University of Wisconsin-Oshkosh
Institutional Review Board (IRB)

STANDARD OPERATING PROCEDURES (SOP)	
SOP Number: 3 Effective Date: May 4, 2016 Updated: April 3, 2019, May 17, 2023 Last Reviewed: May 17, 2023 Prepared By: Anca Miron, Kelly Schill	**Title:** **Informed Consent**

Informed Consent

Purpose:

This standard operating procedure establishes the process for obtaining informed consent from:
1) research participants,
2) parents or guardians of participants who have not obtained legal age (minors), or
3) legally authorized representatives of individuals who are unable to consent.

This standard operating procedure also stipulates when the IRB may approve 1) a waiver of documentation of informed consent or 2) a waiver or alteration of informed consent process.

Informed consent is a process, not just a form. Information must be presented in a clear and complete manner in order for potential participants to voluntarily decide whether or not to participate as a research subject. It is a fundamental mechanism to ensure respect for persons through provision of thoughtful consent. The procedures used in obtaining informed consent should be designed to educate the subject population in terms that they can understand. Therefore, informed consent language and its documentation (especially explanation of the study's purpose, duration, experimental procedures, alternatives, risks, and benefits) must be written in "lay language", (i.e. understandable to the people being asked to participate). The consent document should be concise, focused, and organized to facilitate comprehension. The written presentation of information is used to document the basis for consent and for the subjects' future reference. The consent document should be revised when deficiencies are noted or when additional information will improve the consent process. The researcher should provide participants with an opportunity to obtain a copy of the consent form, even for online studies.

The process of consent begins when an individual identifies a subject as a potential candidate for a research study. The process is complete when a participant or the participant's legally authorized representative provides legally effective informed consent. All steps included in this process from start to finish cohesively establish the informed consent process.

Procedure:

I. Consent Requirements: 45 CFR 46.116

The basic required elements of informed consent can be found in the HHS regulations at 45 CFR 46.116(b). Also see OHRP Informed Consent Tips. The consent document should be concise, focused, and organized to facilitate comprehension.

The regulations require that the following information be conveyed to each subject:

1. A summary/executive statement at the beginning of the consent including key information; see the UWO IRB Consent Template.
2. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
3. A description of any reasonably foreseeable risks or discomforts to the subject;
4. A description of any benefits to the subject or to others which may reasonably be expected from the research;
5. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
6. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
7. For research involving more than minimal risk, 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;
8. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
9. A statement that participation is voluntary, refusal to participate 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.
10. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens (new under Revised Common Rule):
    (i) 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 a possibility; OR
    (ii) 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.

II. Additional Consent Elements: 45 CFR 46.116(b)

When determined to be appropriate by the Institutional Review Board (IRB), subjects must be provided with one or more of the following additional elements of information during the informed consent process (see 45 CFR 46.116(b)):

1. 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;
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 procedures 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; and
6. the approximate number of subjects involved in the study
7. 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; (new under Revised Common Rule)

8. a statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; (new under Revised Common Rule) and
9. 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). (new under Revised Common Rule)

It is up to the IRB to determine in a particular instance whether some or all of the above additional elements must be included as part of the informed consent process for a particular study. The IRB should make this determination based on the nature of the research and its knowledge of the local research context. If the IRB determines that additional elements are appropriate to the research study, this additional information should be considered just as essential as the basic elements of informed consent described in the HHS regulations at 45 CFR 46.116(a). Furthermore, an IRB may require additional information beyond the basic and additional elements be given to subjects during the informed consent process, when in the IRB's judgment the additional information would meaningfully add to the protection of the rights and welfare of the subjects 45 CFR 46.109(b). The IRB may also require that additional information be presented in the consent process to comply with institutional policy and local law.

III. Documentation of Informed Consent: 45 CFR 46.117

1. Informed consent shall be documented under 45 CFR 46.117 by the use of a written consent form approved by the IRB, and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form. (Note: An exception is provided in 46.117 paragraph c, see below Part IV. Waiver of Requirement for Documentation of Consent)

2. The consent form may be either of the following:
   a. **Standard Written Consent Form**: A written consent document that embodies the elements of informed consent required by §46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator should give either the subject or the representative adequate opportunity to read it before it is signed.
      - Electronic Signature: Standard Written Consent can be presented to the participant in an electronic format. 46.117(a) under the revised common rule, now specifically allows electronic signatures and specifies that a written copy must be given to the person signing the consent form.
        - According to OHRP FAQs, electronic signature of the document is allowed if such signatures are legally valid within the jurisdiction where the research is to be conducted.
        - OHRP does not mandate a specific method of electronic signature. Rather, OHRP permits IRBs to adopt such technologies for use as long as the IRB has considered applicable issues such as how the electronic signature is being created, if the signature can be shown to be legitimate, and if the consent or permission document can be produced in hard copy for review by the potential subject. One method of allowable electronic signatures in some jurisdictions is the use of a secure system for electronic or digital signature that provides an encrypted identifiable "signature." If properly obtained, an electronic signature can be considered an "original" for the purposes of recordkeeping.

   b. **Short Form with Oral Presentation**: A short form written consent document, stating that the elements of informed consent required by §46.116 have been presented **orally** to the subject or the subject's legally authorized representative. When this method is used, there

shall be a **witness** to the oral presentation. Also, the IRB shall approve a **written summary** of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form. Additional information on the short form method and a sample short form template can be found on OHRP's website.

IV. Waiver of Requirement for Documentation of Consent: 45 CRF 46.117 (c)

An IRB may waive the requirement for the investigator to **obtain a signature** on the consent form for some or all subjects under 45 CFR 46.117 (c), if it finds either:

a. That the only record linking the subject and the research would be the consent document, and the **principal risk** would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; OR

b. That the research presents **no more than minimal risk** of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

c. It is not the cultural norm for subjects to sign such documents, and the IRB determines that the research is no more than minimal risk and an alternative documentation mechanism is used for documenting informed consent. (New under revised common rule)

"Waivers of documentation" only mean that no signature is obtained; it is still good research practice to document (record) occurrence of the consent process and that the subject agreed to participate in the research.

In cases in which the documentation of consent with signature is waived, the researcher must present (verbally, written, electronically) all required elements of consent to the participant. UW Oshkosh IRB recommends as a best practice that researchers provide prospective participants with an Information Sheet about the research which contains the required elements of consent.

Parental Permission/Consent for Child Participants:
The IRB has the same authority to waive the requirement for parental consent as it does to waive consent in other contexts. In some circumstances, obtaining parental permission may be against the best interest of the child (i.e., studies of abused or neglected children).

Assent for Child Participants:
An IRB may waive the requirement for obtaining and documenting child assent. In determining whether children are capable of assenting, the IRB considers the age, maturity, and psychological state of the children. In most cases, it is appropriate to obtain assent from subjects between the ages of 8 and 17 unless a clear justification for a waiver of assent is provided. The assent should be written and presented in a way the child understands. Assent may be obtained by signature or verbally and documented by the researcher.

V. IRB Latitude to Approve a Consent Procedure that Alters or Waives some or all of the Elements of Consent (45 CFR 46.116)

There are circumstances under which the regulations give IRBs authority to waive or alter the required elements of the consent process. The IRB's authority to waive or alter the consent process is described in section 45 CFR 46.116 (e),(f) of the federal regulations.

1. The first waiver authority is applicable only to research activities designed to study certain aspects of public benefit or service programs; provided **both** of the following conditions under 45 CFR 46.116(e) are met:

    a. The research or project to be conducted is subject to approval of state or local government officials and is designed to study, evaluate or otherwise examine: 1) Public benefit or service programs; 2) Procedures for obtaining benefits or services under those programs; 3) Possible changes in or alternatives to those programs or procedures; or 4)Possible changes in methods or levels of payment for benefits or services under those programs; and
    b. The research could not be practicably carried out without the waiver or alteration.

    Note: The subjects may belong to a vulnerable population

2. The second waiver authority is for research in general. For example, a researcher may request an alteration of the required elements of informed consent for a study involving deception. In some cases, a researcher may request a waiver of the informed consent process. An example of a complete waiver of the informed consent process may be an internet-based or online study when all of the below conditions are met. This second waiver authority is described at 45 CFR 46.116(f), provided **all applicable criteria** are met:

    a. The research involves no more than minimal risk to the subjects
    b. The waiver or alteration will not adversely affect the rights and welfare of the subjects
    c. The research could not practicably be carried out without the waiver or alteration; and
    d. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
    e. If the research involves using identifiable biospecimens, the research could not be practicably be carried out without using such information or biospecimens in an identifiable format. (New under revised Common Rule)
        i. The purpose of this additional criterion is that if the research could be done using non-identifiable information, then that is what should be done. In these cases, researchers shouldn't be using identifiable information because it increases the risk of breaches of privacy or confidentiality.

Screening, Recruiting, or Determining Eligibility 45 CFR 46.116 (g) :
Under the revised Common Rule, an IRB may approve a proposal for the investigator to obtain information or biospecimens to screen, recruit, or determine eligibility of prospective subjects for a research study without informed consent. In other words, the revised Common Rule removes the pre-2018 Common Rule requirement for an IRB to approve a waiver of informed consent for these types of activities. This is applicable if (1) the information is obtained through oral or written communication with the subject or the subject's legally authorized representative, or (2) identifiable private information or identifiable biospecimens are obtained by accessing records or stored identifiable biospecimens. This change harmonizes with FDA.

VII. Special Consent Requirements: Additional Protections for Children Involved as Subjects in Research under 45 CFR 46 Subpart D

2. **Obtaining Parental Permission and Assent from Minors** (45 CFR 46.408)
Regulations provided under 45 CFR 46.408 state the requirements needed for permission by parents or guardians and for assent by children. Parental permission should be obtained prior

to assenting children to participate in a research activity. Research involving minors requires the PI to obtain documented, signed permission from parents allowing their child to participate in research activities (following Consent Requirements outlined in Part I of this SOP) unless waived by the IRB in accord with 45 CFR 46.116(e) and (f). The IRB shall determine that adequate provisions are made for soliciting the assent of the child, when in the judgement of the IRB the children are capable of providing assent.

3. **Requirements for Permission by Parents or Guardians and for Assent by Children**: 45 CFR 46.408

    a. In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate.
    b. In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine, in accordance with and to the extent that consent is required by §46.116 of Subpart A, that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under 45 CFR 46.404 or 45 CFR 46.405. Where research is covered by 45 CFR 46.406 and 45 CFR 46.407 and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.
    c. In addition to the provisions for waiver contained in 45 CFR 46.116(e) and (f), if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements in Subpart A of this part and paragraph (b) of this section, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with federal, state, or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.
    d. Permission by parents or guardians shall be documented in accordance with and to the extent required by 45 CFR 46.117.
    e. When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

4. **Assent of Child**:

Age, maturity and psychological state should all be taken into account when determining if a child is able to assent. When assent is required, the PI must describe in the protocol how assent will be obtained and where it will be documented. Assent may be obtained with a written document or verbally. When assent is obtained, the PI will provide the minor with a written document at an appropriate age and reading level for the child or provide a verbal explanation of the study. The study information should be explained in terms simple enough for the minor(s) to understand. The PI will allow time for the minor to ask questions and for the PI to answer the questions about anything that is not clear.

Information included on the assent form should be written or explained to the extent that the child is able to understand it. The PI should provide the following information when obtaining assent:

a. A statement of what the research is about
b. What the participant is being asked to do
c. What the risks are likely to be
d. What benefits there might be
e. That participation is entirely voluntary

5. **Waiver of Assent**
The Institutional Review Board (IRB) is responsible for deciding whether child assent is required in proposed research activities. The IRB should require child assent unless it can be appropriately waived, or if the child is not capable of providing assent. The regulations at 45 CFR 46.408(a) identify three types of circumstances where the IRB may determine that waiver of children's assent is appropriate:
   a. if the capability of some or all of the children is so limited that they cannot reasonably be consulted;
   b. if the intervention or procedure involved in the research holds out the prospect of direct benefit to the health or well-being of the children and is available only in the context of the research.
   c. if the research meets the same conditions as those for waiver or alteration of informed consent in research involving adults, as specified in the regulations at either 45 CFR 46.116(e) or 45 CFR 46.116(f).

6. **Special Considerations Regarding Obtaining Consent or Assent of Child**
According to the Protection of Pupil Rights Amendment (PPRA), parents/legal guardians have the right to inspect surveys given to their children under 18 and provide active consent when the surveys contain "protected information." There are 8 types of protected information:

   a. Political affiliations of student or student's parent;
   b. Mental or psychological problems of student or student's family;
   c. Sex behavior or attitudes;
   d. Illegal, anti-social, self-incriminating or demeaning behavior;
   e. Critical appraisals of others with whom students have close family relationships;
   f. Legally recognized privileged or analogous relationships;
   g. Religious practices, affiliations or beliefs of student or student's parent;
   h. Income

   Parents/legal guardians have the right to inspect the survey and then grant consent to their child participation, under two conditions:
   - When the surveys are funded in whole or in part by the U.S. Department of Education.
   - When the surveys are funded by sources other than the U.S. Department of Education and that are administered or distributed by educational institutions that receive funds from any Department of Education program (i.e., public elementary and secondary schools and some private schools).

VIII. Consent Process

Obtaining informed consent is more than just having a participant provide their signature for the PI. The entire informed consent process consists of the exchange of appropriately explained information between the research team and the potential participant(s), allowing the potential participants adequate time to review and process the presented information, and to ask questions as necessary; and having the individual provide their voluntary agreement to take part in the study. The regulations for the protection of human subjects require that informed consent be presented "in language understandable to the subject".

Definitions:

- Participant: An adult capable of assenting or consenting to be in a study.
- Investigator: An individual approved by the IRB to obtain informed consent for the specific protocol. This may include the Principal Investigator, Co-PI, or research personnel. These individuals must be listed on the approved protocol.
- Legally Authorized Representative (LAR): A person authorized by statute or court appointment to make decisions on behalf of another, in this case, on behalf of the participant; or one or both biological or adoptive parents when the participant is a minor. The LAR is not considered a participant of the study. If there is not an applicable law addressing the issue of who may serve as a legally authorized representative, institutional policies that are in place in a non-research context (for example, a clinical context) may be used.
- Witness: An individual who attends the informed consent process if the participant or their legally authorized representative cannot read or is a non-English speaker. The impartial witness reads the informed consent form and any other written information supplied to the participant.
- Impartial witness: Similar to a witness except that the impartial witness must not have any relation to the participant(s) and must not be part of the research team.
- Risk: Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Risks encountered in research may be physical, social, psychological, legal, or risks to employment or economic well-being. All risks must be fully disclosed to participants, even if they are no greater than minimal risks.
- Penalty: A punishment imposed or incurred for a violation of law or rule.
- Coercion: Occurs when an overt or implicit threat of harm is intentionally presented by one person to another in order to obtain compliance. For example, a PI might tell a prospective subject that they will lose access to needed health services if they do not participate in the research.
- Undue influence: Occurs through an offer of an excessive or inappropriate reward or other overture in order to obtain compliance. For example, an investigator might promise psychology students extra credit if they participate in the research. If that is the only way a student can earn extra credit, then the investigator is unduly influencing potential subjects. If, however, she offers comparable non-research alternatives for earning extra credit, the possibility of undue influence is minimized.

1. Responsibilities:
   The Principal Investigator listed on the protocol is responsible for ensuring that these procedures are followed as appropriate.

   General tips for an informed consent document are published in a guide from the Centers for Disease Control and Prevention (CDC). These tips include the following:

   - Using plain and simple language
   - Avoiding abbreviations and jargon
   - Limiting sentences to 8-10 words
   - Avoiding long paragraphs
   - Presenting one idea or concept at a time
   - Writing at 8th grade reading level or below

   The consent form must be approved by the IRB prior to use by the PI on a study. Either the participant or the participant's LAR will have read, understood, and signed the form prior to participation in the study. If minors are involved as participants, the PI will have obtained parental permission and assent from the minor.

2. The consent document may be either of the following:

a. A written consent document that includes all elements of informed consent as listed above (45 CFR 46.116). The form may be read to the participant(s) or their LAR. The participant will be given adequate time to read through the document before they provide signature.
b. A short form consent document stating that the elements of informed consent listed above (45 CFR 46.116) have been presented orally to the participant or their LAR. An impartial witness must be present during the presentation when this method is utilized.

The consent document can be in one of two versions: the standard form of consent or the short form of consent, as described below:

A. Consent Process Documented Using the Standard Form of Consent Documentation

1. The standard form is used when no waiver of documentation of informed consent is used and/or no non-English speaking participants are involved.
2. Templates of a consent document can be found on the IRB Forms page. The template must be modified by the PI so it fits the study design. The PI must ensure that all required elements of consent and applicable additional elements are included.
3. The consent form must be in a language that is understandable to the participant(s) and, if possible, should be provided to the prospective subject in advance of the consent discussion.
4. If the prospective subject **cannot read** then a witness (impartial witness recommended) must be present during the entire consent discussion to confirm that the information provided on the consent form, along with any other information provided, was appropriately explained and subsequently understood by the participant. If the prospective subject **cannot speak English**, refer to SOP #4: ***Non-English Speaking Participants*** for appropriate procedure.
5. The consent document will be used as a guide for the verbal explanation of the study. Principal Investigators (or their IRB-approved designees) must fully explain the research intentions to participants, also including the potential risks and benefits that participants may obtain through participation. The PI (or another research personnel on protocol) will follow this procedure for explanation of the research.
6. Following the verbal explanation, the prospective subject will be given adequate time to review the consent document and to ask questions. It is important to note that "adequate time" may even mean hours or days depending on the information exchanged and the time it takes the prospective subject to review that information.
7. Once the individual has had all of their questions answered and has agreed to participate in the study, they will sign and date the consent form (the LAR may sign on behalf of the individual). Once the consent document is signed, the individual is considered a participant.
8. Collection of signatures from the participant and witness (if a witness is required) will generally occur at the same time. The PI signature on the consent form is recommended.
9. The PI's signature cannot pre-date the participant's.
10. The participant will be provided with a copy of the consent form for future reference and as a source of contact information for the PI.
11. The consent document will include contact information for the PI and faculty supervisor (if applicable). If the PI does not wish to provide their personal contact information they can provide information for their departmental office instead.
12. If included, PI signature on the consent form signifies that the participant:
    a. Meets all study criteria
    b. Has appropriately consented
    c. Understands the study requirements

13. A witness must be present to observe the consent process when any of the following situations apply:
    a. When the short form process is used for participants who do not speak English (See SOP #4)
    b. When obtaining informed consent from a participant (in which the IRB deems capable of providing consent) who can understand the language but is not able to read, write, talk, or is blind. In this case, the individual providing informed consent must be able to indicate approval/disapproval by some other means
        - The method utilized to obtain approval/disapproval must be documented on the consent form by the witness.
        - At the end of the informed consent process, the witness must sign and date the consent form. They will attest that consent was voluntarily given by the participant (or their LAR or guardian) and that no element of influence, coercion or other untoward means of obtaining their consent were utilized.
14. When possible, if an individual chooses to withdraw from the study, the individual will be offered a different benefit of equal value to the benefit received by participants. For example, if a student decides to withdraw from a classroom-based research study where extra credit is given for participation, an alternative assignment with similar benefit must be offered to them. Alternative assignments should be comparable in the amount of time and effort to participate in study.

B. Consent Process Documented Using the Short Form of Consent Documentation

1. See **SOP #4**: ***Non-English Speaking Participants***
2. The short form is used when unanticipated non-English speaking participants are included in the study.
    a. Note: The use of the short form consent documentation is not intended to be used when a large population of participants lacking proficiency in the English language are involved in the study. If this is the intention, the PI should plan to use consent documents which have been translated into the native language of the participants.
3. OHRP offers a sample short form written consent document for subjects who do not speak English.

IX. Special Considerations for Consent

A. Individuals with Impaired Consent Capacity and Legally Authorized Representative

If the participant is an adult who is unable to give his or her own consent, the following procedure must be followed:

1. The IRB must have specifically approved the protocol to allow enrollment of individuals unable to give consent.
2. Consent must be obtained from the participant's Legally Authorized Representative (LAR).
3. The IRB may determine whether participant assent is appropriate when the participant has a Legally Authorized Representative.

B. Informed Consent of Non-English Speaking Subjects

See SOP #4: Non-English Speaking Participants for information.

C. Informed Consent when HIPAA Regulations Apply

The Health Insurance Portability and Accountability Act (HIPAA) is a complex regulation that affects many researchers. HIPAA is designed to protect the use and disclosure of individually

identifiable health information. Principal Investigators planning to use or share protected health information for research purposes must use that information in accordance with HIPAA. Where the Privacy Rule requires patient authorization, voluntary consent is not sufficient to permit the use or disclosure of protected health information unless it also satisfies the requirements of a valid authorization. An authorization is a detailed document that gives covered entities permission to use protected health information for specified purposes.

A HIPAA authorization form must specify a number of elements, including:

1. Description of the protected health information to be used and disclosed
2. The person authorized to make the use or disclosure
3. The person to whom the covered entity may make the disclosure
4. An expiration date
5. The purpose for which the information may be used or disclosed.

If a PI plans to work with or disclose protected health information, they may choose to request a waiver or alteration of HIPAA Authorization. A waiver or alteration of HIPAA authorization may be granted by the IRB only if **all** the following criteria are met:

1. The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:
    a. an adequate plan to protect the identifiers from improper use and disclosure;
    b. an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
    c. adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;
2. The research could not practicably be conducted without the waiver or alteration; and
3. The research could not practicably be conducted without access to and use of the protected health information.
4. Please see the UWO IRB consent template language HIPAA Authorization on the website IRB Forms.

D. Informed Consent when FERPA Regulations Apply

The Family Educational Rights and Privacy Act (FERPA) is a Federal law administered by the U.S. Department of Education; 34 CFR Part 99 and applies to all educational agencies and institutions that receive federal funding. FERPA aims to protect the privacy of Student Education Records. Researchers wishing to use FERPA protected student education records for research purposes must follow additional consent requirements. Education records include any record containing personally identifiable information (PII) directly related to the student. PII is not limited to name,but may include indirect identifiers as well. Please see IRB SOP#10 for Guidance on FERPA.

Consent:

Use of educational records for research purposes requires consent. Consent form must include the following to comply with FERPA:

- Specify the records to be disclosed;
- State the purpose of the disclosure;
- Identify the party to whom the disclosure is to be made;
- Include a dated student signature

Exceptions:
Exceptions allowing for the use of educational records for research purposes without consent include:

- The only PII obtained constitutes "directory information" and the student has not opted out of having their information included in the directory;
- The release is to an authorized representative of state/local educational authorities for an audit or evaluation of federal or state supported education programs, or for the enforcement of or compliance with federal legal requirements related to those programs;
    - Investigators must provide IRB with evidence that they are acting as authorized representatives of a state or local educational authority and that their audit or evaluation meets the conditions described above (e.g. a Memorandum of Understanding between university and educational authority);
- The release is to organizations conducting studies for or on behalf of educational agencies or institutions to develop, validate or administer predictive tests; administer student aid programs; or improve instruction;
    - A written agreement which meets criteria listed in FERPA between the university and the educational agency or institution is required.

E. Posting of Consent Document for Clinical Trials

- Posting of clinical trial consent for research conducted or supported by a Common Rule Department or Agency (i.e., NIH, NSF, DOE) on a publicly available federal website designated as repository (ClinicalTrials.gov or designated docket folder on Regulations.gov Docket ID: HHS-OPHS-2018-0021). For a current listing of Federal Departments or Agencies that follow the Common Rule, see: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html
    - Under the revised Common Rule, the term "clinical trial" refers to research studies in which one or more human subjects are prospectively assigned to one or more interventions to evaluate the effects of the intervention on biomedical or behavioral health-related outcomes. For such studies, one IRB-approved version of a consent form that has been used to enroll participants must be posted after recruitment closes, and no later than 60 days after the last study visit. Federal departments or agencies may permit or require redactions as appropriate.

References:

Office for Human Research Protections. Informed Consent FAQs: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html
Centers for Disease Control. "Consent for CDC Research: A Reference for Developing Consent Forms and Oral Scripts." Online: Found at: http://stacks.cdc.gov/view/cdc/12420/

Northwestern University. "Waiver or Alteration of the Requirements for Obtaining Informed Consent." Online: Found at: https://irb.northwestern.edu/process/new-study/informed-consent/waiver-or-alteration-requirements-obtaining-informed-consent. Accessed 4/11/16

University of California, Irvine. "How to Consent." Online: Found at www.research.uci.edu/compliance/human-research-protections/researchers/how-to-consent.html. Accessed on 4/7/2016

University of Massachusetts. "SOP: Informed Consent Process for Research." Online: Found at: www.umassmed.edu/contentassets/d7b0558aeca9412ca5661f55fb7540ce/umms-**hrp-090**---sop---informed-consent-process-for-research.pdf . Accessed on 4/7/16.

University of Wisconsin. FERPA Guidance: https://kb.wisc.edu/sbsedirbs/42988 . Accessed on 2/20/2023

Code of Federal Regulations. Online: Found at:
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html. Accessed on 4/7/16
https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html