Research Involving Human Subjects (School of Education)
Protocol Review Checklist
Updated 11/20/2011

-Allow at least one month for your research protocol to be reviewed and approved.
-Pilot studies and EPPs are not automatically exempt from human subjects review and any work that is to support research efforts may meet the criterion for HSR
-Potential participants should not be contacted before IRB approval.
-PIs are responsible for securing permission from research sites.

Training Requirements: Include evidence of HSR training or date when training is expected to be completed for investigators and project staff (anyone who will have access or contact with participants or HSR data). Information on HSR training is available at http://www.udel.edu/research/preparing/humansub.html.	
Student-conducted Research: Share your submission package and request that you advisor(s) signs off on IRB Net. Protocols are not reviewed without advisor(s) signature.	

Address the following in Protocol, Teacher/adult Consent Form, Parental Consent Form, and Student Assent Form as appropriate.

	Protocol	Teacher Consent	Parent Consent	Student Assent
Clearly explain the purpose of the research in non-technical terms.				
Include a statement in the consent/assent forms that introduces the researcher (*My name is ___ and I am a ___ at the University of Delaware School of Education; This research is being conducted by …)*	*NA*			
Describe the recruitment strategy, including the potential research sites. When available, include documentation of approval from research site.		*NA*	*NA*	*NA*
State the total number (or approximate range) of participants in the research project.				
Describe how participants are eligible to participate in the research project or if the participants are an unselected sample.				
Describe the method by which the participant will be selected from those who met the eligibility requirements. If more participants are recruited than needed, how will study participants be selected (e.g., randomly selected from participants who agree to participate)?				
Provide an adequate description of all of the activities in which the participant will be involved.				
For surveys and interviews, list and/or describe the range of topics that will be addressed.				
State the estimated time required for participant's involvement in <u>each</u> project session (if there will be more than one session).				
State the estimated time required for participant's involvement in <u>total</u> project				
Describe the risks to participants. Most research conducted by SOE has no or very few risks (e.g., missed class time, fatigue, uncomfortable answering some questions, tasks might be challenging). Research involving more than minimal risk are reviewed by Full IRB Board.				
Describe the steps that will be taken to minimize or reduce risks (e.g., tasks are similar to those students regularly participate in during school, researcher will work with teachers to schedule convenient times, participants are informed they can refuse to answer any questions).				

Describe the benefits for participants. Most research conducted by SOE has no guaranteed benefits.				
Describe the benefits of the research to future classes of participants (others who are similar to the participants of this study). Examples include improving instruction or assessment practices, providing information that may inform universities, schools or school districts, etc.				
Include a statement that participation is voluntary and that participants can withdraw from the study with no penalty or loss of privileges.	*NA*			
Include a statement that participants can refuse to answer any question without penalty or loss of privileges.	*NA*			
Confidentiality				
Include a statement that describes whether data to be collected will be confidential (information will be kept private, no name will be disclosed) or anonymous (researcher will not know the identity of the participant)				
Include a description of how confidentiality of data (paper data, electronic data, audio and/or video-recording) will be maintained. Typically this includes the use of a pseudonym or identification number in place of participant's name or other identifiable information.				
If there is a list or file that links participants to their identification code or pseudonym, include a statement of where/how that file is to be stored and secured. This file generally should be more securely stored (e.g., encrypted, locked in separate file cabinet, etc.) and in a separate storage location (e.g., different file cabinet, separate electronic folder).				
Include a statement that describes how data will or will not be shared (e.g., shared with teachers or school district, etc.).				
Include a statement that describes who other than the researcher will have access to the data (e.g., research staff, advisor).				
Include a statement of how data are to be analyzed and what will be reported. Are all findings to be reported at the group levels (e.g., means and standard deviations)? Will a single or multiple case study be presented? Will quotes or examples provided by participants be shared in publications/presentations?				
Describe any conditions under which confidentiality will be breached. (Reporting child abuse or neglect is an example of when confidentiality may be breached but is not typical in research activities that are eligible for exempt or expedited review and have few risks.)				
Include a statement about whether a Certificate of Confidentiality has been obtained or will be obtained. This is an assurance provided by NIH that protects research data from subpoena. This is not typical for SOE research activities (indicate *NA* on protocol).				
Contact Information				
Include contact information for the PI (name, phone, email, address)	*NA*			
For student research, include advisor(s) contact information.	*NA*			
List the University IRB contact. The standard language is: *If you have questions about your rights [or your child's rights] as a research participant or any concerns or complaints about the conduct of the project, please contact: Chair, Human Subjects Review Board, 210 Hullihen Hall, University of*	*NA*			

Delaware, Newark, DE 19716-1551, (ph) 302-831-2137 Note: The phone number has been recently changed from x 2136 to x2317. Use the generic "Chair" rather than an individual's name.				
Audio-recordings and Video-recordings				
Inform the participant that sessions will be audio taped, videotaped, and/or transcribed.				
If audio- or video-recording is optional, provide a separate line for individual to consent for recording. Participants should be prompted to initial (not check) line for permission to record. If participant can opt out of recording, describe what steps will be taken so that they are not recorded.				
Data Storage				
Include a statement of how long data will be stored (minimum of 3 years) or if data are to be kept indefinitely				
Include information describing how data will be secured. Data with identifiable information should be encrypted/stored in lock cabinets in locked offices and data with nonidentifiable information should be stored in password protected systems/stored in locked cabinets. See Data Storage Memo for additional information.				
Formatting of the Consents/Assent Forms				
Place the title of the research project at the top of consent/assent form(s). This title should match the IRBNet project title.	*NA*			
For multiple page consent forms, label each page with page __ of ___ formatting.	*NA*			
For multiple page consent forms, direct the participant to initial each page.	*NA*			
Provide two copies of the consent form to potential participant and direct the participant to keep one copy for his/her records.	*NA*			
Ensure that the text is understandable and written at an appropriate reading level. Follow this link to resources on estimating the readability of the text.	*NA*			
If participation in research is confidential, provide means to secure consent (e.g., envelope to be returned)	*NA*			
If translated copies of consent/assent forms are being used, include them with protocol or submit when translation has been completed.	*NA*			
Assent Forms/Process				
Provide the child/youth an "assent form" that includes, in child-friendly language, a simplified explanation of the purpose of the project.	*NA*	*NA*	*NA*	
Provide a simplified explanation of the activities in which they will participate and their duration.	*NA*	*NA*	*NA*	
In the assent form, provide the child a means by which s/he can indicate assent, or lack of assent, to participate.	*NA*	*NA*	*NA*	
If the child/youth is unable to read and/or comprehend the assent letter, describe the steps to be taken to explain the information contained in the assent form and provide the child/youth a means by which they can orally or gesturally indicate assent. A place to indicate the response and a signature line (with date)	*NA*	*NA*	*NA*	

or the person who is completing the assent process is included.				
Inform parents that if they consent to their child's participation, their child then also will receive an invitation to participate. The decision to participate in research is with the child (i.e.. the child can decide not to participate, even if parent gives permission.	*NA*	*NA*	*NA*	
Research involving UD Students as the <u>Participant</u> in Research				
If the participants are students in a class taught by the PI, additional precautions should be taken to ensure that participation is voluntary. Principal investigators should contact Laura Glass to discuss procedures and research activities that involve students in the Elementary Teacher Education programs and Gail Rys for procedures and research activities that involve students in graduate programs. They are the contacts for getting information about accessing potential participants (e.g., email addresses or other contact information) and to ensure that research activities do not interfere with the academic programs.				
IRB Research protocol/approval process should occur prior to the semester that the research activities are planned.				
Consent should be acquired by a second individual, if possible, and at the beginning of the semester, if possible.				
Data are analyzed after semester grades have been submitted.				
Data are de-identified before analysis				
Clarify for students which research activities are class/course requirements and which are strictly research activities (in these cases, permission should be obtained at the beginning of the semester).				
Clarify which assignments/course requirements will be used for research activities.				
Make participants aware of additional research activities (e.g., audio-recording group discussions) that will occur within courses.				
Make participants aware of additional requirements beyond course requirements that are part of research (e.g., outside of class time interviews, additional activities that are not part of course requirements and are not graded or assessed for class purposes). Alternatives for participating in additional research activities should be provided (e.g., extra credit for interview or alternate extra credit opportunity).				
Precaution should be taken to ascertain that all potential participants are 18 or older. Parental consent and assent is needed for students who are younger than 18.				
Electronic Surveys				
Electronic surveys should be conducted using Qualtrics (see https://delaware.qualtrics.com/ControlPanel/ for info). Survey Monkey and other online survey sources are less secure and not maintained by UD.				
The consent process can be embedded into survey (click NEXT to continue indicates your consent to participate in the study); prompt participants to save or print a copy for their records.				
Include a description of how participants will be recruited/selected (source of email addresses).. Proper permission to access these records should be secured from an appropriate source.				
Other				
Supporting Materials: A copy of all measures/surveys/questionnaires, etc. are included with the				

protocol. If measures cannot be shared (e.g., IQ tests), include a detailed description of measure.				