Informed Consent – Follow Up Related to COVID-19

**[Title of Study]**

As you undoubtedly are aware, the novel coronavirus COVID-19 has had widespread impacts that are also affecting the research project you previously agreed to participate in. The study team has developed this information sheet to explain some of the changes that are taking place due to COVID-19, and see whether you are still willing to participate in this research project. *If using an opt out approach to this update:* If you do not wish to continue participation in light of these changes, please opt out before **XX/XX/XXXX**, using the instructions provided below.

**Procedures**

Originally, researchers had planned to [give a brief review of the procedures from the original informed consent document that are no longer permitted or are being substituted]. Now, researchers will [describe new study procedures in place to manage the restrictions related to COVID-19 or any other changes you are making in light of the virus].

**Alternative Procedures**

Rather than participate in this research with these changes, you might prefer alternatives such as [list any appropriate alternatives here; if not applicable you can delete this section].

**Risks**

[[This remains a minimal risk research study. That means that the risks of participating are no more likely or serious than those you encounter in everyday activities. **OR** This study is still greater than minimal risk, meaning that the risks are [slightly/significantly] higher than those you encounter in everyday activities. **OR** With the changes described above, this study is now greater than minimal risk instead of minimal risk.]] [[The risks or discomforts have not changed, and include [list all foreseeable risks here, and ensure it is consistent with the prompt in your protocol, recalling that loss of confidentiality is nearly always a risk in research studies]. **OR** In addition to the previous risks and discomforts we made you aware of (summarize previous risks), some new risks or discomforts might occur, including [list new risks as a result of changed procedures].]] In order to minimize those risks and discomforts, the researchers will [list what the research team is doing to minimize those risks, and ensure it is consistent with the prompt in your protocol]. If you have a bad research-related experience, you can still contact [contact PERSON] using the contact information below.

**Benefits**

The benefits to this study have not changed. **OR** These new procedures will generate new benefits associated with this study. Namely, [discuss new/existing unchanged benefits].

**Confidentiality**

We will collect your information through [video recordings, audio recordings, interviews, Qualtrics, email… whatever mechanism(s) you are using to collect it, including indirect ones like seeking the information from a third party]. *If you will collect or store data online,* Online activities always carry a risk of a data breach, but we will use systems and processes that minimize breach opportunities. Your privacy, however, may be impacted by participating at home where others (family members, roommates, or others) might be present. If there are accommodations you need to assure your privacy, please contact the researcher using the information provided below to discuss.

*If study timelines have changed*: Originally, we anticipated this study being complete and your [identifying] data/information being destroyed by [month, year]. These changes have required that we [extend/abbreviate] the timeline for this study. *Describe any changes that need to be disclosed based on your original informed consent process and documentation.*

**Voluntary Participation & Withdrawal**

Your participation in this research is always completely voluntary, and if the new information we have provided here changes your mind, please [put instruction here for timely and orderly withdrawal – if an active opt out, tell them how and by when; if they need to simply sign and return the form, just say “do not return this form and we will consider you to have withdrawn”]. If you agree to participate now and change your mind later, you may withdraw at any time by [please provide instructions on how a participant should withdraw once they have initiated research participation]. If you choose to withdraw [after/since] we have already collected information about you, [state what you will do with that information, or the extent to which withdrawal is possible (e.g. completely anonymous participation cannot be withdrawn, as you will be unable to determine whose data is whose)]. Please know that if you withdraw from the study, [describe what, if anything, will happen or stop happening; if nothing, you can delete this sentence]. *If participant is already or may in the future receive services from your clinic/department/unit*, If you decide not to participate, the services you receive from [researcher clinic/department/unit] will not be affected in any way. The researchers may choose to terminate your participation in this research study if [state any circumstances that would lead to termination of a participant’s continued participation. Also state whether and how they will be notified if this happens].

**Compensation [& Costs]**

*Use this section to discuss any changes to the compensation arrangement as a result of the overall changes to your research; remind participants what the original compensation agreement was if there was one.*

*If it is possible for a participant to earn $100 or more in one year from your study* Because this study pays $[amount] for full participation, please know that if you receive more than $600 in payments from Utah State University in a calendar year (January through December), USU is required to report the payments to the Internal Revenue Service (IRS) and a W-9 will be required. *If your study pays $600 or more in one year, use this instead:* Because this study pays $XXX for full participation within one calendar year, the researchers will be required to collect a W-9 for Internal Revenue Service reporting purposes. A W-9 requires that you provide your name, social security number, and address.

Your participation may require that you incur additional costs, including [include any additional costs here, such as new devices that might be necessary in light of the changes, any procedures that may not be covered by health insurance, etc. If none, delete this whole sentence and “& Costs” above].

*Please replace this line with an electronic signature, if you would like. We will give you a final, approved pdf and you are also welcome to apply your signature at that time rather than now.*

[Principal Investigator Name]

Principal Investigator

(435) 797-\_\_\_\_; email@usu.edu

*Please replace this line with an electronic signature*

[Co-Investigator or Student Researcher Name]

Co-Investigator OR Student Investigator

(XXX) XXX-XXXX; email@usu.edu

**Informed Consent [Or delete if using as a Letter of Information]**

By signing below, you agree to participate in this study. You indicate that you understand the risks and benefits of participation, and that you know what you will be asked to do. You also agree that you have asked any questions you might have, and are clear on how to stop your participation in the study if you choose to do so. Please be sure to retain a copy of this form for your records.

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Participant’s Signature Participant’s Name, Printed Date