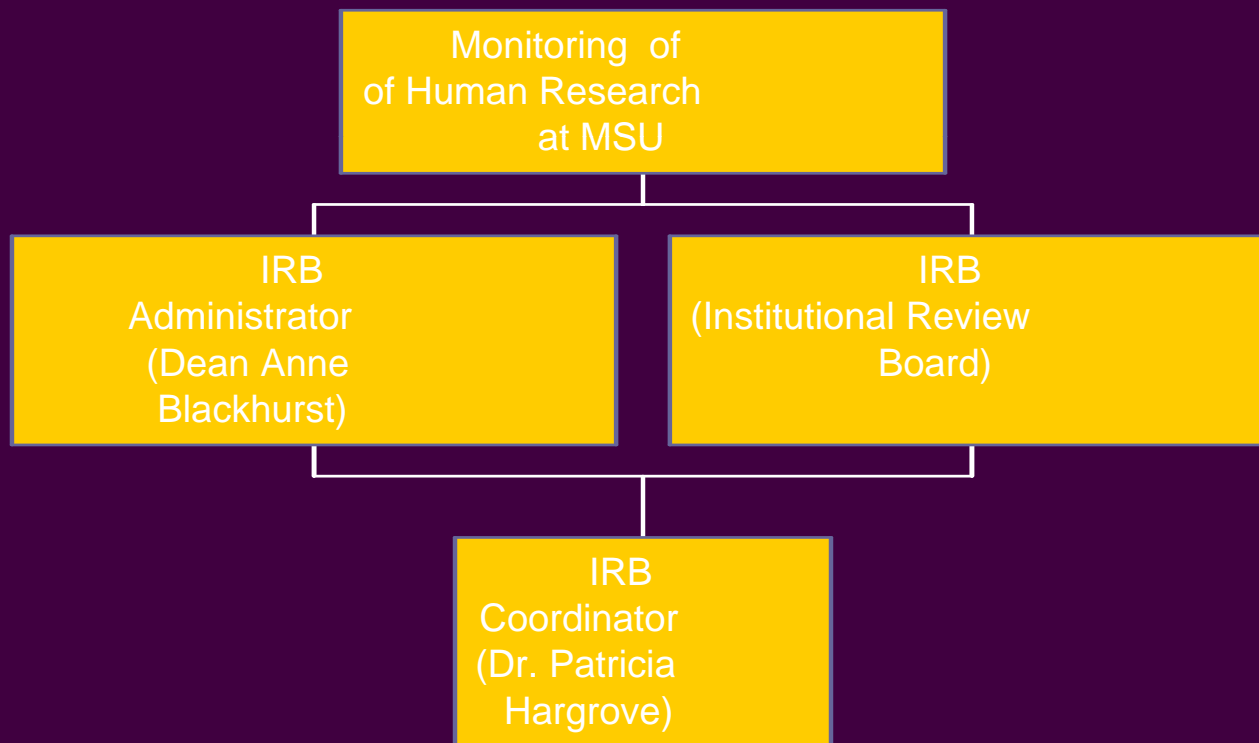


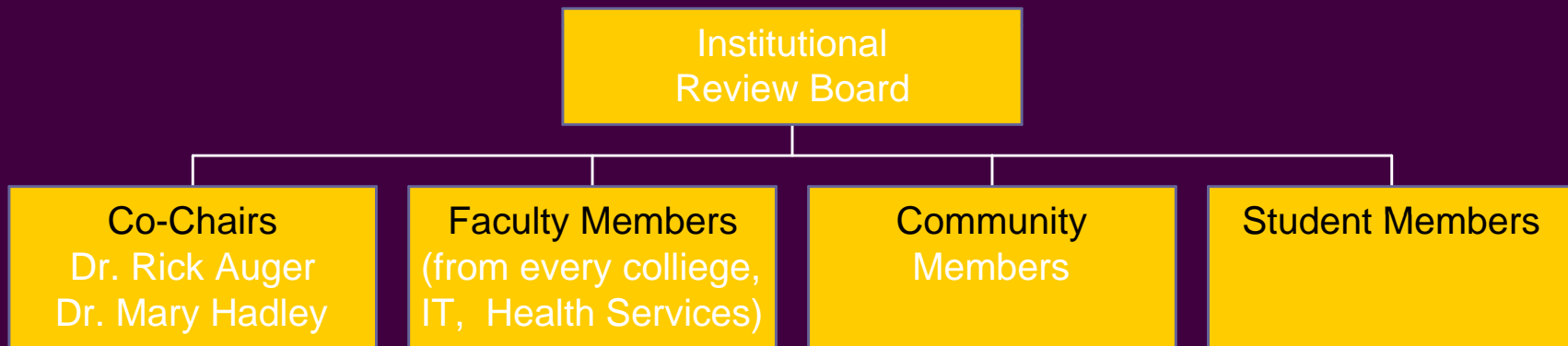
Getting your IRB proposal approved!

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Institutional Review Board - Structure



Institutional Review Board-- Voting Members



1978: The Belmont Report

- Principle 1: Respect for Persons
 - Right to autonomy and self-determination
 - Protecting vulnerable subjects

1978: The Belmont Report

- Principle 2: Beneficence
 - insures the well-being of research participants.
 - There are trade-offs between individual and societal benefits to research.

1978: The Belmont Report

Principle 3: Justice

Distribute the risks and potential benefits of research equally among those who may benefit from the research.

Purpose of the Minnesota State Mankato IRB

- Safeguarding the rights and welfare of subjects in research and related activities.
- Assisting faculty and staff engaged in relevant research from unknowingly committing unethical acts.

Application Formats

- Formats
 - paper
 - online
- Select a single format (I.e., cannot switch)
- Wait until you receive approval to begin data collection.

Steps in Applying to the IRB (paper version)

1. Go to the IRB webpage (<http://grad.mnsu.edu/irb/>).
2. Scroll down middle of page.
3. At “Proposal Submission” click on “IRB Proposal Guidelines”.
4. Complete and submit AF 115 or AH 103 (hard copy only).

Steps in Applying to the IRB (online version)

1. Go to IRB online submission webpage
(<http://grad.mnsu.edu/irb/onlineproposal.html>).
2. Complete the application.
3. Submit the application electronically.

Hints-- General:

- Save early and often (*online*).
- Proposal times out in 60 minutes (*online*).
- Remember: reviewers are not familiar with your field (*online and paper*).
- Watch for changes in deadlines at <http://grad.mnsu.edu/irb/> (*online and paper*).

Hints-- Getting Started Online:

- After clicking “Online submission” button, screen reads “IRB Proposal List”
- If you wish to develop a new proposal, click on submit a proposal.
- If you wish to review a draft or approved proposal,
 - enter proposal # OR
 - scroll down to the list of your proposals

Hints-- Identifying Information:

- Keep title short-- within box
- Select Level:
 - I
 - II
 - III

LEVEL I

- Research involves less than minimal risk.
- Involves measures that are not of a personal nature. Can be in the following formats:
 - Standardized educational tests
 - Surveys
 - Questionnaires
 - Interview

LEVEL I (continued)

- Research activities are concerned with elected/appointed public officials or candidates for public offices. Can use the following measures
 - Standardized educational tests,
 - Surveys,
 - Interviews, and
 - Observations

LEVEL I (continued)

- Research involves the study of existing
 - Data,
 - Documents,
 - records, or
 - Specimens.
- Does not allow for the identification of the participants.

LEVEL I (continued)

- Research involves
 - taste and food quality evaluation, and
 - foods are wholesome and safe.
- Consent forms may not always be necessary
- Expect 5-7 working days for turnaround.

LEVEL II

- Proposals which involve minimal or less risk and are not eligible for Level I review.
- Recordings of identifiable information with minor risks.
- Consent forms are required.
- Expect AT LEAST 10 -13 working days turnaround.

LEVEL III

- Involves the most serious risks.
- Only reviewed at monthly IRB meeting.
MUST be submitted 5 working days in advance.

Hints-- Identifying Information (continued):

- PI and CI: MUST be MSU faculty and staff (not GA, TA, RA).
- Faculty applications: to list student researcher(s)-
-Note name(s) in Special Circumstances box at end.
- Faculty: only room for 1 CI; list other in Special Circumstances box.

Hints-- Identifying Information (continued):

- Faculty: use MSU mailing address, not office.
- All boxes need to be completed.
- Use xxx if necessary EXCEPT
- Use xxx-xxxx for phone number, if there is not a CI.

Hints-- Advisor approval:

- Student applications: must be accompanied by agreement from PI to supervise.
- If PI has trouble providing ok online, send following email to patricia.hargrove@mnsu.edu with Log # and student's name:
- I agree to supervise (insert student's name)'s project. I have read the proposed protocol, and I believe the contents of the proposal are consistent with IRB policy.

Hints-- Project Description:

- #1--- Project Start Date: Should not begin before recommended turnaround times:
 - Level I: 5-7 working days
 - Level II: 10-13 working days
 - Level III: reviewed IRB meeting, must be submitted at least 5 working days prior to meeting
- #1--- Project End Date: approval is for only 1 year.

Hints--Project Description (continued):

- #4: If you have received approval from another IRB, respond 'yes' here.
 - include approval in attachments
 - attach other proposal
 - special conditions for faculty dissertations*
- #5: Pre-existing data, not secondary
 - make very clear in application.

Hints--Project Description (continued):

- #6: anonymity—the state of not being known or identified.
- #6: confidentiality--- the expectation that nothing will be revealed
- #7: Other vulnerable populations:
 - elderly and cognitively impaired.
 - groups subject to coercion

Hint--Project Description (continued):

- #8: If deceiving participants,
- Be sure the proposal contains a rationale for withholding or providing deceptive information.
- Consider debriefing.

Hint--Project Description (continued):

- #9: If recording participants,
- Be sure the proposal contains a description of how you will insure security of recordings.

Hints-- Attachments:

- Keep title short.
- Label revised attachments.
- Include letters of support/permission from other agencies/institutions.
- If do not have a required letter/permission, commit to providing it to IRB prior to beginning data collection.

Hints--Application #2d:

- The term “random” should only be used in its research design/statistical sense.
- Describe what strategy you will be using to randomize in your subject/participant selection.

Hints--Application #2e:

- Discuss risks thoughtfully.
- Risks can be social and/or emotional as well as physical.
- It is rarely accurate to claim that there are no risks.
- Preferred term for Level I proposals-- 'less than minimal.'

Hints--Application #3b:

- The following works:
- The consent forms be locked in a desk/file/cabinet in the the PI's for at least 3 years.

Hints--Consent Forms

- On a survey, a signed Consent form may be omitted BUT
 - Consent information must be provided (*Respect*).

Hints-- Consent Form (continued)

- Signed by a competent adult or legally authorized representative
- Voluntary
- Understandable
- Translated, if not in English
- No deceptions
- Purpose provided
- Procedures clearly described

Hints--Consent Forms (continued)

- Risks listed
- Benefits explained (in the following order):
 - For participants
 - If none for participants, so note.
 - For society

Hints--Consent Forms (continued)

- Provide contact information and rationale for contacting the following:
 - Student investigator (optional)
 - Principal investigator
 - IRB Administrator

Hints-- Consent Forms (continued):

- If participants are under 18 years of age, consent forms (for parents/guardians to provide permission) and assent forms (for minor participants) are required. (*Respect*)
- Consent and assent form are also required for vulnerable adults and prisoners. (*Respect*)

Hints-- Consent Form (continued):

- If using a survey or questionnaire, inform participants they can skip items.
- If using internet, explain that security can be breached and the steps you are taking to minimize risk.

Hints-- Consent Form (continued):

- Clear statement that the project is research within first two sentences .
- Note that participants are free to refuse consent or withdraw without reprisal.

Hints--Design Issues

- Avoid coercion or undue influence versus voluntary actions (*Respect*).
- Insure the right to withdraw from participation without penalty (*Respect*).

Hints-- Design Issues

- Design research so that risks are minimized (*Beneficence*).
- The risks of research are justified by the potential benefits to subjects and/or society (*Beneficence*).

Hints--Design Issues (continued)

- Remember that those who review the IRB proposals are not experts in your area/discipline.
- It is important to explain your procedures clearly.

Resources on MSU Webpage

- Currently available
 - Online and paper submission guides
 - Sample consent and assent forms
 - IRB Information
 - CITI Web-based Training Program (Cooperative Institutional Training Initiative)
 - IRB Presentation for Instructors

- Look for in the future

- A guide to whether a project should be submitted to the IRB
- A checklist for consent forms
- A guide to whether a consent form is needed

- <http://grad.mnsu.edu/irb/>

- patricia.hargrove@mnsu.edu