Informed consent is more than just a signature on a form. It is a process of information exchange between the investigator and their potential participants. Consent continues until the research is complete, and sometimes beyond that when the researcher wants to re-use or share data.

This document presents guidance for informed consent. Most requirements are from the federal regulations known as the revised Common Rule.

**General Principles**

1. Check out the SUU IRB example consent forms.
2. Think about how a potential participant would read your consent form. What would you want to know if you were thinking about participating in the study?
3. Keep your language simple. Ideally, an 8th grader could understand your consent form.
   a. You can check the reading level of your consent form in MS Word. To learn how to do so, google “MS Word Flesch-Kincaid instructions”.
4. Pictures, diagrams, and other visual aids are great on consent forms.
5. Appendices are good too.
6. Exclude jargon (technical terms), or even better include them and define them (perhaps in parentheses :-).
7. If you meet your participants face-to-face, talk with them about your study. Do your best to answer any of their questions.
8. No exculpatory language is allowed. That is, you cannot say (a) participants are giving up any rights, or (b) the researcher, sponsor, institution, school, or its agents are not responsible or liable for any bad effects of their research.
9. As a general rule, you should assume that all adults and children 7 and older are able to provide documented (signed) consent.
   a. Note that even younger children provide consent. For example, after you provide a simple description of what they will do, a child can agree to do it. Then, if the child seems like they want to stop, they no longer consent. You must stop their participation right away. If a baby starts crying, they are done with the study.
10. Carefully re-read your consent form to make sure it is consistent, accurate, and as short and simple as possible.
11. The principal investigator(s) is responsible even when they have other people obtain informed consent. If the principal investigator(s) are graduate or undergraduate students, then their faculty supervisor(s) is responsible.
12. If your research has special considerations, you can request waivers that allow exceptions to the general rules that IRBs apply, including for consent. To request a waiver, tell the IRB what you want to do and justify your request with strong reasons and/or evidence.
Required Sections for All Consent Forms (without IRB-approved waivers)

1. **Key Information**: This is a concise and focused summary of the most useful information about your research project. Include information that is likely to help people understand if they want to participate in your study. Make this information easy to understand.
   a. It should be near the start of your consent form.
   b. This short paragraph should summarize these ideas:
      i. It is a research study.
      ii. Why the research is valuable. That is, why you are doing it.
      iii. What participants will do.
      iv. Expected risks, costs, benefits, and/or compensation for participants.
      v. How long the study will take participants.
      vi. Participation is voluntary.
   c. You do not need to repeat the same information later.
      i. A very short consent form can be made up of the key information only. If more details are not needed later, you can exclude those sections.
      ii. However, if you need to provide more details on a topic, include additional sections, such as those that follow. Note that all of the following topics need to be addressed on your consent form in the Key Information and/or their own sections.

2. **Procedures**: Describe in greater detail what the participant will do.

3. **Risks**: Explain in greater detail any foreseeable risks, costs, or discomforts to the subject.

4. **Benefits**: Describe in greater detail any benefits to participants or to other people that are expected from the research. This includes gains in scientific knowledge and/or improvements in professional practices.

5. **Confidentiality**: Explain for both (a) participant identity, and (b) participant data whether they are (a) confidential or (b) anonymous. Explain your plan for keeping the information confidential or anonymous.
   a. *Anonymous* means the researchers don’t know.
   b. *Confidential* means the researchers know but will keep the information secret.
   c. *Participant identity (or participation)* refers to knowing who your participants are.
   d. *Participant data* refers to the data you collect about participants
   e. For example, “anonymous participation” means you don’t know the identity of your participants.
   f. “Confidential data” would mean you know which participant answered each question, but you will keep that information secret.
   g. Include one of the following two options, as appropriate, IF you collect data/biospecimens for which you can tell whose data/biospecimens is whose. The IRB advises you to choose the first option if you are unsure. Alternatively, you can seek consent for re-using or sharing such data. In that case, see the section below titled, “What if I am using data, I can tell whose data is whose, and I might re-use the data later?”
      i. For later research, we may re-analyze your data or share it with other researchers. If we share it, we will make your data anonymous first.
      ii. We will neither re-analyze your data later nor share it with other researchers.
6. **Contact:** Provide information on whom to contact with questions about the research, such as the PI’s name, affiliation, title, and contact information. Also provide contact information for questions about participant rights, which is the IRB contact information: SUU IRB, irb@suu.edu, 435-586-7964.

7. **Voluntary:** Include a statement that says, “Participation is voluntary. Nothing bad will happen to you if you decide not to do the study. You can change your mind and quit the study at any time.” If relevant to your study, also indicate expected situations in which you might end someone’s participation without their consent, such as if they take too long, show signs of stress, and so on.

8. **Signature:** Provide two lines, each with a label indicating its use. One line is for the participant’s signature, the other is for the participant to put the date (to ensure consent was documented before the study began).

9. **Copy:** Provide a written copy of the consent form to participants for them to keep.

**Required Elements for Some Consent Forms**

Consent has other important aspects. Please read through the following questions. For all that are relevant for your research, you need to read the related section later in this document. Once you have addressed each of them, your consent should be ready for submission with the rest of your IRB application. Before you submit your consent form, carefully re-read it for accuracy and completeness.

- a. **What if I will be doing research with children/minors?** (e.g., under 18 in Utah)
- b. **What if I am doing education research?**
- c. **What if I am using data, I can tell whose data is whose, and I might re-use the data later?**
- d. **What if I am doing consent online (online studies)?**
- e. **What if my study only includes participants with an embarrassing characteristic?**
- f. **What if it is impossible (or unreasonable) to get consent for my study?**
- g. **When can I waive consent (or signatures to indicate consent)?**
- h. **What if I want to screen people to recruit only eligible participants?**
- i. **What if I am doing clinical research?**
- j. **What if my research collects information from participants that they would not want shared with the world?**
- k. **What if I am doing research that is greater than minimal risk?**
- l. **What if I am doing research that involves exercise or other physical activities?**
- m. **What if I am giving food to my participants, or exposing them to drinks, odors, or other chemicals (such as essential oils)?**
- n. **What if my study has an important consideration that is not in this list?**
  
  In that case, please contact the SUU IRB at irb@suu.edu.
a. What if I will be doing research on children/minors (e.g., under 18 in Utah)
   a. Terminology: Adults provide “consent” for themselves. Consent with minors has two facets: Children provide “assent” for themselves; their parents provide “permission.”
   b. The signature of a parent is required to provide permission for children of any age; that is, for any minors.
   c. The SUU policy is that children 7 and older must also sign their name to provide assent.
   d. Children 6 and under must provide verbal consent, if possible.
   e. Assent forms need to use simple words that can be understood by the children.
   f. Permission forms need to address concerns parents might have.
   g. A single form can be used for assent and permission, or separate forms can be used.
   h. Assent/permission forms should have the same information as a consent form.
   i. Include a horizontal line for the following uses (and label them as such), as relevant to your study:
      i. print the child’s name (so it is clear whom the form is about)
      ii. the child’s signature (children 7 years old and older)
      iii. the parent’s signature
      iv. the researcher recording that verbal assent was obtained (children 6 and younger)

b. What if I am doing education research?
   a. For students who are children/minors, the section above also applies.
   b. The SUU policy is that an opt out form is sufficient for research approved under the standard educational exemption, unless (a) FERPA applies, or (b) the research includes audio recording, video recording, or photography. In those cases, “active consent” is required (i.e., signatures of parents/children-participants). Education research approved under any category other than the standard educational exemption requires active consent.
   c. An opt out form should have a location for all relevant parties to sign as an indicator that they opt out.
   d. The opt out form should have the same information as a consent form.
   e. Potential participants (or their parents) can opt out by signature or any other form of communication, such as verbally or over email.
   f. For research involving minors, if either the parent or the child opt out, then you must exclude the child from your study.
   g. Do not describe the potential benefits as if they definitely will happen. Some--or even all--of the participants may not realize the anticipated benefits.
   h. You may say that future students are likely to benefit from what is learned in this study.
   i. Explain on your IRB application how you plan to do establish consent. For example, will you mail a copy of the opt out form directly to parents?
   j. For additional information regarding educational research see the SUU Standard Educational Exemption Guide. (Email irb@suu.edu if you have trouble getting a copy.)

c. What if I am using data, I can tell whose data is whose, and I might re-use the data later?
   a. When you know who provided which data it is called identifiable data.
   b. You cannot re-use identifiable data unless you do one of the following:
i. Get consent before collecting data for future uses of the data, whether you know the future uses advance or not. This is called *broad consent*. This is the preferred solution.
   1. Your consent form should clearly explain in detail how you will store/maintain the data in a secure way that maintains confidentiality.
   2. Your consent form should explain what kinds of research that might be done later with the participants’ data.
   3. Your consent form should explain with whom you might share the data.
   4. Your consent form should explain how long you will keep their data, perhaps even indefinitely, for these potential uses.
ii. If you already collected the data, you can *re-consent* by contacting your participants and getting their permission to re-use the data at a later time.
iii. You can remove all identifiable information.

d. What if I am seeking consent over the internet, such as for an online study?
   a. There is no need for signature.
   b. On your application, you need to justify a waiver of documentation of consent. For example, you could say your study is online and you will not have paper copies for your participants to sign.
   c. At the end of your consent form, say something like, “Click on the continue button if you consent to participate. If not, close this browser window.”
   d. You could provide your email address and/or phone number for questions on your consent form.

e. What if all participants have embarrassing characteristics?
   a. This means, for example, you are doing a study only on people with sexually transmitted infections, who look at pornography, who have a diagnosed mental disorder, or any other socially stigmatized characteristic.
   b. If this applies to your research, disclosure of participant identity could put participants at risk of social embarrassment, affect their jobs, etc.
   c. If disclosure of participant identity could put participants at risk, then your application should explain this and ask for a waiver of documentation of consent. That means you would not require them print or sign their name on the consent form; instead, each participant would choose for themselves if they want to sign the form.
   d. You still need to go through the consent process.
      i. Provide a modified consent form called an *Information Sheet* that does not ask for a signature or name.
      ii. Get verbal consent, if possible.

f. What if I cannot get consent for my study; that is, it is impossible or unreasonable?
   a. Ask for a waiver of consent in your application.
   b. You must provide an explanation (perhaps supported by evidence) of why this is necessary in your application.

g. When can I waive consent, or waive having participants sign the consent form?
   a. The requirement to have participants *sign the consent form* (documentation of consent) can be waived …
o if the signature is the only record linking the subject to the research and the main risk of the study is a breach of confidentiality (in this case, you should ask each participant if they want to sign the form);

o OR if the research is minimal risk with no procedures where written consent is normally required outside a research context (for example, surveys/interviews that are completed online or by telephone);

o OR if participants are from a cultural group in which signing forms is not normal/acceptable practice. Request this waiver in your application and provide evidence and justification in support.

b. Waivers or alterations of informed consent elements can be requested for projects that
   o are minimal risk,
   o AND could not be completed without the waiver/alteration,
   o AND waiver/alteration has no bad effects for participants,
   o AND the research requires data to be identifiable (only for research with identifiable private information),
   o AND participants will be provided additional relevant information after participating, as needed.

c. Request this waiver/alteration request in your application and provide evidence and justification in support.

d. You still need to go through the consent process.

e. Provide a modified consent form called an Information Sheet that does not ask for a signature or name.

f. Get verbal consent, if possible.

h. What if I want to screen participants to recruit only eligible participants?
   a. You can do this if (a) you will obtain screening information through written or oral communication, or (b) you will access identifiable private information or identifiable biospecimens from records or stored identifiable biospecimens.

b. You need to explain your related plan on the IRB application.

i. What if I am doing clinical research?
   a. Clinical research is a study in which people are assigned to one or more interventions, which may include placebo or control, in order to evaluate the effects of the intervention on biomedical or behavioral outcomes related to health.

b. You must identify any procedures that are experimental.

c. You must disclose appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

d. If relevant, you should include a statement that the particular treatment or procedure may involve risks to the subject (embryo or fetus if subject is or may become pregnant) that are currently unforeseeable.
e. If relevant, you should include a statement that significant new findings developed during the course of the research that may relate to the subject’s willingness to continue participation will be provided to the subject.

f. Include a statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects and if so under what conditions.

g. Include a statement about whether or not clinically relevant individual results will be disclosed to the participant.

h. You must post a copy of one IRB-approved informed consent form used to enroll participants on an established, publicly available Federal website. You must post it within this window: (a) after the clinical trial is closed to recruitment, but (b) no later than 60 days after the last study visit by any participant. (Feel free to contact the SUU IRB for help if you need it at irb@suu.edu.)

j. What if my research collects information from participants that they would not want shared with the world?
   a. Collect your data anonymously (so you don’t know whose data is whose), if possible.
   b. If you cannot collect data anonymously, explain in your IRB application why the research could not be carried out using deidentified data.
      i. You must indicate in your application if you are requesting a waiver of documentation or a waiver/alteration of consent elements. You will be required to provide additional information justifying the request.
   c. You at least must keep your data confidential (secret). If you take this approach, explain in the consent form your plan for keeping the participant’s information safe and secure.

k. What if my research is greater than minimal risk?
   a. Explain whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
   b. Indicate whom participants should contact in case of a research-related injury.
   c. Include, as relevant, a statement that the particular treatment or procedure may involve risks to the subject (embryo or fetus if subject is or may become pregnant) that are currently unforeseeable.

l. What if I am doing research that involves exercise?
   a. Include a statement that the particular treatment or procedure may involve risks to the subject (embryo or fetus if subject is or may become pregnant) that are currently unforeseeable.
   b. You are strongly encouraged to include pictures or other graphics of actions/motions that participants will do.

m. What if I am doing research that involves participant consumption of food, liquid, drugs, or chemicals, or exposure to chemicals (such as essential oils)?
   a. Include a statement that the particular treatment or procedure may involve risks to the subject (embryo or fetus if subject is or may become pregnant) that are currently unforeseeable.
If you find you have additional questions that the above document does not address, please email irb@suu.edu, or reach out to the IRB chair Bryan Koenig.