 **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**

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

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

|  |
| --- |
| **Date of Request:** |
|       |

|  |
| --- |
| **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:**  |
|       |
| **How will these changes affect the overall risk/benefit ratio of your study, as well as the willingness of individuals to participate?** |
|       |
| **How many more subjects do you intend to enroll/invite to participate in your study after the proposed modification is approved?** |
|       |

 **Will participants be located in the United States at the time they participate in the study?**

Participants who are located outside of the US at the time of participation may be subject to other

 countries’ data protection laws (e.g. GDPR), even if they are US citizens.

 **[ ]  No** **[ ]  Yes**

 If **Yes**, please state that participants must be located within the US at the time they complete the

 study in the consent form, as well as in all recruitment materials.

 If **No**, please review the [GDPR Guidance](https://research.cc.lehigh.edu/GDPR-Guidance).

|  |
| --- |
| **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, Hangouts Meet, etc.)***(Note: Zoom may* ***not*** *be used for any study that is subject to HIPAA regulations)* |
| [ ]  **Online Survey (e.g. Qualtrics, SurveyMonkey)** |
| **[ ]  Email** |
| **[ ]  Other (describe):**       |

|  |
| --- |
| **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.

|  |
| --- |
| **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**:** |
|       |

|  |
| --- |
| **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.**  |
|       |

 **Describe the specific procedures in place to safeguard the data in the researchers’ possession:**

|  |
| --- |
|       |

|  |
| --- |
| **If using audio / video conferencing (e.g. Zoom, Skype, Hangouts, etc.):**Review the guidance on using audio/video conferencing for research purposes. **Will either the audio or video of participants be recorded and saved for research purposes?****[ ]  No**  **[ ]  Yes** If **Yes,** please describe the length of time these recordings will be maintained and the specific procedures that will be used to safeguard these recordings. This information must also be disclosed to participants as part of the informed consent process. Additionally, describe the manner in which participants will be provided the opportunity to consent to the creation and use of these recordings prior to participating in the study**:** |
|       |