 **Research Integrity**

Alumni Memorial Building

27 Memorial Drive West

Bethlehem, PA 18015

(610) 758-2871

*http://www.lehigh.edu/irb*

**Amendment/Modification Form**

**Adding Remote Study Procedures**

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| **Study Title:** |
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| IRBNet ID: |

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| **Research Personnel:** | | |
| **P.I.’s Name:** |  |

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| **Date of Request:** |
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| **Information about Remote Procedures**  Please provide the following information regarding the changes being made to add remote study procedures. Please **do not include** other changes to your study beyond those necessary to conduct your study remotely. | | |
| **Provide a detailed description of the changes being requested:** | | |
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| **How will these changes affect the overall risk/benefit ratio of your study, as well as the willingness of individuals to participate?** | | |
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| **How many more subjects do you intend to enroll/invite to participate in your study after the proposed modification is approved?** | | |
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| **Remote Procedures Being Added**  All new and revised study materials (e.g. consent language, forms, questionnaires, instruments) should be included in your IRBNet package). |
| **Telephone** |
| **Videoconferencing (e.g. Zoom, Skype)** |
| **Online Survey (e.g. Qualtrics, SurveyMonkey)** |
| **Email** |
| **Other (describe):** |

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| **Request for Waivers / Alteration to Informed Consent**  Non-exempt research is required to document the informed consent of research participants, except in situations where a waiver / alteration has been approved. Please use the following to request a waiver. |

**Requesting a waiver of documentation of informed consent because all of the following are true:**

* The research is not FDA-regulated.
* The only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject or legally authorized representative will be asked whether the subject wants documentation linking the subject with the research, and the subjects wishes will govern.
* The IRB may require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research.

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| **Protection of Participants’ Privacy / Confidentiality** | | |
| **Will the described modifications make it necessary to collect information from participants that could allow them to be identified?**  **No**  **Yes**  **If yes, please describe what identifying information will be collected, and why it is necessary to collect this information:** | | |
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| **Describe the precautions in place to ensure the privacy and confidentiality or anonymity of the participants and/or their data. Specifically, describe if/how data will be de-identified. If participants will be assigned ID numbers, describe how ID numbers will be generated. If a key linking participants’ ID numbers and identities will be maintained, describe how the key will be protected and how long it will be maintained.** | | |
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**Describe the specific procedures in place to safeguard the data in the researchers’ possession:**

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