Human Research Protections (HRP) strives to ensure that people with disabilities have access to all services and content. If you experience any accessibility-related issues with this form or any aspect of the ZOT IRB application process, email [OR-Web-Support@uci.edu](mailto:OR-Web-Support@uci.edu) for assistance.

INSTRUCTIONS

This information is necessary for the IRB to determine whether a waiver of consent, signed consent, or HIPAA Authorization are appropriate. For more information, visit: [Drafting the Informed Consent](https://research.uci.edu/human-research-protections/subject-enrollment/informed-consent/drafting-the-informed-consent-form/) and [Protected Health Information (HIPAA)](https://research.uci.edu/human-research-protections/assessing-risks-and-benefits/privacy-and-confidentiality/protected-health-information-hipaa/).

Answer all questions succinctly using non-technical language as much as possible.

* If a question is a numbered list, respond with a corresponding numbered list.
* If a question is not applicable to the research, state “N/A”.
* If a question is not answered, the IRB does not know if the question was overlooked. This will result in unnecessary “back and forth” for clarification.

1. STUDY INFORMATION

**Short Title:** Specify the short study title.

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| Click or tap here to enter text. |

2. GENERAL WAIVER (NO CONSENT) OR ALTERATION OF CONSENT

*This section is not applicable.*

[**45 CFR 46.116(f):**](https://www.ecfr.gov/current/title-45/part-46#p-46.116(f)) **General waiver or alteration of consent.**

**Assurance:** Provide assurance that all the following are true and addressed in the ‘Privacy and Confidentiality' and 'Risk/Benefit Assessment' sections of the Protocol Narrative.

The research involves no more than minimal risk to participants;

If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;

The waiver or alteration will not adversely affect the rights and welfare of the participants; and

Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

**Return of Information:** Explain whether it is appropriate to provide participants with additional pertinent information after their participation in the research.

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| Click or tap here to enter text. |

**Consent Waiver Rationale:** Specify why the research could not practicably be conducted without the waiver.Practicably means [capable of being done](https://www.hhs.gov/ohrp/sachrp-committee/recommendations/2008-january-31-letter/index.html); it should not be determined by considerations of convenience, cost, or speed.Select all that apply.

It would not be feasible to individually contact the large numbers of potential subjects in the study.

It would not be possible to locate many of the individuals whose records would be used for the study.

Many of the individuals, whose records would be used for the study, are now deceased.

Requiring informed consent may introduce systemic bias into the information.

The risk of contacting the subjects to obtain informed consent is greater than the risk of the study procedures.

Other, *provide scientifically and ethically justifiable rationale.*

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| Click or tap here to enter text. |

3. WAIVER OR ALTERATION OF CONSENT - PUBLIC BENEFIT OR SERVICE PROGRAMS (UNCOMMON)

*This section is not applicable.*

[**45 CFR 46.116(e)**](https://www.ecfr.gov/current/title-45/part-46#p-46.116(e))**: Waiver or alteration of consent in research involving public benefit and service programs conducted by or subject to the approval of state or local officials.**

**Research/Project:** Describe how the research/project is to be conducted by or subject to the approval of state or local government officials.

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| Click or tap here to enter text. |

**Research/Project Focus:** Specify what the research/project is designed to study, evaluate, or otherwise examine and provide the rationale below. Select all that apply.

Public benefit or service programs;

Procedures for obtaining benefits or services under those programs;

Possible changes in or alternatives to those programs or procedures; or

Possible changes in methods or levels of payment for benefits or services under those programs

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**Consent Waiver Rationale:** Specify why the research could not practicably be conducted without the waiver.Practicably means [capable of being done](https://www.hhs.gov/ohrp/sachrp-committee/recommendations/2008-january-31-letter/index.html); it should not be determined by considerations of convenience, cost, or speed.Select all that apply.

It would not be feasible to individually contact the large numbers of potential subjects in the study.

It would not be possible to locate many of the individuals whose records would be used for the study.

Many of the individuals, whose records would be used for the study, are now deceased.

Requiring informed consent may introduce systemic bias into the information.

The risk of contacting the subjects to obtain informed consent is greater than the risk of the study procedures.

Other, *provide scientifically and ethically justifiable rationale.*

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| Click or tap here to enter text. |

4. WAIVER TO OBTAIN SIGNED CONSENT

*This section is not applicable.*

[**45 CFR 46.117(c)**](https://www.ecfr.gov/current/title-45/part-46#p-46.117(c)) **and** [**21 CFR 56.109(c)(1)**](https://www.ecfr.gov/current/title-21/part-56#p-56.109(c)(1))**: Waiver of the requirement to obtain a signed informed consent form for some or all subjects.**

**Signature Waiver Rationale:** Select all that apply and address the required action, as applicable.

|  | **Waiver of Signature Rationale** | **Required Action** |
| --- | --- | --- |
|  | [45 CFR 46.117(c)(1)(i)](https://www.ecfr.gov/current/title-45/part-46#p-46.117(c)(1)(i)):The only record linking the subject and the research would be the consent form, and the principal risk would be potential harm resulting from a breach of confidentiality. | 1. Provide protocol specific justification. 2. Specify if participants be asked whether they want documentation linking them with the research. | |
|  | [45 CFR 46.117(c)(1)(ii)](https://www.ecfr.gov/current/title-45/part-46#p-46.117(c)(1)(ii)) and [21 CFR 56.109(c)(1)](https://www.ecfr.gov/current/title-21/part-56#p-56.109(c)(1)):The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context. | 1. Explain why research procedures do not normally require a signed consent form outside the research environment (e.g., interview, survey, non-invasive health measurements, etc.). 2. **If** [protected health information](https://www.ecfr.gov/current/title-45/part-164#p-164.105(a)(2)(i)(C)) (PHI) **is involved, to confirm that the following information will be conveyed to the participant (i.e., insert in Study Information Sheet):**    1. **what PHI will be collected,**    2. **with whom it will be shared,**    3. **how it will be kept confidential, and**    4. **when it will be destroyed.** | |
|  | [45 CFR 46.117(c)(1)(iii)](https://www.ecfr.gov/current/title-45/part-46#p-46.117(c)(1)(iii)): The participants or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk of harm to participants, and there is an appropriate alternative mechanism documenting that informed consent was obtained. | 1. Specify the distinct cultural group or community and explain why signing forms is not the norm. 2. Specify if there an appropriate alternative mechanism for documenting that informed consent was obtained. | |

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| Click or tap here to enter text. |

**Consent Statement:** Specify if participants will be provided with a [Study Info Sheet: Expedited](https://research.uci.edu/wp-content/uploads/study-information-sheet.docx)

or other written statement regarding that addresses the basic elements of informed consent. *Upload to ZOT IRB: Study Information Sheet or equivalent.*

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5. WAIVER OF HIPAA AUTHORIZATION

*This section is not applicable, end of form.*

[**45 CFR 164.512(i)(2)(ii):**](https://www.ecfr.gov/current/title-45/part-164#p-164.512(i)(2)(ii)) **Waiver, in whole or in part, of HIPAA authorization.**

**Assurance:** Provide assurance that all the following are true and addressed in the ‘Privacy and Confidentiality' and 'Risk/Benefit Assessment' sections of the Protocol Narrative.

The use or disclosure of [protected health information](https://www.ecfr.gov/current/title-45/part-164#p-164.105(a)(2)(i)(C)) (PHI) involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements;

An adequate plan to protect the identifiers from improper use and disclosure;

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

The PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted.

The research could not practicably be conducted without the waiver; and

The research could not practicably be conducted without access to and use of the PHI.

Reasonable efforts to limit PHI to the minimum necessary to accomplish the intended purpose of the research.

**HIPAA Waiver Rationale:** Specify why the research could not practicably be conducted without the waiver.Practicably means [capable of being done](https://www.hhs.gov/ohrp/sachrp-committee/recommendations/2008-january-31-letter/index.html); it should not be determined by considerations of convenience, cost, or speed.Select all that apply.

Only minimal contact information will be obtained for recruitment purposes and prescreening medical records is necessary to identify potential eligible subjects.

It would not be feasible to individually contact the large numbers of potential subjects in the study

It would not be possible to locate many of the individuals whose records would be used for the study

Many of the individuals, whose records would be used for the study, are now deceased

Requiring HIPAA authorization may introduce systemic bias into the information

The risk of contacting the subjects to obtain HIPAA authorization is greater than the risk of the study procedures

Other, *provide scientifically and ethically justifiable rationale*.

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| Click or tap here to enter text. |

**HIPAA Waiver & Information Sharing:** Specify if any entities outside the UCI study team (e.g., contract research organization, sponsor) will access, use, or disclose a research subject’s PHI and explain why the entity need PHI to conduct the study.

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| Click or tap here to enter text. |