|  |
| --- |
| **rpo use only** |
| **expire date:** |
| **category: full or exp** |
| **approved # of subjects:** |
| **billable: yes or no** |

|  |
| --- |
| **The University of Vermont Committees on Human Research**  **Request for Continuing Review** |
| If you plan to continue conducting research beyond your current expiration date, you must complete this form and return it as soon as possible. **Research protocols must have continued approval until primary data analysis has been completed and a final report is submitted**. Submit all materials via interoffice mail to 213 Waterman, Bldg, 85 So. Prospect Street. |

Note: If you are acting as the Operations Center for this protocol, you must also complete and attach the Operations Center Activities Supplement form found on our forms page.

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **CHRMS** |  | **#** |  | | | **Review Period From:** |  | **Date Form Completed:** |  |
| **CHRBSS** |  |  |
| **PROTOCOL TITLE:** | | | |  | | | | | |
|  | | | |
|  | | | | | | | | | |
| **PRINCIPAL INVESTIGATOR:** | | | | |  | | | | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **WHO IS THE PRIMARY CONTACT FOR THIS RESEARCH PROJECT?** ALL IRB communications will be sent to the person listed below. Primary contacts are considered “key personnel” and must complete required human subjects training. | | | | | | |
| Contact Full Name |  | | | | |
| Department /Address |  | | | | |
| Campus Phone Number/Pager |  | | | | |
| Has the contact changed from last year? | |  | Yes |  | No |

|  |  |  |
| --- | --- | --- |
| **1AA. Protocol Status (Check Applicable):** | | |
| **1.a. Protocol Status – *If you are closing the protocol you must complete the remainder of this form as the final report to the Committee.*** | |
|  | |
|  | Work Not Yet Started (If work has not started in three years, the file will be administratively closed per IRB policy.) |
|  | Active - Work in Progress (recruitment, enrollment, interventions, and follow-up all occurring) |
|  | **Follow-Up Only** (enrollment closed, all interventions complete, following subjects for outcome data) |
|  | **Protocol-Defined (primary) Data Analysis** *(any secondary analysis must be IRB approved)* |
|  | **Specimen Work Only** |
|  | **Close the protocol.** (Make sure that if the study is industry sponsored that the study closeout letter is attached.) |

|  |
| --- |
| **Complete all of the following questions if you are closing the protocol, otherwise skip to 1.b.** |
| **1.a.i. Why do you wish to close the Protocol?** |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Work never started | Explain why |  | | |
|  | Work begun but not completed | Explain why |  | | |
|  | Study has been completed (including protocol-defined data analysis) | | | | |
|  | Outside sponsor has closed this site | | | | |
|  | PI is leaving the institution and will not be transferring to another UVM/FAHC investigator | | | | |
|  | Study is being transferred to another institution. | | | Name institution |  |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 1.a.ii. Determination if Protocol Activities are Complete (complete all as applicable) | | | | | | | |
| Have all subjects completed all follow-up visits per protocol? |  | Yes |  | No |  | NA |
| Have you completed collection of all data/specimens? |  | Yes |  | No |  | NA |
| Is the data analysis complete for the protocol-defined specific aims? |  | Yes |  | No |  | NA |
| For sponsored trials, is the study close out visit complete? |  | Yes |  | No |  | NA |

|  |
| --- |
| 1.a.iii. Disposition of the Data for a Closed Protocol |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **a.** | **Will you be keeping the resultant data?**  *Consult the Data Management Guidance for appropriate procedures for maintaining data.* | | | | | | | |
|
|  |  | Yes, continue |  | No, continue to b. | | | | |
|  | How will the data continue to be maintained? | | | | | | | |
|  |  | | | | | | | |
|  | Will you keep identifiers of any kind, direct or coded? | | | |  | Yes |  | No |
|  | If yes, explain how you will maintain security around the identifiers. | | | | | | | |
|  |  | | | | | | | |
|  | If you intend to maintain identifiers, any subsequent secondary analysis after protocol closure requires prior IRB review and approval. Please acknowledge this requirement by checking below. | | | | | | | |
|  |  | I understand subsequent data analysis of identifiable data requires prior IRB review. | | | | | | |

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| b. **Do you intend to bank any identifiable research data obtained from this protocol for future unspecified research?** *(must have authorization or meet authorization waiver criteria)*  *(This includes but is not limited to any raw data such as notes, observations, images, video, paper surveys, biological samples, radiographic images.)* | | | | | | | | | | | |
|  | Yes |  | No | | | | | |  |
| If yes, do you have an approved bank? | | | | | |  | Yes |  | No |
| If yes, list the IRB # | | | |  | and amend the repository protocol to include this new source of information. | | | | |
| If no,you will need to submit a Biological Specimens/Repository protocol for review and approval. *This form can be found on the forms page of our website.* | | | | | | | | | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **1.b.** | Funding Status | | |  | | | | | | | | | | | |
|  | How is this protocol being funded? | | | | | |  | Departmental | | |  | Federal/State | |  | Industry |
|  | | If federal/state funding, complete the following: | | | | | | | | | | | | | |
|  | | | **Sponsor Name** | |  | | | | and InfoEd Proposal # | | | |  | | |
|  | | | | | | | | | (check with your UVM grants administrator if you do not have this information) | | | | | | |
|  | | | **Grant Project Begin Date** | | |  | | | | and End Date | | |  | | |
|  | | | **If the funding ended during this review period, or will end within the next 12 months, how will this research be supported? Explain below** *Note: Any new funding source, with the exception of a change to departmental funding, requires that a new protocol be submitted for review and approval.* | | | | | | | | | | | | |
|  | | |  | | | | | | | | | | | | |
|  | | **If Industry, provide the Company’s billing information below. *(please contact the company for this information each year)*** | | | | | | | | | | | | | |
|  | | Name | | | | |  | | | | | | | | |
|  | | Contact Person Name for the Invoice | | | | |  | | | | | | | | |
|  | | Contact Person E-mail address | | | | |  | | | | | | | | |
|  | | Street Address | | | | |  | | | | | | | | |
|  | | City, State, Zip | | | | |  | | | | | | | | |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **2. RECRUITMENT/ENROLLMENT** | | | | | |
| **a. Are you still enrolling subjects?** |  | **Yes** |  | **No** |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **b. Number of subjects who signed a consent form since study began** | | | | | | | | | |  | | | | |
| **c. Number of subjects who actually started the study (i.e. enrolled)** | | | | | | | | | |  | | | | |
| **d. Number of subjects who remain in the study** | | | | | | | | | |  | | | | |
| **e. Number of subjects who withdrew, discontinued, or died during the study after being enrolled** | | | | | | | | | |  | | | | |
| **f. Number of subjects who completed the study** | | | | | | | | | |  | | | | |
| **g. The currently approved number of subjects for this research** | | | | | | | | | |  | | | | |
| **h. Verify that D + E + F = C.** | | | | | | | | | | | | | | |
|  | | | **Yes** |  | **No If no, explain discrepancy below.** | | | | | | | | |
|  | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | |
| **i. If there were subjects reported in box E above summarize all withdrawals, discontinuations and deaths.** | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | |
| **3. SUMMARY OF ACTIVITIES** | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | |
| **a. Provide a brief summary of the research activities and preliminary observations and findings obtained thus far since the last review.** *Note: If this is a continuing review closure, please provide your final written report here. Attach additional sheets if necessary.* | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | |
|  | | |  | | | | | | | | | | | | |
| **b. Were any amendments to the protocol submitted to the IRB during this review period?** | | | | | | | | | |  | **Yes** | | |  | **No** |
|  | | | If yes, briefly summarize any amendments which impacted human subjects (e.g. required changes to the consent form) | | | | | | | | | | | | |
|  | | |  | | | | | | | | | | | | |
|  | | |  | | | | | | | | | | | | |
| **c. Are you amending the protocol/consent form at the time of this continuing review?** | | | | | | | |  | **Yes** | | |  | **No** | | |
|  | | | | If yes, submit with this continuing review a Request for Modification/Amendment to Approved Protocolform and include a copy of the summary of protocol changes, (if applicable) consent **with changes highlighted and a consent without the highlighting for stamp.** | | | | | | | | | | | |
|  | | | |  | | | | | | | | | | | |
| **d. If this protocol is either a** | | | | | | | | | | | | | | | | |
|  | | | | * Trial of Drugs and Biologics: controlled clinical investigations, other than Phase 1 investigations, of a product subject to FDA regulation or | | | | | | | | | | | | |
|  | | | | * Trial of Devices: Controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, and pediatric post-market surveillance | | | | | | | | | | | | |
|  | | | | You must maintain your registration with clinicaltrials.gov or other applicable registration sites. An affirmative verification or update of the data in the protocol records that have not been closed or terminated is required every six months. Failing to login to the PRS and confirm or update your record(s) every six months, regardless of whether there has been a change to the trial or not, may result in a loss of funding and/or the inability to publish the results of a trial in an ICMJE associated journal. NOTE: You will receive a reminder e-mail notification from clinicaltrials.gov once every six months to update your study information. Information regarding how to update your registration can be found at <http://www.clinicaltrials.gov/ct2/manage-recs/how-edit>. | | | | | | | | | | | | |

|  |  |  |
| --- | --- | --- |
| **4. SAFETY INFORMATION** | | |
| **a.** | **UNANTICIPATED PROBLEMS UAPs - (check all that have occurred over the last review period)** |
|  | OHRP considers UAPs, in general, to include any incident, experience, or outcome that meets all the following criteria:  1. unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;  2. related or possibly related to participation in the research (in this guidance document, *possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and  3. suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized. |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Local adverse events (includes death)** that met the criteria for reporting to the IRB. | | | | | |
| If checked, were these events reported to the IRB? | |  | Yes |  | No |
| If no, complete a “Unanticipated Problem Potentially…” form for each and submit with this continuing review. | | | | | |
| *NOTE: AE reporting is required for Humanitarian Use Device (HUD) protocols.* | | | | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Protocol deviations** potentially affecting risk to subjects or others. | | | | | |
| *Examples include but are not limited to medication or lab errors, breach in confidentiality/HIPAA violation, eligibility criteria not met, improper consent process used, key personnel not appropriately listed on protocol.* | | | | | |
| If checked, was the deviation(s) reported to the IRB? | |  | Yes |  | No |
| If no, complete a “Unanticipated Problem Potentially…” form for each and submit with this continuing review. | | | | | |
|  | | | | | |
| List or attach a list of all other protocol deviations not affecting risk to subjects that occurred during this review period. (examples here include visit off by one day, questionnaires not done) | | | | |
|  | | | | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Complaint** by subject or another person | | | | | |
| If yes, was the information submitted to the IRB? | |  | Yes |  | No |
| If no, complete a “Unanticipated Problem Potentially…” form and submit with this continuing review. | | | | |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Interim findings, publication, toxicity report, or sponsor action letters** | | | | | | |
| If yes, was the information submitted to the IRB? | |  | Yes |  | No |
| If no, complete a “Unanticipated Problem Potentially…” form and submit with this continuing review. | | | | |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Enforcement Action -** e.g. unfavorable audit report, suspension of investigator, FDA form 483 | | | | | | |
| If yes, was the information submitted to the IRB? | |  | Yes |  | No |
| If no, complete a “Unanticipated Problem Potentially…” form and submit with this continuing review. | | | | |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Study personnel misconduct** | | | | | | |
| If yes, was the information submitted to the IRB? | |  | Yes |  | No |
| If no, complete a “Unanticipated Problem Potentially…” form and submit with this continuing review. | | | | |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Incarceration of a research subject** | | | | | | |
| If yes, was the information submitted to the IRB? | |  | Yes |  | No |
| If no, complete a “Unanticipated Problem Potentially…” form and submit with this continuing review. | | | | |

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **b.** | | **DATA SAFETY AND MONITORING** | | | | | | |  | | |
|  | | **i. Does this study have a Data and Safety Monitoring Board in place?** | | | | |  | Yes | |  | No |
|  | If No, skip to b.ii. | | |  |  | |  |  |
|  | | If Yes, were all DSMB reports during the period forwarded to the IRB? | |  | Yes | |  | No |
| If yes, skip to c. |  |  | |  |  |
| If no, complete a “New Safety Information…” form and submit with this continuing review  *Note: If protocol or consent changes are necessary, you must complete a “Unanticipated Problem Potentially…” form and an “Amendment” form for review and approval.* | | | | | |
|  | | **ii. Since there is no Board, were there any significant findings during the review period, as outlined in the protocol monitoring plan, that affects the risk/benefit ratio or the confidentiality and/or** | | | | | | | | | |
|  | **integrity of the data for this study?** | | | | | |  | Yes | |  | No |
|  | | If No, skip to c. | |  |  | |  |  |
|  | | If Yes, was this information forwarded to the IRB? | |  | Yes | |  | No |
|  | | | If Yes, skip to c. |  |  | |  |  |
| If no, complete a “New Safety Information…” form and submit with this continuing review  *Note: If protocol or consent changes are necessary, you must complete a “Unanticipated Problem Potentially…” form and an “Amendment” form for review and approval.* | | | | | |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **c.** | **INVESTIGATIONAL DRUG/DEVICE BROCHURE UPDATES** | | | | | | | |
| **Were there any updates/revisions?** | | |  | Yes |  | No |
| If No, skip to d. | |  |  |  |  |
| If Yes, was the information forwarded to the IRB? | |  | Yes |  | No |
| If Yes, skip to d. |  |  |  |  |
| If no, complete a “New Safety Information…” form and submit with this continuing review  *Note: If protocol or consent changes are necessary, you must complete a “Unanticipated Problem Potentially…” form and an “Amendment” form for review and approval.* | | | | | |

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **d.** | **HUMANITARIAN USE DEVICE (HUDS)** | | | | | |  | **Not applicable** | |
| **Has there been a change in the FDA product labeling since the last review?** | | | | | | | |
| **Check the** [**Listing of CDRH Humanitarian Device Exemptions.**](http://www.fda.gov/medicaldevices/productsandmedicalprocedures/deviceapprovalsandclearances/hdeapprovals/ucm161827.htm) | | | | | | |
|  | Yes |  | No If yes, attach the labeling information. | | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **e.** | | | | **UNEXPECTED BENEFITS** | | | | | | | | | | | |
| **Were any unexpected benefits to subjects discovered during this review period?** | | |  | | Yes | |  | | | No | |
| If yes, explain. | | | | | | | | | | | |
|  | | | | | | | | | | | |
|  | | | | | | | | | | | |
| 5. MONITORING AND CONSENT | | | | | | | | | | | | | | | | |
| a. | Is this study currently monitored by an outside sponsor? | | | | | |  | | Yes | | |  | | No |
| Provide the date of the last sponsor site visit. | |  |
| Does the sponsor provide written documentation of the visit findings? | | | | |  | | Yes | |  | | | No |
| If yes, attach a copy of the documentation from this visit. If the documentation is pending, provide a copy of the most recent previous visit. If the sponsor does not generate formal documentation of the site visit outcome, request that the sponsor provide the overall outcome of the visit and submit with this continuing review. | | | | | | | | | | | | |
| b. | Attach a copy of the last fully executed consent form signed by a subject during this review period. | | | | | | | | | | | | | |
| The subject’s name should be obscured in some manner but all dates and person obtaining consent should be left intact. (If there has been no enrollment during the period, state so below.) | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 6. DISCLOSURE OF FINANCIAL INTEREST | | | | | | | | | | | | | | | |
| **a.** | **Has your relationship with the sponsor changed such that the results of the study may provide a potential financial gain to you, your immediate family members, or any of the co-investigators (key personnel), or their immediate family members, that may give the appearance of a potential conflict of interest?** | | | | | | | | | | | | | |
|  | Yes |  | No | | | | | |  |  |
| If yes, fully describe the nature of the relationship. | | | | | | | |
|  | | | | | | | | | | | | |
| Is this disclosed in the consent form? | | | | | |  | Yes | |  | No | | |
| If no, provide justification for not including this information below. | | | | | | | | | | | |
|  | | | | | | | | | | | |

|  |  |
| --- | --- |
| 7. ADDITIONAL COMMENTS | |
| Provide any additional comments that the IRB should be aware of that may impact the safety of the subjects involved in this research. |
|  |

|  |  |  |  |
| --- | --- | --- | --- |
| **8.** | **PERSONNEL ROSTER** |  | **Check here that you have attached the roster to this submission.** |
|  | We are providing you with the current key personnel roster as part of your continuing review notice. You must print, complete and attach the roster to this submission. If you have new people to add, you must complete a Request for Change in Key Personnel form and also attach to this submission. | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **9. ATTACHMENT TRACKING FOR THIS CONTINUING REVIEW FORM** This section is optional. | | | | |
|  | Version # | Dated | Comments |  |
| Literature per Section 4.A. |  |  |  | |
| Signed Consent per Section 5B. |  |  |  | |
| Other |  |  |  | |

|  |
| --- |
| **10. INVESTIGATOR SIGNATURE** |
| **By signing below, the Principal Investigator assures the information contained on this form is true and accurate.** | | |
|  | |  |
| **Signature** | | **Date** |