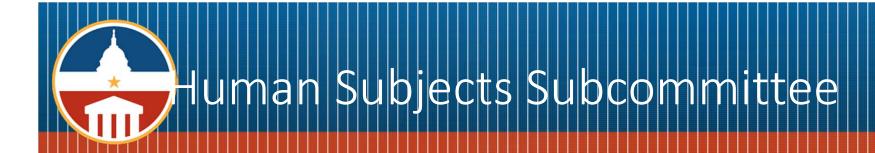


# Human Subjects Subcommittee September 2018 Meeting

#### **Presenters**:

Jane McCutcheon, New York University Debra Murphy, Arizona State University Alexandra Albinak, Johns Hopkins University



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

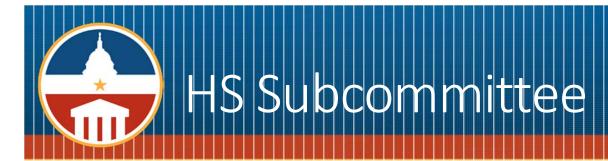
#### **Updates today:**

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



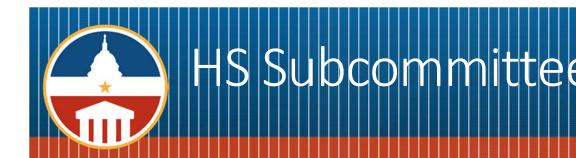
## Common Rule Update

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



### Common Rule Update

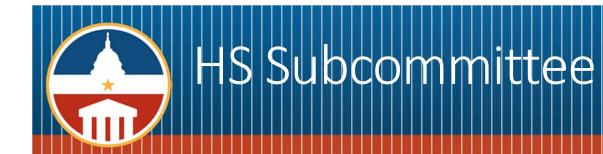
The transition provision in the Final Rule is structured so that regulated entities cannot implement the revised Common Rule in its entirety, in lieu of compliance with the current version of the Common Rule, until the general compliance date noted above. As a result of this delay to the general compliance 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).



#### **Burden Reduction Options:**

#### The three provisions are:

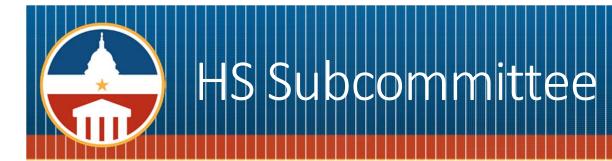
1. Implement the revised definition of "research," which deems certain activities not to be research covered by the Common Rule (Scholarly and Journalistic Activities Not Deemed to be Research)



#### **Burden Reduction Options:**

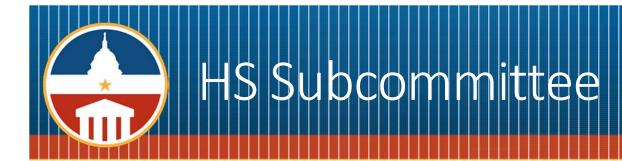
#### The three provisions are:

- (2) When Continuing Review is Not Required
- (3) Elimination of Institutional Review Board (IRB) congruency review (Review of Research Applications and Proposals)



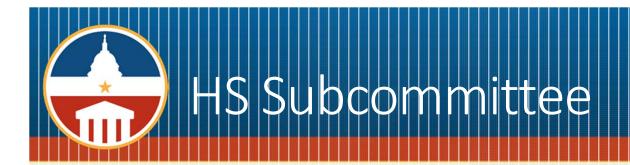
#### Things to consider -

- 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.



#### Things to consider –

 Any study that implements these three burdenreducing 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.



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.

# 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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Lisa Nichols	COGR	Inichols@COGR.edu 11

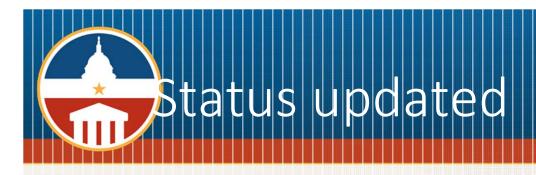


Assist SMART IRB with broad adoption and support through FDP member involvement

Provide feedback on Reliance Agreement and HSC documents, tools and resources

Discuss use cases and specifics of implementation

Maintain open dialogue for bidirectional opportunities



#### 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** 



Work towards a survey has been prioritized high by SMART IRB team
FDP working closely with SMART IRB staff
Currently in process

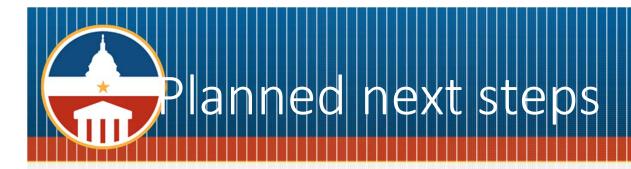
Reviewing/comparing populations

Refining desired outcomes

Putting together specific questions

Developing logistics for administering survey

Target - Fall



# 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 ????