**HUMAN USE RESEARCH**

**WAIVER OR ALTERATION OF CONSENT**

*Note: additional rules apply to research involving investigational drugs/devices. See instructions for details before proceeding.*

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| **Type of request:** | | **Explanation** |
|  | **Waiver** of Informed Consent  *Complete sections 1 and 2* | Consent will not be sought by the investigator for some or all subjects enrolled. The waiver may apply to only part of the study *(e.g., screening phase [for pre-2018 Common Rule research] or a chart review study arm)* or the entire study. |
|  | **Alteration** of Informed Consent  *Complete sections 1 and 2* | Some or all of the elements of informed consent normally required by the IRB are changed or omitted. |
|  | Waiver of **Documentation** of Informed Consent  *Complete sections 1 and 3* | Consent will be obtained, however a consent document will not be signed. This waiver may apply to only part of the study *(e.g., screening phase for pre-2018 Common Rule research)* or the entire study. |

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| **Section 1 – For all requests, describe how the risk in this research is** [**minimal**](https://www.uthscsa.edu/vpr/services/glossary#Minimal-Risk)**:** |

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| **[Click once here to type your answer]** |

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| **Section 2 - For Waiver of consent or alteration of consent requests – address the following questions** |

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| **a. Without the protection of informed consent, how are the rights and welfare of the participants protected (not adversely affected).** |
| **[Click once here to type your answer]** |

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| **b. Explain why it is not practicable to carry out the research without the requested waiver or alteration *(CHOOSE ONE)*** | | | | |
|  | Design issues: | **[Click once here to insert your justification based on study design issues]** |
|  | Feasibility issues: | **[Click once here to insert your justification based on study feasibility issues]** |

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| **c. If the research involves using identifiable private information or identifiable biospecimens, explain why it is not practicable to carry out the research without using such information or biospecimens in an identifiable format *(CHOOSE ONE)*** | | | | |
|  | Design issues: | **[Click once here to insert your justification based on study design issues]** |
|  | Feasibility issues: | **[Click once here to insert your justification based on study feasibility issues]** |

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| **d. If it may be appropriate to provide subjects or legally authorized representative with additional pertinent information after the study is done, explain what type of information you anticipate giving the subjects and how it would be handled.** |
| **[Click once here to type your answer]** |

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| **Section 3 - For waiver of documentation of consent requests – address the following questions** |

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| **a. Acceptable justification for waiver of documentation** -  *Important note: Only justification A B, or C are accepted by the IRB – select the most appropriate justification.* | | | | | | |
|  | **Justification A**  *(Check the applicable statements)* | | | *Both statements must be applicable to use this justification.*  *This justification is not acceptable for* [*FDA regulated research*](https://www.uthscsa.edu/vpr/services/glossary#FDA-Regulated-Research) *(investigational drug/device studies)* |
|  |  | 1. The only record linking the subject and the research would be the informed consent document | | |
|  |  | 2. The principal risk of the study would be potential harm resulting from a breach of confidentiality if a consent form were required. | | |
|  | **Justification B** | | The research involves no procedures for which written consent is normally required outside of the research context. | |
|  | **Justification C** | | Subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm provided there is an appropriate alternative mechanism for documenting that informed consent was obtained. | |

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| **b. Plan for providing information relevant to the research when documentation is waived**  If it may be appropriate to provide subjects with a written statement regarding the research before participation. If so, provide a plan for providing subjects with information about the research. Include a description of the type of information you anticipate providing the subjects (e.g., an information letter). (See [Information Sheet Template](https://www.uthscsa.edu/sites/default/files/Services/forms/information_sheet.doc)) |
| **[Click once here to type your answer]** |

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| **c. Plan for documenting that verbal consent was obtained. *(CHOOSE ONE)*** | | | | |
|  | **Person obtaining consent will write a research note for each subject and place it in the subjects’ research record.**  An example of a research note for consent is: *On [DATE], subject or legally authorized representative was provided information about the study including: purpose, risks, benefits, procedures, etc; subject was provided an opportunity to ask questions and have them answered; and verbal consent was obtained/not obtained to participate in the study*. | |
|  | **Other** | **Describe: [Click once here to type your answer]** |