ECHN Institutional Review Committee
Application for Protocol Renewal/Completion

Manchester Memorial Hospital, 71 Haynes Street, Manchester, CT 06040 (860) 646-1222, ext. 2084
tbuck@echn.org; pdombek@echn.org

This form must be submitted at the time of continuing review or study completion.
All questions relate to the *last* approval period.

SECTION 1: General Information

Study Title:

Changes to Investigators or Key Personnel:
Since the last IRC approval (continuing or initial), have there been any changes in the personnel working on the study? ☐ **Yes** ☐ **No**

If yes, please specify:

Complete the entire section below, including the updated information:

Principal Investigator Information:

Name (First, Last, Degree):

Department:

Mailing Address:

Phone #:

E-mail address:

Co-Investigator(s) Information: (add additional co--investigators, if necessary)

Name (First, Last, Degree):

Department:

Mailing Address:

Phone #:

E-mail address:

Student/Resident Researcher(s) Information: (add additional student researchers, as necessary)

Name (First, Last, Degree):

Department:

Mailing Address:

Phone #:

E-mail address:

Other study personnel:

Name (First, Last, Degree):

Department:

Mailing Address:

Phone #:

E-mail address:

Status of Study:

At what stage is the research? *CHECK ONE ON EACH ROW.*

(a) Recruitment/Enrollment	☐ Not started	☐ Active	☐ Closed	Date completed
(b) Intervention (if any)	☐ Not started	☐ Active	☐ Closed	Date completed
(c) Data collection	☐ Not started	☐ Active	☐ Closed	Date completed
(d) Data analysis	☐ Not started	☐ Active	☐ Closed	Date completed
(e) Write-up of results	☐ Not started	☐ Active	☐ Closed	Date completed

PROJECTED STUDY COMPLETION DATE:

SECTION II: FUNDING:

Has the funding source changed since the last approval/re-approval? ☐ **Yes** ☐ **No**
If yes, please specify:

SECTION III: Conflict of Interest :

Has there been any change since the last approval/re-approval that may potentially pose a conflict of interest? ☐ **Yes** ☐ **No**

ECHN Conflict of Interest Policy and Questionnaire available at http://www.echn.org/academic-affairs
For more information, contact pdombek@echn.org

SECTION IV: Study Summary and Progress Report

Findings
Describe the current status of the research (eg., phase I completed, phase II scheduled to start in two months); provide a summary of findings/analysis conducted during the approval period; state whether the findings are consistent with what you expected; and provide a brief description of the plans for the study during the upcoming approval period. IMPORTANT - Please note that it is not acceptable to simply copy last year's findings section. The IRC must review the activity that occurred within the last approval period. If no work was conducted on this study during the last approval period, please state so and explain why (e.g., too busy with other projects, delay in funding, etc.). If closing the study, please attach a copy of any publications or manuscripts resulting from the study.

Are there any new findings that may impact a participant's willingness to continue this study? Indicate "Yes" or "No." If yes, please describe the findings, and explain how these findings have been communicated to participants.

If applicable, provide a summary of the findings of the data safety monitoring plans/board meetings and the date of the last DSMB meeting. Submit a copy of the most recent DSMB report.

Literature
Provide a summary of the recent literature by other authors that provides new information bearing on this study's risk/benefit analysis, and attach copies of such articles to this form. If a search was conducted in good faith, and you believe that no such literature exists, indicate "**No literature exists**" in the space below this text border.

SECTION V: Amendments

1. Is the protocol being amended per this submission? ☐ **Yes** ☐ **No**
   If yes, an Amendment Review Form needs to be completed and attached to this submission.

2. Was the protocol amended during the last IRC approval period? ☐ **Yes** ☐ **No**
   If yes, please list the approval date(s) for each amendment.

Amendment Approval Date(s):			

SECTION VI: Participants

For each participant population, please complete the following:

Identify each Participant Population in this column (if more than one, identify each)	# of participants approved for the study (inclusive of any approved amendments).	# of participants enrolled (signed a consent form or gave oral consent after reading an information sheet) since last IRC review (continuing or initial).	Total # of participants enrolled to date (all previous years plus this year). See "***Important***" note below.
Total:			

Is enrollment proceeding as expected? ☐ **Yes** ☐ **No**
If no, please provide a short explanation.

Important: If more participants were enrolled than was approved, please complete a Protocol Deviation Report and submit with this Re-approval/Completion form.

Additionally, if you wish to increase the total anticipated enrollment, please complete an Amendment Submission Form and submit with this Re-approval/Completion form.

SECTION VII: Events to be Reported at Re-Approval

Please Note: For each adverse event, complete the ECHN IRC's "Unanticipated Problem Involving Risk to Subjects or Others Report Form". Submit to the IRC (as they occur) only those completed forms where the events meet the definition of an "Unanticipated Problem", per the IRC policy. Also submit to the IRC (as they occur), any Protocol Deviations using the ECHN IRC's "Protocol Deviation Report Form".

Were Unanticipated Problems and/or Protocol Deviations reported to the IRC during the last approval period? ☐ **Yes** ☐ **No**

If yes, please list the IRC acknowledgment letter date(s) for each event in the table below. Note: a description of these previously reported events is NOT required.

Unanticipated Problem/Protocol Deviation Acknowledgement Date(s):

1. Describe any previously unreported Unanticipated Problems/Protocol Deviations

2. Describe if the frequency of these event(s) was different from what you anticipated. If yes, please explain in the space below. ☐ **Yes** ☐ **No**

3. Did the PI or member of the research team remove a subject from the study during the last approval period? If yes, please describe how many participants were removed and the circumstances/reasons for each removal. Include your opinion about whether any of the removals were related to the research procedures. ☐ **Yes** ☐ **No**

4. Did any participant voluntarily withdraw from the study since the last IRC review? If yes, indicate how many subjects withdrew, and at what point during the study they withdrew (i.e., after consenting but before study procedures were initiated). Describe if this number is more or less than expected. Also, if known, please state the reason(s) for withdrawal. ☐ **Yes** ☐ **No**

5. Were there any complaints about the research since the last IRC review? If Yes, please describe how many, the nature of the complaints, and how they were addressed. ☐ **Yes** ☐ **No**

6. Were any audits or inspections conducted by sponsors or other external entities, such as the Food and Drug Administration (FDA), which involved or noted protocol violation(s)? If yes, please submit the audit/corrective action plan report. ☐ **Yes** ☐ **No**

SECTION VIII: IRB Review By Other Institutions

Has another IRB reviewed this study? ☐ **Yes** ☐ **No**

If yes, provide the name of the institution(s) and describe the outcome(s):

Name of Institution(s) **Important -** Please attach the current, unexpired approval/re-approval letters from each institution associated with this study.	Indicate Approval Period	Outcome of Review (e.g. approved, require modifications, deferred, not approved). **Important:**. If the study was not approved or was deferred, please explain in the space below the table.

SECTION IX: Comments From the Principal Investigator

If applicable, please provide additional comments that may be helpful in the IRC's evaluation of the continuation of this study.

SECTION X: Required Attachments

A copy of the most recently stamped informed consent form.

Principal Investigator Certification

I understand Eastern Connecticut Health Network (ECHN) policies concerning research involving human participants and I agree:

1. To comply with all IRC policies, decisions, conditions, and requirements;
2. That this study has been designed, to the best of my knowledge, to protect human participants engaged in research in accordance with the standards set by Eastern Connecticut Health Network, the United States Department of Health and Human Services, the Food and Drug Administration, and any other sponsoring agency;
3. To obtain prior approval from the IRC before amending the research protocol or the approved consent/assent form;

4. To report to the IRC in accordance with IRC policy, any serious adverse event(s) and/or unanticipated problem(s) involving risks to participants;
5. To submit the Re-Approval letter at least yearly, or as needed;
6. That my participation and the participation of any co-investigators does/do not violate Eastern Connecticut Health Network's policy on Individual Conflicts of Interest in Research;
7. That each individual listed as study personnel in this application has a) completed the required human subjects training, and b) are knowledgeable of the study procedures described in the protocol;
8. That each individual listed as study personnel in this application possesses the necessary training and experience for conducting research activities in the role described for them in this research study.
9. All external researchers are required to sign the ECHN Confidentiality Statement for Researchers (available on the ECHN Portal).

Furthermore, by signing below, I also attest that I have appropriate facilities and resources for conducting the study.

Original Signature of Principal Investigator	**Date**

Original Signature of Student/Resident Investigator (Only for Student/Resident-Initiated Research)	**Date**

Revised 1/2016, 6/2016, 8/2017, 5/2018