sIRB Project

PSS Help and FAQs

Comments

1a. Project Name	sIRB Project
1b. Project ID	
1c. Is Your Project an Investigative Project (aka PSS-Lite)?	No
1d. Is your Project Artifact being Reaffirmed or proceeding to Normative directly after being either Informative or STU?	No
1e. Today's Date	
1f. Name of standard being reaffirmed	N/A
1g. Project Artifact Information	
1h. ISO/IEC Standard to Adopt	
1i. Does the standard include excerpted text from one or more ISO, IEC or ISO/IEC standards, but is not an identical or modified adoption?	
1j. Unit of Measure	
2a. Primary/Sponsor WG	Biomedical Research & Regulation
2b. Co-Sponsor WG	Clinical Interoperability Council
2c. Co-Sponsor Level of Involvement	Request periodic project updates; specify period in text box below (e.g. 'Monthly', 'At WGMs', etc.)
2b. Co-Sponsor WG 2	FHIR Infrastructure
2c. Co-Sponsor Level of Involvement	Request periodic project updates; specify period in text box below (e.g. 'Monthly', 'At WGMs', etc.)
2c. Co-Sponsor 2 Update Periods	Monthly, at WGMs, ETC
2d. Project Facilitator	Anita Walden and Ed Hammond

2e. Other Interested Parties (and roles)	National Institute of Health-NCATS Will provide guidance on project direction and scope Federal Drug Administration (FDA): conduct audit of the sites to evaluate the methodology of using FHIR to collect data for clinical research. Vanderbilt will participate on pilot demonstration project
2f. Modeling Facilitator	Michael Rutherford
2g. Publishing Facilitator	James Topping
2h. Vocabulary Facilitator	Julie James
2i. Domain Expert Representative	Meredith Zozus
2j. Business Requirements Analyst	Anita Walden
2k. Conformance Facilitator	Michael rutherford
2l. Other Facilitators	Ed Hammond (Jean Duteau)- FHIR Facilitator
2m. Implementers	Duke University University of Arkansas for Medical Sciences Vanderbilty University
3a. Project Scope	We will develop, test and evaluate data standards to move data and documents from clinical research sites to a single ethics review board in support of the "NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research." The scope of this project will consist of two phases. Phase I – While some standards exist and will be leveraged, significant gaps remain. We will perform an analysis identifying and addressing standards gaps to support comprehensive data and document exchange between sites and sIRBs and providing for re-use of data and documents within clinical studies. Stakeholders from the public and private sectors will vet the analysis through the IRB vendors administrators using the balloting process. Phase II - Develop standards, prototype and demonstrate automated single internal review board (sIRB) data and document exchange. Where needed the following standards will be developed. Existing FHIR resources will be utilized when appropriate, FHIR documents to support the following data collection and exchange (1) Structured (IRB) Reliance Agreement based on National IRB reliance models, (2) Study protocols, (3) Structured recruitment materials and (4) Structured informed consent documents and (5) Reportable medical (Unanticipated events, Adverse Events and Serious Adverse Events) and non-medical events and (6) Continuing Review and Final Progress Report form. FHIR resources will be utilized when appropriate. Implementation Guides will be created. We will review and consider existing standards such as ICSR, other Adverse Event standards (CDISC, ICH E2B) and BRIDG.
Attachments	
3b. Project Need	The Common Rule was updated and the necessary standards do not exist to support required data exchange. The vast majority of federally funded research in the United States will require use of a single IRB and will be impacted by the new sIRB Policy. Currently, independent IRB reviews involve redundant work at the local site and local IRB level and inviting the potential for conflicting decisions, requirements and oversight. The new NIH sIRB policy changes this by eliminating the redundancy and opportunity for conflicting reviews, ultimately increasing the efficiency of clinical studies. The creation and implementation of standards will support the new policy. These standards are needed to maintain the rigor of the ethics review while reducing regulatory burden and research costs. Funding provided by National Center for Advancing Translational Sciences (NCATS)
3c. Security Risk	No
3d. External Drivers	Federal Policy Change- The Common Rule

3e. Objectives/Deliverables and Target Dates	Submit Project Scope Statement -2019 May 23 Gap analysis between needs and existing standards- 2019 March Development of Implementation Guide/s- 2020 February Notification of Intent to STU Ballot of Implementation Guide- 2019 December Ballot Implementation Guide STU- 2020 Jan/May Ballot Reconciliation- 2020 Jan/May Request for Publication- 2020 June Project End Date (all objectives have been met)- 2020 June
3f. Common Names / Keywords / Aliases:	sIRB Project
3g. Lineage	N/A
3h. Project Dependencies	N/A
3i. HL7-Managed Project Document Repository URL:	https://confluence.hl7.org/display/BRR/sIRB+Project+Page
3j. Backwards Compatibility	N/A
3k. Additional Backwards Compatibility Information (if applicable)	
3l. Using Current V3 Data Types?	N/A
3l. Reason for not using current V3 data types?	
3m. External Vocabularies	Unknown
3n. List of Vocabularies	
3o. Earliest prior release and/or version to which the compatibility applies	
4a. Products	FHIR Extensions, FHIR Implementation Guide, FHIR Profiles, White Paper
4b. For FHIR IGs and FHIR Profiles, what product version(s) will the profiles apply to?	Not Sure at this Time
4c. FHIR Profiles Version	
4d. Please define your New Product Definition	
4d. Please define your New Product Family	
5a. Project Intent	White Paper, Implementation Guide (IG) will be created/modified
5a. White Paper Type	Non-balloted WG White Paper
5a. Is the project adopting/endorsing an externally developed IG?	
5a. Externally developed IG is to be (select one)	

5a. Specify external organization	
5a. Revising Current Standard Info	
5b. Project Ballot Type	STU to Normative
5c. Additional Ballot Info	
5d. Joint Copyright	No
5e. I understand I must submit a Joint Copyright Letter of Agreement to the TSC in order for the PSS to receive TSC approval.	no
6a. External Project Collaboration	National Institute of Health
6b. Content Already Developed	
6c. Content externally developed?	
6d. List Developers of Externally Developed Content	
6e. Is this a hosted (externally funded) project?	Yes
6f. Stakeholders	Regulatory Agency, Standards Development Organizations (SDOs)
6f. Other Stakeholders	
6g. Vendors	Pharmaceutical
6g. Other Vendors	
6h. Providers	Healthcare Institutions (hospitals, long term care, home care, mental health), Other
6h. Other Providers	Academic Medical Centers (clinical sites) Electronic Data Capture vendors eIRB System vendors, IRB accreditors, IRB Reliance Organizations, Commercial IRBs
6i. Realm	U.S. Realm Specific
7d. US Realm Approval Date	Jun 18, 2019
7a. Management Group(s) to Review PSS	FHIR
7b. Sponsoring WG Approval Date	May 21, 2019
7c. Co-Sponsor Approval Date	May 07, 2019
7c. Co-Sponsor 2 Approval Date	May 16, 2019
7c. Co-Sponsor 3 Approval Date	
7c. Co-Sponsor 4 Approval Date	
7c. Co-Sponsor 5 Approval Date	

7c. Co-Sponsor 6 Approval Date	
7c. Co-Sponsor 7 Approval Date	
7c. Co-Sponsor 8 Approval Date	
7c. Co-Sponsor 9 Approval Date	
7c. Co-Sponsor 10 Approval Date	
7e. CDA MG Approval Date	
7f. FMG Approval Date	May 22, 2019
7g. V2 MG Approval Date	
7h. Architecture Review Board Approval Date	
7i. Steering Division Approval Date	
7j. TSC Approval Date	