|  |
| --- |
| **The University of Vermont Committees on Human Research**  **Request for Continuing Review for Blood Collection Protocol** |
| If you plan to continue conducting research beyond your current expiration date, you must complete this form and return it as soon as possible. All materials must be submitted electronically to the IRB via InfoEd. Proper security access is needed to make electronic submissions. Visit the [InfoEd Resource Materials](http://www.uvm.edu/~irb/?Page=infoed.html) page for more information. |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **CHRMS**  **or CHRBSS#:** | | |  | | | **Review Period:** | | From: | |  | Date form completed: | | |  |
|  | | |  |  |
|  | |  | | | | | | | | | | | | |
| **PROTOCOL TITLE:** | | |  | | | | | | | | | | | |
|  | | |
|  | | | | | | | | | | | | | | |
| **PRINCIPAL INVESTIGATOR:** | | | | |  | | | | | | | | | |
|  | | | | |  | | | | | | | | | |
| **Dept.** | |  | | | | **Phone Number** | |  | | | **Email** |  | |
|  | | |  | | | | | | | | | | |
| **Campus Address** | | |  | | | | | | | | | | |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **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 |  | | | | Campus Phone Number/Pager | |  |
| Department /Address |  | | | | Email |  | |
| Has the contact changed from last year? | |  | Yes |  | No | | |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **1. PROTOCOL and FUNDING STATUS** | | | | | | | |
|  | | | | | | |
| **1.A.** | | Protocol Status (check one) | | | |
|  | Work Not Yet Started | | | | |
|  | Active - Work in Progress (samples still being taken) | | | | |
|  | Work Completed – Close Protocol (make sure that if the study | | | **Check here if this is your final report:** |  |
|  | is sponsored that the study database is closed before you close locally) | | | (include final summary of activities under section 3) | |
|  | Work Will Not Be Done – Close Protocol – proceed to section 3 and provide reason for withdrawal. | | | | |
|  | |  |  | | |

|  |
| --- |
| **1.a.i. Why do you wish to close the Protocol? (check all that apply)** |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | a. Work never started | Explain why |  | | |
|  | b. Work begun but not completed | Explain why |  | | |
|  | c. Study has been completed (including primary data analysis) | | | | |
|  | d. Outside sponsor has closed this site | | | | |
|  | e. PI is leaving the institution and will not be transferring to another investigator | | | | |
|  | f. Study is being transferred to another institution. | | | Name institution |  |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **1.B.** | **Funding Status** | | |  | | | | | | | | | | | | |
|  | **How is this protocol being funded?** | | | | | |  | **Departmental** | | | |  | **Federal/State** | |  | **Industry** |
|  | | **If federal or 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.** | | | | | | | | | | | | | | |
|  | | 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 donors?** | | | |  | **Yes** | |  | **No** |
| If yes, attach a clean copy (no IRB stamp) of the current consent form. | |  |
| **B. Number of donors who signed a consent form since study onset** | | | | | |  | | |
| **C. Number of donors who donated** | | | | | |  | | |
| **D. Number of these donors that have donated repeatedly during this review period** | | | | | |  | | |
| **E. Number of donors who withdrew, discontinued, or died after consent** | | | | | |  | | |
| **F. The current IRB approved number of donors** | | | | | |  | | |
|  | | | | | | | | |
| **G. 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 since the last review.** | | | | | | | | | | |
|  | | | | | | | | | |
|  |  | | | | | | | | | |
| **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.** | | | | | | | | |

|  |  |  |
| --- | --- | --- |
| **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** 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. | | | | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **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. | | | | |

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

|  |  |  |
| --- | --- | --- |
| 5. CONSENT MONITORING | | |
| A. | 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** |  |  |
|  | |  | | --- | | Please complete the Key Personnel e-form within your continuing review submission in InfoEd. If you have new  people to add, you must complete and submit a Request for Change in Key Personnel form. | | | |

|  |
| --- |
| **9. INVESTIGATOR SIGNATURE** |
| **By signing below, the Principal Investigator assures the information contained on this form is true and accurate.** | | |
|  | |  |
| **Signature** | | **Date** |
|  | |  |
| **Printed Name** | |  |