MORE REGULATORY CHANGES FOR HUMAN SUBJECTS RESEARCH

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IRB Reviews

- Research vs. not research
- Human subject research vs. not human subjects research
- Exempt
- Expedited
- Full Board

- Renewals & modifications
- Noncompliance
- Unanticipated problems
- Complaints

Hot topics

- Recordings
  - Audio
  - Video
- General Data Protection Regulation - GDPR

Changes to Regulations

New Requirement	Impacts	Compliance Date
New Common Rule **OHRP**	Human subjects protocols	Protocols approved on or after January 21, 2019
sIRB **NIH**	Some NIH funded, multi-site human subjects research	Proposals submitted on or after January 25, 2018
New Common Rule Cooperative Research **OHRP**	Human subjects protocols	Protocols approved on or after **January 20, 2020**

New Common Rule Cooperative Research

New Common Rule Cooperative Research: Applicability

- Protocols, involving cooperative research, approved on or after January 20, 2020 must follow the new Common Rule Cooperative Research Regulations.

- Protocols, involving cooperative research, approved prior to January 20, 2020 will continue under the current Common Rule

- Applies to federally funded research

New Cooperative Research:

- Cooperative Research is defined as projects that involve more than one institution.
- Each institution is still responsible for safeguarding the rights and welfare of human subjects at their institution.
- For federally funded Human Subjects Research (HSR)

Terms

- sIRB - single IRB
  - One IRB does official review for multiple sites
- Reviewing IRB - the IRB who does the official review in an sIRB context
  - sIRB = Reviewing IRB
- Relying IRB/site - the site(s) participating in the research but:
  - do not do the official IRB review
  - still have responsibility over the research conducted at that site
  - Local IRB works with local PI and sIRB
- Participating site (psite)- another term used for relying IRB/site
  - Participating site = Relying IRB/site

So what's different?

- Any institution located in the United States that is engaged in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States.
- The reviewing IRB (or sIRB)will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research.
- Exceptions:
  - When more than sIRB is required by law ((including tribal law passed by the official governing body of an American Indian or Alaska Native tribe).
  - Research for which any Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context.

Reliance Agreements

- Reliance agreements aka:
  - Inter Institutional Agreements (IIA)
  - IRB Authorization Agreement (IAA)
- What are they?
  - Contractual agreement defining who is sIRB and who is relying institution
- Why do we need them?
  - FWA
- Who processes them?
  - CMU IRB shepherds them through the process (for now) by working with the other IRBs and internally with the Office of General Counsel (OGC), when needed

SMART IRB

- Not an IRB
- Platform for handling reliances between institutions who are members of SMART IRB
- Must join to use
- Master Agreement
  - One page form
  - Anything beyond master agreement needs to be negotiated

2 review paths in SPARCS

- CMU as relying site/participating site
- CMU as sIRB/reviewing site

CMU as a relying site/participating site

- What does the CMU PI need to do?
  - Contact IRB with sIRB request
  - Gather contact information from reviewing site
  - Reliance agreement
  - Submit in SPARCS IRB as a participating site
    - Copies of IRB approval from sIRB
    - Copy of IRB approved protocol from sIRB
    - Copy of IRB approved consent forms from sIRB

CMU as an sIRB/reviewing site

- What does the CMU PI need to do?
  - Talk to IRB first!
  - May need to use commercial IRB
    - Additional costs
  - Reliance agreement(s)
    - With each site if there are more than one
  - Submit in SPARCS IRB as sIRB
    - Send sites copies of IRB approval from CMU
    - Send sites copy of IRB approved protocol from CMU
    - Send copy of IRB approved consent forms from CMU

Check - In

- Check – Ins are required for sIRB at CMU
- Exempt and expedited protocols will go through a "Check-In" process (Full Board studies require continuing review.)
  - IRB is still required to oversee all human subjects research
  - If CMU is sIRB
    - Exempt - 2 questions regarding status
    - Expedited – a few questions regarding status
    - Reminders will be sent every 2 years after approval to remind researchers to check in
    - Can close study through the check-in process

Check - In

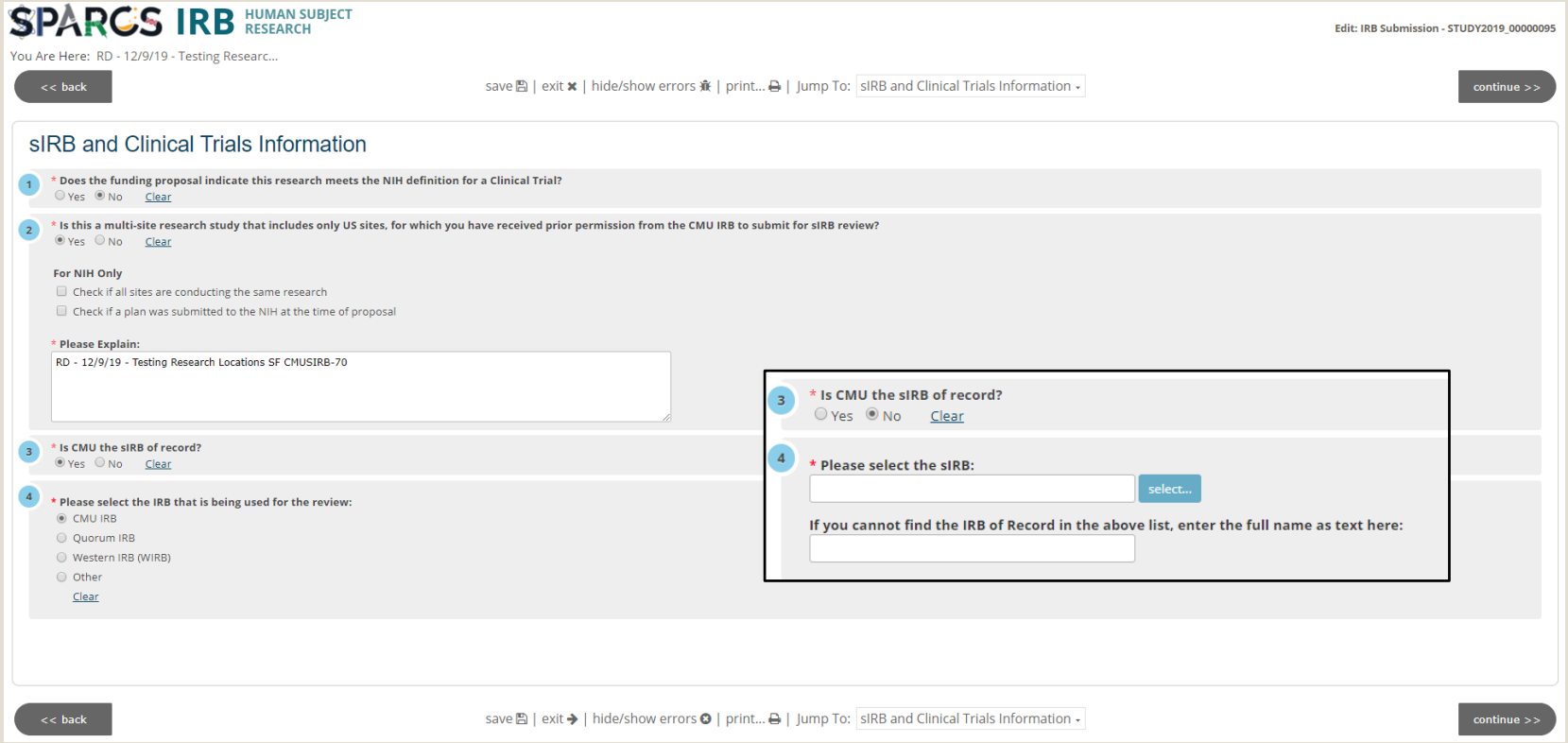
- If CMU is relying site/participating site
  - Check – In date or expiration date on the sIRB approval letter will be entered into SPARCS so reminders are consistent with approval dates or check – in dates from the sIRB
- If CMU is sIRB
  - Check-In will function as it normally does for non sIRB studies

SPARCS IRB Updates

Funding Sources Smartform

- Entering a federal sponsor (direct or prime) or linking to a funding proposal with a federal sponsor (direct or prime) branches the user down the sIRB path.
- If working with a non-federal sponsor who requests a reliance agreement, **REACH OUT TO IRB**. No current mechanism to allow study team to force sIRB branching.

sIRB & Clinical Trials Information



- Inform WHO is the IRB of Record.
- CMU IRB – Branch to External Participating Sites smartform
- Other than CMU IRB – Branch to Participating Sites smartform

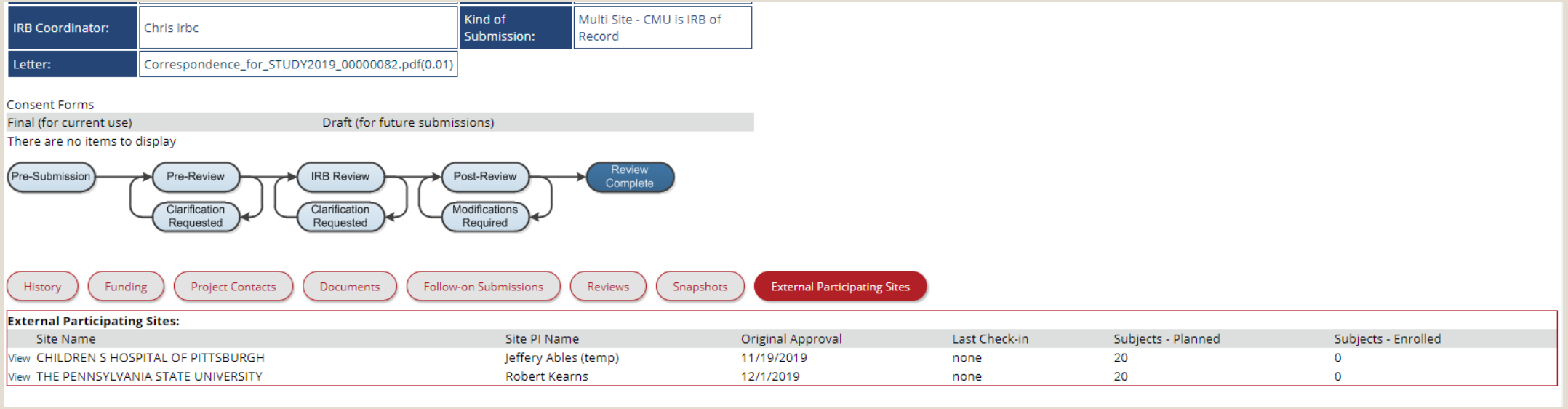
Add External pSite

- Provide any additional funding the pSite is using for this study. Providing additional funding the pSite is using is optional.
- Provide a good email address for pSite PI. Otherwise, Notify External Sites activity will not work properly.
- Provide pSite IRB name and email address.
- Add pSite consent forms as appropriate. If CMU is IRB of record, SPARCS can add our watermark to their consent form.
- Study team cannot add Reliance Agreements. Work with IRB to add Reliance Agreements to the protocol.

New Activities

- Submit External Sites Check-In – Allows study team to submit check-in for pSites.
- Notify External Sites – Use this activity to send consent forms finalized in SPARCS or approved protocols to external site Pis. This activity is captured in the History tab on the protocol workspace.

Workspace Enhancements



IRB Coordinator:	Chris irbc	Kind of Submission:	Multi Site - CMU is IRB of Record
Letter:	Correspondence_for_STUDY2019_00000082.pdf(0.01)		

Consent Forms

Final (for current use) | Draft (for future submissions)

There are no items to display

History | Funding | Project Contacts | Documents | Follow-on Submissions | Reviews | Snapshots | External Participating Sites

External Participating Sites:

	Site Name	Site PI Name	Original Approval	Last Check-in	Subjects - Planned	Subjects - Enrolled
View	CHILDREN S HOSPITAL OF PITTSBURGH	Jeffery Ables (temp)	11/19/2019	none	20	0
View	THE PENNSYLVANIA STATE UNIVERSITY	Robert Kearns	12/1/2019	none	20	0

- External Participating Sites information is now captured on the protocol workspace and updated accordingly.
- Kind of Submission was added to workspace.

Information & Assistance for IRB

- IRB Website (updates are coming):

http://www.cmu.edu/research-compliance/human-subject-research

- sIRB Mailbox:

sirb@Andrew.cmu.edu

- Contacts for sIRB:
  - Teri Reiche treiche@andrew.cmu.edu
  - Susan Brunner sebrunne@andrew.cmu.edu
- IRB Mailbox:

irb-review@andrew.cmu.edu

Contact for IRB:

- Teri Reiche treiche@andrew.cmu.edu
- Doug McFarland dougmc@andrew.cmu.edu
- Jill Schaefer jsschaef@andrew.cmu.edu
- Susan Brunner sebrunne@andrew.cmu.edu
- Gail Kusbit gkusbit@andrew.cmu.edu
- Ellen Conser conser@andrew.cmu.edu

Questions?