**Assigned: Full \_\_\_\_\_ Expedited \_\_\_\_\_\_**

**(leave blank)**

**FORM D**

**UTCOM/EHS IRB**

**APPLICATION TO CONTINUE (RENEW) A PREVIOUSLY APPROVED IRB PROJECT**

Federal Regulations [21 CFR 56.109(e)] require that IRB monitor and review all research involving human subjects at least once a year.

**Failure to complete a continuing review will result in termination of the research study**

Date:  Department:      Telephone:

IRB Project Number:

Principal Investigator Co-Investigator(s)

Research Coordinator: Phone Number:  E-mail Address:

Other Key Research Personnel:

Title of Project

Funding Source

Date of initial IRB approval:  Date of most recent continuing (renewal) IRB approval:

Estimated completion date of the research project: Accrual to Date:

Yes No Has the Food and Drug Administration (FDA) or the Office of Human Research Protection (OHRP) audited your sites since this study was started? (Attach a copy of the audit report).

Yes No Has the company sponsor audited your site since this study was started? (Attach a copy of the audit report).

Yes No Have there been any changes in the protocol or consent form since the initial approval or last review? When were changes approved?

Date **and** Version of most recent protocol

Date **and** Version of the current consent form

Date **and** Version of the current Investigator Brochure (if applicable)

The study is: Open  Closed to subject accrual  Date closed to accrual

**Section A - Protocol Summary**

1. Provide a summary (350 words or less) of the research project including, the purpose, subject population, investigative methodology, procedures applied to subjects, and potential for subject risk.
2. Provide a summary (350 words or less) of all substantive revisions to the research project since the most recent approval.

**Section B - Demographic Information**

**(Questions in this section apply only to your local site.)**

1. Yes  No Has the research project been initiated? If no, explain on a separate sheet.
2. Yes  No Have patients been actively enrolled If yes provide the following:

Provide the number and gender of subjects accrued since activation of the study.

Number Male  Females

Provide the number and gender of subjects accrued since most recent continuing (renewal) approval (not applicable if this request is for first renewal).

Number  Male  Females

Provide the number of all patients in active treatment: Number

Provide the number of all patients in follow-up only: Number

Provide the number of all patients withdrawn: Number

Provide the number of all patients who screen failed: Number

Provide the number of subjects by ethnic origin accrued since activation of the study.

Caucasian; Black , not of Hispanic origin; Hispanic ;

Asian/Pacific Islander ; American Indian/Alaska Native      ;

Other or Unknown

Provide an explanation of whether subject recruitment has complied with NIH and FDA requirements for the inclusion of women, racial/ethnic minorities and children in human subjects research.

**Section C - Problems, Complications, Subject Withdrawal**

**(Questions in this section apply only to your local site and pertain to the period since the most recent IRB approval to initiate or continue the research.)**

1. Yes  No  Did any subjects express complaints about their participation in the research project? If yes, describe these complaints and corrective measures taken, if any.
2. Yes  No  Did any subjects voluntarily withdraw from the study for non-medical reasons?

If yes, describe any known reasons for each subject’s withdrawal.

1. Yes  No Were any subjects prematurely terminated by the investigator from the research study for non-medical reasons (such as poor compliance)? If yes, describe the reasons for each subject’s withdrawal.
2. Yes  No Was there an unusually high frequency of serious but anticipated (expected) adverse events? If yes, describe this finding .
3. Yes  No  Did any subject suffer an unanticipated (unexpected) adverse event, serious adverse event, or death that was reported to the IRB since the last IRB review?

If yes, describe the number of such events and their nature and significance.

1. Yes  No  Were any subjects withdrawn from the study because of medical problems or complications? If yes, describe the medical problem or complication for each subject who was withdrawn.
2. Yes No  Is an Independent Safety Monitor or Data Safety Monitoring Board assigned to periodically review data from this study for risks to participants?

If “Yes”, how often does the monitor or board perform a review?

8. Yes No  Has the Independent Safety Monitor or Data Safety Monitoring Board (DSMB) provided any reports of its reviews?

If “Yes”, attach copie(s) of the report(s) and a narrative summary.

**Section D - Study Results and Risk-Benefit Assessment**

(Questions in this section apply to all study sites and pertain to the entire period since initiation of the study.)

1. What results (preliminary or final) have been obtained in the study? If the study is a multi-center trial, this should be stated and any available result provided, including interim summary reports of data and safety monitoring boards. If there are no results that can be reported to the IRB at this time, this should be stated and explained.

2. Yes  No  Have any external unanticipated problems, unanticipated (unexpected) adverse events, serious adverse events, or deaths been reported? If yes, summarize those developments associated with the research interventions( attached SAE spreadsheet).

1. Yes No  Have any clinical or laboratory research results been published or presented which are relevant to the modification or continuation of this study? If yes, explain these developments .
2. Yes  No  Has anything occurred since the last IRB review which may have altered the risk/benefit assessment?

Answers provided in Section C, #1-6 and Section D, #1-3 should be considered in addressing this question. If the answer is “yes”, describe the current risk/benefit assessment and how it differs from the original assessment.

**Section E - Informed Consent Evaluation**

1. Yes  No  Did any problems occur in obtaining and documenting informed consent? If yes, explain .
2. Yes  No  Is the most recent version of the consent form still acceptable?

In answering this question, it should be considered whether the document is accurate, complete and in language understandable to subjects, and does not exclude any new information about the study procedures or results that should be disclosed to subjects.

**If the answer is yes, attach a copy of the current consent form.**

**If the answer is no, submit a Form C (Application for Revision) and attach copies of the current and revised consent forms.**

1. Yes  No  Has recruitment been completed for this study?

If the answer is yes, do you need a stamped approved consent form to re-consent study participants? Yes  No

1. Yes  No  Have informed consent documents and information pertaining to the identity of the subjects been securely stored? If not, explain .
2. Yes  No  Have any significant new findings developed in the course of the research which may relate to the willingness of current subjects to continue participation? If yes, explain plans implemented to inform subjects of this information.

###### Section F-Conflict of Interest

1. Yes  No  Is there a potential conflict of interest for the Principal Investigator or key research personnel?

If “Yes” check all that apply

* 1. Compensation whose value could be affected by the study outcome.
  2. A proprietary interest in the tested product, including but not limited to, a patent, trademark, copyright or licensing agreement, or the right to receive royalties from product commercialization.
  3. Any equity interest in the sponsor or product whose value cannot be readily determined through reference to public prices (e.g., ownership interest or stock options).
  4. Any equity interest in the sponsor or product that exceeds $10,000, or 5%.
  5. Significant payments or other sorts with a cumulative value of $10,000 made directly by the sponsor to any of the investigators as an unrestricted research or educational grant, equipment, consultation, or honoraria.

**Attach the following: (These items must be attached or the continuing review will be returned for completion.)**

1. Yes  No  A list of all subjects enrolled during the last approval period.

2. Yes  No  A list of any subject remaining in follow-up.

3. Yes  No  A copy of the current approved consent form.

4. Yes  No  A list of all SAEs that have occurred since the last continuing review for subjects enrolled on-site

or through this site. (SEA Spreadsheet)

Signature of Investigator \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date:\_\_\_\_\_\_\_\_\_\_

Signature of Departmental or Program Chairman \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date:\_\_\_\_\_\_\_\_\_\_\_\_

**Applications without all requested information and supporting documents will be returned without IRB review.**

**IRB ACTION**: Approved\_\_\_\_\_\_\_ Approved w/provision(s)\_\_\_\_\_\_\_\_\_Referred for Board Review\_\_\_\_\_\_\_\_\_\_\_\_

COMMENTS:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

IRB Chairman Approval\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_