

**Continuing Review Request Form**

**Instructions**: Complete this form for all research involving human subjects and submit to the IRB Office.

**Continuing Review:** Western Michigan University Homer Stryker M.D. School of Medicine (WMed) is required to conduct **substantive and meaningful continuing review** of research at intervals appropriate to the degree of risk, but not less than once per year. Continuing reviews will be conducted by the convened IRB unless the research falls into one or more of the categories appropriate for expedited review.

The information requested in this report is designed to provide the IRB with the necessary information such that it can make the federally-required determinations codified at 21 CFR Parts 50, 54, & 56, and 45 CFR Part 46.

**PLEASE NOTE: ALL MODIFICATIONS AND/OR CHANGES THAT HAVE NOT BEEN REVIEWED AND APPROVED BY THE IRB MUST BE SUBMITTED USING THE “MODIFICATIONS REQUEST FORM.”**

Incomplete answers may result in the IRB requesting additional information or clarification.

|  |
| --- |
| **Study Title:**  |
| **IRB Number:** |

1. **PRINCIPAL INVESTIGATOR AND RESEARCH TEAM**
	1. **Principal Investigator**

|  |  |
| --- | --- |
| **PI Name:**  | **Date:** Click here to enter a date. |
| **Title:**  | **WMed IRB #:**(for IRB office use only) |

|  |  |
| --- | --- |
| [ ]  Faculty [ ]  Other:       | Department/Unit  |
| Address  |
| Email  | Phone Number  |

* 1. **Research Contact/Research Coordinator**

|  |  |
| --- | --- |
| Name:  | Department/Unit:  |
| Address:  |
| Email:  | Phone Number:  |

1. **CURRENT STATUS OF RESEARCH**
	1. Estimated study completion date: Click here to enter a date.
	2. Current Status of Research *(If all research related activities at WMed are completed, or the study has been terminated, or the study never was conducted use the “Study Closure Form”):*

[ ]  Study is open to enrollment and no subjects have been enrolled to date.

[ ]  Study is open to enrollment and subjects have been enrolled to date.

[ ]  Closed to enrollment but subjects are still on the research plan regimen.

[ ]  Closed to enrollment but follow-up of subjects continues.

[ ]  Closed to enrollment but analysis of identifiable/coded data continues.

[ ]  Closed. All research related activities, including follow-up and data analysis at WMed (or local site) are completed, or the study has been stopped, or the study never was conducted.

1. **UPDATE ON FINDINGS AND LITERATURE**
	1. **Please summarize your findings to date; including preliminary results and interim findings where available** *(State if there are no findings to date)***:**

* 1. **Since the last IRB review, have there been any publications in the literature relevant to this research?**

[ ] No

[ ] Yes**.** List and attach a copy of all publications**:**

1. **UPDATE ON ENROLLMENT**

When completing this section for a multi-center project, the numbers in this section should only include the site or sites for which the WMed IRB is serving as the IRB of record.

1. List the total number of subjects (or charts/record reviewed) approved for enrollment by the IRB. (*You must modify your research plan and receive prospective IRB approval prior to enrolling more subjects than are approved for this study. If you have more than one cohort [patients, family members, treating physicians, etc.] provide answers for each cohort)*:
2. List the total number of subjects enrolled (or charts/records reviewed) since the start of the research study. *(For the purposes of this report, subjects are considered enrolled if they have signed consent. If you have more than one cohort [patients, family members, treating physicians, etc.] provide answers for each cohort)*:
3. List the total number of subjects enrolled (or charts/records to be reviewed) since the last continuing review. *(If this is the first continuing review, List the number of subjects enrolled since study approval. For the purposes of this report, subjects are considered enrolled if they have signed consent. If you have more than one cohort [patients, family members, treating physicians, etc.] provide answers for each cohort.):*
4. Does your study require screening procedures to determine study eligibility?

[ ] No

[ ]  Yes. How many subjects were consented and failed screening procedures *(If you have more than one cohort [patients, family members, treating physicians, etc.] provide answers for each cohort)?*

1. **Number of subjects still active in the study** (includes follow-up procedures) at the time of this review *(If you have more than one cohort [patients, family members, treating physicians, etc.] provide answers for each cohort)*:
2. **Number of subjects that have completed the study** *(If you have more than one cohort [patients, family members, treating physicians, etc.] provide answers for each cohort)*:
3. **Have any subjects been withdrawn from this study to date?**

[ ]  No

[ ]  Yes. Summarize the number of and reasons for the withdrawals:

1. **Number of additional subjects to be enrolled (or charts/records to be reviewed) study** *(If you have more than one cohort [patients, family members, treating physicians, etc.] provide answers for each cohort)*:
2. Provide the cumulative accrual by race/ethnic group and gender for this study:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **American Indian or Alaska Native** | **Asian** | **Black or African American** | **Hispanic or Latino** | **Native Hawaiian or Other Pacific Islander** | **White** | **Totals** |
| **Men** |       |       |       |       |       |       |       |
| **Women** |       |       |       |       |       |       |       |
| **Totals** |       |       |       |       |       |       |       |

[ ] Race/ethnicity and gender and not collected for this study.

1. Has the IRB approved the enrollment of vulnerable populations for this study?*.*

[ ]  No

[ ]  Yes**\*\***

 **\*\*If yes, provide a cumulative accrual by vulnerable population:**

|  |  |
| --- | --- |
| **Category** | **Total Enrolled** |
| **Employees/Students/House Staff/Fellows** |  |
| **Children** |  |
| **Pregnant Women, Fetuses, or Neonates** |  |
| **Prisoners** |  |
| **Adults with Impaired Decision-Making Capacity** |  |
| **Other** *(Describe)***:**  |  |

1. Have any subjects been excluded on the basis of race, ethnicity, preferred language, socioeconomic status, education, gender, or pregnancy?

[ ]  No

[ ]  Yes.Explain**:**

1. **UPDATE ON RESEARCH**
	1. **Since the last IRB review, has any new information become available that impacts the merit, risks, benefits, or other aspects of this research?**

[ ]  No

[ ]  Yes**.** Summarize*(Supporting documentation may be attached)***:**

* 1. Since the last IRB review, have there been any study-wide or multi-center trial reports?

[ ]  No

[ ]  Yes**.** Attach a copy of all multi-center reports.

* 1. **Since the last IRB review, have there been any data and safety monitoring board reports?**

[ ]  No

[ ]  Yes**.** Attach a copy of the most recent report.

* 1. **Since the last IRB review, has the profile of adverse events (in terms of frequency, severity, or specificity) changed?”**

[ ]  No

[ ]  Yes**.** Provide a summary of the changes:

* 1. **Since the last IRB review, have there been any unanticipated problems involving risks to subjects or others?**

[ ]  No

[ ]  Yes. Provide a summary of the problems:

**Unanticipated problems involving risk to participants or others** refers to any incident, experience, outcome, or new information that is unexpected, is related or possibly related to participation in the research, and indicates that subjects or others are at a greater risk of harm (including physical, psychological, economic, legal or social harm) than was previously known or recognized.

* 1. **Since the last IRB review, have any subjects or other complained about the research?**

[ ]  No

[ ]  Yes**.** Provide a summary describing the number and nature of the complaints:

* 1. **Since the last IRB review, have there been any problems or issues with the research not captured by the above questions (e.g., stalled or slow enrollment)?**

[ ]  No

[ ]  Yes. Explain:

* 1. **In the opinion of the PI, have the risks or potential benefits of this research changed?**

[ ]  No

[ ]  Yes. Explain:

1. **ADDITIONAL INFORMATION**
	1. Type of informed consent approved by the IRB *(check all that apply)*:

[ ]  Written Informed Consent Document(s). (*Redacted copy of most recently signed consent)*:

Number of consent forms attached:

[ ]  Oral Script(s)/Letter(s)/Information Sheet(s). (Unsigned)

 Number of oral script(s)/letter(s)/information sheets(s):

[ ]  Waiver of Informed Consent granted

1. **UPDATE ON CONFLICT OF INTEREST DISCLOSURE**

Supplement Form N COI Disclosure Form must be submitted at continuing review whenever the PI or a member of the study team (or person with whom the PI or member of the study team has a personal relationship) has a known or potential conflict of interest.

A Personal Relationship includes the spouse, domestic partner, dependent children, individuals living in the same household, and other individuals with a consensual romantic, intimate, or sexual relationship.

* 1. Does the PI or any member of the study team have a known or potential conflict of interest?

[ ]  Yes. *(Indicate whom):*

[ ]  No

1. **OTHER INFORMATION**

**Please list any other information relevant to the continuation of this study that you believe the IRB should consider:**

1. **PRINCIPAL INVESTIGATOR’S STATEMENT OF ASSURANCE**

I certify that the information provided in this application is complete and correct.

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Principal Investigator Date

**IF SOMEONE OTHER THAN THE PRINCIPAL INVESTIGATOR IS SUBMITTING THIS INFORMATION PLEASE PROVIDE THEIR NAME AND CONTACT INFORMATION BELOW.**

[ ]  N/A

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Study Team Member signature and contact information Date

1. **ATTACHMENTS**

Please attach the following items as applicable and check those attached. *Method of submission is dependent upon the institution’s processes; paper or electronic.*

[ ]  Copy of the latest IRB approved stamped informed consent form(s)

[ ]  Copy of the most recently signed consent form(s) (redacted). *If there is more than one approved consent (e.g., translated version), attach a redacted copy (most recently signed) of all versions.*

[ ]  Copy of the latest IRB approved oral script(s)/letter(s) information sheet(s)

[ ]  Copy of the latest IRB approved stamped assent document(s)

[ ]  Copy of the most recently signed assent document(s) (redacted)

[ ]  Copy of the latest IRB approved stamped translated & authenticated versions of the above consent(s), oral script(s), letter(s), information sheet(s), and/or assent document(s) for persons with limited-English fluency

[ ]  Any newpublication(s) related to the research

[ ]  The most recent Study–wide or Multi-Center Study Report(s)

[ ]  The most recent Data Safety and Monitoring Board Report(s)

[ ]  Training Documentation (*i.e. CITI Certificates for each member of the research team*)

[ ]  Supplement N COI Disclosure Form

[ ]  Other *(Describe)*: