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| **The University of Vermont Committees on Human Research**  **Request for Continuing Review for Repository 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. |

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

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| **🡺** | OTHER KEY PERSONNEL – Complete Section 5. |

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| **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 | | |

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| **1. REPOSITORY AND FUNDING STATUS** | | | |
| **A. Repository Status** | | (Check One): |
|  | No data/specimens have been collected to date. | |
|  | Collection or review of data/specimens continue. | |
|  | Repository is no longer collecting data/specimens, but currently approved protocols continue to receive data, and or samples. | |
|  | Close the repository. Collection and distribution is complete and no further contact with data/specimens is anticipated. Describe the reason for closure below. | |
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| **1.a.i. Why do you wish to close the Protocol? (check all that apply)** |

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|  | 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 bank will not be transferring to another investigator | | | | |
|  | f. Study is being transferred to another institution. | | | Name institution |  |

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| 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 |

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| **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.* | | | | | | | | | | | | | |
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|  | | **If Industry, provide the Company’s billing information below.** | | | | | | | | | | | | | | |
|  | | Name | | | | | | |  | | | | | | | |
|  | | Contact Person Name for the Invoice | | | | | | |  | | | | | | | |
|  | | Contact Person E-mail address | | | | | | |  | | | | | | | |
|  | | Street Address | | | | | | |  | | | | | | | |
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| **2. RECRUITMENT/ENROLLMENT**  **Obtaining an individual’s data or specimens is considered enrolling subjects.** | | | | | | |
| **A. Are you still enrolling subjects?** | |  | **Yes** |  | **No** |
| **B. Number of subjects enrolled since last review** | | | |  | |
| **C. Total number of subjects enrolled since repository was started** | | | |  | |
| **D. Total number of subjects authorized/approved by the IRB** | | | |  | |
| **E. Number of subjects who withdrew consent to allow information/specimens to remain in repository** | | | |  | |
| **F. If there were subjects reported in box E above summarize below** | | | | | |
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| **3. SUMMARY OF ACTIVITIES** | | | | | | | | | | | | | |
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| 1. **Provide a brief summary of the repository activities since the last review.**   **Summarize your experience with each of the three repository operations: collection, storage, and distribution of data or specimens for future use.** *Note: If you are experiencing problems, explain the situation and your plan for resolution.* | | | | | | | | | | | |
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| **B. Were any amendments 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) | | | | | | | | |
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| **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.** | | | | | | | | | | |

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| **D. List the studies at UVM/UVM Medical Center that have received or contributed data/samples to this repository during this review period:** | | | | | |
|  | **Not Applicable** | | | |
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| **IRB #:** | | **Title:** | **Institution** | **IRB Approval Date** |
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| **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. |

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|  | **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. | | | | | |
| *NOTE: AE reporting is required for Humanitarian Use Device (HUD) protocols.* | | | | |

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|  | **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. | | | | | |
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| 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) | | | | |
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|  | **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. | | | | |

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|  | **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. | | | | |

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|  | **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. | | | | |

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|  | **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. | | | | |

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| 5. MONITORING AND CONSENT | | | | | | |
| A. | Did the IRB require the use of a written informed consent document for this repository? | | | | |
|  | | Yes |  | No |
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| If yes, 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.)* | | | |
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| B. | Is this a multi-center repository where collection activities occur at other institutions outside the jurisdiction of the UVM/UVM Medical Center IRB? | | | | |
|  | | Yes |  | No, skip to #6. |
| If yes, have there been any unanticipated problems (as listed above) at the satellite collection sites?  If yes, explain. | | | | |
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| 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. | | | | | | | |
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| Is this disclosed in the consent form? | | | | | |  | Yes | |  | No | | |
| If no, provide justification for not including this information below. | | | | | | | | | | | |
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| **7.** | **PERSONNEL ROSTER** | Please complete the “Continuing Review Personnel Roster eForm” through InfoEd. Once all personnel have been updated on the eForm, click "Save & Complete" on the top right of the page. You will be required to complete the eForm when uploading documents to a new Continuing Review submission. |
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| **8. INVESTIGATOR SIGNATURE** |
| **By signing below, the Principal Investigator assures the information contained on this form is true and accurate.** | | |
|  | |  |
| **Signature** | | **Date** |
|  | |  |
| **Printed Name** | |  |