

Human Subjects – Internal Review Board

Instructions to Researchers

Several documents are required for submission to the Human Subjects – Internal Review Board: (1) an informed Consent Letter, (2) an Assent Letter, (3) a Proposal, and (4) a Submission Form. Consent Letters are necessary for studies involving adults and/or parents of children who will serve as participants. Separate consent letters are necessary when both teachers and parents are involved. Assent Letters are necessary for studies involving children and adolescents. When children are too young to read, the proposal must specify that the Assent letter will be read to child in front of a witness. In such instances, signature space must be provided on the Assent letter for both the researcher and witness.

A Proposal must accompany the submission. The proposal needs to: (1) briefly introduce the topic and provide background (about 1 page), and (2) detail the methods that will be employed. The methods section needs to provide an exact description of all procedures and materials, as well as the activities required of participants. The proposal should provide sufficient detail that the Committee can make an informed decision.

A Submission Sheet must be completed and accompany the proposal and consent/assent letters. Three (3) copies of all documents must be submitted to **Kim Hecksher**, Room 113, Willard Hall. Kill will distribute the information to the Committee for review.

The checklist, beginning on the next page, is used by the Committee. Proposals must pass all items in the checklist and satisfy all requirements identified in the footnotes at the end of the checklist.

Upon submitting all documents to Kim Hecksher, she will give you the date and time when your submission will be reviewed by the Committee. Researchers should attend the review meetings so that they can get immediate feedback, and when necessary, quickly revise and make re-submissions.

Submissions are reviewed monthly by the Committee and must be given to Kim Hecksher at least one week prior to the monthly meeting. The Committee will be meeting on the second Monday of every months for the Fall Semester, 2004:

Monday, September 13, 2:00 p.m.

Monday, October 11, 2:00 p.m.

Monday, November 8, 2:00 p.m.

Monday, December 13, 2:00 p.m.

Reviewer's Checklist

Proposal Title:

Principal Investigator:

Date:

Item Number	Item	Parent Consent Satisfies Item		Teacher Consent Satisfies Item	
		yes	no	yes	no
Introduction					
1.	Provides brief comments that introduce the researcher and explain the purpose of the research project.				
Details of Study					
2.	Describes the selection criteria for eligibility in the research project.				
3.	Describes the total number of participants in the research project.				
Rights of Participants					
4.	Provides assurance to participants that withdrawal from the study or refusal to answer any question will not result in a penalty or loss of privileges.				
5.	Informs participants about the degree and nature of risk associated with participation in the project. A statement of risk must accompany the proposal. Nearly all proposals in the School of Education carry no risk.				
Details of Participation in Study					
6.	Provides an adequate description of the activities in which the participant will be involved.				
7.	For surveys and interviews, participants are informed of the range of topics that will be addressed. ^{1, 2}				
8.	Informs participants about the estimated time required for their involvement in each session (if there is more than one session).				
9.	Informs participants about the estimated time required for their involvement for the total project.				
10.	If applicable, informs participants that sessions will be audio taped and/or transcribed.				
		Parent		Teacher	

Item Number	Item	Consent Satisfies Item		Consent Satisfies Item	
		yes	no	yes	no
Confidentiality					
11.	Informs participants (or the Committee in the proposal) how the researcher will handle a situation where not all student or parent recipients in the classroom provide informed consent to be audiotaped or videotaped (e.g., will non-participants be asked to leave the classroom and/or how will their right not to be audio/videotaped be protected?).				
12.	Informs participants of the manner in which the data will be coded to insure confidentiality (in the event that someone accidentally or intentionally comes into contact with it).				
13.	Informs participants that the data will be secured in a locked cabinet to insure confidentiality. ³				
14.	Informs participants of the names of all individuals who will have access to the secured data.				
15.	Informs participants of the researcher's intention to retain the data indefinitely; or, if the researcher intends to ultimately destroy the data file, when this will take place (e.g., 6 years after publication of the study).				
16.	Informs participants that if they withdraw from the study, all of their data will be destroyed at that time.				
Results					
17.	Informs participants about the manner in which the results of the study will be reported (in the aggregate? individually?).				
18.	Provides participants a means by which they can indicate that they would like to receive a summary of the results of the study and/or a copy of any publications derived from the study.				
Format of Participation Letter					
19.	Consent letter is written at a sixth grade reading level or lower.				
20.	Provides a method for participants to initialize each page of the letter of informed consent/assent and informs participants that they must initialize each page in addition to providing their signature on the signature page at the end of the letter.				
21.	Numbers the pages of the letter of informed consent/assent letter using the convention "page 1 of 3", "page 2 of 3", etc.				

		Parent Consent Satisfies Item		Teacher Consent Satisfies Item	
		yes	no	yes	no
22.	Informs recipients that, if they agree to participate, they should keep one copy of the letter of informed consent (all pages) and return all pages of the other copy (signed) to the researcher.				
When Participants Have Questions/Concerns					
23.	Provides participants a phone number and address that can be used to contact the researcher if the participant has any questions about the nature of this research project. (Note: not necessary for child assent forms accompanying parent letters.)				
24.	Informs participants who they should contact if they have any concerns or complaints about the manner of conduct of the research (i.e., Dr. T. W. Fraser Russell, Vice Provost for Research, 210 Hullihen Hall, University of Delaware, Newark, DE 19716-1551, 302-831-2136).				
When Children are Participants					
25.	Provides prospective child participants a “certificate of informed student assent” that includes, in child-friendly language, a simplified explanation of the purpose of the study and the activities the child will experience and that provides the child a means by which s/he can indicate assent to participate.				
26.	When a prospective child participant is unable to read and/or write, the researcher included a form to be placed in the participant’s file that testifies to the fact that the researcher has orally explained the information in “the letter of informed assent” to the child and that the child has orally indicated assent.				
27.	Informs parents that if they consent to their child’s participation, their child will then also receive a letter inviting his/her participation and requesting his/her written assent.				
28.	Where applicable, directly indicates to parents that the researcher also is requesting permission from the parents to access their child’s school records.				
29.	Where applicable, specifies the specific time period during which the researcher is requesting permission from the parents to access their child’s school records.				

¹A copy of **all** questions on a questionnaire must be submitted to the Committee.

²When conducting interviews, researchers are required to submit a copy of the interview questions. If the researcher is hoping to simply let participants speak about a topic, the researcher still needs to provide the Committee with the structure of the interview, providing which areas will be explored. The researcher should also provide an informed consent letter which fully describes to participants the areas of questioning and providing, when applicable, questions that may be intrusive (e.g., questions about illegal activity).

³Confidential information must be maintained in a locked file cabinet. Researchers are not allowed to take confidential information home.