**POST-IRB APPROVAL**

**INFORMED CONSENT DOCUMENTATION SELF-ASSESSMENT**

**Purpose:** This form is for researchers to use to conduct a self-assessment of their IRB approved study to ensure that the regulatory and institutional requirements for obtaining and documenting informed consent are met. Please keep completed self-assessments with your study related records as documentation of on-going oversight of the study.

If you should have any questions or concerns regarding compliance with obtaining and documenting informed consent, contact the Office of Research Compliance Review at [orcr-deptemail@umich.edu](mailto:orcr-deptemail@umich.edu).

Guidance regarding informed consent can be found at: [Informed Consent Guidelines & Templates](https://research-compliance.umich.edu/informed-consent-guidelines), [Informed Consent Procedures Using Electronic Systems and Remote Use of Paper Documents](https://az.research.umich.edu/medschool/guidance/informed-consent-procedures-using-electronic-systems-and-remote-use-paper), [Seeking Reconsent from Research Participants](https://az.research.umich.edu/medschool/guidance/seeking-reconsent-research-participants), [Waivers and Alterations under OHRP, FDA and HIPAA](https://az.research.umich.edu/medschool/guidance/waivers-and-alterations-under-ohrp-fda-and-hipaa), [IRB-HSBS Informed Consent Guidelines and Templates](https://research-compliance.umich.edu/informed-consent-guidelines), [Guidance for Creating Certified Electronic Copies of Research Documents](https://research-compliance.umich.edu/sites/default/files/resource-download/electronic_documents_certification_guidance.pdf), and [Research Participants with Limited English Proficiency, Low Literacy, Vision Impairments, or Hearing Impairments](https://az.research.umich.edu/medschool/guidance/consent-accommodations-lep-illiterate-deaf-blind).

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| **STUDY INFORMATION** | |
| HUM # | Click or tap here to enter text. |
| Study Title | Click or tap here to enter text. |
| PI Name | Click or tap here to enter text. |
| Date Self-Assessment Completed | Click or tap here to enter text. |
| Person Completing Self-Assessment | Click or tap here to enter text. |

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| **REVIEW OF INFORMED CONSENT DOCUMENTS** | | | |
| Was the IRB approved (i.e., watermarked with HUM# and approval date) version of the consent/assent document used to enroll participants? *Note: documents used to consent participants should be downloaded from the “Documents” tab in the study workplace in eResearch.* | Yes | No | N/A |
| If no, date of report to IRB:  IRB submission #: | | |
| Are there any handwritten modifications to the informed consent document? | Yes | No |  |
| If yes, have original entries been preserved, not obscured? | | |
| Yes | No |  |
| If yes, date of report to IRB:  IRB submission #: | | |
| If consent/assent is obtained electronically, is the electronic version identical to the IRB approved version found in eResearch (i.e., no changes were made to the document after it was downloaded from eResearch)? | Yes | No | N/A |
| If no, date of report to IRB:  IRB submission #: | | |
| Were all consent documents signed by participants prior to enrollment (research procedures)? | Yes | No |  |
| If no, date of report to IRB:  IRB submission #: | | |
| Is there a signed and dated consent form for every participant enrolled in the study? | Yes | No |  |
| If no, date of report to IRB:  IRB submission #: | | |
| Are consent documents properly stored per the IRB approved application (i.e., separate from coded research data)? | Yes | No |  |
| If no, date of report to IRB:  IRB submission #: | | |
| If changes were made to the consent document, were the changes submitted to and approved by the IRB prior to implementation? | Yes | No | N/A |
| If no, date of report to IRB:  IRB submission #: | | |

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| If using an oral script, was the script approved by the IRB prior to implementation? | Yes | No | N/A |
| If no, date of report to IRB:  IRB submission #: | | |
| If study includes children and two-parent signature is required, were signatures obtained from both parents? | Yes | No | N/A |
| If no, date of report to IRB:  IRB submission #: | | |
| **Corrective Actions for documentation of informed consent:** | | | |

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| **REVIEW OF INFORMED CONSENT DOCUMENTATION: ENROLLING ADULTS**  **Use this form for review of informed consent documents for enrolled participants** | | | | | | | | |
| **Participant ID** | **Consent Document Version Date 1** | **\* Subject or LAR Signature & Date** | **Correct ICD Version? 2** | **\*\* PI/Designee Signature & Date** | **Is ICD Complete? 3** | **Re-consent Needed/ Done4** | **NOTES** |
|  |  | Sig: Y  N  Date: | Y  N | Sig: Y  N  Date: | Y  N | Y  N  N/A |  |
|  |  | Sig: Y  N  Date: | Y  N | Sig: Y  N  Date: | Y  N | Y  N  N/A |  |
|  |  | Sig: Y  N  Date: | Y  N | Sig: Y  N  Date: | Y  N | Y  N  N/A |  |
|  |  | Sig: Y  N  Date: | Y  N | Sig: Y  N  Date: | Y  N | Y  N  N/A |  |
|  |  | Sig: Y  N  Date: | Y  N | Sig: Y  N  Date: | Y  N | Y  N  N/A |  |
|  |  | Sig: Y  N  Date: | Y  N | Sig: Y  N  Date: | Y  N | Y  N  N/A |  |
|  |  | Sig: Y  N  Date: | Y  N | Sig: Y  N  Date: | Y  N | Y  N  N/A |  |
|  |  | Sig: Y  N  Date: | Y  N | Sig: Y  N  Date: | Y  N | Y  N  N/A |  |
|  |  | Sig: Y  N  Date: | Y  N | Sig: Y  N  Date: | Y  N | Y  N  N/A |  |
|  |  | Sig: Y  N  Date: | Y  N | Sig: Y  N  Date: | Y  N | Y  N  N/A |  |

1 Ensure that the ICD Version is correct based on the informed consent version history.

2 Ensure consent was the most recently approved version at the time consent was obtained.

3 E.g., all *opt in/out* boxes are completed.

4 Is reconsenting required per the protocol due to an amendment?

\* Ensure the ICD is signed and dated in participant’s own handwriting.

\*\*Ensure the ICD is signed and dated by an investigator/designee that is listed in Section 1 of eResearch.

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| **REVIEW OF INFORMED CONSENT DOCUMENTATION: ENROLLING CHILDREN**  **Use this form for review of informed consent documents for enrolled participants** | | | | | | | | |
| **Participant ID** | **Consent Document Version Date 1** | **Parent(s) Signature & Date2** | **Correct ICD Version? 3** | **PI/Designee Signature & Date** | **Is ICD Complete? 4** | **Is Assent Documented?** | **NOTES** |
|  |  | Sig: Y  N  Date: | Y  N | Sig: Y  N  Date: | Y  N | Y  N  N/A |  |
|  |  | Sig: Y  N  Date: | Y  N | Sig: Y  N  Date: | Y  N | Y  N  N/A |  |
|  |  | Sig: Y  N  Date: | Y  N | Sig: Y  N  Date: | Y  N | Y  N  N/A |  |
|  |  | Sig: Y  N  Date: | Y  N | Sig: Y  N  Date: | Y  N | Y  N  N/A |  |
|  |  | Sig: Y  N  Date: | Y  N | Sig: Y  N  Date: | Y  N | Y  N  N/A |  |
|  |  | Sig: Y  N  Date: | Y  N | Sig: Y  N  Date: | Y  N | Y  N  N/A |  |
|  |  | Sig: Y  N  Date: | Y  N | Sig: Y  N  Date: | Y  N | Y  N  N/A |  |
|  |  | Sig: Y  N  Date: | Y  N | Sig: Y  N  Date: | Y  N | Y  N  N/A |  |
|  |  | Sig: Y  N  Date: | Y  N | Sig: Y  N  Date: | Y  N | Y  N  N/A |  |
|  |  | Sig: Y  N  Date: | Y  N | Sig: Y  N  Date: | Y  N | Y  N  N/A |  |

1 Ensure the ICD version is correct based on the informed consent version history, consider when the approved consent was made available in eResearch.

2 Make sure the signature is signed and dated in the parent's own handwriting. Additional guidance on obtaining parental signatures: [OHRP Research with Children FAQs](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/children-research/index.html)

3 Ensure consent was the most recently approved version at the time consent was obtained.

4 E.g. all *opt in/out* boxes are completed.

**OBSERVATIONS AND FOLLOW-UP (describe any concerns noted above)**

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| **Participant ID** | **Observation** | **Follow-up actions** | **Date and submission # of IRB reporting** | **Date FDA / sponsor notified, if applicable** |
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