



## INFORMED CONSENT TEMPLATE GUIDANCE

**Instructions:** This document provides guidance and language necessary to populate the [template informed consent form](#). The guidance incorporates the regulatory requirements for informed consent. The format may be modified or expanded as indicated to better meet the needs of the research design and/or participant population.

The key information section is a regulatory requirement. There are also basic elements of informed consent. For some simple research studies, some of the basic elements of informed consent are satisfied by the information included in the key information section. Therefore, the information need not be reiterated in the body of the consent. In other cases, the key information section will not sufficiently detail all aspects of the study that a participant needs to consider and much more information will need to be provided in the body of the consent form.

### How to use this document:

- Regular **black text** and formatting, including bolding, are template and should not be removed unless otherwise noted.
- The **[blue-bracketed]** text identifies required elements of informed consent. The blue text also includes considerations as you develop your version of the document. Some considerations may not be applicable to your research. Enter customized information within the brackets.
- The **[red-bracketed]** text are content that are regulatory requirements to be included when applicable to the research.
- **Green text** provides examples or sample phrasing for the blue or red-bracketed text.
- Remove all instructions, all colored text and italics prior to finalizing your consent document.

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Standard Template Text	Required Element of Informed Consent	Required Element, when applicable	Suggested Language/ Phrasing



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**Consent for Research Participation**

**Title:** [Title]

**Sponsor:** [Name of Study Sponsor, if sponsored. If no sponsor, delete this line]

**Researcher(s):** [Name], [Institution (e.g., University of Oregon)]  
[Name], [Institution (e.g., University of Oregon)]

**Researcher Contact Info:** [Phone]  
[Email]

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You are being asked to participate in a research study. The box below highlights key information about this research for you to consider when making a decision whether or not to participate. Carefully consider this information and the more detailed information provided below the box. Please ask questions about any of the information you do not understand before you decide whether to participate.

Key Information for You to Consider	
<ul style="list-style-type: none"><li>• <b>Voluntary Consent.</b> You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate or discontinue participation.</li><li>• <b>Purpose.</b> The purpose of this research is [provide a brief description of why the research is being conducted, no more than 2-3 sentences].</li><li>• <b>Duration.</b> It is expected that your participation will last [expected duration].</li><li>• <b>Procedures and Activities.</b> You will be asked to [briefly highlight the key research activities/procedures].</li><li>• <b>Risks.</b> Some of the foreseeable risks or discomforts of your participation include [describe the most important risks. Consider those most probable and/or highest magnitude of harm].</li><li>• <b>Benefits.</b> Some of the benefits that may be expected include [insert direct benefits, or if no direct benefit to subject state no direct benefit but the researchers hope to learn/gain xyz].</li><li>• <b>Alternatives.</b> As an alternative to participation, you could [note appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject. If there are no alternatives, state that, "Participation is voluntary and the only alternative is to not participate."].</li></ul>	

**Who is conducting this research?**

[Note: This section to be included when multiple institutions are collaborating and/or when a member of the research team has a conflict of interest.]

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The researcher(s) [Name(s)] from [Institution Name(s) (e.g., University of Oregon, etc.)] are asking for your consent to this research. [State whether any member of the research team have a significant financial interest and/or a conflict of interest related to the research. Note: if language has been defined within a formal management plan, this should be included here].

**Why is this research being done?**

[NOTE: If the full purpose is described in the key information summary above, this section may be deleted.]

The purpose of the research is [describe purpose of the study in simple terms]. You are being asked to participate because [state the main reason or list the key inclusion/exclusion criteria that may make the individual eligible to participate (e.g., you are an adult college student or you are receiving services from X organization)]. About [number] people will take part in this research.

**How long will I be in this research?**

[NOTE: If duration is fully detailed in the key information summary above, you may remove this section.]

We expect that your participation will last [state the total time of participation. Consider the duration of participation, frequency (if multiple study visits) and provide relevant information in hours, days, weeks, months, years, or until a certain event. Include the number of times the participant will be involved in research activities, how long each activity or session will take, etc.].

**What happens if I agree to participate in this research?**

[NOTE: If all procedures/activities are described in the key information summary above, you may remove this section.]

If you agree to be in this research, your participation will include [describe, using simple terms, what the participant can expect while participating.]

Using plain language accurately describe what participation in the research entails. Below are details typically included depending on the nature of the research.

For most research studies:

- What the participants will do and what will happen during the research;
- What information about the participant will be obtained, including from secondary sources.
- Where this research will be done.
- Provide a time-line description of the activities, tests and/or procedures that will be done, including any screening procedures. You can use tables or charts if they are helpful to explain the schedule
- If there will be photography, audio or videotaping and what will be recorded.

For research involving survey, questionnaires, and/or interviews:

- Inform participants that they can skip any question that makes them uncomfortable and they can stop at any time.
- It may be appropriate to provide example of the questions being asked. When asking sensitive information, sample questions must be provided.

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Others to consider including:

- If your study involves deception, give as much information as possible.
- If more than one group, describe each group or arm.
- If the research involves random assignment, describe this and the probability of assignment to each group. For example:

You will be put into a study group by chance (like a coin toss/ like drawing straws). You have an \_\_\_\_ out of \_\_\_\_ chance of being placed in each group. You cannot choose your study group.

- If the research involves blinding, include language describing a single (subject only) or double (subject and research team) blind, as appropriate. For example:

During the research, you (or you and the researchers) will not know which group you are in. (The researcher can find out in case of an emergency).

- Describe any follow-up and/or planned future research activities/procedures (e.g., recontact to review quotes, follow-up questions, extension study, follow-up study, analysis of specimens, etc.).
  - Describe whether subjects will be asked to sign a separate consent form.
- Include the following, when applicable:

We will tell you about any new information that may affect your willingness to continue participation in this research.

For research involving interventions, drugs, devices, biospecimen collection and/or biomedical components:

- If blood will be drawn, indicate how often and the amount using the most appropriate unit of measurement; use a lay example for reference (e.g., teaspoons or tablespoons).
- Identify any experimental procedures.
- Identify all drugs, devices, and tests performed that are approved for marketed use.
- Identify all unapproved drugs, devices, tests, and procedures unapproved for marketed use.
  - For studies conducted under an IND, IDE, or abbreviated IDE, state: name of the product or device] is investigational, which means that it is not approved by the Food and Drug Administration (FDA).
  - Identify all approved drugs, devices, tests, and procedures being used in a novel fashion as experimental.
  - Describe any relevant information about the test article and the control (if used).
  - For research on investigational drugs or devices, list any options for the participant to get the drug/device after the research, and who will pay for this.
- If this is a treatment study, indicate whether the study treatment will be available at the end of the study.
- Explain whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.
- For research involving biospecimens, the following statement needs to be included:

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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).

**What happens to the information collected for this research?**

Information [and/or specimens] collected for this research will be used to [describe how information will be published and disseminated and whether identifiable information would be included such as name. You may use the suggested language below as applicable].

- Your name will not be used in any [e.g., published reports, conference presentations, etc.] about this study.
- We may publish/present the results of this research. However, we will keep your name and other identifying information confidential – OR -
- With your permission, your name will be used in [e.g., conferences, published reports] about this study.

Discuss whether information and/or specimens collected for this research will be shared and under what circumstances [i.e., data set shared with other researchers, data deposited in a formal repository, etc.].

If the research involves the collection of identifiable private information and/or identifiable biospecimens, one of the following statements must be included:

- Identifiers might be removed from identifiable private information and/or identifiable biospecimens collected in this research. After removal of identifiers, the information and/or biospecimens may be used for future research or distributed to another investigator for future research without obtaining additional consent. – OR -
- Information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

For clinical trials regulated by the FDA, the following statement must be included:

- A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

**How will my privacy and data confidentiality be protected?**

We will take measures to protect your privacy. Despite taking steps to protect your privacy, we can never fully guarantee your privacy will be protected. Measures we will take include:

- Discuss steps that you will take to protect participant privacy, (e.g., conduct research in private setting and/or other space consideration, security parameters of online survey platforms,
- Discuss any known limits to protecting privacy (e.g., group participation and knowing who other participants are, research setting, etc.).

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We will take measures to protect the security of all your personal information, but we can never fully guarantee confidentiality of all study information. Measures we will take include:

- Discuss steps that you will take to protect confidentiality (e.g., where will data be stored, who will have access to the data, how will data be transferred, when will data be de-identified, security of storage (online), etc.)
- Discuss any known limits to protecting confidentiality (e.g., limits of data security and storage, data collected in group settings, user agreements, etc.).

Individuals and organization that conduct or monitor this research may be permitted access to and inspect the research records. This may include access to your private information and [\[include any other records\]](#). These individuals and organizations include: [\[Edit the list below as appropriate for your research\]](#).

- The Institutional Review Board (IRB) that reviewed this research
- Government regulatory agencies
- The Food and Drug Administration (if FDA regulated)
- The study sponsor (if sponsored)
- People who work with the study sponsor
- Any other individuals/entities
- When the procedures include communicable disease testing, include any disclosures mandated by state-law.

In circumstances where a research team may need to breach confidentiality (e.g., participant disclosing intent to harm self or others), the following statement should be included:

We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy. You should understand that the researcher is not prevented from taking steps, including reporting to authorities, to prevent serious harm of yourself or others.

For studies in which mandatory reporting is a requirement, the following statement must be included:

The research team includes individuals who are mandatory reporters. If the research team has reasonable cause to suspect abuse or neglect of a child or adult, a report may be required under Oregon State Law. In such a case, the research team may be obligated to breach confidentiality and may be required to disclose personal information.

For studies that have been issued a Certificate of Confidentiality, NIH has specific criteria for disclosure to participants. Studies that involve collection or use of identifiable sensitive information may have a Certificate of Confidentiality through NIH either because:

- A Certificate of Confidentiality was automatically issued with the terms and conditions of the award (only studies funded on or after December 2016) – **OR**-
- The research team has applied for and obtained a Certificate of Confidentiality from NIH.

NIH expects researchers tell participants about the protections afforded by the Certificate of Confidentiality. NIH provides the sample language below which should be adapted to the study participants and subject matter of the research:

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This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

Additionally include the following language as applicable:

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by [THE AGENCY] which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

Language such as the following should be included if researcher intends to disclose information covered by a Certificate, such as potential child abuse, or intent to hurt self or others in response to specific federal, state, or local laws:

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of [list what will be reported, such as child abuse and neglect, or harm to self or others].

Language such as the following should be included if researcher intends to disclose information covered by a Certificate, with the consent of research participants:

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document [restate what will be disclosed, such as including research data in the medical record].

### **What are the risks if I participate in this research?**

[NOTE: If all risks are disclosed in the key information summary above and/or are limited to breach of privacy and/or confidentiality, delete.]

The risks or discomforts of participating in this research include [detail any known risk of harm that the participant may experience in simple language. Any risks listed in the protocol must be addressed in the consent form. List risks and discomforts in order of most common and most likely to occur, with least likely to occur listed last. Also, list any rare, but serious risks. If there are many risks, use a bulleted format. If known, provide the percentage or range of occurrence for the risks. Describe the duration of the risks and

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discomforts. Note whether the risks and discomforts will go away when the study drug, device, or activity/procedure is stopped.]

Commonly categories of risks to cover:

- Physical risks
- Psychological risks (e.g., embarrassment, fear or guilt)
- Privacy risks (e.g., disclosure of private information)
- Legal risks (e.g., legal prosecution or being reported for child abuse)
- Social risks (e.g., social ostracizing or discrimination)
- Economic risks (e.g., having to pay money out-of-pocket for research or medical expenses, losing health insurance, or being unable to obtain a job)

For some simple minimal risk studies, a brief statement similar to the following addresses the scope of risk associated with participating:

There may be risks of stress, emotional distress, inconvenience and possible loss of privacy and confidentiality associated with participating in a research study.

The following are additional aspects of risks to include if applicable:

- Side effects of any comparator drugs.
- Any risks associated with washout, withholding treatment, or randomization of treatment.
- When the risk profile is not well known, this should be discussed.
- When there may be unknown risks associated with participation, include the following:

In addition to these risks, taking part in this research may have risks that are unknown or currently unforeseeable.

- If the study involves pregnant women or women of child-bearing potential:
- If there are known risks to an embryo or fetus associated with participation, include:

Taking part in this research may hurt a pregnancy or fetus in the following ways: [include the ways that are known].

- If the study may involve risks to an embryo or fetus or procedures whose risk profile in pregnancy is not well known:

Taking part in this may hurt a pregnancy or fetus in unknown ways. These may be minor or so severe as to cause death.

### **What are the benefits of participating in this research?**

[NOTE: If all benefits are disclosed in the key information summary above, you may delete.]

You may or may not benefit from participating in this research.

Choose the applicable language to include:

- If there are no expected benefits to the subject but possible benefits to scientific knowledge:

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There are no known direct benefits to you from participating in this study. However, it is hoped that information gained from this study will help [describe anticipated generalized societal benefit of the research].

- If there are no expected benefits to the subject but possible benefits to others:

There are no known direct benefits to you from your taking part in this research. While we cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include [describe any benefits to others].

- If there are possible benefits to the subject, detail any known direct benefits that the participant may experience from participating in the study. Include:

We cannot promise any benefits to you or others from your participation in this research. However, possible benefits to you include [describe any direct benefits to the subject. If benefits from taking part may not continue after this research has ended, state these]. Possible benefits to others include [describe any benefits to others].

**What are my responsibilities if I choose to participate in this research?**

[Include this section only when applicable, otherwise, delete.]

If you take part in this research, you will be responsible for: [Describe the responsibilities of the subject].

Consider the following and include as applicable:

- Any requirements to follow the instructions as provided by the study team and to give them any new information about new medications, new medical issues, etc.
- Any requirements to avoid certain activities or refrain from taking certain drugs
- Any situations where the subjects should immediately contact the investigator or immediately seek medical attention
- Any warning or precautions that the subject needs to know
- Any warnings regarding pregnancy or fathering a child
- Any requirements to for the subject or the subject's partner to abstain from sexual relations or use contraception
- Any requirements to keep research articles out of the reach of children or others
- Any requirements to promptly report certain side effects to the investigator
- Any requirements to avoid or minimize contact with others

**What other choices do I have besides participation in this research?**

[NOTE: If there are no alternatives or these have been fully disclosed in the key information summary above, delete.]

It is your choice to participate or not to participate in this research.

Choose one of the following options:

- If there are alternatives, include the following:

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Instead of being in this research, your choices may include:

- List the major approved alternative options such as drugs / devices / procedures/activities, if any that might be advantageous to the subject
  - Consider, based on the indication and population, whether an alternative might include no active treatment but support and management of pain and other symptoms to be as comfortable as possible through the remainder of life.
- If there are no alternatives:

Your alternative is to not take part in the research.

### **What if I want to stop participating in this research?**

Taking part in this research study is your decision. Your participation in this study is voluntary. You do not have to take part in this study, but if you do, you can stop at any time. You have the right to choose not to participate in any study activity or completely withdraw from continued participation at any point in this study without penalty or loss of benefits to which you are otherwise entitled. Your decision whether or not to participate will not affect your relationship with the researchers or the University of Oregon.

If applicable, discuss the process for participants to withdraw once the study has begun:

- Including if participants can request their information not be used for research or if there are any limitations to requesting their information also be withdrawn (e.g., data has already been de-identified and no link remains).
  - If you are using an audio or video tape, address how the participant's recording will be destroyed should they decide to withdraw.

- Include the following if there are procedures for orderly termination of taking part in the research:

If you decide to leave this research, contact the research team so that the investigator can [describe the procedures for orderly termination by the subject].

- Include the following if there are potential adverse consequences to a subject who withdraws:

If you decide to leave the research early, there may be risks with this decision. These may include [describe the adverse consequences].

- Include any circumstance in which the researcher would withdraw a participant (e.g. noncompliance with study procedures). Include all reasons for withdrawal described in the protocol.

The investigators may stop you from taking part in this study. Reasons for withdrawal might include [edit the list below as applicable for the research]:

- It is in your best interest
- You have a side effect that requires stopping the research
- You need a treatment not allowed in this research
- You become pregnant

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- The research is canceled by the FDA or the sponsor
- You are unable to take the research medication
- You are unable to keep your scheduled appointments

**Will it cost me money to take part in this research?**

[Include this section only when a participant may potentially question if there are costs associated with participation, otherwise, delete.]

Select one of the following statements and complete as indicated:

- There are no costs associated with participation in this research study – OR-
- Taking part in this research may lead to additional costs to you, such as [describe]. These costs are [discuss who is responsible including the following]:
  - Discuss who is responsible for this costs, including if the research team will cover these costs.
  - If costs are the responsibility of the participant or will be billed to a third party payer, include the following language:

In some cases, insurance does not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

**What if I am injured because of participating in this research?**

[This section must be included for any study that is greater than minimal risk or when the study involves the possibility of injury. Delete if not applicable.]

If you are injured or get sick because of being in this research, call the researchers immediately.

Choose the applicable language to include:

- For most studies conducted at UO, the following language should be used as medical costs associated with a research-related injury will be the responsibility of the participant:
  - In the event you suffer a research -related injury your medical expenses will be your responsibility or that of your insurance company (or other third-party payer), although you are not precluded from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research. If you are a UO student or employee and are covered by a UO medical plan, that plan might have terms that apply to your injury.
- If collaborating with a medical institution or if the study sponsor will cover costs in the event of a research related injury, edit the language here to provide:
  - An explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

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"The sponsor has made plans to pay for medical costs associated with research-related injuries. More information can be found at \_\_\_\_."

If you experience harm because of the project, you can ask the State of Oregon to pay you. If you have been harmed, there are two University representatives you need to contact. Here are their addresses and phone numbers:

**General Counsel/ Office of the President**

1226 University of Oregon  
Eugene, OR 97403-1226  
(541) 346-3082

**Research Compliance Services**

5237 University of Oregon  
Eugene, OR 97403-5237  
(541) 346-2510

A law called the Oregon Tort Claims Act may limit the amount of money you can receive from the State of Oregon if you are harmed.

**Will I be paid for participating in this research?**

Address whether or not subjects will be compensated for participation. Select and include the statements that apply to your research:

- You will not be paid for taking part in this research.
- For taking part in this research, you may be paid up to a total of \$\_\_\_\_\_ [cash/check/gift card]. Your compensation will be broken down as follows:
  - Describe payment schedule (i.e., how payment will be prorated in circumstance of incomplete participation or time-based payments). State in terms of amount of compensation.
  - Describe when and how payments will be made.
- For taking part in this research, you may receive up to a total of [describe course credit or other non-monetary compensation to be issued]. Your compensation will be broken down as follows:
  - Describe the distribution schedule (i.e., how will compensation be prorated in circumstance of incomplete participation or time-based compensation). State in terms of amount of compensation.
  - Describe when and how compensation will be made.

If the study includes biospecimens, when appropriate, include the following statement:

Your specimens, even if identifiers are removed, may be used for commercial profit. You [will or will not] share in this commercial profit.

If participants will be compensated, select the language applicable to the monetary value of the compensation:

- If compensating a total value of \$100 or less, state:

Please be aware, compensation for participation in research studies may be considered taxable income.

- If compensating a total value of \$100.01-\$599.99, state:

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Please be aware, compensation for participation in research may be considered taxable income. The University requires tracking for compensation that is paid to you; this may include your name and contact information. This information is stored confidentially and separate from research data. If you receive \$600 or more in a calendar year, you may be contacted to provide additional information (e.g. Social Security Number) for tax reporting purposes.

- If compensating a total value of \$600 or greater, state:

Please be aware, compensation for participation in research may be considered taxable income. The University requires tracking for compensation that is paid to you; this may include your name and contact information. Because you will receive \$600 or more in a calendar year, you will be asked to provide additional (e.g. Social Security Number) information for tax reporting purposes. This information is stored confidentially and separate from research data.

### Who can answer my questions about this research?

If you have questions, concerns, or have experienced a research related injury, contact the research team at:

[Insert Name of PI]

[Phone number that is answered/attended to regularly]

[Confidential email that is answered/attended to regularly]

An Institutional Review Board ("IRB") is overseeing this research. An IRB is a group of people who perform independent review of research studies to ensure the rights and welfare of participants are protected. UO Research Compliance Services is the office that supports the UO IRB. If you have questions about your rights or wish to speak with someone other than the research team, you may contact:

Research Compliance Services  
5237 University of Oregon  
Eugene, OR 97403-5237  
(541) 346-2510

### 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. I understand that I am not waiving any legal rights. I have been provided with a copy of this consent form. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

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**INFORMED CONSENT  
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If using audio/video/photography in the research include the following:

As described above, you will be [audio/video recorded and/or photographed] while performing the activities described above. [Recordings/photographs] will be used for [data analysis only/included in conference presentations/used for educational purposes, etc.].

- Initial the space below if you consent to the use of [audio/video or photographs] as described.

\_\_\_ I agree to the use of [audio/video recording or photography]

If requesting permission to identify an individual as having participated in the research, include the following:

With your permission, your name will be used in [e.g., conferences, published reports] about this study.

- Initial in the space below if you consent to the use of your name as described.

\_\_\_ I agree to the use of my name [and any other pieces of information]

---

Name of Adult Participant

---

Signature of Adult Participant

---

Date**Researcher Signature** (to be completed at time of informed consent)

I have explained the research to the participant and answered all of his/her questions. I believe that he/she understands the information described in this consent form and freely consents to participate.

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Name of Research Team Member

---

Signature of Research Team Member

---

Date

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