

**Institutional Review Board (IRB)**

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**Continuing Review of Protocol Involving Human Subjects §46.109(e)**

[**http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.109**](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.109)

**Previous IRB Review Date:** Click or tap here to enter text. **Approval Expiration Date:** Click or tap here to enter text.

**Title:** Click or tap here to enter text. **Project End Date:** Click or tap here to enter text.

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| **Principal Investigator/Co-Principal Investigator(s)** | | **UHCL Email *(REQUIRED)*** | |
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| **Faculty Sponsor** | | **UHCL Email *(REQUIRED)*** | |
| Click or tap here to enter text. | | Click or tap here to enter text. | |
| **Student Researcher(s)** | **UHCL Email *(REQUIRED)*** | | **Alternate Email *(REQUIRED)*** |
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1. **Status Report**
2. Provide the total number of subjects enrolled to date: Click or tap here to enter text.
3. Provide demographics of subjects enrolled to date: Click or tap here to enter text.
4. Provide information about additional enrollment of subjects expected for upcoming period: Click or tap here to enter text.
5. Provide information about subjects recruited –

D1. the number from whom data were received: Click or tap here to enter text.

D2. the number who withdrew or were dropped and reasons: Click or tap here to enter text.

D3. the number of complaints received from subjects about the study or their participation: Click or tap here to enter text.

1. Provide details of any unanticipated problems or adverse events involving risks to subjects encountered to date: Click or tap here to enter text.
2. Provide current assessment of the research and its related risks and benefits; e.g., any findings in the research that affect the risk-benefit ratio or suggest a need to amend or modify research protocol; any problems with privacy or confidentiality; etc.: Click or tap here to enter text.
3. Provide summarization of modifications made to the original protocol: Click or tap here to enter text.
4. Provide amended informed consent form in two versions: modified version to be given to newly recruited participants and marked-up version identifying changes to the original informed consent form.
5. **Protocol/Study Design** *[See email with originally approved protocol attached.]*

If there are no changes in the design or protocol, please state below. If there are any modifications to the design or protocol, provide revised protocol with changes indicated by different font color. Click or tap here to enter text.

1. **Informed Consent** *[See email with originally approved informed consent attached.]*

If there are no changes to the informed consent form, please state below. If the informed consent forms needs to be revised, attach modified version for CPHS review and approval and marked-up version of original informed consent form. [See item (h) above]. Click or tap here to enter text.

1. **Instruments** *[See email with originally approved instruments attached.]*

Provide any new instruments or changes to originally approved instrument for IRB review and approval.

If there are no changes, please state below. Click or tap here to enter text.