relationship with a researcher if the researcher has authority to make decisions about the student's grades, performance, and/or progress. Student should be clearly informed that research participation is not a mandatory requirement of the course. If credit is awarded for research participation, students not wishing to participate or who do not follow through with research participation must be given a choice of a reasonable alternate academic activity that is comparable in time, effort, and credits earned. Penalizing those who do not follow through violates 45 CFR 46.116(a) (8).

Enrollment of individuals with a potential status relationship, including family members of the research team, should be declared in the application to the IRB and justification for the inclusion of these subjects provided. The IRB will then assess on a case-by-case basis whether the inclusion is warranted by the protocol, the recruitment and consent process are free from undue influence, and the privacy of these subjects as well as the confidentiality of their data will be protected adequately. The IRB chair or co-chairs or their designees may decide individual cases.

Minnesota State Mankato IRB will consider the following factors in support of potential exceptions to the general prohibition on enrollment of subjects with potential status relationships with the research team:

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1. The research presents minimal risk (see 45 CFR 46.102(j)) to subjects.
2. If the potential subjects are students or employees, participation in the research represents a potential educational opportunity for those individuals.
3. The recruitment of these subjects involves only indirect methods (i.e., potential subjects are not recruited on a personal basis). These subjects are recruited through the posting of IRB-approved flyers/ads or through IRB-approved communications sent out to a larger group (e.g., mass mailings through email or letters).
4. The consent process will not be conducted by someone with whom the potential subject has a status relationship.
5. If the research is conducted within the classroom setting, the instructor is blinded to the identity of participants. For example, a third party who is not in a status relationship with the students could receive data directly from the participants and strip the data of identifiers before providing the information to the researcher who is in a status relationship with the students.

Informed Consent

Informed consent is the voluntary agreement to participate in research obtained from a participant (or his/her legally authorized representative) prior to participation. The consent process must permit the individual or legally authorized representative to exercise free power of choice without undue inducement or any element of deceit, fraud, force, duress, or other form of coercion or constraint. Requirements for obtaining informed consent are provided in 45 CFR 46.116(a). Basic elements of informed consent are provided in 45 CFR 46.116(b).

In addition to the basic elements, the IRB requires some additional elements that are listed in the IRBs Informed Consent Form Check List.

The IRB has the authority to observe or have a third party observe the consent process and the research (45 CFR 46.109(g)).

Obtaining informed consent

1. Research investigators are responsible for obtaining informed consent in accordance with 45 CFR 46.116. Guidance for obtaining consent from non-English speakers is available.

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2. Consent which could include verbal consent shall be documented as outlined in 45 CFR 46.117. A waiver of consent, elements of informed consent, or documentation of consent may be approved in situations authorized by the IRB in accordance with 45 CFR 46.117(c) or 45 CFR 46.116(f)(3).
3. Consistent with FDA policy, participants must consent to any screening procedures to determine eligibility to participate in clinical research. However, IRB could if appropriate, approve a waiver of documentation of consent. Under certain circumstances listed in 45 CFR 46.116(g), consent is not required for screening purposes.
4. In the case of minors (persons under the legal age), parental permission and assent procedures are provided in Subpart D of 45 CFR 46.408.

Storage of Documented Consent Forms

1. Research investigators are responsible for storage of the documented (signed) consent forms (and assent forms if applicable) in a secure location at th University. In accordance with federal regulations, consent documents must be maintained for three (3) years after closure of the research.
2. If the PI leaves the employment of the University prior to the 3 years, measures must be taken to store the consent forms in the former department, and the IRB should be informed of the new location by submitting a Revision. If storage within the department is not feasible, then the PI should (a) make sure the consent forms are labeled with the IRBNet Id Number, (b) hand carry the consent forms to the office of the IRB Administrator, and (c) request that the office of the IRB Administrator take responsibility for storing the consent forms for the remaining portion of the 3 years.
3. If someone else is going to 'take over' and complete the research, a Revision changing the name of the PI must also be submitted. In addition, the name of the PI listed in the IRBNet system needs to be updated. Contact the IRB Director BEFORE you submit the Revision for assistance with the name change in IRBNet.
4. If documented electronic consent is obtained (e.g. Qualtrics), the PI must download and store copies of the forms in a secure location. Secure locations would be computers and devices that have a Minnesota State asset tag number, an encrypted thumb drive, MavDisk, One Drive cloud storage or if paper documents a locked cabinet in a locked room to which only the PI has access. Links to online resources are not sufficient as they can change or break.

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Preemption

The informed consent requirements in this policy are not intended to preempt any applicable federal, state, local laws, MinnState policies or University policies which may require additional information to be disclosed for informed consent to be legally effective.

Certificate of Confidentiality

Researchers engaged in federally funded research that is not anonymous to the researcher and that includes the study of participant use or abuse of controlled substances or other possibly self-incriminating responses will be required to state their intent to acquire a Certificate of Confidentiality (CoC) from an appropriate agency before recruitment or data collection can begin. Certificates must be shared with the IRB before research including recruitment begins. CoCs are issued automatically for any NIH-funded projects using identifiable, sensitive information.

If you believe your research requires this protection or if you have any questions, please refer to https://grants.nih.gov/policy/humansubjects/coc.htm.

Vulnerable Populations

Research involving populations such as fetuses/pregnant women, children, prisoners, parolees, addicts, persons who are HIV positive or have with Acquired Immune Deficiency Syndrome (HIV/AIDS), cognitively impaired persons, and others in conditions of dependency, helplessness, or deprivation (including vulnerable populations as defined by Minnesota (Minn. Stat. § 626.5572, subd. 21 and vulnerable) and federal statutes may require additional precautions and procedures to assure their protection.

FDA guidelines broaden the scope of different types of "vulnerable subjects" to include: "individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, of a retaliatory response from senior members of the hierarchy or institution in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental, and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable subjects may include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency rooms, ethnic minority groups, homeless persons, nomads, refugees, children, and those incapable of giving consent."

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Other groups, such as racial minorities, the economically disadvantaged, the very sick, and the institutionalized are described as vulnerable populations by the Belmont Report and are therefore provided similar protection when used as research participants. Some groups, such as racial minorities, are not considered vulnerable populations if included in a general population.

Whenever potential participants are persons of diminished capacity but capable of giving assent, the researcher must obtain their assent in addition to obtaining consent to participate in research from their guardian before involving them in a study.

Where participants are drawn from vulnerable groups, compensation may under certain circumstances cast doubt upon the voluntariness of their consent. In such circumstances, the IRB may either limit or disapprove compensation (e.g., prisoners, etc.).

Access to Institutional Records for Research Purposes

Access to Records for Research Purposes

A researcher may have access to non-Minnesota State University institutional records (e.g., hospital, health service agency, etc.), that are not protected by privacy laws if the institution agrees in writing to the accessing. A copy of the permission letter to access records must be provided to the IRB. The researcher may not obtain names or other identifiers from the records without first obtaining documented consent. Recruitment and data collection shall not begin prior to approval by the IRB.

Access to University Resources

Internal Requests

Research proposals involving use of any University resources external to the researcher's specific unit (e.g. center, department, office, etc.) including, but not limited to, human resources, physical resources, (e.g. requesting IT to send e-mail to all staff), University property, both real and personal, and any other resources that may be considered property under the domain of the University and/or the Minnesota State System shall be reviewed by the IRB Administrator for approval. Recruitment and data collection shall not begin until approval is received from the IRB Administrator.

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The approval shall be kept on file in the office of the IRB Administrator, in compliance with the applicable University policies and procedures. The approval letter will include instructions and a link to a form that must be completed if researchers wish to use resources outside their units.

External Requests

University procedure requires external researchers who wish to obtain access to participants who are employees or students at Minnesota State, Mankato to submit an Access to Participants Application for review by the IRB Administrator for approval. The required application can be obtained from the Director.

Reliance Agreements

If another IRB is acting as the IRB of record, the Minnesota State University, Mankato investigator may be required to submit documents approved by the reviewing IRB into IRBNet (e.g. the application, the consent form, the recruitment documents, the approval letter, etc.). Contact the IRB Director for assistance and direction.

The Minnesota State University, Mankato IRB Director will review Level I and II submissions and inform the IRB Administrator if the Reliance Agreement should be approved. Level III submissions will require full board review.

A copy of any fully executed Reliance Agreement will be kept on file in the Office of the Associate Vice President of Research and Dean of Graduate Studies.

Although the Minnesota State University, Mankato IRB does not provide any oversight when an external IRB is the reviewing IRB, the Minnesota State University, Mankato IRB remains responsible for the research activities that take place at Minnesota State University, Mankato. The Minnesota State University, Mankato IRB requires that all revisions to approved research and continuing reviews be updated to Mankato IRBNet site to ensure that the research approval hasn't lapsed, and the most current approved documents are being used.

If the Minnesota State University, Mankato IRB is the IRB of record, a copy of the fully executed Reliance Agreement will be kept on file in the Office of the Associate Vice President of Research and Dean of Graduate Studies. and the researcher for whom the reliance agreement was approved will load a copy to the IRBNet site for the approved project.

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Cooperative Research Projects and Single IRB of Record (sIRB)

At this time, Minnesota State University, Mankato's IRB has decided to use Advarra (https://advarra.com) as the sIRB if a sIRB of record is required. Researchers are advised to include funding for Advarra in their proposals.

Initiation of this process is the responsibility of the investigator.

Revisions to Approved Applications

Minor changes to an approved application may be requested by completion of the Application Revision form found in the Forms and Templates link in IRBNet and submission through the IRBNet system. Initiation of any changes must not be undertaken before IRB approval.

Continuing Review

Continuing review requirements are found in 45 CFR 46.109(f). Federally Funded Level II and III research that will continue for a period of more than one year require continuing review and approval by the IRB prior to the end of the approval period. The IRB will request more frequent reviews when the element of risk and the nature of the project warrant. At the time of initial approval, the IRB will inform the investigator if the length of approval is less than 364 days, and if verification from sources other than the investigators is required as part of the continuing review. IRBNet sends reminders to the research team at least 30 days prior to the of expiration date of approval. Researchers may be reminded 120 days in advance of the expiration date of the research. However, they should not submit a Continuation request until 30 days before the expiration date.

If the research application remains substantively unchanged at the end of the approval period, the responsible investigator will complete a Continuing Review Form found in the Forms and Templates link in IRBNet. When completed, the form will be loaded into IRBNet prior to the end of the approval period.

Failure to provide a request to continue approved research before the expiration date will result in the research being closed and all recruitment and data collection must cease. If the researchers wish to continue after closure, the process must start over with a new application.

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Failure to Follow Approved Procedures

Any non-compliance by research investigators with the requirements of the IRB shall be reported promptly to the IRB Director for appropriate follow-up. The IRB Director will consult with the IRB Administrator to determine appropriate action. The IRB Director will make a report to the IRB.

If a project is not being conducted in accordance with the Board's requirements and/or conditions, the IRB Director in consultation with the IRB Administrator has the authority to terminate or suspend its approval of the research and to confiscate any data collected.

Adverse Reaction/Unanticipated Problems Report

The guidelines established by the Minnesota State University, Mankato Institutional Review Board are based on information provided by OHRP regarding Adverse Events/Unanticipated Problems and OHRP Guidance on Reporting.

Reporting Process

It is the responsibility of all investigators whether students, staff, or faculty conducting research on humans at or under the auspices of the University to report immediately (preferably within 24 hours) (phone, e-mail, in person) to the IRB Director and/or IRB Administrator any adverse reaction, unanticipated event/ problem or situation or condition that leads to harm, injury, or negative effect to a research participant.

Subsequently, a written report must reach the IRB Administrator within 3 working days of the incident. The IRB Administrator who will inform the IRB Director and Chair or Co-chairs. They will determine if or when the IRB will be informed of the incident.

The IRB Director is available for consultation and assistance in reporting either an adverse event or unanticipated problem to the IRB Administrator. In the case of DHHS funded projects, the IRB Administrator must report such incidents to the DHHS (OHRP and if required the FDA).

The following information will be included in the written report:

1. Information Required in Report to the IRB Administrator
    a. Date of report,
    b. IRBNet Id Number and title of proposal,
    c. Principal Investigator of research study (must be faculty [not adjunct] or staff),

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d. Date of incident/reaction,

e. Description of the incident,

f. Cause of incident/reaction,

g. Any steps taken as a result of the incident e.g. participant went to emergency ward,

h. Steps to be taken to avoid incident/reaction in the future, and

i. Signature of principal investigator.

Additional information may be requested.

1. Types of Action IRB may take include but are not limited to:[3]

   a. Requesting the investigator make modifications to the protocol

   b. Requiring more frequent review of the protocol (e.g., more often that the minimal of annual review)

   c. Requesting the investigator modify the consent process or consent documents

   d. Requiring the investigator to provide additional information to current and/or past participants or re-consenting to participation

   e. Requiring additional training of the investigator and/or study staff

   f. Reconsideration of IRB approval

   g. Implementation of monitoring of the research

   h. Implementation of monitoring of the consent process

   i. Recommendation to the IRB Administrator to suspend the privileges of an investigator or study team member to conduct human subjects research

   j. Suspension of the research

   k. Termination of the research

[3] https://kb.wisconsin.edu/page.php?id=19243&no_frill=1 (January 2020)

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University Responsibilities

The University will provide both meeting space and enough staff to support the IRB's review and record-keeping duties, and training of staff and members.

The University assumes full responsibility for IRB policy.

Administrative Functions and Responsibilities

It is the responsibility of the Associate Vice President of Research and Dean of the College of Graduate Studies (IRB Administrator) to assure that the policies and procedures concerned with projects involving human participants are carried out in accordance with this manual and with any institutional assurances made by the University.

The chain of authority for all IRB issues shall be as follows: initial concerns shall first be presented to the IRB Director, Chair, or Co-Chair, if unresolved shall proceed to the IRB committee, next to IRB Administrator, and if still unresolved to the Provost and Senior Vice President for Academic Affairs and finally to the President of the University.

1. The IRB Administrator is the person authorized to sign for the University on issues related to the IRB.
2. The IRB Administrator will assure availability on the University Web site to current IRB policies and procedures.
3. In addition, the IRB Administrator has the authority and responsibility for promptly reporting to the NIH-OPRR a variety of issues. In conjunction with this requirement, the IRB Administrator must be prepared to receive and act on information received from a variety of sources, such as human participants, research investigators, the Office of Research and Sponsored Programs (RASP), the IRB, or other institutional staff. For reporting purposes, the procedures described below are to be followed:
    a. Non-compliance
    b. Injuries to human participants
    c. Unanticipated problems
    d. Suspension or termination of IRB approval
    Whenever the IRB suspends or terminates approval of research, the IRB Administrator, in consultation with the IRB Director, Chair, or Co-Chairs, shall construct a letter that states the reasons for the IRB's action.

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The letter shall be delivered promptly via IRBNet to the research PI, and if necessary, the Provost and Senior Vice President for Academic Affairs, and, the OPRR. The minutes of
an IRB meeting will document the suspension or termination and any discussion around the issue.

4. The IRB Administrator shall assure the preparation and maintenance of adequate documentation of IRB activities, including the following:
    a. Copies of all research applications reviewed and any supporting documentation that accompanies the applications for at least three years after closure of the research.
    b. Records of continuing review activities.
    c. Copies of all correspondence between the IRB and the research investigators.
    d. Written procedures for the IRB.
    e. Copies of Reliance agreements.
5. The IRB Administrator shall assure accessibility of IRB records for inspection and copying by authorized representatives of HHS at reasonable times and in a reasonable manner.

Certification Requirements

Federal granting agencies use the term Certification (Part II page 19 Section 5.4) to mean IRB has approved the research protocol, consent document, and any other research related documents (e.g. surveys, etc.) and any revisions.

The PI is responsible for submitting a certification to the Office of Research and Sponsored Programs. RASP will coordinate submission on behalf of the University to HHS and all other funding agencies as appropriate.

The IRB Administrator shall ensure that research involving Investigational Drugs or Medical Devices complies with FDA 21 CFR 56 and 21 CFR 812. Current FDA Information Sheets are available from the FDA.

Additional Resources

Examples of Reliance Agreements can be found at Reliance Agreement and Reliance Agreement-2.

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