

***INSTRUCTIONS: Delete this section before finalizing your consent form to submit with your IRB protocol application. The language should be modified as appropriate for your study. Provide relevant information in the sections below, replacing italicized directions/guidance (anything in this font color) with information specific to your study, and deleting sections that do not apply to your research.***

*I am/we are asking you to participate in a research study titled "TITLE". I/We will describe this study to you and answer any of your questions. This study is being led by Name of PI, Department at Cornell University. (If the PI is a student) The Faculty Advisor for this study is Name, Department at Cornell University. (If externally funded) This study is being funded by a grant/contract/gift from Name of Sponsor/Funder.*

### **What the study is about**

The purpose of this research is to....

*Provide a clear, concise explanation in lay language of the purposes of the research, including prominent use of the term "research." (Note: the IRB can waive this element if the study requires deception. In such cases, a debriefing statement should also be used to inform participants at an appropriate time after their involvement in the study.)*

### **What we will ask you to do**

*I/We will ask you to...*

*Explain in simple, non-scientific language what will happen to the participant or what s/he will be asked to do in the study. Describe the participant time commitment for each component, as well as the total time for participation. All procedures listed in the IRB application and funding proposal should be described, and any experimental procedures (interventions, manipulations, treatments) specifically noted.*

### **Risks and discomforts**

*In simple, non-scientific language, describe any reasonably foreseeable risks or discomforts:*

- Legal risks (e.g., possibility of discovering activities that may require reporting to authorities, possibility of being arrested)*
- Physical risks (e.g., nausea, muscle aches, rashes, infection, discomfort)*
- Social or economic risks (e.g., loss of confidentiality; effect on financial standing, employability, or insurability)*
- Emotional risks (e.g., feelings of sadness or anxiety)*

***If there are no known risks, state: I/We do not anticipate any risks from participating in this research.***

### **Benefits**

*Describe any probable benefits of participation. Be sure to distinguish between a likely direct benefit (e.g., from therapeutic or intervention research) and a possible indirect benefit (e.g., reflecting on an experience may lead to a better understanding of oneself). **If there are no direct benefits, indicate that there are none.***

***Describe the expected benefits to society or scientific knowledge: e.g., "...information from this study may benefit other people now or in the future..." or "...we hope to learn more about \_\_\_\_\_ ..."***

*Note: Compensation, financial incentives, learning about how experiments are conducted, receiving a gift, or earning extra credit for being a research participant are not "benefits" and should not be listed here.*

## Incentives for participation

*(Note: when deciding if and how to compensate research participants, please review the [Cornell Buying Manual Section 630: Human Research Participant Payments](#).)*

*Indicate whether the participant will receive incentives/compensation or extra credit for being in the study. If participants will not receive any incentives, state this. If students will receive course credit for participation, ways of earning equivalent credit without participating in the research should be described here.*

*If identifiable information will be shared with Cornell business service centers, Procurement, etc., to process payments, include the following:*

Your name and contact information may need to be shared with Cornell University finance staff to process your payment, but they will not receive any research data or other details about the study.

*If participants will be paid \$100-599:*

Payment for participation in research may be considered taxable income. The University requires tracking for compensation that is paid to you; this may include your name and contact information. If you receive \$600 or more in a calendar year, you may be contacted to provide additional information (e.g., Social Security Number) for tax reporting purposes. This information is stored confidentially and separate from research data.

*If participants will be paid \$600 or more:*

Payment for participation in research may be considered taxable income. The University requires tracking for compensation that is paid to you; this may include your name and contact information. Because you will receive \$600 or more in a calendar year, you will be asked to provide additional information (e.g., Social Security Number) for tax reporting purposes. This information is stored confidentially and separate from research data.

## Audio/Video Recording

*If audio and/or video recording devices will be used, explain why these are needed and what will be done with them upon completion of the research (kept indefinitely, archived after transcription, destroyed after X years).*

*ONLY IF USING A SIGNED CONSENT, provide a separate signature line for the participant to be audio/video recorded, if the recording is optional for participation. For example:*

Please sign below if you are willing to have this interview recorded (*specify audio or video*). You may still participate in this study if you are not willing to have the interview recorded.

I do not want to have this interview recorded.

I am willing to have this interview recorded:

Signed: \_\_\_\_\_

Date: \_\_\_\_\_

*If you will take photographs or make audio, video, or other recordings that you want to use for activities beyond research analysis (publications, presentations, other promotional purposes), include a section that:*

- Informs the participant that you are making a [type(s) of media used] recording in which the person's name, likeness, image, and/or voice will be included;*

- *Asks the participant to grant you the right to make, use and publish recordings in whole or in part in media forms now known (such as film, slides, and digital audio) or developed in the future. This includes the right to edit or duplicate any images/recordings;*
- *Explains the limitations on reproduction, distribution, performance, or display of images/recordings;*
- *Explains that the participant does not have rights to inspect or approve the finished product or printed/published matter that uses the images/recordings or versions of the images/recordings; and*
- *Explains that the participant will not receive any financial compensation for commercial and/or non-commercial (as appropriate) uses of the images/recordings.*

*The same signature line above may be used for this performance release information.*

### **Privacy/Confidentiality/Data Security**

*Explain briefly, and in lay terms, how you will protect the participant's privacy and/or confidentiality.*

- *De-identification of data*
- *If you will completely de-identify data, or keep identifying information separate from research data (e.g. signed consent forms kept separate from the survey data and the two will not be connected)*
- *If you plan to keep identifying information with the data, state this here*
- *If you are not planning to collect any identifying information at all (as in anonymous surveys).*
- *Physical security of data/research files*
- *Who will have access to identifying information*
- *How will sensitive data be kept secure in an electronic environment*

*This next section is required for all federally funded research, and recommended for all other studies:*

We will do our best to keep your participation in this research study confidential to the extent permitted by law; however, it is possible that other people may need to review the research records and may find out about your participation in this study. For example, the following people/groups may check and copy records about this research:

- The Office for Human Research Protections in the U. S. Department of Health and Human Services
- *(For sponsored studies, add:)* The research study sponsor, *Name of Sponsor*
- Cornell University's Institutional Review Board (a committee that reviews and approves research studies) and the Office for Research Integrity and Assurance

*If using Qualtrics for survey collection, include the following statement:*

We anticipate that your participation in this survey presents no greater risk than everyday use of the Internet.

*If using another survey vendor to administer online surveys, include the following statement:*

Please note that the survey(s) [is/are] being conducted with the help of [company name], a company not affiliated with Cornell and with its own privacy and security policies that you can find at its website. We anticipate that your participation in this survey presents no greater risk than everyday use of the Internet.

*When the research involves e-mail communication, include the following statement:*

Please note that email communication is neither private nor secure. Though [I am/we are] taking precautions to protect your privacy, you should be aware that information sent through e-mail could be read by a third party.

*For sensitive research data with identifiers, stored in the cloud or on servers, or transmitted via the internet, consider including the following statement:*

Data may exist on backups and server logs beyond the timeframe of this research project.

**OR**

Your confidentiality will be kept to the degree permitted by the technology being used. We cannot guarantee against interception of data sent via the internet by third parties.

### **Sharing De-identified Data Collected in this Research**

*(If you may share data without identifiers: We strongly recommend that you include this section in your consent, to inform participants that you may share de-identified data you collect from them. Certain sponsors now require researchers to make available their de-identified data to the research community, as do a growing number of journals. If you choose not to include the following language and later wish to share de-identified data, you may not be able to do so without re-contacting participants to obtain consent.)*

De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

### **Future use of Identifiable Data or Specimens Collected in this Research**

*In addition to the recommended data sharing language, above, if you are collecting identifiable data or identifiable biospecimens, you must include one of the following:*

Identifiers might be removed and the de-identified information or biospecimens used for future research without additional consent.

**OR**

Identifiable information might be used for future research with obtaining your consent.

**OR**

Your information or biospecimens will not be used or distributed for future research studies.

### **Information about use of your biospecimens**

*If you are collecting biospecimens, you must include the following:*

Specimens collected from you for this study and/or information derived from your specimens *will/may/will not* be used to generate commercial profit. You will/will not share in any commercial value or other compensation from products developed using these specimens.

*If clinically-relevant research results may be generated, you must include this statement:* You *will/will not* receive any clinically relevant results discovered about you and/or the general subject population.

*If your study may involve whole genome sequencing, include this statement:* This research *may/will* include whole genome sequencing.

### **Certificate of Confidentiality**

*If this project is covered by an NIH Certificate of Confidentiality (CoC), you must inform participants. Review details [here](#). If applicable, use this text:*

To help us protect your privacy, this study is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). With this Certificate, we cannot be forced (for example by court order or subpoena) to disclose information that may identify you in any federal, state, local, civil, criminal, legislative,

administrative, or other proceedings. In general, we cannot disclose information that may identify you to any other person who is not connected with this research, unless you give consent for that information to be disclosed. *[If applicable:]* The researchers will use the Certificate to resist any demands for information that would identify you, except to prevent serious harm to you or others. *[If applicable:]* A Certificate of Confidentiality does not prevent the researcher from voluntarily disclosing information about you, without your consent in incidents such as child abuse, and intent to harm yourself or others. You should understand that a Certificate of Confidentiality does not prevent you, or a member of your family, from voluntarily releasing information about yourself or your involvement in this study.

### **Clinical Trial**

*If the IRB informs you that the study is a “clinical trial,” you should include language such as the following, identifying the study as a clinical trial and stating that the study will be listed on ClinicalTrials.gov. For NIH-funded trials this is required; for all others this is strongly suggested:* This study is classified as a clinical trial and will be registered online at <http://www.ClinicalTrials.gov>. The website will not include any information that can identify you, but will include a summary of results once the research is completed. You can search this publicly available website at any time.

### **Taking part is voluntary**

*Explain that the participant's involvement is voluntary, the participant may refuse to participate before the study begins, discontinue at any time, or skip any questions/procedures that may make him/her feel uncomfortable, with no penalty to him/her, and no effect on the compensation earned before withdrawing, or their academic standing, record, or relationship with the university or other organization or service that may be involved with the research.*

*If completing all research materials (e.g., answering all survey or interview questions; meeting a minimal requirement of entries in a weekly/monthly log) is required for participation, you must make this condition clear to them here. State that people can choose not to participate if they are uncomfortable with these conditions.*

### **Follow up studies** *(Include this section if you will or might approach participants for a follow up study)*

We may contact you again to request your participation in a follow up study. As always, your participation will be voluntary and we will ask for your explicit consent to participate in any of the follow up studies.

*Explicit consent may not be necessary. Here is suggested language if you choose to ask for specific consent:*

May we contact you again to request your participation in a follow up study? Yes/No

### **If you have questions**

*Explain how the participant can contact you with questions or concerns. A standard statement follows:*

The main researcher conducting this study is *[principal investigator's name]*, a *[professor, graduate/undergraduate student, etc.]* at Cornell University. Please ask any questions you have now. If you have questions later, you may contact *[principal investigator's name]* at *[email address]* or at *[phone number]*. If you have any questions or concerns regarding your rights as a subject in this study, you may contact the Institutional Review Board (IRB) for Human Participants at 607-255-6182 or access their website at <https://researchservices.cornell.edu/offices/IRB>. You may also report your concerns or complaints anonymously through Ethicspoint online at [www.hotline.cornell.edu](http://www.hotline.cornell.edu) or by calling toll free at 1-866-293-3077. Ethicspoint is an independent organization that serves as a liaison between the University and the person bringing the complaint so that anonymity can be ensured.

*If participants will be given a copy of this form, or some other information sheet, indicate that here.*

**Statement of Consent** *(Include next segment only if you are using signed, written consent. **Signed consent may not be necessary for certain minimal risk social and behavioral research**, and you can instead request a waiver of documentation of consent. Furthermore, signed consent cannot be used if you tell participants that your study is anonymous. For online studies, asking participants to click on an “I approve” box is usually sufficient).*

I have read the above information, and have received answers to any questions I asked. I consent to take part in the study.

Your Signature \_\_\_\_\_ Date \_\_\_\_\_

Your Name (printed) \_\_\_\_\_

Signature of person obtaining consent \_\_\_\_\_ Date \_\_\_\_\_

Printed name of person obtaining consent \_\_\_\_\_

This consent form will be kept by the researcher for five years beyond the end of the study.