Consent Form Checklist

General Instructions:

- A consent form is required for every study, unless otherwise waived by the IRB.
- Participants must be given a copy of the consent form, or if participation is online, allowed the opportunity to print the consent form for their records.
- For all applications, consent forms must be submitted in their final versions.
- Try to leave space for the IRB to stamp your consent form as approved. The stamp is around 1 x 2 inches.

Consent Form Writing Advice:

- Format your consent form so that it is easy to read.
    - Bullet points, bold and underlined text, pictures, and diagrams are all good ways to make your form easy to read and understand.
    - We recommend at least 11-point font or a larger font based on your audience.
    - Avoid large blocks of text.
- Write in simple and direct terms that are appropriate for the person reading it.
    - Please write in second ("you will complete…") or third person ("Participants will complete…"). HHS indicates that use of the first person for the perspective of participants ("I will.." or "I understand that…") can be coercive.
    - Use words familiar to the average reader. Avoid jargon.
    - Define any unfamiliar terms or acronyms when first used.
    - Use short, simple, and direct sentences. Avoid repetition.
    - Test your document's readability.

Required Elements on the Consent Form:

☐ **1. A title that includes "Western Washington University" and the name of the study.** The study name listed on the consent form does not need to match your grant title or IRB application title.

Consent Form Checklist

This is just a reference point for what the participant is signing. This is also helpful for the IRB if you have multiple consent forms in one study.

☐ **2. The name and contact information of the PI and any other researchers who will have contact with participants.** The list should also include their position in relation to the study and their contact information. The list can be placed at the top of the form under a "Researchers" heading or somewhere in the body of the consent form.

☐ **3. The following (or equivalent) introductory paragraph stating that the study involves research and an explanation of informed consent:**
We are asking you to be in a research study. Participation is voluntary. The purpose of this form is to give you the information you will need to help you decide whether to participate. Please read the form carefully. You may ask questions about anything that is not clear. When we have answered all of your questions, you can decide if you want to be in the study or not. This process is called "informed consent."

☐ **4. A statement describing how participants will receive a copy of the consent form**. For electronic consent, this would be a description of how participants can print a copy for their records.

☐ **5. An explanation of the purpose of the research.** Use lay-language – spell out acronyms, define or leave out jargon words, use words appropriate for the subject's reading level.

☐ **6. Describe the specific study tasks that the subject will be asked to complete. Include:**

- The expected duration of the subject's participation. If there are several parts, for example a questionnaire and then a focus group, indicate the duration of each part.
- If applicable, an identification of procedures which are experimental.
- For survey or questionnaire research:
  - The general scope of the questions that will be asked.
  - A statement about whether subjects may refuse to answer any questions or item in any test, questionnaire, or interview.
- For classroom research, where the questions are also required coursework, be specific about the coursework that will be included as data if they opt into participation.
- For biological sample collection, specify the size of samples (if appropriate) and purpose of collection

☐ **7. Describe any reasonably foreseeable risks or discomforts of participation.** Consider both physical and mental risks to research, including stress, discomfort, anxiety, risks from breach of confidentiality, invasion of privacy. The goal is to be truthful about what people might experience. Questionnaires, for example, may cause a risk of anxiety or discomfort when

answering the questions. For studies with little to no risk, do not make a blanket statement that "there are no risks." You can say that there are no known or anticipated risks.

- For studies with links between identifiers and data, address the risk of a breach of confidentiality, however unlikely. You can combine this information into the Confidentiality section or have it here in the Risks section. *For example: We take every precaution to protect your information, though no guarantee of security can be absolute. We believe the chances of you being identified are low due to the protections in place for your privacy.*
- If your research involves genetic research, you must address the risk of tracing DNA samples back to the individual.

☐ **8. Describe the alternatives, if any, to taking part in the study**
Describe the alternate procedure or option that is available to those who choose not to participate. For example, if an assignment is a required for course credit but is also required to be included in the research, then a comparable alternative need to be provided.

☐ **9. Describe the possible benefits of participation to the subject and/or society**

- If there are no benefits, state that there are no benefits to participation.
- For studies regulated by the FDA, compensation to research subjects cannot be referred to as a benefit. Rather, compensation is meant to reimburse for time and effort.

☐ **10. Describe the compensation or incentive, if any (including money, service, course credit, free food, etc.).**

- If there is pro-rated compensation then describe the pro-rating.
- If the subject will <u>not</u> receive compensation for partial completion of the study then include that information.
- If there are any costs to the subject directly as part of participation, describe those here.
- When subjects are compensated using funds administered by or through Western Washington University, see our Human Subjects Research Compliance Manual for guidance. If tax reporting is required, this information should be disclosed. *For Example: If you make over $600 in research payments from Western Washington University in a calendar year, the university will report that as income to the IRS. For this reason, we will need to collect your social security number.*

☐ **11. Disclose if there is any financial conflict of interest of the investigator.**

☐ **12. Describe the data and privacy protections in place for participants.**

- (1) Describe the protections in place for the data. *For example: "Your data will be stored on a secure server."*
- (2) Describe how identifying information is connected to the data.
  - If you would like to use terms like "anonymous" or "confidential" please also briefly define what you mean in the text.
  - When data is linked to identifiers:
    - Say whether the link between their contact information and data will be retained (and for how long) or destroyed (and when).
    - For state or federally funded research, consider the retention requirements for research data when determining a link destruction date. *For example: The link between your ID number and contact information will be kept by the researchers through the end of the study.*
    - If MTurk is being used and worker IDs are collected, subjects should be notified that their ID might be linked to identifying information on their public profile. *For example: Depending on your Amazon profile settings, your MTurk ID is linkable to your public profile page and any identifying information on your profile. Researchers will not access your Amazon public profile page. Your MTurk worker ID will be stored separately from your data.*
- (3) Describe any limits to protections. For example, if you need/plan to report information about child abuse, elder abuse, or harm to self or others.

The text of this section will vary significantly based on the study. Here are examples of common scenarios:

- **No identifying information collected**
  - Example studies
    - An online survey that is posted online for anyone to access that doesn't ask for anyone's name or contact information, so you never know who completed it.
    - The researcher asks people they meet on the street to answer a few questions and they never have their names.
  - Example text:
    - "Your name and contact information will not be collected. Your data cannot be linked back to you."
  - Note:
    - This type of collection is sometimes referred to as "anonymous", but if you use this term, please still also describe what this means. For example: "Your participation is anonymous. Your name and contact information will not be collected. Your data cannot be linked back to you."

- **Identifiers collected (linked either indirectly or directly)**
  - Example studies:
    - An audio-recorded or video recorded interview. (direct link)
      - Mention whether the audio/video will be transcribed.
      - If transcribed, mention whether the transcription will be de-identified.
      - Mention whether the raw audio/video will be kept or deleted.

      For example: *"Your interview will be audio recorded and transcribed. After removing any identifying information from the transcription, the audio file will be deleted. At that point, we will no longer know which transcription is yours."*

    - A survey where the participant writes down or types their name or contact information on the survey and it stays that way. (directly link)

      For example: *"We will keep your contact information connected to your data."*

    - A researcher has a list where names are matched to ID numbers. The data is labeled with the ID number and not the person's name. The list of names is kept separately from the data. (indirect link)

      For example: *"You will be given an ID number for this study, which will be used to label your data. The link between this ID number and your name and other identifying information will be stored separately*.

    - A researcher has a list of names of people who agreed to be interviewed for recruitment, but during the interview the researcher does not record the person's name. (indirect link)

      For example: "*Your contact information will never be connected to your data. After this interview, we will delete your identifying information."*

☐ **13. For research involving collection of identifiable private information or identifiable biospecimens, include a statement regarding use in future research**
One of these two types of statements need to be included:

1. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be possibility; OR
2. A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

☐ **14. Include a statement that participants are free to withdraw from the study at any time, without penalty or loss of benefits to which they are otherwise entitled.**

- If applicable, describe what will happen with subject data or samples upon withdrawal. Will the data be kept or destroyed? Can the subject request that their samples or data be destroyed? If yes, how can they submit that request?
  For example: If you withdraw, the study will keep your data. You can submit a request to [insert email address or mailing address] to withdraw your data up until the study ends. After the study ends, we will no longer be able to link you with your data.
- Be sure to note any limits to withdrawal. For example, if the participant is only able to withdraw up until their data is de-identified, at which point you would no longer be able to link the person back to their data.

☐ **15. Include information about research Participant Rights, which include:**

- If they have questions about the study, they can contact the researcher. Either reference that contact information is provided at the top of the form or include it here.
- If they have questions about their rights as a research participant, they can contact the Western Washington University Office of Research and Sponsored Programs (RSP) at compliance@wwu.edu or (360) 650-2146.

☐ **16. Include a statement of what will indicate consent.**

- You can write this section in second or third person. Try to match this section to the point of the view of the consent form. If you wrote in second person for the rest of the consent form, it makes more sense to use second person for the consent statement.
  Example of "second person" point of view: By signing below you are saying that you have read this form, that you have had your questions answered, that you understand the tasks involved, and volunteer to take part in this research.
- Unless you have a waiver of documentation of consent, you must have a line for the subject to print, sign, and date.
- If you have a waiver of documentation of consent (either because your study is eligible for exemption or you have applied and received IRB approval for it) include language to indicate what specific action indicates their consent to participate. *For example: "By*

clicking 'submit' you are saying that you have read this form, that you understand the tasks involved, and that you are consenting to participate."

Additional Requirements for Federally Funded Research

☐ **17. A Concise Summary Introduction**

Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a subject in understanding the reasons why one might or might not want to participate in the research. What this looks like will be highly dependent on the research. Please contact our office if you are unsure.

☐ **18. Identify the sponsor.**

☐ **19. Describe what will occur in the case of a Research-Related Injury**

This section can be separate or incorporated into the "Research Participant Rights" section below or another applicable paragraph. For minimal risk exempt studies, the IRB may be able to waive this section if it seems inappropriate to include based on the tasks involved.

- Include a statement that if the subject believes they have been harmed due to participation, they can contact the researchers of the study.
- Whether medical treatment is available if an injury occurs. If medical treatment is available, describe what it consists of and where to receive additional information. You may say that if a subject is injured as a result of participation, they will be referred for treatment, which will be billed like any normal doctor's visit.
- If appropriate, a 24-hour emergency contact number.
- Whether any compensation is available in the event of harm.

Consent Form Checklist

Additional Elements as Appropriate

☐ **A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable**

☐ **Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent or the legally authorized representative's consent**

☐ **Any additional costs to the subject that may result from participation in the research**

☐ **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**

☐ **The approximate number of subjects involved in the study**

☐ **If your research involves accessing student education records in any way, FERPA requires explicit consent for that use and disclosure. You must:**

(1) Specify the records that may be disclosed;
(2) State the purpose of the disclosure; and
(3) Identify the party or class of parties to whom the disclosure may be made.

"Signed and dated written consent" may include a record and signature in electronic form that— (1) Identifies and authenticates a particular person as the source of the electronic consent; and (2) Indicates such person's approval of the information contained in the electronic consent.

☐ **If you are requesting medical records (or any information covered by the Health Insurance Portability and Accountability Act) you can include all necessary components for a HIPAA authorization**. We recommend though that this language actually be placed on a separate HIPAA authorization form, rather than in the consent form.

- A specific description of the protected health information (PHI) being disclosed.
- The individuals who will be authorized to access the records.
- The place(s) where the information will be requested.
- The purpose of the disclosure for this research.
- And expected expiration of the disclosure permissions (the terms "end of the research study" or that there will be "no expiration" may be used)
- A statement that they have a right to revoke this authorization in writing and either (1) the exceptions to the right to revoke and a description of how the individual may revoke

Authorization or (2) reference to the corresponding sections of the covered entity's Notice of Privacy Practices.

- Notice of the covered entity's ability or inability to condition treatment, payment, enrollment, or eligibility for benefits on the Authorization, including research-related treatment, and, if applicable, consequences of refusing to sign the Authorization.
- The potential for the PHI to be re-disclosed by the recipient and no longer protected by the Privacy Rule. This statement does not require an analysis of risk for re-disclosure but may be a general statement that the Privacy Rule may no longer protect health information.

☐ **A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit**

☐ **A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions**

☐ **For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen)**