**Supplemental Consent Template Language**

**Focus Groups:**

“Although we ask everyone in the group to respect the privacy and confidentiality of participants, and to keep the discussion in the group confidential, we cannot guarantee this. Please keep this in mind when choosing what to share in the group setting.”

**Internet/Email Data Collection**

“We will work to make sure that no one sees your survey responses without approval. However, because we are using the internet, there is a chance that someone could intercept or access your online responses without permission. In some cases, this information could be used to identify you. [if encrypted] Your data will be encrypted (converted into a code) to reduce the risk that other people can view the responses.”

**Mandated Reporter Language (related to child abuse or neglect):**

In studies in which researchers will be probing for or are likely to elicit information about child abuse or neglect, the following statement (or a variation of it) should be included:

"If we learn about current or ongoing child abuse or neglect, we will report this to the appropriate authorities."

**Raffles/Lotteries**

If you will offer a raffle or drawing as an incentive, please include the following in the consent form:

* A complete description of the number and types of prizes and their values
* Specific information on when the winners will be chosen and how they will be notified
* A statement that winners are responsible for all taxes

Also, please note that no single prizes valued over $600 should be offered without consulting university legal.

**University of Chicago student:**

“You may choose not to participate or to stop your participation in this research at any time. This will not affect your class standing or grades at University of Chicago.”

**University of Chicago employee:**

“Your participation in this research is in no way a part of your university duties, and your refusal to participate will not in any way affect your employment with the university, or the benefits, privileges, or opportunities associated with your employment at University of Chicago.”

**Certificate of Confidentiality (CoC language)** [Remove references to biospecimens if not applicable]

“This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

Exceptions to data confidentiality:

The researchers will voluntarily disclose information to the appropriate authorities about evidence of child abuse, and intent to hurt yourself or others. In addition, 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 research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. Finally, the Certificate may not be used to withhold information from the Federal government needed for auditing or evaluating Federally funded Projects or information needed by the FDA.”

**For studies required to post on Clinical Trials.gov**

“A description of this clinical trial will be available on [http://www.ClinicalTrials.gov](http://www.clinicaltrials.gov/), as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.”

**Example Other Optional Elements (to be offered with Yes/No or Agree/Disagree boxes:**

“The researchers may retain your contact information in order to contact you in the future to see whether you are interested in participating in other research studies.”

“The researchers may use your direct quotes in publications and presentations related to this research. Please note that if direct quotes are used, a pseudonym (fake name) will be used and direct identifiers will not be linked to your quotations.”

“The researchers may use your real name and direct quotes in publications and presentations related to this research.”

“The researchers may use your real name in publications and presentations related to this research.”

“The *[photographs, video recordings, audio recordings, etc.]* collected as part of this research can be included in publications and presentations about this research study that may be seen by other researchers and the general public.”

“Identifiable *[photographs, video recordings, audio recordings, data, etc.]*collected as part of this research can be stored indefinitely in an archive that will be available to other researchers for use in future research studies without your additional informed consent. Please note that if you decide to withdraw from the study as outlined in this document and materials or data have already been submitted to an archive and/or distributed to other researchers, it is possible that your data will not be able to be removed. When possible, however, your data will be withdrawn upon your decision to leave the study.”

“De-identified *[photographs, video recordings, audio recordings, data, etc.]*collected as part of this research can be stored indefinitely in an archive that will be available to other researchers for use in future research studies without your additional informed consent. Please note that if you decide to withdraw from the study as outlined in this document and de-identified materials or data have already been submitted to an archive and/or distributed to other researchers, it is possible that your data will not be able to be removed. When possible, however, your data will be withdrawn upon your decision to leave the study.”

“The researchers may retain any leftover *[blood, tissue, etc.]* samples taken during the study and use them for other research not related to this study without your additional informed consent. If you agree to participate, the university may sell or share your samples and information with others, such as private companies, government agencies, or other universities. Your samples and personal information may be used to make new products or technologies. You will not be paid if these new products or technologies are sold or make money.”

 **GINA:**

“The Genetic Information Nondiscrimination Act (GINA) is a federal law that may help protect you from health insurance or employment discrimination based on genetic information. GINA is a federal law that will protect you in the following ways:

* Health insurance companies and group plans may not request genetic information from this research;
* Health insurance companies and group plans may not use your genetic information when making decisions regarding your eligibility or premiums;
* Employers with 15 or more employees may not use your genetic information when making a decision to hire, promote, or fire you or when setting the terms of your employment.

GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed genetic condition or disease.”

**NIH dbGaP:**

“If you agree to take part in this study, your genetic and health information (if applicable, add “a portion of your specimen”) will be placed into one or more scientific databases. In particular, the National Institutes of Health maintains a database called “dbGaP.” A researcher who wants to study information from dbGaP must work with the group overseeing the database to obtain the information, and security measures are in place to protect these data. Researchers with an approved study will be able to see and use some of your information, but your name and other information that could directly identify you (such as your name or address) will not be placed into the database. There is a risk that someone could use your unique genetic information to trace data back to you or your family, but this risk is very small.

If you decide to withdraw from the study as outlined in this form, your data will be withdrawn from these databases if possible. Please note that if your data have already been submitted to an NIH database and distributed to other researchers, or if your data have been de-identified and can no longer be linked back to you, your data will not be able to be withdrawn.”