**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 Process](https://research.medicine.umich.edu/office-research/institutional-review-boards-irbmed/guidance/informed-consent/informed-consent-process) and [Re-consenting Study Subjects](https://research.medicine.umich.edu/office-research/institutional-review-boards-irbmed/guidance/reconsenting-study-subjects).

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| **STUDY INFORMATION** | |
| HUM # |  |
| Study Title |  |
| PI Name |  |
| Date Self-Assessment Completed |  |
| Person Completing Self-Assessment |  |

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| **REVIEW OF INFORMED CONSENT DOCUMENTS** | |
| Was the IRB approved (i.e. watermarked) version of the consent/assent used to enroll subjects? *Note: documents used to consent subjects should be printed from the “Documents” tab in the study workplace in eResearch.* | Yes ☐ No ☐  If No, date of report to IRB: |
| Are there any handwritten modifications to the informed consent document? | Yes ☐ No ☐  If Yes, have original entries been preserved, not obscured?  Yes ☐ No ☐ |
| Were all consent documents signed by subjects prior to enrollment (research procedures)? | Yes ☐ No ☐  If No, date of report to IRB: |
| Is there a signed and dated consent form for every subject in the study? | Yes ☐ No ☐  If No, date of report to IRB: |
| 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: |
| If changes were made to the consent document, were the changes submitted to and approved by the IRB? | Yes ☐ No ☐  If No, date of report to IRB: |
| If using an oral script, was the script approved by the IRB? | Yes ☐ No ☐  If No, date of report to IRB: |
| If study includes children and two-parent signature is required, were signatures obtained from both parents? | Yes ☐ No ☐  If No, date of report to IRB: |
| **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 subjects** | | | | | | | | |
| **Subject ID** | **ICD 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 ☐ |  |
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1 Ensure that the ICD Version is correct based on the informed consent version history.

2 Is the subject signature date within the ICD version date?

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 subject’s own handwriting

\*\*Ensure the ICD is signed and dated by 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 subjects** | | | | | | | | |
| **Subject ID** | **ICD 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 ☐ |  |
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1 Ensure the ICD version is correct based on the informed consent version history

2 Make sure signature is signed and dated in 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 Is subject signature date within the ICD version date

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

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

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| **Subject ID** | **Observation** | **Follow-up actions** | **Date of IRB reporting** | **IRB response** | **Date FDA sponsor notified** |
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