OFFICE OF RESEARCH COMPLIANCE REVIEW
UNIVERSITY OF MICHIGAN

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.

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 Process and Re-consenting Study Subjects.

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

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INFORMED CONSENT PROCESS	
The consent process minimizes the possibility of undue influence or coercion.	Yes ◯ No ◯
The consent discussion and document are in a language that is understandable to participants and is culturally appropriate	Yes ◯ No ◯
The consent process does not include any exculpatory language and the information is provided to subjects in a way that does not waive (or appear to waive) any of the subject's legal rights, or releases or appears to release the investigator, sponsor, institution or its agents from liability for negligence.	Yes ◯ No ◯
The consent process (whether documented or oral) includes the basic and appropriate elements of consent.	Yes ◯ No ◯
An IRB approved study team member obtains informed consent from all subjects.	Yes ◯ No ◯
Informed consent is obtained before any research activities begin.	Yes ◯ No ◯
The consent process provides subjects sufficient time to consider whether or not they want to participate.	Yes ◯ No ◯
Subjects are provided with a copy of the informed consent document (a signed copy if using/disclosing PHI or following ICH-GCP).	Yes ◯ No ◯
Were any subjects consented using a process that differed from the IRB approved process?	Yes ◯ No ◯ If yes, date of report to IRB:
Consenting takes place in a private, reasonably comfortable environment.	Yes ◯ No ◯
Corrective Actions for the Informed Consent Process:	

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INFORMED CONSENT VERSION HISTORY	
Date Approved	**Expiration Date**