Carnegie Mellon University

Do not use this form. Use the msword form online at the course website instead. -BJ

For IRB Office Use

IRB No:_____

Rec'd:_____

APPLICATION FOR IRB REVIEW OF RESEARCH INVOLVING HUMAN SUBJECTS

(Not for exempt research)

Please complete this application as thoroughly as possible. Your application should include the following:

1. A consent form using the current CMU template that the participants and/or parent/guardian will be required to sign.
2. A copy of any questionnaires, surveys, images, de-briefings that will be used.
3. A copy of any recruitment documents (including advertisements, flyers, letters, invitations, email) to be used;
4. A copy of the training certificates for all individuals working on the research unless they are on file with the CMU IRB. Training is available at: http://phrp.nihtraining.com/users/login.php
5. If the PI is a student, the faculty advisor must submit a Faculty Advisor Assurance Form.

Please email all documents to irb-review@andrew.cmu.edu. For assistance call CMU Research Compliance @ 412-268-5460 or email irb-review@andrew.cmu.edu. Additional information and templates are available at http://www.cmu.edu/osp/regulatory-compliance/human-subjects.html

1. Protocol		
Title:		
☐ This is a previously approved study that has lapsed.	Previous IRB No: HS	
2. Principal Investigator (PI)		
Name:	Department:	
Telephone:	E-mail:	Training Cert. ☐ Attached ☐ On File
☐ I am a student. If so, please provide information about your faculty advisor below.		
Faculty Advisor Name:	E-mail:	Training Cert. ☐ Attached ☐ On File
If a student is the PI, the faculty advisor must complete and submit a Faculty Advisor Assurance Form.		
If there is someone other than PI to correspond with regarding this protocol, please list below.		
Contact Person Name:	Telephone:	E-mail:
Business Manager for your department:	E-mail:	
3. Co-investigators		
Name:	E-mail:	Training Cert. ☐ Attached ☐ On File
Name:	E-mail:	Training Cert. ☐ Attached ☐ On File
Name:	E-mail:	Training Cert. ☐ Attached ☐ On File
Name:	E-mail:	Training Cert. ☐ Attached ☐ On File
Name:	E-mail:	Training Cert. ☐ Attached ☐ On File
Name:	E-mail:	Training Cert. ☐ Attached ☐ On File
Name:	E-mail:	Training Cert. ☐ Attached ☐ On File
4. Funding		
☐ Unfunded research	Sponsor/Source:	

For IRB Office Use

IRB No:_____

Rec'd:_____

☐ External Funding	SPEX Proposal #:
☐ Internal Funding	Oracle String:
Grant Title:	

If you don't know the funding/grant information, please get it from your department's business manager.

5. Protocol Description

Provide, in lay terms, a summary of your proposed study as outlined below. You may attach the protocol to this form if you like.

Purpose of the study.

Describe the research procedures (include the activity, location and time required of the participant).

Who will be asked to participate?

Will questionnaires or surveys be used? ☐ Yes ☐ No

Will tasks be done on a computer? ☐ Yes ☐ No If yes, how will the tasks be accessed? ☐ Remotely via the internet? ☐ In the research lab? ☐ Other, please explain:

Will deception be used? ☐ Yes ☐ No If yes, describe how participants will be debriefed. Please include the de-briefing material and/or script.

Will the research be conducted on the CMU campus? ☐ Yes ☐ No If no, please indicate the location(s).

If applicable, please attach documentation of permission to conduct research in private, non-CMU space.

6. Participants

Will any of the following classes of vulnerable subjects be involved in the proposed study? *(check all that apply)*

Class	*Comments*
Pregnant women, human fetuses ☐ Yes ☐ No ☐ Pregnant women will not be specifically included or excluded. (See http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm, research that is incidental to pregnancy and has no risk to the fetus can only include pregnant women if ALL aspects of Subpart B are met.)	
Neonates ☐ Yes ☐ No	

For IRB Office Use

IRB No:_____

Rec'd:_____

Prisoners ☐ Yes ☐ No	
Children ☐ Yes ☐ No	

Individuals with compromised mental status ☐ Yes ☐ No If yes, indicate how this will be determined.

Will the participants be capable of understanding the nature of the study and the consent process? ☐ Yes ☐ No

If no, explain.

What is the age range of participants in the proposed study?

How many participants are needed for the study?	How was that number determined?

What do you estimate the ratio of males to females be? Will this be reflective of the local population? ☐ Yes

☐ No Will you target a certain population? ☐ Yes ☐ No Please explain

What do you estimate the percentage of minorities will be?

Please list inclusion and exclusion criteria.

7. Participant Recruitment

Describe how participant recruitment will be performed. Include how and by whom potential participants are

introduced to the study.

Check all boxes below that apply.

☐ CMU directory	☐ Postings, Flyers	☐ Radio, TV

For IRB Office Use

IRB No:_____

Rec'd:_____

☐ E-mail solicitation Indicate how the email addresses are obtained:

☐ Web-based solicitation. Specify sites:

☐ Participant Pool. Specify what pool:

☐ Other, please specify:

Please attach any recruiting materials you plan to use and the text of e-mail or web-based solicitations you will use.

8. Consent

Do you plan to use consent forms? ☐ Yes ☐ No

If no, you must complete the section below on waiver of informed consent.

If yes, describe how consent will be obtained and by whom.

If participants are minors will assent forms be used? ☐ Yes ☐ No If No, please explain.

Will the consent form be presented on paper or online? ☐ Paper ☐ Online

Are you requesting to use a consent format that is different from the CMU model consent? ☐ Yes ☐ No

If yes, please explain.

Are you requesting a waiver of informed consent? ☐ Yes ☐ No

If yes, please explain how each of the elements listed apply to your study:

1. The research involves no more than minimal risk to the subjects;
2. The waiver will not adversely affect the rights and welfare of the subjects;
3. The research could not practicably be carried out without the waiver and ;
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

For IRB Office Use

IRB No:_____

Rec'd:_____

Are you requesting a waiver of written documentation (signed) of informed consent? ☐ Yes ☐ No

If yes, please answer the following questions.

1. Will the only record linking the participant and the research be the consent document and the principal risk to the participant harm would be from breach of confidentiality? ☐ Yes ☐ No
2. Do you consider this a minimal risk study that involves no procedures for which written consent is normally required outside of research? ☐ Yes ☐ No

9. Risks and Benefits

Will participants receive intangible benefit from the study? ☐ Yes ☐ No

Discuss the direct and indirect benefits to participants.

Discuss the risks to participants.

Discuss how any risks will be managed and/or minimized.

If deception is involved, please explain.

Indicate the degree of physical or psychological risk you believe the research poses to human subjects *(check which one applies).*

☐ Minimal Risk: A risk is minimal where 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 of during the performance o routine physical or psychological examinations or tests.

☐ Greater than Minimal Risk: A risk is greater than minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Describe how the study fits in this risk level.

For IRB Office Use

IRB No:_____

Rec'd:_____

10. Participant Compensation and Costs		
Are participants to be compensated for the study? ☐ Yes ☐ No If yes, what is the amount, type and source of funds?		
Amount:	Source:	Type (gift card, cash):
Will participants who are students be offered class credit? ☐ Yes ☐ No		
Are other inducements planned to recruit participants? ☐ Yes ☐ No If yes, please describe.		
Are there any costs to participants? ☐ Yes ☐ No If yes, please explain.		
Will you compensate participants for injury resulting from participation? ☐ Yes ☐ No ☐ NA If yes, please describe.		

11. Confidentiality and Data Security	
Will personal identifiers be collected? ☐ Yes ☐ No	Will identifiers be translated to a code? ☐ Yes ☐ No
Will recordings be made (audio, video)? ☐ Yes ☐ No If yes, please describe.	
Is the information so sensitive that you will obtain a certificate of confidentiality from NIH? ☐ Yes ☐ No	
Who will have access to data (surveys, questionnaires, recordings, interview records, etc.)?	
Describe how you will protect participant confidentiality and secure research records (Will they be stored on a secure computer, locked cabinet, etc?).	

For IRB Office Use

IRB No:_____

Rec'd:_____

Describe your process for monitoring data to ensure that study goals are met. (Review of lab notebooks, meetings to review data, etc.)

12. Conflict of Interest

Do you or any individual who is associated with or responsible for the design, the conduct of or the reporting of this research have an economic or financial interest in, or act as an officer or director for any outside entity whose interests could reasonably appear to be affected by this research project: ☐ Yes ☐ No

If yes, please provide detailed information to permit the IRB to determine if such involvement should be disclosed to

potential research subjects.

13. Cooperating Institutions

Is this research being done in cooperation with any institutions, individuals or organizations not affiliated with CMU?

☐ Yes ☐ No If yes, please list and describe their role.

Have you received IRB approval from another IRB for this study? ☐ Yes ☐ No ☐ Pending

If yes, please attach a copy of the IRB approval.

If applicable, please provide the name(s) and address(es) of all officials authorizing to access human subjects in

cooperating institutions not affiliated with CMU.

Please attach documentation of approval.

Principal Investigator's Assurance Statement for Using Human Subjects in Research

I certify that the information provided in this IRB application is complete and accurate.

I understand that as Principal Investigator, I have ultimate responsibility for the conduct of IRB approved studies, the ethical performance of protocols, the protection of the rights and welfare of human participants, and strict adherence to the studies protocol and any stipulations imposed by Carnegie Mellon University Institutional Review Board.

I understand that it is my responsibility to ensure that the human participants' involvement as described in the funding proposal(s) is consistent in principle, to that contained in the IRB application. I will submit modifications and/or changes to the IRB as necessary.

I agree to comply with all Carnegie Mellon University policies and procedures, as well as with all applicable federal, state, and local laws, regarding the protection of human participants in research, including, but not limited to:

- Ensuring all investigators and key study personnel have completed human subjects training program;
- Ensuring protocols are conducted by qualified personnel following the approved IRB application;

For IRB Office Use

IRB No:_____

Rec'd:_____

- Implementing no changes in approved IRB applications or informed consent documents without prior IRB approval in accordance with CMU IRB policy (except in an emergency, if necessary to safeguard the well-being of a human participant, and will report to the IRB within 1 day of such change);
- Obtaining the legally effective informed consent from human participants or their representative, using only the currently approved date-stamped informed consent documents, and providing a copy to the participant.
- Ensuring that only IRB-approved investigators for this study obtain informed consent from potential subjects.
- Informing participants of any relevant new information regarding their participation in the research that becomes available.
- Promptly reporting to the IRB any new information involving risks to research participants, including reporting to the IRB, Data Safety and Monitoring Boards, sponsors and appropriate federal agencies any adverse experiences and all unanticipated problems involving risks to human subjects or others that occur in the course of the research.
- If unavailable to conduct research personally, as when on sabbatical leave or vacation, arrangements for another investigator to assume direct responsibility for studies will be made through modification requests to the IRB;
- Promptly providing the IRB with any information requested relative to protocols;
- Promptly and completely complying with IRB decisions to suspend or withdraw approval for projects;
- Obtaining Continuing Review approval prior to the date the approval for a study expires (approval for the study will automatically expire);
- Maintaining accurate and complete research records, including, but not limited to, all informed consent documents for 3 years from the date of study completion;
- Informing the CMU IRB of all locations in which human participants will be recruited for protocols and being responsible for obtaining and maintaining current IRB approvals/letters of cooperation when applicable;
- Complying with federal, state and local laws and regulations and sponsor terms and conditions; and
- Complying with CMU policies on the responsible conduct of research.

_____ _____

Principal Investigator Name and Signature Date

Note: If e-mailed from the PI's CMU e-mail account a hand written signature is not needed. Please type in name and date. If the PI is a student, the faculty advisor must submit a Faculty Advisor Assurance Form.

Please email all documents to irb-review@andrew.cmu.edu.

Note: Links to the policies and Federal regulations for the protection of human research subjects (including the Code of Federal Regulations [.CF.R.] Title 45 CFR Part 46 and Title 21 C.F.R. parts 50 and 56) are available on the IRB web page (http://www.cmu.edu/provost/spon-res/compliance/hs.htm).

Comments: