FEDERAL DEMONSTRATION PARTNERSHIP

Redefining the Government & University Research Partnership

Human Subjects Subcommittee

September 2018 Meeting

Presenters:

Jane McCutcheon, New York University

Debra Murphy, Arizona State University

Alexandra Albinak, Johns Hopkins University

Human Subjects Subcommittee

Human Subject Protections Subcommittee is part of the Research Compliance Committee.

Updates today:

- IRB Wizard
- Common Rule
- SMART IRB
- NIH RFI

Common Rule Update

The Final Rule delays the general compliance date of the 2018 Requirements for an additional 6-month period until January 21, 2019.

Common Rule Update

The transition provision in the Final Rule is structured so that regulated entities cannot implement the revised Common Rule in its entirety, in lieu of compliance with the current version of the Common Rule, until the general compliance date noted above. As a result of this delay to the general compliance date, regulated entities will be required, with an exception, to continue to comply with the requirements of the pre-2018 version of the Common Rule until January 21, 2019. The exception to this general rule is that institutions will be permitted (but not required) to implement, for certain studies, three burden-reducing provisions of the 2018 requirements during the delay period (July 19, 2018 through January 20, 2019).

HS Subcommittee

Burden Reduction Options:

The three provisions are:

1. Implement the revised definition of "research," which deems certain activities not to be research covered by the Common Rule (Scholarly and Journalistic Activities Not Deemed to be Research)

HS Subcommittee

Burden Reduction Options:

The three provisions are:

(2) When Continuing Review is Not Required

(3) Elimination of Institutional Review Board (IRB) congruency review (Review of Research Applications and Proposals)

HS Subcommittee

Things to consider –

- Institutions taking advantage of the three-burden reducing provisions must comply with all other pre-2018 Requirements during the delay period.
- The three burden-reducing provisions of the 2018 Requirements can only be implemented during the delay period with respect to studies initiated prior to January 21, 2019 that will transition to compliance with the revised Common Rule.

HS Subcommittee

Things to consider –

- Any study that implements these three burden-reducing provisions during the delay period must, beginning on January 21, 2019, comply with all of the 2018 Requirements for the balance of the study's duration.

HS Subcommittee

Request for Information (RFI): Registration and Results Reporting Standards for Prospective Basic Science Studies Involving Human Participants

Notice Number: NOT-OD-18-217
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-217.html

Through a Request for Information, NIH is requesting input on the standards NIH should use in assuring adequate registration and results information reporting for fundamental research studies involving human participants – hereafter referred to as "prospective basic science studies involving human participants."

We encourage Institutions, Investigators and Individuals to provide their input to NIH regarding this important initiative.

FEDERAL DEMONSTRATION PARTNERSHIP

Redefining the Government & University Research Partnership

FDP / SMART IRB Reliance Agreement Taskforce

Speaker:

Alex Albinak, Johns Hopkins University

FDP Meeting – Sept 2018

Taskforce Members

Member	Organization	Contact email
Lynette Arias (co-facilitator)	University of Washington	ariasl@uw.edu
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FDP & SMART IRB Partnership Taskforce Purpose / Intent

Utilize broad FDP membership for **input & advocacy**
Assist SMART IRB with **broad adoption** and support through FDP member involvement
Provide feedback on Reliance Agreement and HSC documents, tools and resources
Discuss use cases and specifics of implementation
Maintain open dialogue for bidirectional opportunities

Status updated

Taskforce continues to have regular calls/conversation

SMART IRB team has confirmed value of Task Force – reaffirmed our partnership

- Feeds into their changes on current supporting docs and flexibility guidance
- Has broadened the perspective and input provided
- Plan in continue to include Task Force feedback going forward

Current priority - survey

Joint FDP/SMART IRB Survey

Work towards a survey has been prioritized high by SMART IRB team

FDP working closely with SMART IRB staff

Currently in process

- Reviewing/comparing populations
- Refining desired outcomes
- Putting together specific questions
- Developing logistics for administering survey

Target – Fall

Planned next steps

SMART IRB utilizing feedback to determine whether a version 2.0 of Reliance Agreement should be undertaken:

- FDP / SMART IRB Taskforce
- Participating organizations during 1st year of implementation
- Implications of Common Rule
- Other committees and groups (HSC, etc.)
- Add others, as appropriate , including feedback in this session

Clarifications vs. significant revisions that would require resigning of the Agreement?

If substantive revisions proposed, comment period for broad audience will be provided

HS Subcommittee

Questions ????