OFFICE OF RESEARCH COMPLIANCE REVIEW
UNIVERSITY OF MICHIGAN

POST-IRB APPROVAL
STUDY DOCUMENTATION SELF-ASSESSMENT

Purpose: This form is for researchers to conduct a self-assessment of their IRB approved study to ensure that the regulatory and institutional requirements for documenting study activities are being met. Depending on the type of study and sponsor, different regulatory documentation is required. Studies that are not clinical trials may not require all of the documents listed on this form, but use of these documents is a best practice. Documents should be signed and dated by a member of the study team. Studies following ICH-GCP should make sure all essential documentation listed in section 8 are collected (CVs, licenses, IRB approvals, monitoring reports, etc.). Please keep completed self-assessments with your study related records.

If you should have any questions or concerns regarding compliance with study documentation, contact the Office of Research Compliance Review at orcr-deptemail@umich.edu.

Additional study documentation resources are available at: MICHR Resource Center: Study Management Templates and Guidance

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

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STUDY LEVEL DOCUMENTATION		
Adverse Event Log Documentation of adverse events (AEs) including: subject ID, description of AE, AE status, AE severity, whether the AE is a UaP, outcome notifications, and IRB reporting.	Yes ◯ No ◯ N/A ◯	Comments:
Delegation, Training and Signature Log Documentation of all personnel tasks, delegated by the principal investigator, and their training to protocol.	Yes ◯ No ◯ N/A ◯	Comments:
Enrollment Log Documentation of subject enrollment including: subject initials, demographics, date of consent, whether a copy of the consent was given to the subject, whether the subject enrolled in the study, and reason for not enrolling.	Yes ◯ No ◯ N/A ◯	Comments:
eResearch Submission Tracking Log Documentation of all IRB submissions including: type, submission date and IRB approval date.	Yes ◯ No ◯ N/A ◯	Comments:
Protocol Deviation Tracking Log Documentation of all protocol deviations including: subject ID, deviation date, level of deviation, description, date of IRB submission, date of IRB response, and date FDA sponsor notified.	Yes ◯ No ◯ N/A ◯	Comments:
Screening Recruitment Log Documentation of screening of potential subjects including: subject initials, date of screening, whether the subject was eligible, whether the subject consented, reason for screen failure, recruitment source, and name of study personnel who performed the screening.	Yes ◯ No ◯ N/A ◯	Comments:
Monitoring Log Documentation of all monitoring visits including: type of visit (initiation, periodic, close-out), name and role of monitor, monitor signature, and study personnel signature.	Yes ◯ No ◯ N/A ◯	Comments:

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STUDY LEVEL DOCUMENTATION		
Study Close-Out Checklist Documentation that all study files were reviewed and all applicable items are present.	Yes ◯ No ◯ N/A ◯	Comments:
Study Schema A schematic description of study procedures by visit.	Yes ◯ No ◯ N/A ◯	Comments:
Withdrawal/Termination Log Documentation of participants who withdrew from the study or were terminated from the study and the reason why.	Yes ◯ No ◯ N/A ◯	Comments:
Study Communication Documentation of study team meetings, DSMBs, site communications, etc.	Yes ◯ No ◯ N/A ◯	Comments:

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SUBJECT LEVEL DOCUMENTATION		
Eligibility Checklist Documentation that each subject has met the inclusion/exclusion criteria as outlined in the IRB approved application and protocol.	Yes ◯ No ◯ N/A ◯	Comments:
Study Visit Checklist Documentation that each subject has completed study visits and accompanying procedures as outlined in the IRB approved application and protocol.	Yes ◯ No ◯ N/A ◯	Comments:
Subject Contact Sheet Documentation of each subject's contact information (e.g. name, email, phone number). *Note: identifying information should be stored per the IRB approved application.*	Yes ◯ No ◯ N/A ◯	Comments:
Compensation Record Documentation of compensation provided to each subject as outlined in the IRB approved application.	Yes ◯ No ◯ N/A ◯	Comments:
Adverse Event Report Form Documentation of adverse events/protocol deviations experienced by subjects. *Note: adverse events and protocol deviations should be reported to the IRB per the IRB approved application.*	Yes ◯ No ◯ N/A ◯	Comments:
Concomitant Medications Documentation of concomitant medications for each subject.	Yes ◯ No ◯ N/A ◯	Comments: