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| **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)** |       |       |       |

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| **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.

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| **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).
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|  [ ]  By checking here, I attest that the information provided in this form is accurate.  | Date:        |