Consent Form Template for Minimal Risk Research
Instructions for Use

This template was developed as a tool to facilitate the development of consent forms that include elements required by federal regulation. It is a guide but the language that is provided can and should be customized to apply to your study. You are not required to use this template or consent format, however readability and health literacy factors have been considered and incorporated into this template.

You may use this template consent form if your research protocol:

1. presents no more than *minimal risk* of harm to the research participants; and
2. the research involves only procedures included in categories 1 through 7 on the Expedited Review Categories list of research that may be reviewed through an expedited review procedure.

* Minimal Risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. [45 CFR 46.102]

Please consult the following documents available on the CUMC IRB website for additional sample language that may be relevant to your research study:
1. Consent Form Builder Sample Language
2. Consent form Addendum for the Audio/Video/Photographic Recording of Human Subjects
3. Genetics Research - Sample Text for Consent Form

The RASCAL Consent Form module also provides Helpful Consent Form Information.

HIPAA Authorization language is not included in this template. If your study will create or use Protected Health Information (PHI), you will need to create a HIPAA authorization form via the RASCAL HIPAA module.

This consent template was produced by Elaine Larson, Ph.D., Dodi Meyers, M.D., Elizabeth Cohn, DNSc., through efforts of a grant together with support from Laurence Butaud-Rebbaa in the Columbia IRB. The template was reviewed and accepted by the Columbia IRB.