**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](https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf) should make sure all essential documentation listed in section 8 are maintained in study records (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](mailto:orcr-deptemail@umich.edu).

Additional study documentation resources are available at: [ORCR Study Templates DropBox](https://www.dropbox.com/home/UMOR-ORCR%20Dropbox/ORCR%20Study%20Templates)

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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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| **STUDY LEVEL DOCUMENTATION** | | | | |
| [**Adverse Event Log**](https://www.dropbox.com/home/UMOR-ORCR%20Dropbox/ORCR%20Study%20Templates/Study%20level%20templates?preview=Adverse+Event.UaP+Log.docx)  Documentation of adverse events (AEs) including: participant ID, description of AE, AE status, AE severity, whether the AE is a [UaP](https://az.research.umich.edu/medschool/guidance/unanticipated-problems-involving-risks-subjects-or-others), outcome notifications, and IRB reporting. | Yes | No | N/A | Comments: |
| [**Delegation, Training and Signature Log**](https://www.dropbox.com/home/UMOR-ORCR%20Dropbox/ORCR%20Study%20Templates/Study%20level%20templates?preview=Delegation%2C+Training+and+Signature+Log_v.0.xlsx)  Documentation of all study personnel, assigned tasks, as delegated by the principal investigator, and [training](https://www.dropbox.com/home/UMOR-ORCR%20Dropbox/ORCR%20Study%20Templates/Study%20level%20templates?preview=Training+Documentation+Log.docx) to protocol. | Yes | No | N/A | Comments: |
| [**Enrollment Log**](https://www.dropbox.com/home/UMOR-ORCR%20Dropbox/ORCR%20Study%20Templates/Study%20level%20templates?preview=Enrollment+Log_v.0.xlsx)  Documentation of participant enrollment including: participant ID, date of consent, whether a copy of the consent was given to the participant, whether the participant enrolled in the study, and reason for not enrolling. | Yes | No | N/A | Comments: |
| [**eResearch Submission Tracking Log**](https://www.dropbox.com/home/UMOR-ORCR%20Dropbox/ORCR%20Study%20Templates/Study%20level%20templates?preview=eResearch+Submission+Tracking+Log.docx)  Documentation of all IRB submissions including: submission ID#, submission date and IRB approval date. | Yes | No | N/A | Comments: |
| [**Protocol Deviation Tracking Log**](https://www.dropbox.com/home/UMOR-ORCR%20Dropbox/ORCR%20Study%20Templates/Study%20level%20templates?preview=Protocol+Deviation+Tracking+Log.docx)  Documentation of all protocol deviations including: participant ID, deviation date, PI assessment of deviation, description, date of IRB submission, date of IRB acknowledgement, and date sponsor notified, if applicable. | Yes | No | N/A | Comments: |
| [**Screening Recruitment Log**](https://www.dropbox.com/home/UMOR-ORCR%20Dropbox/ORCR%20Study%20Templates/Study%20level%20templates?preview=Screening+Recruitment+Log.docx)  Documentation of screening of potential participants including: date of screening, whether the participant was eligible, whether the participant provided consent, reason for screen failure, and name of study personnel who performed the screening. | Yes | No | N/A | Comments: |

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| **STUDY LEVEL DOCUMENTATION** | | | | |
| [**Monitoring Log**](https://www.dropbox.com/home/UMOR-ORCR%20Dropbox/ORCR%20Study%20Templates/Study%20level%20templates?preview=Site+Visit+Log+for+Monitoring.docx)  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: |
| [**Retained Fluid and Tissue Log**](https://www.dropbox.com/home/UMOR-ORCR%20Dropbox/ORCR%20Study%20Templates/Study%20level%20templates?preview=Retained+Fluid+and+Tissue+Log.docx)  Documentation of sample (fluid/tissue) storage, including date and type of samples collected, storage location, and processing and destruction dates. | Yes | No | N/A | Comments: |
| [**Study Close-Out Checklist**](https://www.dropbox.com/home/UMOR-ORCR%20Dropbox/ORCR%20Study%20Templates/Study%20level%20templates?preview=Study+Close-Out+Checklist+%28Sample%29.docx)  Documentation that all study files were reviewed and all applicable items are present. | Yes | No | N/A | Comments: |
| [**Study Schema**](https://www.dropbox.com/home/UMOR-ORCR%20Dropbox/ORCR%20Study%20Templates/Study%20level%20templates?preview=Study+Schema+%28Sample%29.docx)  A schematic description of study procedures by visit. | Yes | No | N/A | Comments: |
| [**Withdrawal/Termination Log**](https://www.dropbox.com/home/UMOR-ORCR%20Dropbox/ORCR%20Study%20Templates/Study%20level%20templates?preview=Withdrawal.Termination+Log_v.0.xlsx)  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](https://www.dropbox.com/home/UMOR-ORCR%20Dropbox/ORCR%20Study%20Templates/Study%20level%20templates?preview=Study+Meeting+Minutes.docx), DSMBs, site communications, etc. | Yes | No | N/A | Comments: |
| [**Study Transition Form for Change in Study Coordinator**](https://www.dropbox.com/home/UMOR-ORCR%20Dropbox/ORCR%20Study%20Templates/Study%20level%20templates?preview=Study+Transition+Form+for+Change+in+Research+Coordinator.docx)  Documentation when there is a change in study coordinators to ensure there is a smooth transition, and that all applicable study documents are properly updated. | Yes | No | N/A | Comments: |

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| **PARTICIPANT LEVEL DOCUMENTATION** | | | | |
| [**Eligibility Checklist**](https://www.dropbox.com/home/UMOR-ORCR%20Dropbox/ORCR%20Study%20Templates/Subject%20level%20templates?preview=Eligibility+Checklist_Sample.docx)  Documentation that each participant has met the inclusion/exclusion criteria as outlined in the IRB approved application and protocol. | Yes | No | N/A | Comments: |
| [**Study Visit Checklist**](https://www.dropbox.com/home/UMOR-ORCR%20Dropbox/ORCR%20Study%20Templates/Subject%20level%20templates?preview=Visit+Checklist.docx)  Documentation that each participant has completed study visits and accompanying procedures as outlined in the IRB approved application and protocol. | Yes | No | N/A | Comments: |
| [**Projected Participant Visit Calculator**](https://www.dropbox.com/home/UMOR-ORCR%20Dropbox/ORCR%20Study%20Templates/Subject%20level%20templates?preview=Projection+of+Subject+Visits+%28Sample+Calculator%29_v.0.xlsx)  This document can be used to calculate visit windows for study participants to help ensure scheduled visits occur within protocol specified timepoints. | Yes | No | N/A | Comments: |
| [**Participant Contact Information**](https://www.dropbox.com/home/UMOR-ORCR%20Dropbox/ORCR%20Study%20Templates/Subject%20level%20templates?preview=Subject+Contact+Information.docx)  [Documentation](https://www.dropbox.com/home/UMOR-ORCR%20Dropbox/ORCR%20Study%20Templates/Subject%20level%20templates?preview=Subject+Contact+Information.docx) of each participant’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: |
| [**Telephone Contact Note**](https://www.dropbox.com/home/UMOR-ORCR%20Dropbox/ORCR%20Study%20Templates/Subject%20level%20templates?preview=Telephone+Contact+Note.docx)  Documentation of phone contact attempts with participants, including date, a summary of the contact, and follow up action required. | Yes | No | N/A | Comments: |
| [**Participant Compensation Log**](https://www.dropbox.com/home/UMOR-ORCR%20Dropbox/ORCR%20Study%20Templates/Study%20level%20templates?preview=Participant+Compensation+Tracking+Log.docx)  Documentation of participant compensation, including date of payment, amount of payment, and type of payment. | Yes | No | N/A | Comments: |
| [**Adverse Event Report Form**](https://www.dropbox.com/home/UMOR-ORCR%20Dropbox/ORCR%20Study%20Templates/Subject%20level%20templates?preview=Adverse+Event+Report+Form+for+Single+Event.docx)  Documentation of adverse events/protocol deviations experienced by participants. *Note: adverse events and protocol deviations should be reported to the IRB per the IRB approved application.* | Yes | No | N/A | Comments: |

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| [**Concomitant Medications**](https://www.dropbox.com/home/UMOR-ORCR%20Dropbox/ORCR%20Study%20Templates/Subject%20level%20templates?preview=Concomitant+Medications.docx)  Documentation of concomitant medications for each participant. | Yes | No | N/A | Comments: |