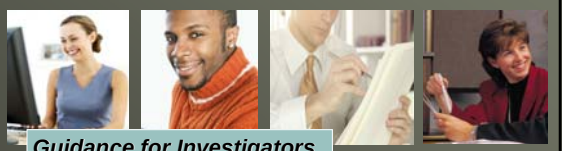
The Process of IRB Review –

Steps to Approval of Your Research Project



Guidance for Investigators

Overview

- What is the purpose of IRB review?
- How much time should I plan for?
- How does the review process work?
- What level of review is required for my project?
- How can I ensure that my research will be approved by the IRB?
- What are the requirements for approval?

Purpose of IRB Review

Three basic ethical principles apply to the conduct of research involving human subjects/participants: respect for persons, beneficence, and justice

Federal regulations require that an Institutional Review Board (IRB) review human subjects research to ensure that the rights and welfare of participants will be protected.

NDSU's IRB membership is composed of faculty representatives, and unaffiliated members with various backgrounds as either scientists or non-scientists

IRB review must occur *prior* to initiation of any research procedures involving human research participants.

What projects constitute 'human subjects research' and require NDSU IRB review and approval? (see FAQ page on IRB web site)

Time Frame for IRB Approval

The length of time to obtain IRB approval will depend on several factors:

- quality of the application submitted
- current volume of applications submitted and under review
- type of review required

- Upon submission of a ***complete*** application, review will generally require:
  - Exempt certification >> 5 -7 working days
  - Expedited review >> 10-14 working days
  - Full review >> 15 working days, if received 2 weeks prior to the meeting date (IRB meets once/month)
- Plan accordingly and allow sufficient time for:
  - completing the training requirement
  - carefully preparing the protocol application
  - the IRB review process applicable to your project
  - possible requests for revisions or additional information

Submitting the IRB application well in advance of your planned start date (at least several weeks or more) is highly recommended!

IRB Review Process

- The investigator initiates the process of review by submitting an application to the IRB office.
- IRB staff will screen the application and may request additional information or revisions if it is incomplete or contains inconsistencies.
- Once the application is complete, the IRB will assign the applicable level of review. The application will be reviewed utilizing specific criteria.
- If the protocol fails to meet the criteria for approval, more information or revisions will be requested. Should significant changes be needed, the revised protocol will require a new review.
- Once the application meets all criteria for approval, the IRB will issue an approval letter.

Requests for minor changes are not uncommon; the research may being only AFTER receipt of an approval letter from the IRB.

Levels of IRB Review

In general, the type of review required is based on the potential for risk of harm or discomfort, and/or involvement of any vulnerable groups in the research. There are 3 levels of review:

- Exempt certification: Research may be eligible if it meets the criteria specified in one or more of 6 allowable categories. In general, projects involving public observation, taste tests, and some surveys or interviews with adults may be eligible.
  - The categories of research eligible for exemption are described in detail in the 'Exempt Protocol Form' available on the IRB website.
  - Qualified IRB staff or the IRB Chair review all claims of exemption.

Regardless of the level of review, the same basic ethical principles will apply to all research involving human participants: Respect for persons, beneficence and justice.

Levels of IRB Review, cont.

- Expedited review: Research may be eligible if it involves no more than minimal risks, and meets the criteria specified in one or more of 9 allowable categories. In general, projects involving interventions, surveys of a sensitive nature, and/or child participants may be eligible.
  - Expedited review is performed by the IRB Chair, or 1 or 2 experienced members.
  - The categories of expedited review are listed in the 'Expedited Categories Attachment' available on the IRB web site.
  - The categories of research eligible for expedited review or exemption are specified by federal regulations.
  - Many research projects at NDSU are eligible for expedited review or exemption.

In cases where the eligibility for exemption or expedited review is questionable, the IRB uses caution and may require a higher level of review to ensure adequate subject protections and compliance with federal regulations.

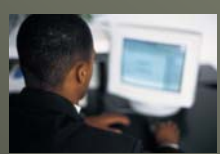
Levels of IRB Review, cont.

- Full review: Research not eligible under the above 2 levels is reviewed by the board at a convened meeting. In general, these projects will involve more risks, vulnerable populations, invasive surveys or interviews, clinical or experimental interventions or procedures.
  - While the investigator is encouraged to make a preliminary decision regarding the review level of the application, the IRB will make the final assignment of the level of review.
  - Should the IRB determine that a particular project does not qualify for exempt or expedited review, as the investigator had initially anticipated, the IRB may request additional information, and will assign the project for review at the eligible level. Additional time for review may be required.

The IRB may be cited for noncompliance if the review process does not meet federal requirements (ie, approving a protocol under an ineligible review category, or failing to review sufficient information or documents.)

Steps to Obtaining IRB approval

- How can I ensure my research will be approved by the IRB?
- How do I get started?



#1: Complete or update training

- Training on the protection of human subjects in research is required for the principal investigator, co-investigator, and any research team member who will have a role with the human subjects portion of the project:
  - designing or planning the study
  - recruiting participants
  - obtaining informed consent
  - performing research procedures with human subjects
  - analyzing identifiable data
- NDSU requires that training be updated every 3 years in order to maintain current knowledge of the ethical principles and regulatory requirements.

Understanding the basic principles and requirements is key to planning and conducting research projects that will protect the rights and welfare of participants.

#2: Plan for subject protections

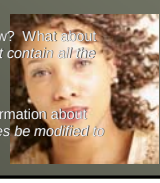
- Carefully consider subject protections as you plan the research project:
  - How will you select participants; how will they be invited to take part in your research?
  - How will you provide them with all the information they should know?
  - Will they be able to make a free choice about participating?
  - How will you protect them from potential risks or harms?
  - What procedures will you use to protect their privacy?
  - If you will promise confidentiality, how will you prevent any accidental breach of research data?
  - If you intend to involve children, prisoners, or other groups considered to be vulnerable in the research, have you considered additional protections?

If these issues are adequately considered during the planning stages, you will be better prepared to complete the IRB application and meet the criteria for approval.

Picture yourself as a participant:

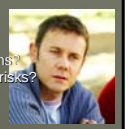
In considering protection measures, it helps to put yourself in the participant's place. Consider whether you, or a family member, would feel comfortable participating in this research.

- **Recruitment and subject selection:**
  - Would I feel any pressure to take part in the research, even though I may not want to? *(How can this process be changed to eliminate this?)*
- **Consent process:**
  - Would I get all the information I would want to know? What about other options for me? *(Does the consent document contain all the required elements?)*
- **Privacy:**
  - Would I feel comfortable revealing that type of information about me in this context/setting? *(How can the procedures be modified to respect individuals' privacy?)*



Picture yourself as a participant, cont.:

- **Research interventions and data collection:**
  - Would I realize what I was getting into? *(Is the consent process clear and complete?)*
- **Risks and harms:**
  - Would I have information about all potential risks and harms?
  - Would I be sure that I will not be exposed to unnecessary risks? What do I do if I'm injured? *(How can risks for subjects be minimized?)*
- **Confidentiality:**
  - Would I be told who would see my information and how it would be reported or released?
  - What concerns would I have if my information got into someone else's hands? Could they figure out which responses or data were mine? If so, would this be embarrassing, or get me into trouble? *(Are the data security measures sufficiently robust?)*



#3: Select the applicable protocol form

The IRB website Forms page has 2 different protocol forms:

- 'Exemption Protocol Form'
  - If your project qualifies under one of the 6 applicable categories, use this form.
- 'Protocol Form'
  - If your project would *not* be eligible for exemption, use this form.

If unsure which form would apply for your project:

- ***Consult guidance in the 'Exemption Protocol Form'***
- ***Consult your faculty advisor, IRB staff or IRB Chair, or***
- ***Use the 'Protocol Form', and the IRB will assign the appropriate review category***

#4: Complete the form thoroughly

- Check each response for completeness, adequate detail and description, and consistency
- Use optional checklists available on the web site

Sufficiently detailed information is needed in order for the IRB to make the required determinations for approval. Careful attention to detail when completing the IRB application will minimize the need for requests for missing information or documents.

#5: Avoid these common errors

- Missing or incomplete responses
- Insufficient detail in description of procedures
- Inconsistent responses within the protocol form
- List of research team members incomplete, or includes individuals with no role in the human subjects portion of the project
- Missing attachments or permission letter(s)
- Assurance page does not include signatures
- Funding proposal not attached
- Misunderstanding of eligibility for exempt status

Initiating research with human subjects prior to receiving IRB approval is a violation of NDSU policy and federal regulations.

#6: Include applicable consent document(s)

- Oral script, cover letter or information sheet
- Recruitment ads, notices, or invitations
- Parent/guardian permission forms
- Child or Youth Assent forms

Follow the instructions and suggested templates on the IRB web site

Ensure that the process of consent and any documents:

- include all required and any applicable elements
- are easily understandable to the least educated participant
- contain no jargon or exculpatory language
- are consistent with information in the protocol form (as applicable)

All information that will be shown or provided to participants is considered to be a part of the process of informed consent, and requires IRB approval.

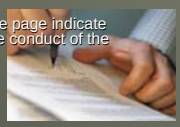
#7: Include other applicable documentation

- Children in Research Attachment
- Prisoners in Research Attachment
- Additional Materials Attachment
- HIPAA Research Attachment
- Request for Consent Waiver or Alteration Attachment
- Documentation from outside entity collaborating or assisting with research
- Funding proposal

The protocol forms contain prompts to indicate when this documentation will be applicable.

#8: Obtain departmental approval

- The appropriate department/unit-level approval is required prior to submission of the application to the IRB.
- The signature of your department Chair/Head, Director or Dean on the assurance page of the protocol (last page) signifies their approval of the project as scientifically valid and meeting the standards of the department or unit.
- Signatures of the PI and Co-I on the assurance page indicate acknowledgment of their responsibilities in the conduct of the research.



The IRB will not process protocol applications lacking these signatures.

#9: Submit the application to the IRB office

- Campus mail, or delivery to Rm 130, Research 1
- Fax to 701-231-8098
- Email to ndsu.irb@ndsu.edu
- Note that the assurance page must be either mailed, faxed, or scanned to show signatures.
- Submit one signed copy, plus an electronic copy (if an expedited or full review will be required)

Requirements for IRB Approval

In order to approve research, the IRB must review the protocol application and determine that the following criteria are met:

- Risks for participants will be minimized
- Risks will be reasonable in relation to any benefits
- Subject selection will be equitable
- Informed consent will be sought, and documented as appropriate
- There will be adequate provisions to protect subjects' privacy and the confidentiality of their information, as applicable
- Additional safeguards are in place for those likely to be vulnerable to coercion or undue influence.
- The research will be monitored for safety, as applicable

#10: Respond to IRB requests

- During the screening process, the IRB staff may request additional information or missing document(s) in order to obtain a complete application for the reviewers.
- After the review process, the IRB may require changes or additional information in order for the project to meet the criteria for approval.
- You will be provided with justification for each request; feel free to ask questions if you are unsure of the requirement for any changes or additional information.

A prompt and thorough response to these requests will streamline the process of obtaining approval.

Additional Resources

IRB web site: www.ndsu.edu/research/irb

- Current protocol forms
- Informed consent instructions and suggested templates
- Guidelines and policy
- IRB meeting schedule
- IRB Membership list
- Online training links, campus training schedule
- Federal OHRP and FDA sites
- Contact info for IRB staff and IRB Chair: ndsu.irb@ndsu.edu