Andrews University
International Development Program

Human Subjects Research

Criteria for Application for Research Involving Human Subjects

Documents for the Institutional Review Board (IRB) Application

1. Download Application Form from (http://www.andrews.edu/services/research/research_compliance/institutional_review/apply_form.html)
2. Research Protocol
3. Institutional consent
4. Certificate from IRB tutorial/training (http://www.andrews.edu/services/research/rearch_compliance/institutional_review/irb-training.html)

If the research includes more than secondary data the application should include:

5. Data collection instrument(s)
6. Informed consent

Research Protocol

The Research Protocol is a statement of the researcher's project design and a description of his/her responsibilities toward the human subjects involved in the research. Maximum 2000 words.

Every student in the MIDA program is expected to submit an application to the Office of Research and Creative Scholarship as partial fulfillment for the course Research Project (IDAS697). Preparation of the application will be commenced after the Research Proposal has been approved by the Research Mentor first, and then the Concentration Advisor.

The **Research Protocol** is a synopsis of the proposal and will be approved by the Concentration Research Mentor. The entire IRB application documents will be submitted for review to the Institutional Review Board (IRB) at irb@andrews.edu with a copy to the students Concentration Advisor and Research Mentor. The signature on the IRB application is that of the Concentration Advisor (faculty of Andrews University).

Letters of Institutional Consent

A letter of institutional consent is a formal letter and should:

1. be written on an Institution's/Company's letterhead;
2. mention the researcher/investigator by name;
3. mention the title of the study for which institutional consent is being given;
4. be dated;
5. include the name and the title/office of the individual within the institution providing the consent;
6. be signed.
7. be addressed to:

   Institutional Review Board
   Andrews University
   Berrien Springs, MI 49104-0355

Then scan and send by e-mail attachment to irb@andrews.edu with a copy to the Concentration Advisor.

How to Create a Research Protocol

To ensure effective review by the IRB the following components should be included to provide the reader with background information of the research question under study, the rationale for the study, detailed methodology, and the potential importance of the research. The Research Protocol should have a cover page.

1. Title of Study (use level one heading)

2. Objectives
   The purpose of the study (research questions and/or study objectives) should be clearly and succinctly stated.

3. Background and Rationale
   Summarize and synthesize the available research (including published data) to provide justification for the study. Evaluate prior research for relevance to the research question under study. Describe the significance of the research including potential benefits for individual subjects or society at large.

4. Research Design/Methodology
   The research design should be identified and be appropriate to answer the research question(s) under study. Describe the type of research proposed (qualitative, survey) and specific study design that will be used.

5. Sample
   Describe the sampling approach to be used. Identify the procedures that will be used to recruit, and follow the subjects/participants/informants. How they will be involved, including the criteria used for determining the inclusion/exclusion of subjects. Identify number of subjects to be enrolled, characteristics (age range, male/female) and whether this will be a random or convenience sample.

6. Detailed study procedures
   Methods of collecting data and for avoiding/minimizing risks and discomforts to subjects. Include a timeline for subject participation in the project. Identify details for establishing confidentiality and protecting privacy of participants or informants. Detailed explanation of how the subjects will give informed consent. This section should describe in adequate detail the potential risks and benefits.

7. Data Analysis
   Specify the analytic techniques the researcher will use to answer the study questions. Indicate the statistical procedures (eg specific descriptive) that will be used and why the procedures are appropriate. For qualitative data, specify the proposed analytic approaches.

8. References
   Include a reference list of literature cited to support the protocol statement.

Example of institutional consent letter. Should be on letterhead.

19 May 2004

Institutional Review Board
Andrews University
Berrien Springs, MI 49104-0355

Blue Chips Development College gives Mr. Smiley Turn permission to conduct research with students of our institution for a study entitled *"the impact of graduate education on the professional and personal development of women students between the ages of 18 and 30"*.

The approved research activity will involve a focus group with women students in graduate programs and will provide the basis of commencing a recruitment initiative aimed at men joining graduate education programs.

Please feel free to contact me if you have any comments or questions on BCLO@hotmail.com.

Sincerely,

signature

Mr. XXXXXXXXX
Academic Principal