JEFFERSON—Office of Human Research

# **CONTINUING OR FINAL REVIEW OF RESEARCH PROTOCOLS**

# **INVOLVING HUMAN SUBJECTS**

**Version Date – FOR OHR USE: 11/11/21**

***(Complete all items - Form must be typewritten)***

TYPE OF APPLICATION:  CONTINUING REVIEW  FINAL REPORT

INITIAL REVIEW WAS:  FULL or EXPEDITED  *(Noted on approval letter)*

TITLE OF PROTOCOL:

IRB CONTROL #:

TJU SPONSORED PROGRAMS ACCOUNT NUMBER: **080-**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

PI:

DEPARTMENT: FUNDING AGENCY:

**Is OHR-9 being submitted simultaneously with an amendment (OHR-12)? \_\_\_\_\_\_YES \_\_\_\_\_\_\_NO**

**Note: Please ensure that no patient identifiers (name, DOB, MR#, etc.) appear on the documents you upload (e.g. SAE reports, monitoring reports, etc.). If the document must be uploaded as part of the submission, please redact all patient identifiers before uploading.**

**Each copy set should be collated in the order shown in the tables below.**

For continuing review of a study initially given full review

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Form | OHR-9 | Current **IRB-approved**  OHR-2 or  OHR-4 or OHR‑15 | Off-site AE summary from past year | On-site SAE reports from past year | Current OHR-3 or stamped OHR-8 (with version number and date) | Clean copy OHR-8, *if enrollment open* | Current drug or device brochure | Sponsor protocol | If the study was originally approved as expedited by the IRB, then you may submit continuing review as expedited. |
| # of hardcopies | 3 | 3 | 3 | 3 | 3 | 1 | 1 | 1 |
| For continuing review of an expedited study | | | | | | | |
| For expedited reviews, submit all appropriate documents (see first row of table) electronically using the Portal. Hardcopies are not required for expedited reviews. | | | | | | | |

For a final review

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Form | OHR-9 | Current **IRB-approved** OHR-2 or  OHR-4 or OHR-15 | Off-site AE summary from past year | On-site SAE reports from past year | Current OHR-3 or stamped OHR-8 |
| # of hardcopies | For final reports, submit all appropriate documents (see first row of this table) electronically using the Portal. Hardcopies are not required for final reports. | | | | |

Humanitarian Use Device Studies: Please treat HUD study as research and answer all questions below (i.e., number of enrollments, SAE/UAP, etc.).

1. **FDA REGULATION**

**Is your study FDA Regulated?**   NO. If No, Proceed to Part B, Continuing Review Determination.

YES. If Yes, Proceed to Part C, Study Status.

**FDA-regulated studies involve investigational drugs, devices, or biologic products, or products approved by FDA that are used in a study in an off-label manner. These products may or may not be associated with an IND#, IDE#, or HDE# (***see table in Part C of OHR-2***).**

1. **CONTINUING REVIEW DETERMINATION**

Has this study progressed to the point that it involves only one or both of the following? Check all that apply. If neither apply, proceed to Part C, Study Status.

Data analysis, including analysis of identifiable private information or identifiable biospecimens, and/or;

Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

If one or both of the boxes above are checked, skip to Part D.

1. **STUDY STATUS**

Study is active and subject recruitment/chart review/tissue collection is ongoing.

Chart review/tissue collection is completed. Study is in data analysis.

Enrollment is closed. Please check numbers 1, 2 or 3 below. (*A new stamped consent form will not be issued.)*

1. Subjects are receiving study treatment or are undergoing study procedures.
2. Study is in follow-up. Subjects are not receiving study treatment.
3. Numbers 1 or 2 are checked. However, a new stamped consent form is required.

Study enrollment is suspended. *(Please provide reason and relevant correspondence.)*

Study has expired. PI certifies that no subjects were enrolled or study procedures occurred after the expiration date.

Study is completed. This represents the final report.

**D. ENROLLMENT & RISK DATA**

|  |  |  |  |
| --- | --- | --- | --- |
| 1. Date of first IRB approval:  2. Date of most recent continuing review  approval:  3. Period of that approval\*: *(See approval letter)*  1 yr. \_\_\_ 6 mo. \_\_\_ Other \_\_\_\_\_ |  | 4. Date of first on-site subject enrollment:  5. Date of most recent on-site subject  enrollment:  6. IRB-approved enrollment number: |  |
|  |  |
|  |  |

***\*If this is first continuing review, then provide period of first IRB approval.***

7a. If the study does not involve interaction with subjects (e.g., database or chart review), indicate the number of subjects entered or charts reviewed to date: \_\_\_\_\_. **(Skip to Section G, Progress Report.)**

7b. If the study is a registry, **complete Section D, Section E, and then skip to Section G, Progress Report.**

7c. If the study is a collection of pre-existing (stored) biological specimens collected for reasons other than this study, indicate the number of specimens collected to date: \_\_\_\_\_. **(Skip to Section G, Progress Report.)**

|  |  |  |  |
| --- | --- | --- | --- |
|  | | **Since Last IRB Approval (Initial or Continuing Review)** | **Total to Date** |
| 8. Number of subjects enrolled:  *[Note: for the purposes of the OHR-9, “subjects enrolled” is defined as subjects who have successfully screened and been randomized or allocated or begun study procedures.]* | |  |  |
| ***For the items in the box below, provide only one response. Do not respond in shaded columns.***  9. Number of subjects currently receiving study intervention:  10. Number of subjects on follow-up not receiving intervention:  11. Number of subjects completed study (no longer being followed):  12. Number of withdrawals, lost to follow-up, deaths:  (Please provide brief details for entire study to date in section C. Any deaths listed here should not be listed in this section as completed subjects, even if death is a pre-specified protocol endpoint.) |  |  |  |
| **\_\_\_\_\_\_** |
| **\_\_\_\_\_\_** |
| **\_\_\_\_\_\_** |
| **\_\_\_\_\_\_** |

**E. DEMOGRAPHIC TABLE**

Federal regulations mandate equitable selection of research subjects, unless there is scientific basis for exclusion of subjects based on age, sex, race and/or ethnicity. Please provide the number of on-site subjects enrolled in the study to date, according to classification. **Total should be equal to item #8, “Total to Date” column, above**.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | Native  American | Asian | Black Non-Hispanic | Hispanic | White Non-Hispanic | Other/  Unknown | **TOTAL**  **TO DATE** |
| Adult-Female |  |  |  |  |  |  |  |
| Adult-Male |  |  |  |  |  |  |  |
| Child-Female |  |  |  |  |  |  |  |
| Child-Male |  |  |  |  |  |  |  |
| **TOTAL**  **TO DATE** |  |  |  |  |  |  |  |

**F. PROGRESS REPORT (All items must be completed whether submission is for continuing or final review).**

1. Interim findings: Provide at least a 3-4 sentence synopsis describing what has or has not occurred in the study, plus data related to subject responses to intervention, if applicable. Attach copies of any publications or abstracts that have resulted from the research. Provide information/reports from other sites if multi-center trial and if data are available.

2. Subject Withdrawals, Lost to Follow-Up, and Deaths (Since the Beginning of the Study):

None -OR- Complete the Table Below (Use one row for each applicable subject. Add more rows as needed.)

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Subject # / Allocation #** | **Date of Occurrence (MM/YY)** | **\*Reason/Cause** |
| Withdrawals |  |  |  |
|  |  |  |  |
|  |  |  |  |
| Lost to Follow-Up |  |  |  |
|  |  |  |  |
|  |  |  |  |
| Deaths |  |  |  |
|  |  |  |  |
|  |  |  |  |

***\* Please provide a brief description of Reason/Cause (i.e., heart attack, disease progression). If the Reason/Cause was an SAE/UAP that occurred since the last continuing review, include the SAE/UAP report/summary with your submission.***

3. Describe any subject grievances or complaints.

4. Provide an itemization of amendments submitted within the past year.

5. Provide a list of all study personnel additions/removals approved within the past year.

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **Role** | **Added/**  **Removed** | **Date of Addition/**  **Removal\*** |
|  | Investigator  Co-Investigator  Key Personnel | Added  Removed |  |
|  | Investigator  Co-Investigator  Key Personnel | Added  Removed |  |
|  | Investigator  Co-Investigator  Key Personnel | Added  Removed |  |

***\*The date of addition/removal is the IRB approval date***

6. Please provide all serious adverse events (SAEs) and unanticipated problems (UAPs) that have occurred since the initial submission or last continuing review (whichever was more recent). This includes SAEs and UAPs that have already been submitted to the IRB. Note that grade 1 and 2 AEs do not have to be reported to OHR. This information may be in the form of individual SAE/UAP reports or summary reports from eSAEy and eazUP. These should be uploaded to the IRB Portal with the other submission documents.

7. Were additional risks added to the consent form within the past year? Yes\_\_\_ No\_\_\_ If **YES**, please itemize:

8. Have you had any audits or monitoring visits (internal or external) within the past year? Yes\_\_\_ No\_\_\_ If **YES**, please attach report(s) or explain why unavailable.

9. Has a Data & Safety Monitoring Board (DSMB) or sponsor reviewed study-wide adverse events and interim findings? Yes\_\_\_\_ No\_\_\_\_ NA\_\_\_\_\_ If **YES**, please attach report(s) or explain why unavailable.

10. Have there been any protocol deviations/violations? If **YES**, please provide a log of the events including any corrective measures taken.

11. If this study is multi-center, are there any relevant multi-center trial reports that the IRB should be made aware of?

Yes\_\_\_ No\_\_\_ If **YES**, please attach report(s).

12. Has the enrollment for the past year been less than projected? Yes\_\_\_ No\_\_\_ If **YES**, please explain how you intend to improve enrollment:

13. Are facilities and number of support staff the same as at the time of the original application?

Yes \_\_\_\_\_ No \_\_\_\_\_ If **NO**, provide details of any changes.

14. If drug or device trial, has there been any change in FDA status? Yes \_\_\_\_\_ No \_\_\_\_\_ If **YES**, please explain and attach copies of any correspondence with the FDA. Include copy of annual report to FDA.

15. If research involves drug or device for which you or a co-investigator hold the IND or IDE, please attach copy of the last progress report to the FDA.

16. **Literature Review**: As Principal Investigator of this study, I certify that I have conducted a review of the relevant literature published in the past year, and I have found that the literature indicates:

No change in the risk/benefit ratio for subjects on this study, and no cause for subjects to reconsider their participation in the study.

Change in the risk/benefit ratio for subjects on this study and/or cause for subjects to reconsider their participation in the study. *Please explain and cite relevant articles*

17. If the consent form has been revised since the last IRB approval, it must be submitted separately with an OHR-12. Please versify that no revisions have been made to the consent form since the last IRB approval.

No revisions have been made to the consent form since the last IRB approval.

Revisions have been made and have been/will be submitted with an OHR-12.

NA (no consent form(s) will be submitted)

18. The following list of procedures (referred to as MCARE procedures) is used to determine which investigator signature line option should be used in the consent form.

There have been no changes to the MCARE procedures required for this study.

-OR- There have been changes, which are recorded below:

None - The study does not involve any of these procedures -OR- Check All that Apply:

1. Administration of anesthesia (local, general, conscious sedation, etc.)
2. Performance of surgical procedures
3. Administration of chemotherapy and therapeutic radiation
4. Administration of blood and/or human source products
5. Refusal to allow transfusion of blood and/or human source products
6. Insertion of a surgical device or appliance
7. Performance of abortion
8. Performance of sterilization
9. Performance of any HIV-related testing (See Policy #113.58, HIV Testing, for specific documentation requirements)
10. Performance of ECT
11. Administration of an experimental medication, use of an experimental device, use of an approved medication or device in an experimental manner or the removal of bone, fluids or tissue for use in research or in the manufacture of a product. Experimental procedures and consent forms must be approved by the Institutional Review Board (“IRB”).
12. Invasive procedures, such as halo placement, central venous catheterization, pulmonary artery catheterization
13. Performance of vaginal delivery/cesarean section

19. Based on the answer above, select the appropriate option for the investigator signature line. The option you choose must match the option in the consent form.

There have been no changes to the MCARE procedures required for this study and the investigator signature line option in the consent form will remain the same.

-OR- Note: If one of the following options is selected, it must match the investigator signature line in the consent form.

Include for studies involving MCARE procedures.

By signing below, you the physician investigator, certify that you and/or a qualified practitioner who is also a co-investigator or key personnel, reviewed the purpose, procedures, risks, benefits, and alternatives to participation with the study participant. The other elements of consent may be provided by properly trained and qualified key personnel.

Include for all other studies.

By signing below, you the investigator, certify that you, a co-investigator, or other properly trained and qualified key personnel, reviewed the elements of consent with the study participant.

20. If your study involves MCARE procedures, but you do not intend to have a physician investigator or a qualified practitioner who is also a co-investigator or key personnel review the purpose, procedures, risks, benefits, and alternatives to participation with the study participant, please provide the rationale.

**G. PROGRESS REPORT: CHART REVIEW/BIOLOGICAL SPECIMEN COLLECTION/DATABASE OR REGISTRY**

1. Provide a synopsis of results so far and describe any data analysis that has taken place. If no data have been collected or analyzed, please indicate why.

2. Have any publications or presentations resulted from the research? If yes, please attach copies.

**H. FOR FINAL REPORTS**

1. Please provide a bibliography of publications, abstracts and presentations to date.

2. If no publications to date, are publications planned or in preparation? If yes, please briefly describe.

3. Are future trials or grant applications related to this research planned? If so, please briefly describe.

4. Have the data collected changed clinical practice? Please explain.

**I. CERTIFICATION OF CONFLICTS OF INTEREST**

This section is addressed to the Principal Investigator, and applies to the Principal Investigator, Co-Investigators and all Key Personnel. Generally, Key Personnel are individuals who are contributing to the conduct of the study. The PI should check the appropriate boxes and provide the required information as needed. Refer to University Policy 107.03, Attachment 2 for more detailed information.

1. Do you (the PI) or a family member maintain a relationship with the sponsor OR do you maintain an ownership interest in intellectual property that may be related to the research? [ ]YES [ ]NO

2. If yes, have you disclosed details about the relationship to the COI Committee via COI-Smart? [ ]YES [ ]NO

• If yes, please provide the date of disclosure or a copy of the disclosure confirmation received from Jefferson Conflicts of Interest Committee via COI Smart (from noreply@coi-smart.com).

• If no, please disclose via COI Smart using the link on the [Office of Legal Affairs Conflict of Interest Page](https://www.jefferson.edu/university/counsel/coi.html). If you have questions or need access, please contact the COI Office at [JeffCOISmart@jefferson.edu](mailto:JeffCOISmart@jefferson.edu) .

Family member: includes spouse, dependent children, and all other persons living in the same household

3. Are you aware of any study personnel identified for this study who have relationships or interests as described above? [ ]YES [ ]NO

• If yes, please name the individual(s) and briefly describe the relationships/interests:

• These individuals must immediately report their relationships/interests in COI-Smart using the link on the [Office of Legal Affairs Conflict of Interest Page](https://www.jefferson.edu/university/counsel/coi.html), if they have not already done so.

If the COI Committee has issued a COI management plan for any research personnel identified on this study, please include the management plan(s) with this application.

**J. CERTIFICATION:** I certify that the information contained above is correct, that the consent form currently reflects any and all modifications since the last approval by the Institutional Review Board, and that: [check where relevant]

**Under federal mandate,** **there is a signed consent form on file with the Principal Investigator for every subject studied at Jefferson, and each subject at Jefferson has received a signed copy of the consent form.** *(If this is not true, please provide a brief explanation. Do not check if no subjects enrolled.)*

**-OR-**

**The Institutional Review Board approved the study without a need to obtain written consent from subjects.**

**K. SIGNATURES**

|  |  |  |
| --- | --- | --- |
|  |  |  |
| ***Individual Completing This Report*** | Date | Telephone and/or Fax Number |
|  |  | |
| Printed Name | E-mail Address | |
|  |  |  |
| ***Principal Investigator*** | Date | Telephone and/or Fax Number |
|  |  | |
| Printed Name | E-mail Address | |