Elements of Informed Consent

Every human subject research study, even one that is exempt, needs an informed consent document that enables subjects to understand the research, what is expected of them, and the potential risk of harm and benefits of the study. The document should use language understandable by the subjects of the study (e.g., avoid scientific and technical terms) and include the following elements.

1. Introduction (with a statement that this is research).
2. Purpose of study.

IF DECEPTION IS USED, include a statement that the research cannot be fully described at this time, but at the conclusion of participation, an explanation will be provided.

3. Description of study procedures, including these features:
   - Duration of subject involvement (e.g., 10 minutes, 2 hours).
   - Identification of potential risks or discomforts to the subjects who will participate in the study.
   - Identification of any procedures that are experimental.
   - Confidentiality of records statement—how this will be accomplished.
   - If on-line workers (e.g., MTurk) are subjects of a survey, the consent document must indicate that (a) the data collected can be linked to a user's public profile (e.g., www.mturk.com/mturk/contact), (b) the worker ID will not be shared with anyone or associated with any survey responses. If relevant, it should be noted that on-line worker IDs are used to disburse compensation for participation.
   - The informed consent document should indicate whether a debriefing will occur after the subject's participation ends and that appropriate resources for assistance will be identified for participants.
4. Statement of voluntary participation, including the option for subjects to withdraw from the study at any time without penalty.
   - If a study subject is a **minor**, then the consent form must indicate the means by which the assent of the minor will be obtained and indicate that the minor may withdraw his/her assent at any time without penalty.
   - If there is payment involved, include the details (amount/type/form that payment will take).
5. A clear statement of consent to participate in the study.
   - If the subject is willing to participate or if the subject's parent/guardian/legal representative is willing to allow participation, provide two copies of the signed Consent Form; one for the subject or the subject's parent/guardian/legal representative and one to be retained by the PI. If the subject or legal representative is unable to read and understand the written consent form**,** it must be verbally presented in an understandable manner.
   - If your data will be anonymous (i.e., not linking individual names with data nor recording any names of research subjects and/or information that can be identified to a particular research subject), you may request a waiver of written informed consent. Please attach a separate sheet indicating this request.
6. The investigator's name and contact information.

Please include the following text in your informed consent document:

"This project has been reviewed and approved by the Franklin & Marshall College Institutional Review Board. Questions concerning your rights as a participant in this research may also be addressed to Annalisa Crannell, Ph.D., Office of the Provost, 113, Old Main, acrannel@fandm.edu, (717) 358-3985."