Holyoke Community College IRB

APPLICATION FOR CONTINUING REVIEW or STUDY CLOSURE

Name of Principal Investigator: ..... **Date:** .....
Address ..... **Email:** ..... **Phone:** .....
Full Title of Protocol:

I. Summary of Progress *Attach a separate sheet, if necessary.*

A) Give a summary of your progress to date.

B) Have you had any publication additions or recent literature citations of your study? ☐ Yes ☐ No
Have you presented your study at any conference or other events? ☐ Yes ☐ No
If yes, describe and list all publications and presentations.

II. Indicate the Current Status of Human Participant Use.

A) ☐ Participants have been run. *Total number of participants run to date:* .....
☐ No participants have been run to date. *Will run participants starting:* .....
☐ Participant intervention/participation is completed *Completion occurred on :* .....
☐ No participants have been or will be enrolled (*chart review or existing data*)

III. Close the Study

Please provide final study report, progress reports, and publications to the IRB as they become available.

☐ Close the study. Enrollment and follow-up are complete and no further contact with participants/records/specimens is anticipated. Describe the reason for closure (e.g., enrollment goals achieved, reason for early termination).

IV. Data and Safety Monitoring

A) Have any new or increased risks been identified since the most recent IRB review? ☐ Yes ☐ No
If yes, explain the risks and what precautions have been taken to minimize those risks.

B) Have changes in the scientific literature, or interim experience with this or related studies, changed your assessment of potential risks or benefits to study subjects? ☐ Yes ☐ No

If yes, describe the literature or experience.

V. Funding/Grants

Status: ☐ Proposal ☐ Funding Pending ☐ Funded ☐ Not Awarded (applied for funding but was not awarded) ☐ Not Applicable (never applied for funding)

Title of Grant (if different than IRB title): .....
Sponsor: ..... PI on Grant: .....
Sponsor #: ..... Is the funding from a Federal source? ☐ Yes ☐ No

VI. Withdrawal, Complaints, Adverse Events and Unanticipated Problems

A) Have participants been withdrawn in the past approval period by the Principal Investigator? ☐ Yes ☐ No
Have participants self-withdrawn from the study in the past approval period? ☐ Yes ☐ No
If you answered yes to either of the above, explain how many of each and the reasons for withdrawal.

B) Have there been participant complaints about the research during this past approval period? ☐ Yes ☐ No
If you answered yes, explain how many complaints have been received as well as what they were and what measures were subsequently taken to guard against similar occurrences.

C) Have there been any adverse events during the past approval period? ☐ Yes ☐ No
If yes, were the adverse events reported to the IRB office? ☐ Yes ☐ No
If you answered no, please contact the IRB Chair immediately.

D) Have there been any unanticipated problems during the past approval period? ☐ Yes ☐ No
If yes, were the unanticipated problems reported to the IRB office? ☐ Yes ☐ No
If you answered no, please contact the IRB Chair immediately.

VII. Protocol Modification

Do you wish to make any changes to the protocol at this time? ☐ Yes ☐ No
*If yes, please submit an **Application for Protocol Modification** to the IRB.*

VIII.

As Principal Investigator, I certify that to the best of my knowledge:
The information provided on all pages is correct and no other procedures will be used in this protocol. I agree to conduct this research as described in the attached supporting documents and I will request and receive approval from the IRB for changes prior to implementing any changes in the protocol. I will comply with HCC IRB policies for conducting ethical research and I will be responsible for ensuring that my co-investigator(s)/student researcher(s) comply with this protocol. Any unanticipated problems and/or adverse events in the course of this study will be reported promptly to the IRB Chair.

_____
Principal Investigator's Signature

_____
Typed Name Date

Faculty Advisor Assurance *(Necessary if PI is a student)*

As Faculty Advisor, I certify that:
The research described in this protocol is being conducted under my supervision. I am both familiar with, and approve of the procedures that are being utilized. I agree with the risk assessment to human participants as detailed in this protocol application. I will ensure that this research is conducted in an ethical manner, and in compliance with HCC IRB policies.

_____
Faculty Advisor's Signature

_____
Typed Name Date