CHS IRB Form 100F
Title of Study:

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

Request for Continuing IRB Approval

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 summarize the research activities since the last IRB approval; excluding amendment approvals.

4. Since the last IRB approval (excluding amendment approvals), were there any participant withdrawals from the study or complaints about the research activities?

☐ Yes ☐ No

5. Since the last IRB approval (excluding amendment approvals), were there any unexpected problems or adverse events involving risks to participants?

☐ Yes ☐ No

6. Since the last IRB approval (excluding amendment approvals), were there any changes to your study (including with recruitment, informed consent, study design and/or research procedures, research personnel, study location, etc…)?

☐ Yes ☐ No

7. Do you plan to recruit new participants?

☐ Yes ☐ No

8. Do you plan to collect new or additional data from current research participants?

☐ Yes ☐ No

Proposed changes to the study

1. Please select ALL the categories of amendment(s) you are requesting.

☐ No changes are being made

☐ Change in Study Title

☐ Change in Principal Investigator

☐ Addition of/change in research personnel

☐ Addition of/change in funding source

☐ Change in research/study design, methods or procedures (i.e.: observations, interventions, collection of samples or information etc…)

☐ Addition of/change to study population

☐ Addition of/change to recruitment or compensation procedure(s)

☐ Addition of/change to survey(s), questionnaire(s), or other instruments- please attach revised documents

☐ Addition of/change to the identifiers collected in the study, or any others that would impact the privacy and confidentiality of the study participants

☐ Addition of/change to informed consent/assent document(s) and/or procedures- please attach related documents

☐ Other changes

2. From each category chosen above, please describe the changes you are proposing. (Write N/A if no changes.)

3. Please state the reasons you are making amendments to the study.

4. Are any of these changes the result of something that occurred during human participant interaction or an unexpected event?

☐ Yes ☐ No

5. Will the proposed changes have an impact on the risks or benefits to research participants? Please explain.

6. Do these changes involve information that might relate to a subject's willingness to continue to take part in research?

☐ Yes ☐ No

CHS IRB Form 100F
Title of Study:

Please include a clean copy of the consent forms, debriefing scripts or any other study materials that you plan to use for this project in the coming year.

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