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| **INSTRUCTIONS:** ***Please complete the Investigator Self-Assessment to confirm study documentation maintained in your regulatory files.*** *If you have questions while filling out the Investigator Self-Assessment, or would like the Quality Improvement Program (QIP) team to complete the assessment for you, please contact us (http://www.hsph.harvard.edu/orarc).*  |
| 1. Human Research – Regulatory Documentation
 |
| Principal Investigator |  |
| Protocol #/Study Title | **/** |
| Person(s) Completing Checklist |  |
| Date Completed |  |
|  |
| 1. IRB Submissions and Documentation
 |
| Continuing review(s): **Total Number:** |
| Modification Request(s): **Total Number:** |
| Reportable New Information form(s): **Total** **Number:** |
|  |
| [ ]  Yes [ ]  No | **All IRB submissions and documentation are maintained in ESTR.** *If yes, confirm that a note to file is included in the study Regulatory Binder pointing to ESTR as the repository for IRB documentation by checking here* [ ]  *and skip to Section 2 - Essential Documents* |
| **Complete the below section for IRB submissions and documentation not maintained in ESTR** |
| [ ]  Yes [ ]  No | Initial IRB application, signed and dated |
| [ ]  Yes [ ]  No | Initial IRB approval letter |
| [ ]  Yes [ ]  No [ ]  N/A | Continuing review application(s) |
| [ ]  Yes [ ]  No [ ]  N/A | Continuing review approval letter(s) |
| [ ]  Yes [ ]  No [ ]  N/A | Modification application(s) |
| [ ]  Yes [ ]  No [ ]  N/A | Modification approval letter(s) |
| [ ]  Yes [ ]  No [ ]  N/A | Reportable New Information (RNI) submission  |
| [ ]  Yes [ ]  No [ ]  N/A | Reportable New Information (RNI) acknowledgment(s)  |
| [ ]  Yes [ ]  No [ ]  N/A | Notification letter(s) of IRB disapproval, deferral, modifications required by the IRB to secure approval |
| [ ]  Yes [ ]  No [ ]  N/A | Correspondence with the IRB in response to IRB actions (disapproval, deferral, modifications required) |
| [ ]  Yes [ ]  No [ ]  N/A | Notifications of Suspension of IRB Approval or Termination of IRB Approval |
| [ ]  Yes [ ]  No [ ]  N/A | Significant correspondence with the IRB (email, letter, log of phone conversation) |
| [ ]  Yes [ ]  No | HLC Research Protocol: most recently approved version |
| [ ]  Yes [ ]  No [ ]  N/A | HLC Research Protocol: all previous versions |
| [ ]  Yes [ ]  No [ ]  N/A | Recruitment materials (e.g., ads, scripts, flyers, emails, etc.): most recently approved version |
| [ ]  Yes [ ]  No [ ]  N/A | Recruitment materials: all previous versions |
| IRB Submissions and Documentation not maintained in ESTR *(continued)*  |
| [ ]  Yes [ ]  No [ ]  N/A | Consent document(s): most recently approved version  |
| [ ]  Yes [ ]  No [ ]  N/A | Consent document(s): all previous versions |
| [ ]  Yes [ ]  No [ ]  N/A | Parental permission/assent document(s): most recently approved version |
| [ ]  Yes [ ]  No [ ]  N/A | Parental permission/assent document(s): all previous versions |
| [ ]  Yes [ ]  No [ ]  N/A | Information provided to participants, e.g., brochure, information sheet, results letter, etc.: most recently approved version |
| [ ]  Yes [ ]  No [ ]  N/A | Information provided to participants, e.g., brochure, information sheet, results letter, etc.: all previous versions |
| [ ]  Yes [ ]  No [ ]  N/A | Study tools, data collection or source documents, e.g., survey/questionnaire, data collection forms: most recently approved version |
| [ ]  Yes [ ]  No [ ]  N/A | Study tools, data collection or source documents, e.g., survey/questionnaire, data collection forms: all previous versions |
| Comments (optional) | Additional information on any No or N/A response above:  |
|  |
| 1. Essential Documents *(as applicable)*
 |
| [ ]  Yes [ ]  No [ ]  N/A | Funding documents (e.g., Grant, Sponsor’s Protocol, etc.)  |
| [ ]  Yes [ ]  No [ ]  N/A | Annual grant progress reports submitted to funding agency/sponsorTotal number:  |
| [ ]  Yes [ ]  No [ ]  N/A | Correspondences to and from the funding agency/sponsor (e.g., Agreement Letters) |
| [ ]  Yes [ ]  No | Human Research Training certificates on file for investigators and study staff  |
| [ ]  Yes [ ]  No | All human research training certificates are valid (completed within the past 3 years) |
| [ ]  Yes [ ]  No [ ]  N/A | All other relevant training on file for investigators and study staff (e.g., Good Clinical Practice, training specifically noted in the protocol, etc.) |
| [ ]  Yes [ ]  No | CVs or other relevant documents (biosketch/resume) evidencing qualifications of PI, co-investigators, and all study personnel |
| [ ]  Yes [ ]  No | CVs/other relevant information have been updated within the past 2 years |
| [ ]  Yes [ ]  No | CVs/other relevant information are signed and dated |
| [ ]  Yes [ ]  No [ ]  N/A | Valid professional licenses/certifications for all study staff (as applicable for protocol related activities) *(\*For FDA-regulated protocols: required for each investigator/staff member listed on the 1572 or Investigator Statement)*  |
| [ ]  Yes [ ]  No [ ]  N/A | Other communications with external/non-Harvard IRBs (e.g., Ethical Review Board approval, Community Advisory Board approval, significant email correspondence indicating non- engagement, etc.) |
| [ ]  Yes [ ]  No [ ]  N/A | Data Monitoring Committee (DMC) or Data Safety Monitoring Board (DSMB) Reports, meeting minutes or indications of DMC/DSMB review/recommendations |
| [ ]  Yes [ ]  No [ ]  N/A | Have all DMC/DSMB reports been submitted to the IRB?  |
| [ ]  Yes [ ]  No [ ]  N/A | Signed agreements/contracts between parties (e.g., MOU, DUA, MTA) |
| [ ]  Yes [ ]  No [ ]  N/A | CRFs/standardized data collection tools not created by the study team (e.g. common assessments, standardized interviews, etc.)  |
| [ ]  Yes [ ]  No [ ]  N/A | HSPH or HMS/HSDM IRB roster of members with documentation of HSPH or HMS/HSDM Federalwide Assurance (FWA) Number *(\*required for FDA-regulated protocols or when required by sponsor)*  |
| Comments (optional) | Additional information on any No or N/A response above:  |
|  |
| 1. Logs
 | *\* The following logs indicated by an asterisk (\*) are required for FDA-regulated protocols and/or if the sponsor requires investigators to follow ICH GCP. For all other studies, QIP recommends using these logs (as applicable) to facilitate and support regulatory compliance. Templates for all logs can be found on QIP’s* [*Study Management Tools*](http://www.hsph.harvard.edu/orarc/hlc-qip) *page found at* [*www.hsph.harvard.edu/orarc/hlc-qip*](http://www.hsph.harvard.edu/orarc/hlc-qip)*.*  |
| [ ]  Yes [ ]  No [ ]  N/A | ***\****Study Staff Signature Log  |
| [ ]  Yes [ ]  No | The log documents signatures and initials of all relevant study staff |
| [ ]  Yes [ ]  No | All relevant study staff listed are IRB approved |
| [ ]  Yes [ ]  No [ ]  N/A | Delegation of Responsibility Log (may be combined with Study Staff Signature Log) |
| [ ]  Yes [ ]  No | Delegation Log reflects all study staff  |
| [ ]  Yes [ ]  No | Delegation Log reflects study staff start and end dates |
| [ ]  Yes [ ]  No | All staff delegated Human Research activities on the Log are IRB Approved |
| [ ]  Yes [ ]  No | Delegation Log captures PI’s signature/initials |
| [ ]  Yes [ ]  No [ ]  N/A | Training Log (for human research training or other study-specific training requirements)  |
| [ ]  Yes [ ]  No [ ]  N/A | IRB Submission Log (for external/local IRB/ERB or CAB submissions, notifications, required responses, and approvals) |
| [ ]  Yes [ ]  No [ ]  N/A | Reportable New Information Log (Adverse Events, Unanticipated Problem involving risk to participants or others, deviations from the IRB approved protocol) |
| [ ]  Yes [ ]  No [ ]  N/A | Monitoring/Auditing/Site Visit Log |
| [ ]  Yes [ ]  No | Monitoring/Auditing/Site Visit Log includes the reason for monitoring/site visit activities |
| 3a Participant Logs | ***No enrolled participants*** *[ ]  (Skip to section 3b)* |
| [ ]  Yes [ ]  No [ ]  N/A | ***\**** Participant Enrollment Log. **Number enrolled:**  |
| [ ]  Yes [ ]  No [ ]  N/A | ***\**** Participant Screening Log. **Number screened:**  |
| [ ]  Yes [ ]  No [ ]  N/A | Subject Payment Log |
| 3b Data/Specimen Logs | ***No Data or specimens received from external sources*** *[ ]  (Skip to section 4)* |
| [ ]  Yes [ ]  No [ ]  N/A | Biological Specimens/Data Receipt Log |
| Comments (optional) | Additional information on any No or N/A response above:  |
|  |
| 1. Lab
 | *No clinical lab assessments [ ]  (Skip to section 5)* *\* The following items are required for FDA-regulated protocols and/or if the sponsor requires investigators to follow ICH GCP.*  |
| [ ]  Yes [ ]  No [ ]  N/A | Normal lab/reference values and all updates for clinical labs |
| [ ]  Yes [ ]  No [ ]  N/A | Lab certification and all updates for labs that are used for diagnosis, treatment, prevention, and/or assessment (e.g. CAP, CLIA) |
| [ ]  Yes [ ]  No [ ]  N/A | Lab director's current (within past 2 years) CV for research labs that will not be reporting any Participant-specific results for diagnosis, treatment, prevention, and/or assessment |
| Comments (optional) | Additional information on any No or N/A response above:  |
|  |
| 1. Additional Study Documentation, Data Storage and Retention
 |
| [ ]  Yes [ ]  No [ ]  N/A | If a [clinical trial](https://www.hsph.harvard.edu/regulatory-affairs-and-research-compliance/hlc-qip/clinicaltrials-gov/), indicate where this trial has been registered[ ]  ClinicalTrials.gov; provide NCT # [ ]  Other, please specify:  |
| [ ]  Yes [ ]  | The registration record is in good standing |
| [ ]  Yes [ ]  No | Participant files and study data (including secondary use data) are stored securely in compliance with the IRB approved protocol and the [Harvard University Information Security Policy](https://policy.security.harvard.edu/). |
| [ ]  Yes [ ]  No | Regulatory documentation (e.g., contents of the Regulatory Binder) will be retained for at least seven years after the end of the research project or research activity, or longer if required by sponsor |
| Comments (optional) | Additional information on any No or N/A response above:  |
|  |