

**Oklahoma State University Center for Health Sciences**

**Institutional Review Board**

**1111 W. 17th St**

**Tulsa, OK 74107**

**918-561-1400**

**Modification of Approved Human Research**

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| **Use to request a modification to previously approved research** | | |
| **IRB Number:** | |  |
| **Protocol Name:** | |  |
| **Investigator:** | |  |
| **Primary Contact:** | |  |
| **Numbers of Subjects Enrolled Locally:** | |  |
| **Does this modification include a change in study personnel?**   Yes No  If yes, if any contact information has changed or any study personnel have been added and are not currently in the IRB database, a **Contact Information Form** must be completed and included with this submission. | | |
| **Study Status as a Result of this Modification** | | |
|  | Enrollment is suspended. Effective Date:       If not previously reported, please explain: | |
|  | Enrollment is suspended. Request to re-open upon approval of this revision/addition. | |
|  | Actively enrolling subjects. | |
|  | Enrollment is permanently closed. Effective Date:   * Are subjects receiving active intervention?  Yes No * Are subjects on long-term follow-up?  Yes No | |
| **Summarize the Modification or Attach a Summary:** | | |
|  | | |
| Explain what the plan is for communicating these changes to the subject(s). If these changes will not be communicated to subject(s), explain why: | | |

Provide the following when they have been *modified* or are new, and submit to the OSU CHS IRB

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| **Documents** | **Version # and/or Date (as applicable)** | **Check Box if Submitting with this Modification** |
| Protocol |  |  |
| Data Collection Instruments (if investigator initiated research) |  |  |
| **All written material to be provided to or meant to be seen or heard by subjects, including:** | | |
| Evaluation Instruments (to be completed by subjects) and Surveys |  |  |
| Advertisements (printed, audio, and video) |  |  |
| Recruitment Materials (letters, phone scripts, posters) |  |  |
| Consent Documents or Information Sheets |  |  |
| Foreign language version of any written material to be provided to or meant to be seen or heard by subjects. |  |  |
| If consent will not be documented in writing, a script of information to be provided orally |  |  |
| **Provide the following documents when they exist:** | | |
| Grant Application |  |  |
| Investigator’s brochure for each investigational drug/biologic |  |  |
| Package insert for each marketed drug/biologic |  |  |
| Product information for each investigational device |  |  |
| Contact Information Form *(for all new individuals and any individuals with updated information)* |  |  |
| Other: |  |  |
| Other: |  |  |
| Other: |  |  |

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| --- | --- |
| **Investigator Acknowledgement** | |
| I agree to conduct this Human Research in accordance with applicable regulations and the organization’s policies and procedures. | |
| Investigator Signature | Date |
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