CONSENT FORM GUIDELINES & SAMPLES

What is Informed Consent?
Voluntary informed consent is a prerequisite for a human subject to participate in a research study. Consent is a process: the subject is informed about the study purpose, methods, and possible risks and benefits of participating; and given an opportunity to ask questions and time to make an informed decision about participating. Consent from subjects must obtained freely without any unjustified influence.

The completed and signed consent form is a legal document in which the human subject agrees to participate in the study.

What are the requirements for a legally effective consent form?
The requirement to obtain informed consent of individuals before involving them in research is found on respect for persons, one of the principles guiding human subjects research described in the Belmont Report.

Subjects must be allowed to:
- Ask questions and seek clarification from the investigator
- Freely decide whether to initially enroll in the research, or to later withdraw from or continue participating in the research.

The informed consent process should ensure that all critical information about a study is completely disclosed, and that prospective subjects or their legally authorized representatives understand the research so that they can make informed choices.

What are the requirements for children participating in a study?
Parental and guardian permission is required for all human subjects research involving minors unless waived by the IRB. An assent form may also be required for an individual who is not competent to give legally informed consent, such as a minor.

What are the IRB consent form requirements?
For most studies, the consent form is required. The IRB may modify or waive consent form requirements – but is not required to do so – only in certain circumstances. The Consent Waiver Request form must be submitted for a waiver to be considered.

Instructions:
1. Consent form templates for each type of review – exempt, expedited, and full board – are provided on the following pages (instructional copy is in red – delete before uploading your consent form to IRBNet)
2. Choose the template that best fits the requirements for your study
3. Blue, italicized text in parentheses represents the specific information about your study that you must add to the document; the text you replace must be in plain text, not blue and italicized
4. Delete any bolded, underlined template text that you did not replace
5. Use plain language that is, in general, at an eighth-grade reading level

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Exempt Review Template
May be used on anonymous written surveys, anonymous online surveys and questionnaires, given verbally in anonymous interviews, etc.

Consent Form: *(Name of Research Study)*

What is this research study about?
This research study is designed to *(provide a short description of the research)*. We hope to learn *(state the purpose of the study/what it is designed to discover or establish)*.

All data collected for this study is anonymous and will not be linked back to any of your identifying information.

What activities will this study involve?
If you decide to participate, you will be asked to *(describe procedures used to collect data, how long each will take, and its frequency)*.

How much time will this take?
Participation will require approximately *(estimate the total time required and, if there are multiple activities, how much time each will take)*.

Are there any risks for participating?
There are no appreciable risks from participating in this study. *(If the study presents no risks or benefits to participants)*.

*(If the study presents risks, use this statement: The risks associated with this study are [describe risks]).*

Are there any benefits for participating?
If the study offers benefits, use this statement: The benefits reasonably expected from this study are [describe benefits]. If extra credit is offered, inform subjects that there may be alternative, non-research activities offered and who to contact for more information.

What are my rights as a participant?
Participation in this study is voluntary and you may stop at any time. You may decide not to participate or to discontinue participation at any time without penalty or loss of benefits. A decision not to participate or withdraw will not affect your current or future relationship with *(Winona State University and/or the institution/agency on whose behalf the research is being conducted)*.

Who can I contact if I have questions or concerns about this study?
If you have any questions about the study or your participation, contact *(identify and provide phone numbers for the researchers and; for student researchers, only provide the name and phone number of the faculty project advisor)*.

Who can I contact if I have questions about my rights as a participant?
If you have questions about your rights as a participant, contact Human Protections Administrator Brett Ayers at 507-457-5519 or bayers@winona.edu. This project has been reviewed by the Winona State University Institutional Review Board for the protection of human subjects.

*(For online surveys, questionnaires, etc. use the following statements to indicate agreement to participate:*

  a. If you agree to participate, responding to the [survey, questionnaire, interview] questions constitutes your consent. Participation is voluntary and you may stop participating at any time.

  b. Click “Yes” if you agree to participate in this study. Click “No” if you do not wish to participate in this study. Participation is voluntary and you may stop participating at any time.*
Expedited Review Template

Consent Form: *(Name of Research Study)*

**What is this research study about?**
You are invited to participate in a research study designed to *(provide a short description of the research)*. We hope to learn *(state the purpose of the study/what it is designed to discover or establish)*.

**What activities will this study involve?**
If you decide to participate, you will be asked to *(describe procedures used to collect data, how long each will take, and its frequency)*.

**How much time will this take?**
The study will begin on *(give estimated date or time)* and end on *(give estimated date or time)*. *(If the study requires several sessions, note the number and approximate time for each session)*. We estimate participating in the study will require *(estimate the total time required)* of your time.

**What will be done with the data collected during this study?**
*(If the data collected is anonymous, use the following: The information you gave will be anonymous which means that your name will not be collected or linked to the data. All information you gave will be handled confidentially.)*

*(If the data collected can be linked with identifying information, use the following: The information you give will be (describe procedures for de-identifying or coding the data).)*

All information collected will be stored *(describe procedures for storing data)*. When the study is completed, *(describe how data will be handled when the study is concluded)*.

**Are there any risks for participating?**
There are no appreciable risks from participating in this study. *(If the study presents no risks or benefits to participants)*.

*(If the study presents physical, psychological, professional, and/or personal risks, use this statement: The risks associated with this study are [describe risks]. These risks will be minimized by [describe procedures used to minimize risks to subjects]).*

**Are there any benefits for participating?**
There are no appreciable benefits from participating in this study. *(If the study offers benefits, use this statement: The benefits reasonably expected from this study are [describe benefits]. If extra credit is offered, inform subjects that there may be alternative, non-research activities offered and who to contact for more information).*

**What are my rights as a participant?**
Participation in this study is voluntary and you may stop at any time. You may decide not to participate or to discontinue participation at any time without penalty or loss of benefits. A decision not to participate or withdraw will not affect your current or future relationship with *(Winona State University and/or the institution/agency on whose behalf the research is being conducted)*.

**Who can I contact if I have questions or concerns about this study?**
The main researcher conducting this study is *(PI name), a (professor, staff member, student, etc.) at Winona State University. The faculty advisor for this study is (advisor name, phone, email)*. You may ask any questions you have about the study and your participation now or later during the study.
Who can I contact if I have questions about my rights as a participant?
If you have questions or concerns about your participation in the study, contact the Human Protections Administrator Brett Ayers at 507-457-5519 or bayers@winona.edu. This project has been reviewed by the Winona State University Institutional Review Board for the protection of human subjects.

You will be given a copy of this form to keep for your records.

Agreement to Participate
Participation in this study is voluntary. You may withdraw at any time. Your signature indicates that the study has been explained, you have had an opportunity to ask questions, and you have decided to participate.

Your signature: ____________________________ Date _________

Your name (printed): __________________________

Signature of person obtaining consent: __________________________ Date __________

Name of person obtaining consent (printed): __________________________
Consent Form: (Name of Research Study)

What is this research study about?
You are invited to participate in a research study designed to (provide a short description of the research). We hope to learn (state the purpose of the study/what it is designed to discover or establish).

What activities will this study involve?
If you decide to participate, you will be asked to (describe procedures used to collect data, how long each will take, and its frequency).

How much time will this take?
The study will begin on (give estimated date or time) and end on (give estimated date or time). (If the study requires several sessions, note the number and approximate time for each session). We estimate participating in the study will require (estimate the total time required) of your time.

What are the possible risks or discomforts of this study?
(Describe any procedure that is experimental. Describe any actual or potential discomfort, inconvenience, harm, and risks [physical, psychological, social, financial or other] which may be reasonably expected.).

(If any deception is involved, include the following statement: The research cannot be fully described at this time, but an explanation will be provided after your participation has concluded.).

(If appropriate, include the following statement: Participation in this study, if you become pregnant, may involve currently unforeseeable risks to an embryo or fetus.).

(If appropriate, include the following statement: Any new findings developed during this research study which may affect your willingness to continue participation will be provided to you.)

(If appropriate include the following information: In the event of a research-related injury, medical treatment or therapeutic intervention will be available as it is to members of the public. This includes first aid and emergency hospital treatment. Payment for any treatments must be provided by you and your third payer, if any (such as health insurance). It is your responsibility to determine the extent of your health coverage.)

(If there are no known risks to the study, include the following statement: We do not anticipate any risks from participating in this research study.).

What are the possible benefits of this study?
(Describe any benefits which may reasonably be expected. If the subject will receive any compensation, describe the amount or type or state. If subjects will receive compensation but have the opportunity to participate in another equitable activity to receive similar compensation, the alternative must be described.)

(If appropriate describe any additional costs to the subject that may result from participation in the research).

(Describe appropriate alternative procedures that might be advantageous to the subject, if any. Any standard treatment that is being withheld must be disclosed.)

If there is no financial compensation, include the following statement: There is no financial compensation for your participation in this study.

(If there are no known benefits to the study, state: I/We do not anticipate any benefits from participating in this research.)
How will the information collected about me be protected?
Data collected during this study will be (explain procedures for assuring data privacy [e.g. use of numbered identifiers, locked files, restricted access, destruction of the data after a specified period, etc.]).

If the results of this study are published or presented, no names will be associated with the data cited. Any information obtained through this study that can be identified with you will be disclosed only with your permission.

(If you will release information to other researchers or involuntarily (e.g. upon subpoena) state the specific circumstances, to whom the information will be furnished, and the nature and purpose of the disclosure).

What are my rights as a participant?
Participation in this study is voluntary and you may stop at any time. You may decide not to participate or to discontinue participation at any time without penalty or loss of benefits. A decision not to participate or withdraw will not affect your current or future relationship with (Winona State University and/or the institution/agency on whose behalf the research is being conducted).

(Include the following if appropriate: If you decide to withdraw, potential consequences that might result include [describe potential consequences]. The orderly procedure for ending your participation requires [describe the person(s) to be contacted or procedures to be followed]).

(Include the following if appropriate: The investigator may end your participation in the study without your consent if [describe the circumstances under which this might occur]).

Who can I contact if I have questions or concerns about this study?
The main researcher conducting this study is (PI name), a (professor, staff member, student, etc.) at Winona State University. The faculty advisor for this study is (advisor name, phone, email). You may ask any questions you have about the study and your participation now or later during the study.

Who can I contact if I have questions about my rights as a participant?
If you have questions or concerns about your participation in the study, contact the Human Protections Administrator Brett Ayers at 507-457-5519 or bayers@winona.edu. This project has been reviewed by the Winona State University Institutional Review Board for the protection of human subjects.

Agreement to Participate
You are deciding whether or not to participate in this study. Participation is voluntary. You may withdraw at any time after signing this form. Your signature indicates that you have read the information above, had an opportunity to ask questions, and decided to participate.

Your signature: ____________________________ Date _________

Your name (printed): ____________________________________________

Parent, guardian, authorized representative signature (if appropriate): __________________________

Witness signature (if appropriate): __________________________ Date: _________

Signature of person obtaining consent: ___________________________ Date____________

Name of person obtaining consent (printed): __________________________
Assent Form Template

When children are asked to participate in research studies, PIs must explain the study and obtain the child’s agreement to take part. The assent form is separate from obtaining a parent or guardian’s permission for the child to participate. The Winona State IRB requires that assent of a minor child be sought when the child is seven years or older, unless the child’s decision-making capacity is impaired.

For children 7-12 years of age, the assent form must be simple enough for the child to understand what he or she is agreeing to do. For children 13-17, the PI should follow the informed consent template appropriate for the type of study and its review; however, it is very important that language used be suitable to the subject’s reading level.

If the subject population includes a range of ages, it may be necessary to use more than one assent form. The template below is appropriate for the 7-10 years group.

Assent Form: (Name of Research Study)

We are asking you to participate in a research study. A research study is a way to learn more about people. Our research study is about (state the purpose of the study/what it is designed to discover in simple language).

If you decide that you want to be part of this study, you will be asked to (provide a brief description of the research activities and how much time will be involved).

Here are some things about this study that you should know. These are (describes procedures that may take a long time, cause discomfort, or other risks). Your parents know about this study, too.

Not everyone who participates in this study will benefit from it. A benefit is something good that happens to you. We think the benefits of this study might be (provide a brief description of benefits).

(If the study involves treatment or intervention, include this statement: If you do not want to participate in this study, we will tell you what other kinds of treatments are available for you.)

When we finish the study, we will write a report of what we learned. The report will not include your name or that you were in the study.

You can ask questions about this research study at any time. If you decide not to finish, you can ask us to stop.

If you sign this paper, it means you have read this and that you want to be in the study. If you don’t want to be in the study, don’t sign this paper. Being in the study is up to you and no one will be upset if you don’t be part of it or decide not to finish.

I want to be in this study (signature): ________________________ Date ________

Your name (printed): __________________________________________________________________________

Signature of person obtaining consent: ________________________ Date________________

Name of person obtaining consent (printed): ______________________________________________________
Creating Your Own Consent Form

It is recommended that you use the consent form template appropriate to your study. If you do not follow one of the sample templates, federal regulations require that the following specific elements be included.

Note that the 2018 revisions to the Common Rule require that “key information” essential to a “reasonable person’s” decision-making appear at the beginning of the consent form. In addition, the PI must make it clear that he or she will provide sufficient opportunity and time to improve the subject’s understanding by offering more information or answering questions about the research.

1. **A statement that the study involves research.** Use of the first person (e.g., "I understand that...") can suggestive and constitute coercive influence. Make it clear the subject is an invited participant: "You are invited to participate in a research study designed to ..."

2. **An explanation of the purposes of the research.** Avoid scientific jargon and “legalese.” Think of the document as a teaching tool.

3. **The expected duration of participation.** Identify the estimated starting and ending dates of the study and the amount of the subject's time required.

4. **A description of the procedures.** Describe the subject’s' expected overall experience and/or the individual activities involved or procedures to be followed, how long they will take, frequency, etc.

5. **Identification of any procedures that are experimental.** Explain the research activity, how it is experimental, (e.g., a new drug, extra tests, separate research records, or nonstandard means of management, such as flipping a coin for random assignment or other design issues).

6. **A description of any reasonably foreseeable risks or discomforts.** Identify reasonably foreseeable harms, discomforts, inconvenience, and risks (i.e., physical, psychological, social, financial, or otherwise) associated with participation. If additional risks are identified during the study, the consent process and documentation will require revisions to inform subjects as they are re-contacted or newly contacted. If deception is used, include a statement indicating, “the study cannot be described fully at this time, but will be explained at the conclusion of participation.”

7. **A description of any benefits to the subject or to others that may reasonably be expected from the research.** If payment is given, it must not be coercive in amount or method of distribution.

8. **A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.** Describe any alternatives to participating in the research project. For example, in drug studies the medication(s) may be available through a family doctor or clinic. At educational institutions, if students are offered extra credit for participating, an equitable alternative method for earning extra credit must be available for those students who chose not to participate.

9. **A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.** Subjects must be told the extent to which their personally identifiable private information will be held in confidence. For example, some studies require disclosure of information to other parties. Some may require securing a certificate of confidentiality to protect the investigator from involuntary release (e.g., subpoena) of the names or other identifying characteristics of subjects.
10. For research involving more than minimal risk, an explanation as to whether any compensation will be offered, and if medical treatments are available should injury occur and, if so, what they consist of or where further information may be obtained. If research-related injury (i.e., physical, psychological, social, financial, or otherwise) is possible in research that is more than minimal risk, an explanation must be given of whatever voluntary compensation and treatment will be provided. Describe what the institution is voluntarily willing to do in terms of providing for compensation for medical or therapeutic treatment. Subjects should not be given the impression that they are agreeing to waive their legal rights and will not have recourse to seek satisfaction beyond the institution's voluntarily chosen limits.

11. An explanation that questions may be asked about the research at any time, along with whom to contact for answers.

12. An explanation of whom to contact for answers to questions about the research subjects' rights.

13. An explanation of whom to contact in the event of a research-related injury to the subject. The regulations provide for the identification of contact persons who would be knowledgeable to answer questions in the three areas above (11-12-13). These three areas must be explicitly stated and addressed in the consent process and documentation. Because of potential conflicts of interest, a single person is not likely to be appropriate to answer questions in all areas. Questions about the research are frequently best answered by the investigator(s). However, questions about the rights of research subjects or research-related injuries (where applicable) may best be referred to those not on the research team, such as the IRB human protections administrator or other institutional officials. Each consent document can be expected to have at least two names with local telephone numbers for contacts to answer questions in these specified areas.

14. A statement that participation is voluntary, refusal will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled. The statement regarding voluntary participation and the right to withdraw at any time can be taken almost verbatim from the regulations. It is important not to overlook the need to point out that no penalty or loss of benefits will occur by not participating or withdrawing at any time. It is equally important to alert potential subjects to any foreseeable consequences should they unilaterally withdraw while dependent on some intervention to maintain normal function.

The following additional elements must also be included, if appropriate:

1. A statement that a 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.

2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

3. Any additional costs to the subject that may result from participation in the research.

4. The consequences of a subject's decision to withdraw from the research and procedure for orderly termination of participation by the subject.

5. A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject.

6. The approximate number of subjects involved in the study.