**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)