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| **The University of Vermont Committees on Human Research**  **Request for Continuing Review**  **Health Records 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**. 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** |  | **#** | |  | | | **Review Period From:** |  | **Date Form Completed:** |  |
| **CHRBSS** |  |  |  | | |
| **Protocol Title:** | | | | |  | | | | | |
| **Principal Investigator:** | | | | |  | | | | | |

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| **Primary Contact** | | | | | | | | | |
| Contact Full Name |  | | | | |  | Email |  |
| Department /Address |  | | | | |  | Phone |  |
| Has the contact changed from last year? | |  | Yes |  | No | | | |

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| **1AA. Protocol Status** | | |
|  | Work Not Yet Started (If work has not started in three years, the file will be administratively closed per IRB policy.) |
|  | Work in Progress |
|  | **Close the Protocol** *Complete the remainder of this form as the final report to the Committee.* |

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| **Reason for protocol closure** |

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|  | Work never started | | Explain |  |
|  | Work begun but not completed | | Explain |  |
|  | Study has been completed (including protocol-defined data analysis) | | | |
|  | **Disposition of Data**  At time of study completion the IRB must confirm the disposition of any identifiable data. In your initial submission, you outlined a plan with regards to resultant identifiable data.  **Describe the plan below.** | | | |
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| **2.** | **Status of Funding** | | | | | | |
|  | Is there any external funding for this project? | Yes | |  | No |  |
|  | **If yes, list sponsor name here** | |  | | | | |
|  | If it is a federal sponsor list InfoEd # here | |  | | | | |

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| **3. Number of Records Reviewed** | |
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| **4. Summary of Activities or Final Report** | | |
| **Provide a summary of activities.** *If you are closing the protocol, please provide your final written report here.* | |
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| **5. Unanticipated Problems (UAP)** | | |
|  | 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.  **Describe any unanticipated problems.** |
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| 6. Written Consent | | | NA |  |  |
|  | If applicable, 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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| 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. |
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| **8.** | **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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| **9. INVESTIGATOR SIGNATURE** |
| **By signing below, the Principal Investigator assures the information contained on this form is true and accurate.** | | | |
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| **Signature** | | **Date** |