**University of Wisconsin Oshkosh IRB**

**Checklist for Expedited Review** [**45 CFR 46.110**](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.110)

**Revised Common Rule (Effective 1-19-18)**

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| **Protocol Number (entered by IRB staff):** | | |
| **Project Title:** | | |
| **Principal Investigator(s):** | **Student Name (if applicable):** | |
| **IRB Expedited Reviewer:** | | **Date Reviewed:** |

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| **Criteria:**  ***To be eligible for expedited review, the proposed research must meet at least one of the categories below, and involve no procedures not included in this list (***[***45 CFR.46.110***](http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm)***). Indicate below all categories that apply to the proposed research.*** |
| **Expedited Category #1**  **Clinical studies of drugs and medical devices only when condition (a) or (b) is met.**   1. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.) 2. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.   **Expedited Category #2** **Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:**   1. from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or 2. from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.   **Expedited Category #3** **Prospective collection of biological specimens for research purposes by noninvasive means.**  Examples:   1. hair and nail clippings in a nondisfiguring manner; 2. deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; 3. permanent teeth if routine patient care indicates a need for extraction; 4. excreta and external secretions (including sweat); 5. uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; 6. placenta removed at delivery; 7. amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; 8. supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; 9. mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; 10. sputum collected after saline mist nebulization.   **Expedited Category #4**  **Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.**  Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)  Examples:   1. physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject=s privacy; 2. weighing or testing sensory acuity; 3. magnetic resonance imaging; 4. electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; 5. moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.   **Expedited Category #5**  **Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).**  (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101(b)(4)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101). This listing refers only to research that is not exempt.)  **Expedited Category #6**  **Collection of data from voice, video, digital, or image recordings made for research purposes.**  **Expedited Category #7**  **Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.**  (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101(b)(2) and (b)(3)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101). This listing refers only to research that is not exempt.)  **Expedited Category #8**  **Continuing review of research previously approved by the convened IRB as follows:**   1. **where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or** 2. **where no subjects have been enrolled and no additional risks have been identified; or** 3. **where the remaining research activities are limited to data analysis.**   **Expedited Category #9**  **Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories 2-8 do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.** |

**Applicability of the Expedited Categories:**

Expedited review procedures can be considered when research activities:

1. minimal risk to human subjects OR new: rationale why study is more than minimal risk is documented by IRB
2. involve only procedures listed in one or more of the nine categories.

The categories 1-7 apply regardless of the age of subjects, except as noted. Researchers are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) also apply to expedited review.

**When Expedited Review Categories do not apply**

* The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
* The expedited review procedure may not be used for classified research involving human subjects.

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| [**45 CFR 46.111**](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.111) **Criteria for IRB Approval of Research** | | |
| **In order to approve research, the IRB shall determine that all of the following 7 criteria are met. When some or all of the subjects are likely to be vulnerable, additional safeguards have been included in the study to protect the rights and welfare of these subjects.** | | |
|  | 1. **Risks** | |
|  | 1a | Are risks clearly identified and explained? |
| 1b | Risks to subjects are minimized: By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, AND |
| 1c  or  N/A | Risks to subjects are minimized: Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes |
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|  | 1. **Benefits**   Risks to subjects are reasonable in relation to anticipated benefits. In evaluating risks and benefits, reviewers should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility. | |
|  | 2a | Benefits to subjects and to society at large are clearly described and explained |
| 2b | Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. |
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|  | 1. **Selection of Subjects is Equitable**   In making this assessment reviewers should take into account the purposes of the research and the setting in which the research will be conducted and, It should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. | |
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|  | 1. **Informed Consent**   Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by [45 CFR 46.116](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116#46.116). The requirements for informed consent (or for altering or waiving the requirement for informed consent) apply regardless of whether research is reviewed by the convened IRB or under an expedited procedure. | |
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|  | 1. **Documentation of Informed Consent**   Informed consent will be appropriately documented, in accordance with, and to the extent required by [45 CFR 46.117](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.117#46.117) | |
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|  | 1. **Safety of Subjects**   When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. | |
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|  | 1. **Privacy and Confidentiality**   There are adequate provisions to protect theprivacy of subjects and to maintain the confidentiality of data. | |
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| **INFORMED CONSENT** | | | | | |
| **Consent Process Selected for Research: (Select one method in blue below and all applicable criteria)** | | | | | |
| ***Documentation of Informed Consent***: Informed consent will be appropriately signed by subject or LAR (new: even in electronic format), in accordance with, and to the extent required by [45 CFR 46.117](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.117#46.117). New: the consent document may be read to the subject and the subject or LAR will receive a written copy of the consent form. | | | | | |
| 5a1 | | | Standard consent document is proposed **OR** | | |
| 5a2 | | | Short form consent document is proposed (Non-English Speaking Participants) | | |
|  | | | | 5a2i | Verbal consent script is attached |
| 5a2ii | Witness and subject signature line appears on short form consent document **and** |
| 5a2iii | Summary sheet is provided which includes basic elements and additional elements that were presented orally with new: key information presented first. Witness signs this. |
| Short Form Process: | * Subject or LAR signs the short form and receives a copy of 1) short form AND 2) summary sheet. * A witness observes the oral presentation of consent information and signs the 1) short form AND 2) IRB-approved summary information sheet. * The person obtaining consent signs the summary information sheet. * Signature waiver not allowed for short form consent process |
| ***Request for a Waiver for Documentation/Signature of Informed Consent*** [45 CFR 46.117 (C)](http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/#46.117)  An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds any of the following: | | | | | |
| Select at least **one** of the following criteria: | | | The only record linking the participant and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality OR | | |
| the research presents no more than minimal risk to the participant and involves no procedures for which written consent is normally required outside of the research setting | | |
|  | | | New: It is not the cultural norm for subjects to sign such documents, and the IRB determines, 1) the research is no more than minimal risk  AND 2) an alternative documentation mechanism is used for documenting informed consent | | |
| ***Request for a Waiver or Alteration of Some or all of the Elements of Informed Consent*** If criteria in 45 CFR [46.116](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.116) (E) or (F) are met: | | | | | |
| **Both** criteria must be met per [46.116](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.116c) (e) | | | The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; AND  The research could not practicably be carried out without the waiver or alteration.  Note: Subjects may be vulnerable, economically disadvantaged, elderly, or decisionally impaired. | | |
| **All** applicable criteria are met per [46.116)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.116d)(f) | | | The research involves no more than minimal risk to the subjects  The waiver or alteration will not adversely affect the rights and welfare of the subjects  The research could not be practically carried out without the waiver or alteration  Whenever appropriate, the subjects will be provided with pertinent information after participation  New: If the research involves using identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format. | | |
| **INFORMED CONSENT CHECKLIST** [**46.116**](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.116) | | | | | |
| **New: Concise Presentation of Key Information 46.116 (a)** | | | | | |
|  | Consent begins with concise, focused, and organized presentation of key information  1a)  Key information is organized and presented in a way that facilitates comprehension  1b)  Key information will assist in understanding the reasons why one might or might not choose to participate in the research.  Note: This new section is NOT eligible for waiver or alteration of consent. | | | | |
| **Basic Required Elements of Consent 46.116 (b)** | | | | | |
|  | 1. **A statement that the study involves research**   1a) An explanation of the purposes of the research  1b) The expected duration of the subject's participation  1c) A description of the procedures to be followed  1d) Identification of any procedures which are experimental  OR  N/A | | | | |
|  | 1. **A description of any reasonably foreseeable risks or discomforts to the subject** | | | | |
|  | 1. **A description of any benefits to the subject or to others which may reasonably be expected from the research** | | | | |
|  | 1. **A disclosure of appropriate alternative procedures or course of treatment, if any, that may be advantageous to the subject** OR  N/A | | | | |
|  | 1. **A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained** | | | | |
|  | 1. **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** OR  N/A | | | | |
|  | 1. **Identification of whom to contact for answers to pertinent questions about the research**   7a) Identification of researcher and contact information  7b) Identification of whom to contact for answers to questions about the research subjects' rights  7c) Identification of whom to contact in the event of a research-related injury to the subject  OR  N/A | | | | |
|  | 1. **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** | | | | |
|  | 1. **New: Research collecting identifiable information and/or identifiable private information and/or identifiable biospecimens must state plan for future use.**   9a) State that collected samples/data may be de-identified and used for future research or be given to another investigator for future research without additional informed consent  OR  9b) State that collected samples/data will not be used for future research, even if de-identified | | | | |
| **Additional Elements That May Be Required by the IRB (when found appropriate)** [**46.116**](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.116) **(c)** | | | | | |
|  | N/A | 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 | | | |
|  | N/A | Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent | | | |
|  | N/A | Any additional costs to the subject that may result from participation in the research | | | |
|  | N/A | The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject | | | |
|  | N/A | 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 | | | |
|  | N/A | The approximate number of subjects involved in the study | | | |
|  | N/A | New: A statement regarding whether clinically relevant research results will be given to the subject and under what conditions. Note: There may be College of American Pathologists (CAP) and Clinical Laboratory Improvement Amendments (CLIA) to consider relating to the return of research results to subjects. | | | |
|  | N/A | New: A statement that biospecimens, even if de-identified, may be used for commercial profit and whether/if that profit will be shared | | | |
|  | N/A | New: For research involving biospecimens, whether the research will or might include (specifically) whole genome or exome sequencing | | | |
| **Other Consent Considerations** | | | | | |
|  | Project clearly describes a plan/procedure for obtaining prospective, legally effective informed consent from each research subject or the subject's legally authorized representative. | | | | |
|  | Consent will be sought under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence | | | | |
|  | The information that is given/presented to the subject is in a language understandable to the subject or the representative. | | | | |
|  | Consent process and documents do not contain any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence. Unless the consent process is waived, an appropriate written consent document is provided. | | | | |
|  | All applicable federal, state, local laws or policies will be followed in order for informed consent to be legally effective. | | | | |

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| **REVIEWERS DETERMINATIONS** |
| **Attachments/Appendices**: All necessary attachments are included (recruitment flyers or script, site permission when applicable, consent document(s), surveys or questionnaires, interview scripts, CITI training completion reports, etc.)  Please note any missing attachments/appendices here: |
| **Reviewer’s Recommendation for Approval/Revisions (select one):**  **Approve as Submitted**  **Request Changes (to secure approval)-** placereviewer comments below and check (a) or (b):   1. Revisions requested are administrative in nature and can be verified by IRB Staff 2. Revisions requested need to be sent back to Expedited Reviewer(s) to verify satisfaction for approval   **Request Full Board Review** |
| **Reviewer Risk Determination (select one):**  **Minimal Risk**  **More than Minimal Risk**: Provide rationale why study is more than minimal risk required under Sec\_.115(a)(8): |
| **Reviewer Continuing Review Determination (select one):**  **Continuing Review Requested.** Indicate the frequency for review:  6 month 12 month  Other:  Provide justification for continuing review (required):  **OR**  **Continuing Review Not Requested** |

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| **Reviewer Comments:** |