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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/sponsor  Total 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: | |
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