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Background:

Only certain types of minimal risk research qualify for exempt level of review. Researchers can use the Exempt Self-Assessment Tool to preliminarily assess whether their study qualifies for exemption.

In order to ensure ethical conduct of research, exempt research that includes a participant interaction (e.g., interviews, survey completion, etc.) must begin with a consent process. While researchers are encouraged to use the consent template provided on our Applications, Forms, and Guidance webpage, some exempt research may benefit from using an abbreviated consent script/form.

Consent Process:

The process for obtaining informed consent is more than just a form. It is the procedure in which information is provided to participants to ensure they can make an informed decision about participating in the research. Researchers will need to explain the process for obtaining consent in the exempt application and/or research plan. Consent may be obtained in a written, verbal, or remote manner.

When in-person study procedures are completed, it may be appropriate to provide a consent form to the participant to read and then obtain a signature on the consent form after answering any questions. Written signatures are not required for exempt research so in some cases researchers may find it more appropriate to read the script aloud to participants and obtain a verbal consent in which the participant verbally agrees to participant. In other situations where the research may be conducted remotely, researchers may program the consent script into survey software, so the first page of the survey is the consent script with a programmed yes/no question asking the participant if they agree to participate.

Minimum Requirements:

The Requirements for Informed Consent are dictated by the federal regulations and required for non-exempt research. However, consent for exempt research does not need all the elements. At a minimum, the informed consent process for exempt research must include the following information:

- That the activity involves research.
- A description of the procedures.
- That participation is voluntary.
- Name and contact information for the Researcher.

Additional Requirements (when applicable)

There are times when additional consent language is needed. Examples of when additional consent information may be required include but are not limited to the following:

- Information about risks must be included if the research information is recorded in a way that participants can be readily identified (directly or indirectly by combining information or using a key/code) AND any disclosure of the responses outside of the research context would reasonably place the participant at risk of criminal or civil liability or be damaging to the participant, financial standing, employability, educational advancement, or reputation.
    - Sample language: It is possible that someone outside of the study may see your responses. If that were to happen, [explain specific risk]. However, we will take measures to protect your information to minimize the chance this will happen.
- If the research qualifies for exempt category 3 (research involving a benign behavioral intervention) AND the study involves deceiving participants regarding the nature or purposes of the research, the participant must authorize any deception through prospective agreement, such as consent, in which the participant is informed that they will be unaware of or misled regarding the nature or purposes of the research.
    - Sample language: There are aspects of the research that you will be [unaware of OR misled about]. We will explain these aspects after your participation is complete.
- Certificate of Confidentiality (CoC) language is required in the consent form/process for NIH sponsored research that involves collecting identifiable sensitive information. Researchers can also request a CoC for unfunded research or research funded by sources other than the NIH.
    - NIH provides Example Informed Consent Language.
- If you may save contact information and use it to recontact participants, participants/subjects should consent to that re-contact. This may be an optional part of the study.
    - Sample language:
        - We may contact you in the future about [insert reason for planned contact]. OR
        - We would like to contact you in the future about [insert reason for planned contact]. This is optional. You may choose to participate in the study without allowing re-contact. Do you agree that we can keep your contact information and re-contact you in the future?
            - ☐ Yes, you can save my contact details and re-contact me in the future
            - ☐ No, you cannot save my contact details or re-contact me in the future
- Disclosures when direct quotes and/or direct attribution to participants is planned (e.g., by citing their name or other identifying information). This may be an optional part of the study.

- Sample language:
  - We will use [describe identifiable information] in the [describe final product such as published papers, conference presentations, etc.], so it is possible someone may recognize you. OR
  - We would like to cite you by name in the final research in order to give you credit for your contribution. Do you agree that we can cite you by name?
    - ☐ Yes, you can cite me by name in the final publication/report
    - ☐ No, you cannot cite me by name in the final publication/report

- Confirmation of age or other inclusion/exclusion criteria.
  - Sample language:
    - Are you [insert inclusion criteria such as 18 years of age or older]?
      - ☐ Yes
      - ☐ No

      Note: For an online consent process, an answer that excludes someone from participation should take them to a thank you page that also informs them why they are not eligible for the research.
    - Do you agree to participate in this research?
      - ☐ Yes, and I confirm I am [insert inclusion criteria].

- Some research involves additional levels of permission. For example, if audio recording is optional, a consent form may ask if the person agrees to audio recording.
  - Sample language:
    - Do you agree to participate?
      - ☐ Yes
      - ☐ No

      If yes: we would like to [insert optional activity, such as "audio record your responses"]. Is that ok with you?

- Additional consent information is required when recruiting from a UO approved human subjects pool. This language is outlined on the Research Compliance Participant Pools webpage.
- Depending on the payment amount, payment/compensation language may be required by the UO Business Affairs Policy on Payments to Participants.
- RCS staff may request additional language as needed on a case-by-case basis, as there are other situations that may require additional language to be included in the consent process.

Template:

Instructions:

See exempt consent template below. Researchers should be careful when using the template to ensure the wording is revised as needed to ensure the information is accurate and appropriate for their research as well as their consent process. For example, if you will be obtaining signed consent, you will need to include a signature line. If any of the additional information applies as noted above, that information should be incorporated into the template.

In some cases, it may be appropriate to replace the "Do you agree to participate?" text with "The completion of this [insert research activity such as survey] indicates your consent to participate." It is particularly important to avoid a yes/no checkbox and/or signature option on paper-based surveys in which participants may return the survey but overlook the instruction to mark their consent.

Basic Exempt Consent Script Template:

You are invited to participate in a research study. If you decide to participate in this study, you will be asked to [insert description of study procedures]. Participation is expected to last [insert duration of study procedures]. Your participation in this study is completely voluntary. You can choose not to participate. Even if you decide to join now, you can change your mind later. If you have any questions about the study, you can contact [insert researcher name and contact information].

Do you agree to participate?

- ☐ Yes [insert signature section if appropriate for consent process]
- ☐ No

Optional Signature section:

STATEMENT OF CONSENT

I have had the opportunity to read and consider the information in this form. I have asked any questions necessary to make a decision about my participation. I understand that I can ask additional questions throughout my participation.

I understand that by signing below, I volunteer to participate in this research.

Name of Adult Participant	Signature of Adult Participant	Date