|  |  |  |  |
| --- | --- | --- | --- |
| **Use to request a modification to previously approved research** | | | |
| **IRB Docket No.:** |  | | |
| **Study Nickname:** |  | | |
| **Study Title:** |  | | |
| **Principal Investigator: (Name, Email address, Phone)** |  |  |  |
| **Additional Contact:**  **(Name, Email address, Phone)** |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Current Protocol Status**  *Check all that are true or not applicable* | | | |
|  | The research is permanently closed to enrollment at this institution. | | |
|  | All subjects enrolled at this institution have completed all-research related interventions and interactions, including interventions and interactions related to collection of long-term follow-up data. | | |
|  | No additional identifiable private information about the subjects is being obtained by this institution’s investigator. | | |
|  | Analysis of private identifiable information at this institution is completed. *(This can be checked even if a statistical center at another institution will analyze private identifiable from subjects enrolled at this institution.)* | | |
| **If all above items are checked, the research may be closed.** | | | |
|  | Change to Principal Investigator | Include a letter from the previous PI agreeing to the change or from the Dept. Chair explaining the reason to proceed without the previous PI’s agreement | |
|  | Subjects are currently enrolled | | |
|  | Current subjects will be notified of these changes | | *If either is checked, ensure that the submitted documents describe how current or former subjects will be notified. If they will not be notified, provide a justification for why not.* |
|  | Former subjects will be notified of these changes | |

Provide a description and justification for the modification. Please include a list of the documents that have been modified.

**Instructions**

Update the Application for Initial Review Form (HRP-200).

Update the ***Investigator Study Plan*** if affected by the modifications.

Provide one copy of the following documents if affected by the modification:

* FORM: Application for Initial Review (HRP-200).
* Updated Investigator Study Plan (in tracked changes)
* All written materials to be provided to or meant to be seen or heard or completed by subjects, including:
  + Data collection instruments (questionnaires, etc.; do not submit case report forms).
  + Evaluation instruments and surveys
  + Advertisements (printed, audio, and video)
  + Recruitment materials and scripts
  + Consent documents
* If consent will not be documented in writing, a script of information to be provided orally to subjects

Provide one copy of the following documents ***if they have been modified***:

* Grant application
* Complete sponsor protocol including DHHS-approved protocol
* DHHS-approved sample consent document
* Current investigator brochure for each investigational drug
* Current package insert for each marketed drug
* Current product information for each investigational device
* Foreign language version of any written material to be provided to or meant to be seen or heard by subjects.

|  |  |
| --- | --- |
| **Investigator Acknowledgment** | |
| **The following check boxes must be checked before sending:**  By checking below you are verifying that:   * **Yes**  You have obtained the financial interest status (“Yes” or “No”) for each member of the research staff. * **Yes**  You have obtained the agreement of each research staff to his/her role in the research. * **Yes**  You have obtained the agreement, if applicable, of any other clinical unit or service (outside of your own department) being asked to serve as a recruitment or study conduct site. * **Yes**  You will conduct this Human Research in accordance with requirements in the INVESTIGATOR MANUAL (HRP-103). | |
| By checking here, I attest that the information provided in this form is accurate. | Date: |