

IRB RENEWAL FORM



SECTION A: General Information

IRB Approval Number:

Project Title:

Principal Investigator(s):

Co-Principal Investigator(s):

Is this research being funded by an external funding agency?

YES **NO**

SECTION B: Status of Project

Project not yet started. No subjects enrolled. Planning on enrollment within the next year.

New subject enrollment currently in progress.

Enrollment closed but subjects are still involved in data collection procedures.

Subject involvement complete, data analysis in progress, including analysis of identifiable private information/biospecimens.

Subject involvement complete, currently accessing clinical data from clinical care procedures

Other (describe):

If subject involvement is complete and data analysis involves no identifiable information, stop and submit a FINAL REPORT instead.

SECTION C: General Study Information

Provide a brief summary of the study progress to date. If enrollment has not begun, explain the reason for the delay and likelihood that subjects will be enrolled in the next year.

Do you have any proposed changes/amendments to your protocol application?

NO **YES** *If YES, submit a MODIFICATION FORM to explain the proposed changes. Changes cannot be implemented until you receive IRB approval.*

If you still have active subjects, attach a copy of the current consent form(s). This includes assent forms, verbal consent scripts, etc. List the attached consent documents below.

Not applicable

Documents attached:

To your knowledge, since the last protocol approval, has there been any new information, either through the study itself or outside sources (e.g., journal articles, conferences, etc.) that is relevant to IRB review (e.g., understood anticipated risks/benefits have changed)?

NO **YES** *If yes, please provide a summary of the changes as an attachment.*

SECTION D: Participants

Indicate the total number of participants that have been enrolled to date. If you have multiple subject pools (e.g., parents and children) indicate how many total participants have been recruited for each SEPARATE group.

PARTICIPANT GROUP**NUMBER ENROLLED**

PARTICIPANT GROUP	NUMBER ENROLLED

Comments:

Indicate the anticipated number of additional/new participants to be recruited in order to complete the study. If you have multiple subject pools indicate how many anticipated participants are needed for each SEPARATE group.

PARTICIPANT GROUP**NUMBER ENROLLED**

PARTICIPANT GROUP	NUMBER ENROLLED

Comments:

Provide a summary of any subject attrition since the last IRB review, and reasons for attrition, if known.

SECTION E: Adverse/Unanticipated Events

Provide a summary of both any unanticipated problems and available information regarding adverse events.

If an unanticipated problem or adverse event occurred, was an INTERIM REPORT submitted?

NA**YES****NO**

Have you received any complaints about the research?

NO**YES**

If yes, please describe the complaint and how it was handled.

SECTION F: Data Storage

Where are your project files being stored? Indicate specific locations. *NOTE: A copy must be stored o COCC's campus.*

Have you verified the status of all project files, and confirmed they are safe and secure? *NOTE: Data must be kept for at least three years after project is completed.*

NO**YES**

If no, please explain.

SECTION G: Investigator Comments

Please provide any additional information that may be helpful for the IRB's review of this renewal.

SECTION H: Signatures

By signing this form, the Principal Investigator attests that (s)he has read the information submitted for IRB review.

**Principal Investigator
(PRINT)**

Signature

Date

Submit as a scanned PDF to the IRB Chair at irb@cocc.edu.