

Note: 8 Basic elements of consent required by the regulations (see guidance doc)

The consent form is the IRB application text in brief: go into greater detail on the research description for the IRB including how the form will be presented to the subject.

Research Consent Form

Introduce yourself/research team/faculty advisor and your connection to Miami. Briefly describe the reason for conducting the research, e.g. We are conducting this survey to help understand... whatever it is you are studying. Use the title if that is explanatory. Mention that participation is voluntary.

Introduce yourself /project
Potential Benefits?

Briefly describe the activities of subjects., e.g. a 20 minute survey, a 1 hour interview, running on a treadmill. Describe the type of data that will be collected (notes, audio recordings, video recordings etc).

Describe activities

Describe the degree of confidentiality that is inherent to the research design and how that will be accomplished. For example, names or other identifying information will not be noted in the data. Or, the researcher will have a list linking the data to identity using a code number, but that list will only be available to the researcher and stored separately from the data.

Describe confidentiality, discuss risk and use of the data

Discuss risk and how that risk will be minimized. For example: *"The research involves an online survey, The survey software will be communicating with your computer and recording data that could identify the computer through the IP address. However, the IP address will not be reported to the researcher."* Include an estimate of the number of subjects.

Describe to the subjects how the data will be presented publicly, e.g. *"Although identifying information will be collected, the data will be analyzed for all subjects and presented in aggregate summary form. Data will not be presented in a way that the individuals could be identified. Quotations will only be used with your permission."*

Describe that the subjects can withdraw from the research and how they would do so. If there is a distinction between participation for non-research purposes (e.g, school lunch program) and research activities (an evaluation of the program), emphasize that participation in the program would not be effected by a decision not to consent to research participation.

Describe voluntariness

Provide contact information and phrase it like this: *For questions about the research, please contact me (email address and phone number) or my faculty advisor (email address). For questions or concerns about the rights of research subjects or the voluntariness of this consent procedure, please contact the Research Compliance Office at Miami: (513) 529-3600 or humansubjects@miamioh.edu.*

Provide contact information

Assurance/consent section:

If you agree to participate in this research/allow collection information from or about your child for this research project : add Title, Please sign below, detach the signature section and return to us. Please keep the information above for future reference.

Subject Name (Printed)

Subject/Legal Guardian Signature

Date

Sometimes include check/initial boxes for agreeing to specific procedures, e.g:

- ☐ I agree to allow the interview to be video taped and that the images are collected only for accurate note-taking and will never be used publicly unless I give explicit permission.

If there is deception - include a debriefing process

Note: this is not a contract so do not imply a commitment by the subject, also, please do not use the word "understand" or imply by signing that the subject/guardian understands the project.

Presentation “take-home” Messages:

- Keep the application and consent form concise but complete
 - Describe your procedures, do not just make promises (e.g. Not: “I promise to protect your identity”, rather, “The survey will not ask for your identity and if you inadvertently provide identifying information, we will omit that information. from the records”
 - You are not studying the average subject, there are all sort of people with all sorts of vulnerabilities
 - You are not your subject, do not assume since the answers to your Q would not harm you that they would not harm others.
 - Put yourself in the place of the subject... would you volunteer given the information you provide?
 - Get permission from the property owner/manager to conduct the research on their property (including MU campus: Q3b)
 - Use non-technical language, understanding is needed for subject consent and for the IRB to review and approve
 - Use your Miami email address (with the new domain) for correspondence and with subjects and IRB
 - Distinguish between the normal activities of the subjects and research activities
 - Read the guidance document as you complete applications
-

For the research description in the application, describe in some detail how you are going to accomplish what has been agreed to in the consent form. Consult the guidance document provided with the application. In addition, consider this:

Q1: Risk/cost should be outweighed by benefit. Describe benefits to society.

Q2: Describe the people from whom data is to be collected. Consider and identify the vulnerabilities of these people . About how many subjects will there be? What population is to be described? The IRB uses this information for risk assessment

Q3A: How will you contact the subjects? Will they feel pressured to agree (friends family, student, employee)

Q3B: Describe where you will conduct the research, this relates to risk as well as feasibility.

Q3C: How will consent/assent be presented? Will they feel like they can say no?

Q3D: Plan your research. Refer to forms, survey instruments, interview questions. The IRB uses this to evaluate study feasibility (if the research cannot practically be completed, the notion of benefit is questionable), and risk (i.e., what information you are collecting).

Q3E: Confidentiality: Given your methods, what do you need to do to accomplish the confidentiality promised by your consent form? Computer security? Could you collect the information relatively anonymously? Given the demographic information you collect, what population could the subject have been drawn from. For example, this person could be any one of 16000 Miami undergrads vs. this person could be any one of the 15 or so Miami grad that self-identify as Miami tribe members.

Q4: Describe the risks and methods to deal with issues that might arise. For example, “these interview questions might upset the subject or reveal that they have a problem that should be addressed. I will provide contact information for local resources (counseling). For social workers/teachers: e.g. “This information will be kept as confidential as the law allows. If someone is at risk of harm, as a teacher I am required by law to report this information to an appropriate authority.”

Appendices to the application include anything the subjects see and other documents supporting your research.