Legal Services Department
Institutional Review Board
Phone: (716) 821-4477
Fax: (716) 821-4465

Protocol Approval Request for Research Involving Human Participants

1. Title of Protocol

2. Contact Information

2.1 Principal Investigator (PI)

Name/ Phone Number	
Email Address	
Department	
Location/Address	

Status ☐Student ☐Resident/Fellow ☐Nurse ☐Physician

☐Other:

2.2 Co-PIs and members of the research team:

Name	Email Address	Department	Organization (if not CHS)

3. Funding Information

Indicate the source of funding of your project

Sponsor Name	
Address	
Contact Name	
Email address	

☐This research is unfunded (student/resident/nurse/fellow)

Study Design, Methods, and Procedures

1. Type of project/study: Please select ALL of the categories of work that apply:

☐ Active collection of data (not human biologic materials or physiological data)

☐ Active collection and use of biologic materials and physiological data

☐ Use of physiological or biomedical devices, drugs, biologics or chemical agents

☐ Use of existing data (not biological materials)

☐ Use of existing human biologic materials

2. Please provide a lay summary of the study, including the purpose, research questions and hypothesis to be evaluated.

3. Please describe briefly how this study will contribute to existing knowledge in the field.

Participants, Recruitment, and Compensation

1. Please provide the estimated number of participants you plan to recruit and time frame for your study.

2. Please provide the age range of participants.

3. Please select all the categories of participants that will be included in your study.

☐Healthy Adult Volunteers ☐ Children under 18 years of age

☐Medical/Nursing Students ☐ CHS Employees

☐Cognitively Impaired Persons ☐Pregnant or Nursing Women

☐Prisoners or Individuals under detention or probation ☐People in Foreign Countries

☐People Unable to Read, Speak or Understand English ☐People with limited literacy

☐People with Specific Health Conditions ☐None of the above

☐Other

4. Please select all of the tools that you plan to use to recruit your participants.

☐Flyers ☐Notices

☐Mailers (Post) ☐Online Advertisements

☐Email ☐Use of internet, social media, or online networking sites

☐TV, Radio, Print Advertisement ☐Face-to-face Public Intercept

☐Presentations

☐Other

5. Please describe each recruitment method to be used (include with submission if applicable).

6. Describe the inclusion or exclusion criteria for participants as applicable in this study.

7. Will participants be compensated for their participation? ☐ Yes ☐ No

If yes, explain:

8. Please describe the tasks that the participants will be asked to perform for each phase of the study.

9. Please provide an estimate of the time commitment from each participant for each phase of the study.

Risks and Benefits

1. From the list below, please select ALL of the potential risks that are involved in your study.

☐ Use of deceptive techniques

☐ Use of private records (such as educational or medical records

☐ Manipulation of psychological or social state such as sensory deprivation social isolation, psychological stress

☐ Probing for personal or sensitive information in surveys or interviews (i.e.: private behaviors, employer assessments)

☐ Presentation of materials which some participants may consider sensitive, offensive, threatening or degrading

☐ Social or economic risk (reputational, cultural, employability, etc.)

☐ Identification of child, spousal, or elder abuse

☐ Identification of illegal activity

☐ Risk of injury or bodily harm

☐ Other risks (please specify)

☐ There are no risks of any kind to any participants enrolled in this study

2. Describe the nature and degree of the risks or harms selected above. All of the risks/harms must be disclosed in the consent form.

3. Describe the steps that will be taken to minimize risks or harms and protect the welfare of participants. Include a description of how you will handle an adverse or unexpected outcome that could be potentially harmful (i.e.: suicidal ideation). If the study will include protected populations, identify each group and provide an explanatory paragraph for each group.

4. Describe any benefit that individuals may reasonably expect from participation. If there are none, stat NONE.

5. Describe the anticipated benefits of this study to society, academic knowledge, or both.

Privacy and Confidentiality

1. Will you or any member of your research team collect or have access to any of the personal identifiers listed below? Select all that apply.

☐ Name

☐ Date of Birth

☐ Mailing or email address

☐ Phone or fax numbers

☐Social Security numbers

☐ Medical Records

☐ License, certificate, or vehicle ID

☐ IP address

☐ Biometric identifiers

☐Photos/images/audio recordings

☐ Signatures, handwriting samples

☐ Any unique identifier not mentioned above:

☐ No member of the research team will have access to any personal identifiers.

Consent Process

Please refer to the IRB policy on Informed Consent and the Informed Consent template on IRBNet.org.

1. Will you use a written informed consent document?

☐ Yes

☐ No, I am seeking a waiver of written informed consent

☐ Not applicable

2. Will you obtain written assent for children and individuals under 18?

☐ Yes

☐ No, I am seeking a waiver of written informed consent

☐ Not applicable

3. Will you obtain written parental or guardian permission for children and individuals under 18?

☐ Yes

☐ No, I am seeking a waiver of written informed consent

☐ Not applicable

CHS IRB Form 100A
Title of Study:

Financial Conflict of Interest Disclosure

Financial conflicts of interest related to research require that personnel conducting research involving human participants at Catholic Health must disclose known significant financial interests that would reasonably appear to be affected by the research project and that if the interest is deemed to constitute a conflict of interest with the proposed research, the conflict be managed prior to their engagement in the research with human participants. Significant interests include:

1. An equity interest in an external entity that, when aggregated for the investigator and the investigators spouse/partner and dependent children over the past 12 months and expected over the next 12 months exceeds $5000 in value and/or represents more than 5% ownership interest.
2. Salary, royalties or other payments from an external entity that, when aggregated for the investigator and the investigators spouse/partner and dependent children over the past 12 months and expected over the next 12 months exceeds $5000

1. Have all study personnel completed the Catholic Health System Conflict of Interest Form?

☐ Yes ☐ No

2. Have all study personnel disclosed significant financial interest that are reasonably related to this research?

☐ Yes ☐ No

3. Do any of the personnel, their spouses/partners, or dependent children have any significant financial interests that are reasonably related to this research?

☐ Yes ☐ No

4. Do any of the personnel, their spouses/partners, or dependent children have any personal financial interest or commitment with any company or entity that sponsors or supports this research?

☐ Yes ☐ No

Signature

This page is to be signed by the principal investigator (PI). If the principal investigator is a resident, nurse, or student, the supervisor must also sign in the box below.

Principal Investigator

I certify that the information I provide in this application is correct and complete. I also pledge that I will not change any of the procedures, forms, or protocols used in this study without first seeking review and approval from the Catholic Health Institutional Review Board.

☐ Attestation of Principal Investigator

_____ _____

Name/Signature of PI Date

☐ Attestation of Supervisor (if applicable)

_____ _____

Name/Signature of PI Date

_____ _____

Chairperson Signature Date

_____ _____

Approval Date Expiration Date