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| **Study Stage:** Start-up-Conduct-Termination |

 

**Purpose:** This template is one way to document the initial consenting process, along with the informed consent document (ICD).

**Useful to:** The Principal Investigator or any study team member that is delegated authority to obtain consent from potential research participants.Those obtaining informed consent should be on the IRB application.

**Instructions:**

* In cases where additional parties may be required, such as translators, parents, legally authorized representatives, modify the template to include the names and roles of those present during the consenting discussion.
* Make sure that the template, as you adapt it, conforms to any specifics that were included in your IRB application or approval.
* If the study is required to conform to GCP (for example under its contract with a sponsor), then modify the template’s question, “Was a copy of the consent document provided to the participant?” to say, “Prior to a subject’s participation in the trial, was the participant or the participant’s legally authorized representative given a copy of the written informed consent form that was signed and personally dated by the subject or by the subject's legally acceptable representative, and by the person who conducted the informed consent discussion?”
* Provide a complete response to each question on the form.
* If the process extends over more than one day or one discussion, use the comments field to explain the process.

**Best Practice Recommendation:**

* If a Sponsor provides a template, complete it as instructed. Otherwise, this template is recommended.
* Place the completed template in the research participant’s research study record so that it is easily accessible for monitoring visits, internal audits, etc. This process could also be documented in the MiChart record.
* Of note, the signed (ICD) document should be uploaded into the electronic medical record, unless otherwise excluded from this.

**Reference(s):**

**FDA:** A Guide to Informed Consent <http://www.fda.gov/RegulatoryInformation/Guidances/ucm126431.htm>

**FDA:**

[Conduct of Clinical Trials of Medical Products During COVID-19 Public Health Emergency (fda.gov)](https://www.fda.gov/media/136238/download)

**Informed Consent FAQs**

<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html>

**ORCR:** <https://research-compliance.umich.edu/research-integrity/office-research-compliance-review-orcr/self-assessment-tools-investigators>

**IRB Umich:**

[Informed Consent & Assent Templates | Office of Research (umich.edu)](https://research.medicine.umich.edu/our-units/institutional-review-boards-irbmed/informed-consent-assent-templates)

**Template History:**

**Last updated**: 6/07/2022

**Version** 2.4

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| **Study Name:**  | **IRB HUM #:** |
| **Principal Investigator:** | **Participant ID:**  |

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|  **Item** | **Y/N** | **Comments** |
| Were all elements of the consent document presented to the participant and/or legally authorized representative? |  |  |
| Does the participant and/or legally authorized representative affirm that all of his/ her questions were answered?  |  |  |
| Does the participant and/or legally authorized representative appear to understand all aspects of participation? |  |  |
| Does the participant and/or legally authorized representative voluntarily agree to enroll in the study?  |  |  |
| Was the consent document signed by necessary study personnel and participant and/or legally authorized representative prior to the performance of any study-related procedures? |  |  |
| Was a copy of the consent document provided to the participant? |  |  |

**Signature and date of designee (IRB approved) who conducted the consent process and completed this form**

**Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date \_\_\_\_\_\_\_\_\_\_\_Time of consent \_\_\_\_\_\_\_\_\_\_\_ (if applicable)**