**ANNUAL PROTOCOL REVIEW**

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| **CHRMS #:** |  | **Title:** |  | **PI:** |  |

Date of Review**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** Last Review: **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** Person Completing Review: **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

1. **DOES AN AMENDMENT FORM NEED TO BE SUBMITTED?  Reviewed, NONE APPLIES**

Protocol change \*check version dates (includes scientific changes to protocol, eligibility/ineligibility criteria changes, changes in protocol procedure, change requiring re-consent, change in study title)

Status change (closed to accrual, study suspension)

Additions or changes to surveys/questionnaires

Changes to consent form or assent form (check version dates)

Request for review of retention or recruitment material

Change in compensation

Increase in accrual target

Request to share data/specimens with another institution

***If any boxes are checked, complete and submit amendment form*** [**https://www.uvm.edu/sites/default/files/media/amend-cover-form\_InfoEd\_13.docx**](https://www.uvm.edu/sites/default/files/media/amend-cover-form_InfoEd_13.docx)

1. **DOES A SAFETY FORM NEED TO BE SUBMITTED?  Reviewed, NONE APPLIES**

☐ Unanticipated problem or noncompliance ***potentially involving risk*** to subjects or others?

Local adverse event, including death, which is both unexpected and related or possibly related

Medication or lab error

Breach of confidentiality

Significant protocol deviation/non-compliance

Improper consent process or wrong form

Research-related complaint

Intentional change to protocol without IRB approval

Interim findings

Enforcement action

Study personnel misconduct

Omission of key personnel when they are conducting research

Incarceration of a research subject

***If any boxes are checked, complete and submit Unanticipated Problem or noncompliance potentially involving Risk to Subjects or Others:***

[**https://www.uvm.edu/sites/default/files/media/uanticipatedproblemform\_InfoEd\_18.doc**](https://www.uvm.edu/sites/default/files/media/uanticipatedproblemform_InfoEd_18.doc)

New safety information to be reported that ***does not affect risk*** to subjects or others?

Drug Study: Administrative letter, DSMB Report, Drug Development Update, FDA approval, IDB

Revision

Device Study: Administrative letter, Annual device report, DSMB report, IDB revision, FDA approval,

HUD labeling change, Instructions for Use (IFU)

***If any boxes are checked, complete and submit New Safety information Not Affecting Risk to Subjects or Others:*** [**https://www.uvm.edu/sites/default/files/media/newsafetyform\_norisk\_InfoEd\_3.doc**](https://www.uvm.edu/sites/default/files/media/newsafetyform_norisk_InfoEd_3.doc)

1. **DOES AN UPDATED KEY PERSONNEL FORM NEED TO BE SUBMITTED  Reviewed, NONE APPLIES**

\*\*\* Review currently approved KP list supplied

Are all key personnel listed still actively working on this protocol?

Are any staff working on this protocol that are not listed as key personnel?

Does the contact person listed need to be changed?

**If any boxes are checked, complete and submit Key Personnel form** [**https://www.uvm.edu/sites/default/files/media/personnel\_change\_form\_PI\_with\_Clinical\_Trial\_question\_InfoEd.docx**](https://www.uvm.edu/sites/default/files/media/personnel_change_form_PI_with_Clinical_Trial_question_InfoEd.docx)