**POST-IRB APPROVAL**

**INFORMED CONSENT PROCESS 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. See [Informed Consent Documentation Tool](https://research-compliance.umich.edu/sites/default/files/resource-download/informed_consent_documentation_word_version_0.docx).

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.

Guidance regarding the informed consent process 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), and [U-MIC’s on the Informed Consent Process](https://www.dropbox.com/sh/q0228h2jasqnhys/AAA3BFITMydhVi84X1JGxt5la?dl=0).

**Reminder:** While the initial discussion about the study with prospective participants is critical so that participants know what they are agreeing to before they consent, ideally the consent process should be an ongoing conversation throughout the course of the study. Study team members should be available to answer questions and encourage participants to ask questions or voice concerns, tell participants about changes in the study procedures or risks or alternatives, and allow participants to withdraw from the study for any reason at any time.

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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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| **INFORMED CONSENT PROCESS** |
| The consent process minimizes the possibility of undue influence or coercion. [OHRP Informed Consent FAQs](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html) | Yes [ ]  | No [ ]  | N/A [ ]  |
| The consent discussion and document are in a language that is understandable to participants and is culturally appropriate. [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) | Yes [ ]  | No [ ]  | N/A [ ]  |
| The consent process does not include any exculpatory language and the information is provided to participants in a way that does not waive (or appear to waive) any of the participant’s legal rights, or releases or appears to release the investigator, sponsor, institution, or its agents from liability for negligence. OHRP and FDA consider [*exculpatory language*](https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/guidance-exculpatory-language/index.html) to be language which has the general effect of freeing or appearing to free an individual or an entity from malpractice, negligence, blame, fault, or guilt. | Yes [ ]  | No [ ]  | N/A [ ]  |
| The consent process (whether documented or oral) includes the [basic and appropriate elements of consent](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/checklists/index.html). | Yes [ ]  | No [ ]  | N/A [ ]  |
| An IRB approved study team member obtains informed consent from all participants. | Yes [ ]  | No [ ]  | N/A [ ]  |
| Informed consent is obtained before any research activities begin. | Yes [ ]  | No [ ]  | N/A [ ]  |
| The consent process provides participants sufficient time to consider whether or not they want to participate. | Yes [ ]  | No [ ]  | N/A [ ]  |
| Participants are provided with a copy of the informed consent document (a signed copy if using/disclosing PHI or following ICH-GCP). | Yes [ ]  | No [ ]  | N/A [ ]  |
| Were any participants consented using a process that differed from the IRB approved process? | Yes [ ]  | No [ ]  | N/A [ ]  |
| If yes, date of report to IRB:  |
| Consenting takes place in a private, reasonably comfortable environment. | Yes [ ]  | No [ ]  | N/A [ ]  |
| If the IRB approves a request to [waive the *documentation* of informed consent](https://research-compliance.umich.edu/waivers-informed-consent-guidelines), meaning the study team must provide a participant with the required consent information, but the study team is not required to obtain the participant's signature on the informed consent document, the study team should document that the informed consent process occurred (date, time, study team member that obtained consent). | Yes [ ]  | No [ ]  | N/A [ ]  |
| **Corrective Actions for the Informed Consent Process:**  |

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| **INFORMED CONSENT VERSION HISTORY** |
| **Date Approved by IRB** | **Expiration Date, if applicable** |
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