

Andrews University
Institutional Review Board
Handbook

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Introduction

The Andrews University Institutional Review Board (IRB) is responsible for the review of all human subjects research conducted by Andrews University faculty, staff or students, or at Andrews University by other entities. The IRB is registered with the Department of Health and Human Services Office of Human Research Protections (OHRP) and operates under a Federal Wide Assurance (FWA). The FWA insures that the University IRB policies and procedures abide by the guidelines established by the Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (*The Belmont Report*) and the OHRP Code of Federal Regulations "Protection of Human Research Subjects."

The Belmont Report identified three basic ethical principles that should guide all research involving human subjects:

- **Respect for persons:** indicates: 1) that individuals should be treated as autonomous agents that require informed, voluntary consent to engage in the research and 2) that persons with diminished autonomy are entitled to protection
- **Beneficence:** is an obligation to: 1) do no harm and 2) maximize possible benefits and minimize possible harms
- **Justice:** means there should be fairness in distribution of both the benefits and the risks associated with the research.

The IRB seeks to create a collaborative relationship with the research community to assure that research with human subjects is conducted in accordance with legal requirements and ethical principles. These principles require the balancing of risks to subjects against the scientific knowledge to be gained and the potential benefits to subjects and society. The IRB also focuses on the informed consent process to assure that subject participation in research is voluntary.

IRB Governance

The Scholarly Research Council serves as the governing body for the IRB. The Scholarly Research Council approves policies recommended by the IRB, and oversees the work of the IRB. All policies voted by the Scholarly Research Council must be in harmony with federal government guidelines.

The IRB Chair will provide an annual report of IRB activities to the Scholarly Research Council. Non-substantive procedural changes approved by the IRB are to be reported to the Scholarly Research Council. Substantive procedural changes and all policy changes that have been approved by the IRB are recommended to the Scholarly Research Council. Approval by the council is required prior to implementation of substantive procedural or policy changes.

The Andrews University Provost or designee is the administrative officer with responsibility for the IRB. The IRB will report to the Provost or designee in the event of (a) any unanticipated problems involving risks to human subjects, (b) any serious non-compliance by a Principal Investigator, or (c) any suspension or termination of IRB approval. All appeals related to IRB decisions will be handled by the Provost or designee (see Dispute section below).

The Research Integrity and Compliance Officer will oversee the day-to-day details of the IRB Office in close cooperation with the IRB Chair.

While the Scholarly Research Council and Provost have designated responsibilities related to the IRB, no decision by the IRB related to the approval or disapproval of an application can be overruled by either of them or by any other person or group. However, other university entities may impose restrictions on or disallow research that has been approved by the IRB.

IRB Jurisdiction

According to the OHRP Code, all **research** involving **human subjects** is to be reviewed and approved by the IRB, where “human subjects” and “research” are defined as:

- **“Human subject** means a living individual about whom an investigator conducting research obtains (1) Data through intervention or interaction with the individual or (2) Identifiable private information.”
- **“Research** means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”

Andrews University has widened the scope of the IRB to also include research projects that may not necessarily contribute to generalizable knowledge. In most cases, however, these projects will be evaluated by the IRB as being “Exempt from IRB Review”.

IRB Membership

IRB members are appointed by the Provost or designee following the guidelines below, in consultation with the Director of the Office of Research and Creative Scholarship and the School Deans. The IRB consists of six to ten or more members. The membership is to include representation from all of the major fields that conduct substantial human subjects research at the University and at least one faculty member selected from a non-science discipline (e.g., other than behavioral, biological, or physical sciences). This representation ensures that the IRB possesses sufficient knowledge of the local research context. The IRB shall consist of:

- One or two faculty members from the College of Arts & Sciences
- One or two faculty members from the School of Health Professions
- One or two faculty members from the School of Education
- One or two faculty members from the Seventh-day Adventist Theological Seminary
- One member of the community who is not affiliated with the University
- One graduate student member

The graduate student member is appointed by the Provost or designee, upon consultation with the Graduate Dean, for a one-year term. Each of the other members is appointed for a three-year term, with approximately 1/3 of the membership replaced or reappointed each year. Typically, individuals do not serve for more than two consecutive three-year terms. All members are voting members of the IRB.

A prisoner representative (prisoner, prison chaplain, or social worker licensed to work with prison populations) will be appointed by the Provost or designee to serve as an alternate member of the IRB. Attendance of the prisoner representative is required at any IRB meeting that reviews research projects involving prison populations.

Members will be appointed by the Provost or designee, as needed, to serve as alternate members of the IRB to evaluate applications in languages other than English.

The Associate Dean for Research shall be a non-voting ex-officio member.

The Research Integrity and Compliance Officer will serve as the non-voting secretary of the IRB.

The Provost or designee will appoint the IRB Chair from among the faculty members of the IRB.

Operation of the IRB

The IRB will meet monthly throughout the year as dictated by the volume of applications requiring full review. The IRB Secretary will determine and publish meeting dates at the beginning of each academic year.

An IRB member will absent her/himself from the vote on any application in which the member has a conflict of interest (e.g., as the Principal Investigator, research advisor, or having financial interest in the research). This action will be noted in the IRB minutes.

The presence of a majority of voting members (including one member from a non-science discipline) will constitute a quorum for the conduct of business at regular meetings of the IRB. All decisions will be reached by a simple majority of the voting members present.

All IRB members must complete the online training tutorial produced by the National Institutes of Health (<http://phrp.nihtraining.com/>) or an approved equivalent training tutorial, and submit a valid certificate of completion to the IRB Office (certificates are valid for three years).

The IRB Review Process

Principal investigators who are planning research projects requiring individual applications are responsible for initiating the review process by submitting an application with all necessary forms as described below, to the IRB Office. Copies of the forms and instructions may be obtained on-line from the Andrews University IRB web site:

www.andrews.edu/services/research/research_compliance/institutional_review/index.html.

Information about required forms and procedures may also be obtained directly from the IRB Office (269-471-6361).

The IRB application

A full description of the planned research must be submitted by completing an application for IRB review form and submitting required supporting documents. Complete applications should be emailed directly to the IRB at IRB@andrews.edu.

For most researchers, all documents included in the application must be in English. If any oral or written materials will be presented to the subjects in a language other than English, versions in both English and the other language must be included in the application. This would include recruitment materials, consent forms, surveys, and interview or focus group questions.

If the researcher is in an Andrews University program in which the instruction and evaluation is conducted in a language other than English and the research would fall under the "Exempt from IRB Review" or "Expedited Review" categories, the documents may be submitted to the IRB in the language used in the Andrews University program. For these cases, the

application will be evaluated by an IRB member who is fluent in the language to determine the appropriate categorization. If the project is determined to need Full Review, the documents must be presented to the IRB in English.

There are three IRB application forms: for studies requiring Expedited or Full Review, for studies that are Exempt from IRB Review, and for studies only using pre-existing data. The information requested in the application form may be submitted either on the application form itself or in an attached protocol.

The following elements are included in the application forms where appropriate.

- a. General information
 - i. Study title
 - ii. Researcher information
 - iii. Advisor information
 - iv. IRB Training Certificates
- b. What is the purpose of the research?
- c. Who are the subjects?
- d. How are the subjects recruited or selected?
- e. How will informed consent to participate be obtained from the subjects?
- f. What experimental conditions will be used? Will any subjects be at risk due to these conditions?
- g. What are the data collection procedures?
 - i. Where
 - ii. What
 - iii. How
 - iv. Who
- h. Will the data be treated confidentially?

An application that is evaluated by Expedited Review or Full Review must include the exact research procedures to be used and all questions included in surveys, interviews, or focus groups. An application that is categorized as “Exempt from IRB Review” and only collects data through surveys, interviews, or focus groups, only needs to include a sample of each type of question included.

The Principal Investigator and co-investigators listed on the IRB application must complete the National Institutes of Health online training tutorial (<http://phrp.nihtraining.com/>) or an approved equivalent training tutorial, and submit a valid certificate of completion with the IRB application (certificates are valid for three years). For applications submitted by student researchers, the advisor who gives written approval for the IRB application must also complete the training and submit a certificate to the IRB Office.

Students participating in a cohort taught in a language other than English may use alternative training materials in the language of instruction, if such materials are available. The alternative training materials to be used must be approved by the IRB Office.

All materials must be submitted for IRB review in electronic form. The materials submitted should include:

- a completed IRB application form
- separate attachments as appropriate
 - a protocol (if information is not supplied on the application form)
 - investigator and advisor training certificates

advisor approval letter/email
institutional approval letter(s)
recruiting document(s)
informed consent/assent form(s)
data collection instrument(s).

IRB review

When an application is received at IRB@andrews.edu, the IRB Office will assign a tracking number and check the application to confirm that all required materials have been submitted. For purposes of tracking, the Principal Investigator (PI) should refer to the assigned tracking number in all correspondence. If the application is incomplete, the PI (and research advisor, if applicable) will be contacted directly with a request for the missing information. Incomplete applications for which there has been no communication from the PI for a period of three months will be closed. In order to insure that only accurate and updated materials are reviewed, it is important that for each resubmission the PI email a complete set of the application materials, even if some of the documents have not changed.

Once the complete application is received, it will be classified into one of the categories described in the following section.

Normally, feedback on Exempt from IRB Review applications will be returned to the PI within one week of receipt of the complete application, feedback on Expedited Review applications within two weeks, and feedback on Full Review applications within three days after the IRB meeting at which it is evaluated.

Changes or clarifications to all applications may be requested by the IRB Secretary, IRB Chair or the full IRB. After the PI makes the requested changes, the re-submitted research application will be re-evaluated by the IRB Secretary, IRB Chair or full IRB.

After the application has been reviewed or evaluated, a letter will be emailed to the PI (and the research advisor, if applicable), certifying that the research application has been reviewed, and has been granted exemption status, been approved, or been denied. The research may begin once the PI receives either an IRB letter of exemption or letter of IRB approval.

The approval of an application reviewed by Expedited Review or Full Review procedures is effective as of the date of the approval letter and valid until the conclusion date specified in the letter. The IRB approval may not be for more than 12 months.

Data collection may not begin until the application has been approved by the IRB. If the application is not approved, the research project may not proceed.

Review categories

All research involving human subjects requires IRB evaluation to determine if it is exempt from IRB review or needs to be reviewed and approved by the IRB. Neither the investigator nor the advisor can declare that a project does not need IRB review or approval. Only the IRB can determine that research involving data collection using human subjects is Exempt from IRB Review. The IRB does not approve an exempt study – it just categorizes the project as being “Exempt from IRB Review.” However, for these studies, if the investigator plans to make any substantial changes to the procedures, the changes must be reported to and approved by the IRB.

Two types of data-gathering activities that some might consider being research do not need to be evaluated by the IRB.

1. Administrative evaluation: Routine surveys gathered by university offices (where confidentiality is maintained)
 - Alumni surveys
 - Freshman testing
 - Senior surveys
 - Senior testing
2. Routine in-class evaluation: in-class data routinely gathered by an instructor related to normal class activities or procedures (usually not anonymous)
 - Surveys
 - Tests

Also, student research projects that are assigned and evaluated by the instructor do not need to be evaluated individually by the IRB, but may be evaluated by the IRB Chair as a group if the research projects have the following characteristics:

- There is no more than minimal risk
- No data is collected from minors or other vulnerable subjects
- There is no dissemination of results outside of the class

Once a year the instructor of a class that involves student research with these three characteristics must notify the IRB Office that research projects of this type will be done, and the projects for the class can be approved in advance without needing to submit the individual applications to the IRB Office.

It is the responsibility of the instructor of the class to inform the students of the policies and requirements of Andrews University and the federal government related to human subjects research and that all research should follow ethical and professional guidelines.

All other research activities involving human subjects at Andrews University are classified into one of the following three categories:

- Research evaluated by the IRB chair or designee as being "Exempt from IRB Review"
- Research requiring "Expedited Review" by the IRB Chair or a designee appointed by the IRB chair from among IRB members
- Research requiring "Full Review" by the IRB

Research evaluated by the IRB Chair or designee as being Exempt from IRB Review.

Research requiring IRB evaluation will be declared to be "Exempt from IRB Review" if it does not include any of the nine criteria listed below under the Full Review and Expedited Review categories and can be classified under one of the following OHRP categories:

1. Research done in established educational settings and involving normal educational practices.
2. Research using surveys, interviews, observation of public behavior, or educational tests.
3. Research involving elected or appointed public officials, or candidates for public office.
4. Research involving use of existing data, documents, records, or pathological or diagnostic specimens.

5. Research conducted or approved by department or agency heads designed to study, evaluate or examine public benefits or service programs.
6. Research involving taste and food quality evaluation and consumer acceptance studies.

The OHRP Code of Federal Regulations, paragraph 46.101(b) contains additional information related to these categories.

Although the IRB Office may determine that a project is Exempt from IRB Review, the IRB must still conduct an “exempt evaluation” to ensure compliance with the ethical principles of respect for persons, beneficence, and justice.

Even though the research project has been determined to be Exempt from IRB Review, any substantive changes in the research methodology or in the selection of participants must be submitted to the IRB Office for review before being implemented. If any adverse events occur, they must be reported to the IRB Office as soon as possible (see “Changes to Research Procedures” below).

Research requiring Expedited Review by the IRB Chair or designee.

Research may be evaluated under an Expedited Review process by the IRB Chair or designee if it does not fall in one of the Exempt categories or it includes ANY of the following:

1. Identification of subjects is possible (data is not anonymous) and identification may place subjects at risk
2. Data deals with private or sensitive topics
3. There is either audio or video recording of the data

Research requiring Full Review by the IRB.

Research may require Full Review by the IRB if it does not fall in one of the Exempt categories or it includes ANY of the following:

1. More than minimal risk (e.g., physical, psychological, economic, social, or legal) to subjects
2. Any subjects younger than 18 (except for research not needed to be submitted to the IRB - administrative evaluation or routine in-class evaluation)
3. Any subjects likely to be vulnerable to coercion or undue influence (e.g., pregnant women, prisoners, mentally impaired)
4. Coercion or undue pressure involved in selecting or recruiting subjects
5. Significant concealment related to research procedures
6. Deception related to research procedures
7. Invasive procedures

All documents included in applications requiring Full Review will be made available to all members of the IRB no later than seven days prior to the meeting at which it is to be considered.

A report of the actions related to all research proposals not evaluated by Full Review (proposals categorized as Exempt from IRB Review or evaluated through Expedited Review) are presented to the full IRB at its next regularly scheduled meeting. The full board must approve the actions taken by the IRB Office related to the proposals evaluated by Expedited Review.

Disputes

If a Principal Investigator disputes a decision of the IRB (e.g., a denial or required change in an application), the PI may request in writing that the full IRB review the decision at its next regularly scheduled meeting. The PI may provide the IRB with written arguments and supporting materials in advance of the meeting and/or may choose to appear before the IRB in person to discuss the issue. If the PI remains unsatisfied with the outcome of the IRB's reconsideration, he or she may consult with the Provost or designee, who may choose to mediate further discussion between the PI and the IRB. Once any mediation has concluded, the decision of the IRB is final; there is no further appeal. No decision by the IRB can be overruled by any person or group.

After IRB Review

Changes to research procedures

It is common for researchers to change their procedures after their applications have been accepted by their advisor, committee, and/or IRB. As it relates to the IRB, all changes in procedures must be submitted to the IRB. If an application has required Expedited Review or Full Review, all changes other than administrative application corrections (e.g., typographical and spelling errors) must be approved by the IRB before being implemented. The changes must be submitted to the IRB Office on the Modification of Procedures Form.

If an application submitted to the IRB has been categorized by the IRB chair or designee as Exempt from IRB Review, any substantive changes in methodology, whether planned or unplanned, including recruitment of subjects, procedures administered to subjects, data collection, and treatment of the data must be approved by the IRB before being implemented. The changes must be submitted to the IRB office on the Modification of Procedures Form.

Examples of substantive changes would include:

1. Changing the type of subjects recruited
2. Collecting data from a different organization or site
3. Changing the experimental treatment
4. Changing from written consent to implied consent
5. Changing information on the consent form
6. Changing the type of questions for a survey, interview or focus group
7. Changing data collection from surveys to interviews or from interviews to focus groups even though the questions remain the same
8. Adding audio or video recordings
9. Changing the method of storing of data that would affect confidentiality of the data

For applications that have been categorized as Exempt from IRB Review, minor or trivial methodology changes must be reported to the IRB Office, but do not need IRB approval before being implemented. These changes should be reported as soon as they occur but no later than one week after their occurrence.

Examples of minor or trivial changes would include:

1. Changing the sample size
2. Minor changes in the wording of a recruitment document
3. Minor changes in the wording of questions for a survey, interview, or focus group
4. Minor changes in the wording on a consent form

5. Adding questions to surveys, interviews, or focus groups that are similar to questions already approved
6. Changing the dates for data collection
7. Minor changes in data storage procedures
8. Altering the amount of time required for an interview
9. Changing the size of the focus groups
10. Change in equally qualified study personnel.

However, changes necessary to deal with emergency situations that involve risk or harm to the subjects can be implemented immediately, but the changes should be reported to the IRB Office as soon as they occur, but no later than one week after their occurrence.

Unanticipated problems and adverse events

All unanticipated problems or adverse events related to an approved project or a project evaluated by the IRB chair or designee as Exempt from IRB Review must be reported to the IRB Office as soon as possible after they occur but no later than one week after their occurrence. Unanticipated problems are those that are unexpected in terms of nature, severity, or frequency, related to participation in the research, and places subjects at a greater risk of harm. An adverse event is an unanticipated problem in which harm greater than that described in the application has actually resulted.

Extensions

For projects approved through Expedited Review or Full Review, the approval period is for a maximum of 12 months. Two months prior to the end of the approval period, the Research Integrity and Compliance Officer will notify the Principal Investigator of the end date of the approval period and indicate that if the project is to continue beyond that date, an extension must be requested and approved.

The PI must request an extension from the IRB no later than 4 weeks prior to the approval expiration date. Information must be provided on the Project Renewal Form related to:

1. The current status of the project, including the amount of data collected
2. Any changes in the application
3. Any adverse events that have occurred
4. The reason for the extension.

If a request for extension is not made by the PI, the IRB research approval will terminate at the date specified in the approval letter and the file will be closed.

If, after this time, the investigator wishes to complete the study, a complete new application must be submitted in which case the work done on the prior application may be included as part of the new application. In this case, however, no work can be done on the research until the new application has been approved.

Violations

In general, all research requiring applications to be submitted to the IRB must follow the following guidelines:

1. No data can be collected before receiving a letter from the IRB indicating that the application has been approved or declared to be Exempt from IRB Review.

2. No data can be collected after the expiration of IRB approval.
3. Only procedures specified in the application approved or categorized as Exempt from IRB Review by the IRB can be followed.
4. All changes in these procedures must be approved by the IRB Office before being implemented (for exceptions, see the previous section).

Situations may arise where the research under IRB jurisdiction is not conducted in accordance with these guidelines. When the IRB becomes aware that one or more of the above guidelines may have been violated, the IRB Office will begin an investigation.

The consequences associated with the violation will depend on the following factors:

1. When the violation occurred (before or after IRB approval, or after expiration of IRB approval)
2. Whether risk or increased risk to subjects was involved
3. If the violation was reported to the IRB Office in a timely manner
4. The extent to which the investigator had been informed of the IRB approval process
5. The truthfulness of the investigator in communication with the IRB Office related to the research
6. Whether the investigator had previous violations
7. Whether the violation was intentional or unintentional

IRB violations may result in consequences to both the investigator and the research.

The consequences will be administered by both the IRB and by other university entities, including the advisor, program, school (college), and/or university administration.

Possible actions taken by the IRB include:

- Educate the investigator
- Educate the advisor
- Educate the administrators of the investigator's program or department
- Notify the advisor and program of the violation
- Require submission of a new application
- Write a letter describing the violation to be placed in the file of the investigator and/or advisor
- Suspend or terminate approval of the research
- Notify the U.S. Office for Human Research Protections Division of Compliance
 - Oversight of the violation (the OHRP will be notified no later than seven days after the investigation of the violation has been concluded)

Possible actions taken by other university entities include:

- Place a letter from the IRB describing the violation in the file of the investigator and/or advisor
- Educate or discipline faculty in the investigator's program or department
- Require data collected to be destroyed or not used in any research report
- Suspend or terminate the research project
- Assign a failing grade to the research
- Expel the investigator

Project review

Research approved under Expedited Review or Full Review must be reviewed by the IRB at the end of the approval period. Although applications are typically approved for one year

(the maximum allowable under Federal Law), the IRB may determine that the degree of risk to human subjects requires more frequent review and/or as part of the review, require verification from sources other than the investigators that no material changes have occurred since previous IRB review. More frequent review or additional verification may be required if the project involves unusual levels or types of risk to subjects, or there is reasonable doubt that the project will be carried out as proposed.

Project completion

Once the research approved as Expedited Review or Full Review is completed, the PI (or research advisor) must notify the IRB, so that the IRB can close the file.

Records retention

All records must be retained by the PI and the IRB for three (3) years after the completion of the project. Applicable records include, but are not limited to, research applications, informed consent documents, progress reports, reports of any injuries to subjects, and all related correspondence concerning the use of human subjects.

IRB Issues

Concealment or deception related to research procedures

Definition

Concealment is withholding all or some information from the subjects that would likely influence their decision to participate in the research.

Deception is providing incorrect information to subjects where knowing the correct information would likely influence their decision to participate in the research.

Evidence needed

Recruitment methods

Recruitment documents

Consent forms

Debriefing process if there was any initial concealment or deception

Criteria for approval

Normally, consent must be based on complete information. Before a subject is asked to give consent for participating in a research project, there should be full and clear description of the purpose of the research study and the procedures that relate to the subject, including sufficient information to allow the subject to determine the risk involved in participating in the research. Normally there should be no concealment of information or deception that might affect the decision of the subjects to participate in the study.

Concealment or deception can only occur if necessary to conduct the research properly. In some cases it is not possible to carry out the research without withholding some or all information from the subject, or deceiving the subject (providing wrong information). In order for research to be approved by the IRB in these cases, five conditions must be present:

1. convincing evidence is presented in the application that it is not feasible to conduct the research without concealment or deception

2. there must be no more than minimal risk to the subjects (unless there is overwhelming evidence that the benefits of the research outweigh the degree of risk)
3. the consent form must advise subjects that they are not receiving all of the relevant information prior to the study, but they will be fully informed at its conclusion
4. at the conclusion of the research all subjects will be debriefed with full information regarding the issues related to the concealment and/or deception
5. at the conclusion of the debriefing all subjects will be offered the opportunity to withhold the use of their data if they are unhappy with the concealment or deception.

Data dealing with private or sensitive topics

Definition

Private topics are those that a person would normally not want their personal information to be made public.

Sensitive topics are those included in the research that are likely to have harmful consequences for the participants in the research. For example, consideration of some topics might cause undue psychological discomfort to some subjects that might result in conditions that would need to be addressed by a mental health professional.

Evidence needed

Examples of all types of survey, interview, or focus group items/questions, types of observations, and types of activities participated in by the subjects

Criteria for approval

The consent form describes the private or sensitive topics to be dealt with.

Private or sensitive topics are dealt with in such a way to as to minimize the degree of discomfort that would result.

If discomfort is likely to occur, subjects must be provided with information how the discomfort can be dealt with, usually by providing persons to contact for help.

External consent

Consent Form from Attending Physician and/or Other Health Care Professionals.

In situations where an individual is currently being treated or evaluated by a physician and/or other health care professional for a condition related to the objective of the research study, the researcher is required to obtain the consent of the physician and/or health care professional prior to involving such research subjects in the study.

Institutional Consent from Non-Andrews University Entities.

An Institutional Consent Letter is required if the research is being done at an institution off the Andrews University campus. Separate Institutional Consent Letters are required for each site where the research will be conducted. The Institutional Consent Letter requires the following items:

1. be written on the institution's/company's letterhead

2. identify the researcher/investigator by name
3. include the title of the study for which institutional consent is being given
4. acknowledgement that the signatory has read the protocol
5. the letter must be dated
6. include the name and the title/office of the individual within the institution providing the consent
7. signed by a person from the institution who is authorized by the institution to give institutional consent.

If the research is conducted at another institution that has its own IRB, that institution must also review and approve the research application. The Andrews University IRB will normally request evidence of review and agreement from the host institution's IRB.

Including minors

Definition

A minor is defined as anyone below the age of 18.

Evidence needed

Description of the potential age range of all subjects

The extra protection provided to protect their rights and welfare

Criteria for approval

A parent must give signed consent for their child to participate in the research on a form that details the full extent of how their child will be involved in the research.

A minor aged 7-17 who is able must give signed assent to participate in the research on a form that details the full extent of how they will be involved in the research.

Additional safeguards for protection from risk are required.

Informed consent

Subjects must have sufficient information to make an informed decision to participate in the research study. All subjects must give either signed written informed consent or implied informed consent prior to their participation in the research.

If subjects cannot give informed consent, it must be obtained from their legal representatives. For example, when subjects are minors (under 18) or when they are mentally incapacitated, the consent of legal representatives is required.

The requirement for a signed consent form may be waived if the subjects are under no pressure to participate in the research, the research presents no more than minimal risk of harm to the subjects, and the research does not involve any procedures for which written consent is normally required outside of the research context. If there is any doubt whether coercion or unusual pressure might be occurring in recruiting subjects, an Informed Consent Form must be completed by each subject.

In cases where the documentation requirement is waived, the investigator must provide subjects with an oral or written statement describing the research which includes the relevant information normally found in the consent form. This might include situations such as:

1. attending a focus group where subjects attend voluntarily with no coercion and recruitment materials include the relevant information found in the consent form
2. administering a web-based survey where the instructions clearly state the relevant information found in the consent form.

Consent documents must be clearly written and understandable to subjects. The consent form should include language that is non-technical. The use of scientific, technical, or medical terms or abbreviations should be limited, but where used, should be plainly defined. If the Informed Consent Form will be used in a language other than English, copies of the consent form must be submitted with the application in both that language and in an English translation (unless the application is not required to be in English).

Written Informed Consent Form.

The Informed Consent Form must include the following:

1. Descriptive information
 - a. the relationship of the research and/or researcher to Andrews University. In cases where an anonymously-returned questionnaire substitutes as a form of implied consent, the questionnaire instructions or accompanying cover letter should clearly identify how the research is connected with Andrews University
 - b. a statement that the activity involves research
 - c. where the research activity will occur
 - d. procedures to be followed including identification of any experimental treatments or procedures and the type of data collected
 - e. appropriate alternative procedures or course of treatment (in instances where therapeutic procedures are involved), if any, that might be advantageous to the subjects
 - f. the amount of time required for the subjects' participation
 - g. how confidentiality of records will be maintained or if the data will be collected anonymously
2. Risks/Benefits
 - a. the purpose of the research
 - b. the benefit to the subject or to others
 - c. a description more than minimal risk that may be involved in the research
 - d. for research which may involve more than minimal risk of injury the subject should be informed of the following statement which must appear in the consent form: (to be modified for off-campus research). *"In the unlikely event of injury resulting from this research, Andrews University is not able to offer financial compensation or to absorb the costs of medical treatment. However, assistance will be provided to research subjects in obtaining emergency treatment and professional services that are available to the community generally at nearby facilities. My signature below acknowledges my consent to voluntarily participate in this research project. Such participation does not release the investigator(s), sponsor(s) or granting agency(ies) from their professional and ethical responsibility to me."*
3. Participation details
 - a. a statement that participation is voluntary, that refusal to participate involves no penalty or loss of benefit to which the subjects are otherwise entitled, and that the subjects may discontinue participation at any time without penalty or loss of benefits to which the subjects are otherwise entitled if they had completed their participation in the research

- b. if deception is involved, a statement must be included to the effect that “*We cannot explain all of the details of the study to you at this time, but they will be explained fully at the conclusion of the study.*”
- 4. Contact information
 - a. an offer to answer any questions or to receive comments if there are problems
 - b. contact information for the investigator and the advisor or impartial third party
 - c. contact information for the Andrews University IRB Office
- 5. Agreement
 - a. a statement stating that the subject agrees to participate in the research
 - b. a space for the dated signature of the subject
 - c. a space for a witness to sign if the consent form is only to be read to the subject or if the subject is unable to sign

Assent Form for minors.

Minors who are old enough to understand the procedures of the research must either sign an Assent Form that includes the relevant portions of the above information written in a simplified form that would be understood by the subject, or if this is not possible, give informed verbal assent. A parent or guardian’s signature indicating approval for the minor to participate in the research is required on the Assent Form.

Maintaining anonymity/confidentiality

Definition

Data is classified as anonymous if there is no way that anyone can trace the data back to the subject providing the data. Data is considered to be anonymous if it has either been collected in such a way that it would not be possible to connect the subject to the data, no identifying information has been recorded with the data, or all identifying information has been removed from the data.

Data collected in the following ways must not include any identifying information in order to be considered to be anonymous:

- Conducting an interview
- Observing a subject
- Collecting a survey from an individual by hand
- Responding to a survey by email
- Getting data from private records that contain the subjects’ names
- Administering a treatment to a subject in person.

Data collected in the following ways cannot be anonymous:

- Conducting a focus group
- Making audio or video recordings of subject responses
- Including sufficient demographic information on a survey to make it possible to identify the subjects

Data is considered to be confidential if it meets two criteria:

1. The data is kept in a secure location so only the researcher or other authorized individuals can match the data with the subject providing the data
2. The research will not report any results that would make it possible to link the data or the results to the subject.

Evidence needed

What information will be collected from or related to the subjects?

How will the data be stored?

Who will have access to the data?

Criteria for approval

All data of a private nature or data that could place a subject at risk if revealed must be collected and dealt with in such a way as to protect the subject. The normal procedures to deal with this are to either collect the data anonymously, only record data that could not be used to identify the subjects, or to treat the data confidentially.

Data is eligible to be considered as “Exempt from IRB Review” under the following conditions:

1. Anonymous data
2. No data was recorded that contained information that would allow anyone to match the data with the subjects
3. Public data
4. Data that would not place a subject at risk if revealed.

Data that contains information that makes it possible to identify subjects must be treated confidentially and stored securely.

More than minimal risk

Definition of risk

Risk is conceived broadly to include the probability of harm or injury of any sort. There are many sources of risks, including:

1. physical harm (e.g., from experimental procedures)
2. psychological harm from things such as:
 - a. required to participate in stress-inducing activities
 - b. the topics addressed by survey or interview questions
 - c. the topics addressed by focus group questions or the responses of other focus group members
 - d. divulging private information through lack of anonymity or confidentiality
 - e. knowledge of audio or video taping without previous consent
 - f. coercion involved in recruitment
3. economic harm (e.g., loss of job, reduced earnings)
4. social harm (e.g., lack of social standing)
5. legal harm (e.g., deportation).

A risk is considered to be minimal when the probability and magnitude of harm or discomfort anticipated in the proposed 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.

Evidence needed to establish the degree of risk

Detailed treatment procedures

Examples of all types of survey/focus group items/questions

Evidence needed to determine how risk has been handled

Persons to contact if person has psychological effects from the research

Description of methods used to ensure anonymity and/or confidentiality (see above)
Criteria for approval

Procedures are implemented that minimize risk

Procedures are provided to deal with risk or harm that may occur during the research

Benefit must outweigh risk

The degree of risk is used as one criterion to use in deciding whether research is Exempt from IRB Review, or requires Expedited Review or Full Review. The degree of risk can vary from “minimal” to “significant.” The concept of “minimal risk” is very important in risk assessment and is the only category of risk defined in federal regulations.

Pressure or coercion involved in selecting or recruiting subjects

Definition

Pressure or coercion are involved when conditions are established that encourage or require subjects to participate in the research.

Evidence needed

Methods for recruiting subjects

Recruitment documents/materials

Methods for presenting and collecting consent forms

Consent and/or Assent forms

Criteria for approval

Consent must be voluntary

Subjects must not be exposed to any undue pressure to participate in the research.

Pressure ranges from offering small incentives to participate (usually acceptable) to requiring subjects to participate (usually not acceptable).

If the researcher is in a position of authority related to the subjects such as employer-employee, teacher-student, or pastor-parishioner, the authority figure may inform the subjects that participation is voluntary, but in subtle ways undue pressure may be exerted to participate. While encouragement to participate is allowed, undue pressure is not. In all cases coercion should be either eliminated or minimized.

If there is any doubt whether coercion or undue pressure might be occurring, an Informed Consent Form that emphasizes the voluntary nature of the participation must be completed by each subject. In this case, it is desirable to give the consent form to subjects at least a day prior to collecting the form with the subject's signature.

The following are examples of situations where coercion or undue pressure is used inappropriately and causes undue psychological risk:

1. an instructor requires students to perform a task outside of normal educational practice
2. an instructor gives a large amount of extra credit for participating in the research
3. a survey is collected in such a way as to embarrass the subject if the survey was not handed in

4. face-to-face recruitment such as asking for volunteers by raising their hand in a public situation where failure to respond might be viewed in a negative manner
5. completing a survey in a public meeting where not participating would be awkward
6. putting pressure on friends to participate in the research project.

Quality control

IRB responsibility

The main responsibility of the IRB is to monitor human subjects research to ensure that it adheres to federal government policy, primarily in the area of risk to the subjects.

The main areas that IRB evaluates are:

1. Methods of selecting or recruiting subjects
2. Procedures involving subjects
3. Use of the data.

The main criteria that are evaluated relate to:

1. Anonymity and confidentiality
2. Informed consent
3. Pressure or coercion
4. Risk.

In the process of evaluating an application, members of the IRB may find procedures that are of less than adequate quality, but would not need to be modified to protect human subjects. Examples would include:

1. Having an inadequate sample size
2. Including poorly worded questions on a survey
3. Using an out-of-date procedure.

If, in the opinion of the IRB, the procedures used would invalidate the research findings, damage the reputation of Andrews University, or involve risk that would be greater than that warranted by the benefit to be gained by the research, the IRB may require the procedures to be modified before approval. Otherwise, the IRB may point out the poor procedures to the researcher and suggest alternatives, but the modifications will have no effect on the approval or disapproval of the research.

Recording data

Definition

All data is recorded in one or more ways, including:

By the subject

Handwritten on a survey

E-mail response

By the researcher

Handwritten

Typed on a computer

By a physical device

Audio (tape) recorder

Video recorder

Computer (e.g., web survey with an on-line database)
Instrument recording physical characteristics

Evidence needed

How the data will be recorded
How confidentiality of the data will be maintained
How data will be stored

Criteria for approval

The consent form describes the recording and how the data will be treated confidentially.
The data will be treated confidentially
The recordings will be stored securely for a minimum of three years.

Subjects from a vulnerable population

Definition

A person who is likely to be vulnerable to coercion or undue influence
The following subjects are considered to be “vulnerable” subjects and require special consideration:

1. Minors
2. Prisoners
3. Pregnant women
4. Mentally disabled persons
5. Economically or educationally disadvantaged persons.

Evidence needed

The extra protection provided to protect their rights and welfare

Criteria for approval

Additional safeguards for protection from risk are required.

Using invasive procedures

Definition

An invasive procedure is a medical procedure that involves penetrating the body.

Evidence needed

Details of any treatment given to subjects

Criteria for approval

The consent form describes the invasive procedures in detail.
There is no reasonable alternative to using invasive procedures to obtain the data.
The benefit gained by using invasive procedures outweighs the possible harm.
Procedures are done by qualified personnel and with supervision if needed.
Risk is minimized.