SMART TALK

A Community Forum to Explore Issues Surrounding Single IRB Review

Funded by the NIH National Center for Advancing Translational Sciences through its Clinical and Translational Science Awards Program, grant number 3UL1TR002541-01S1.

What Is SMART Talk?

An approximately monthly forum with:

- Presentations on topics relevant for single IRB review
- Q&A on topic presented as well as questions submitted when participants register

Open and free to anyone with interest

Upcoming sessions

March: Harmonization Working Group Recommendations on Ancillary Reviews

Likely April: Harmonization Working Group Recommendations on Conflicts of Interest

May: No SMART Talk – AAHRPP virtual conference

NEW! SMART IRB Institutional Profile

- Any Participating Institution may complete an Online Institutional Profile
- Profiles may only be completed and submitted by an institution's designated POC or Alternate POC
- Now available in the SMART IRB Joinder platform

SMART IRB Joinder

Admin View | Admin User | Logout

Welcome to Joinder

Choose an existing institution card or click on the + sign to select another institution

Harvard Medical School (HMS) and H arvard School of Dental Medicine (HS DM)

FWA00007071

Verified

Select an institution

Institution Details

Submission

Past Agreement(s)

Institutional Profile

Download Agreement

The Agreement for Harvard University Faculty of Medicine is ready for download. Please download the pre-filled Agreement below.

SMART IRB Agreement Version 2.0

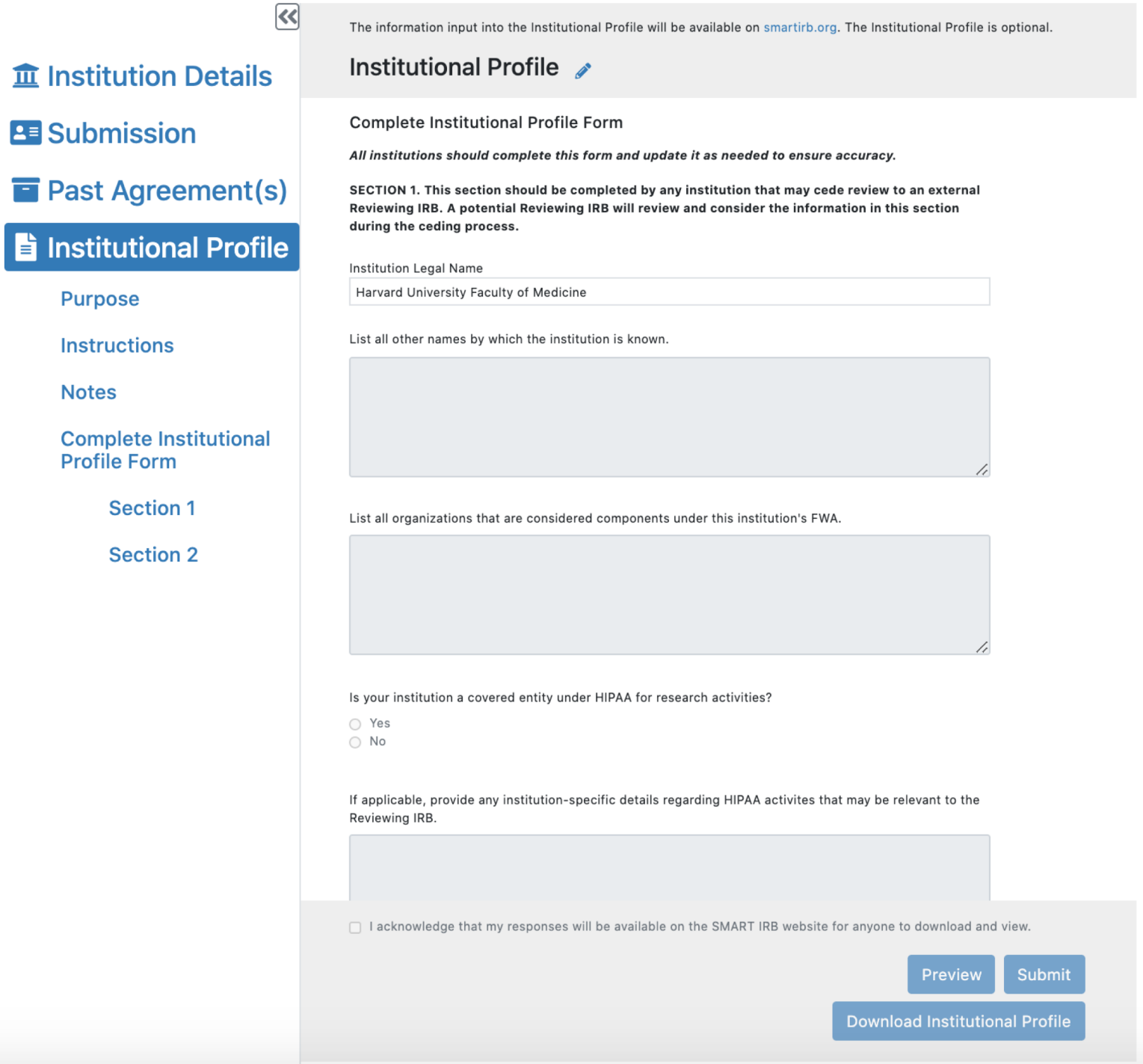
Download Agreement PDF

Upload Agreement

Once you have reviewed and confirmed the information on your Agreement PDF, please have your institution's Institution Official (as documented on the verified Institution Details form) sign the agreement, and upload the signed form below.

Select file... Browse ...

Only one PDF can be uploaded.


Institution Details
Submission
Past Agreement(s)
Institutional Profile
Purpose
Instructions
Notes
Complete Institutional Profile Form
Section 1
Section 2
The information input into the Institutional Profile will be available on smartirb.org. The Institutional Profile is optional.
Institutional Profile
Complete Institutional Profile Form
All institutions should complete this form and update it as needed to ensure accuracy.
SECTION 1. This section should be completed by any institution that may cede review to an external Reviewing IRB. A potential Reviewing IRB will review and consider the information in this section during the ceding process.
Institution Legal Name
Harvard University Faculty of Medicine
List all other names by which the institution is known.
List all organizations that are considered components under this institution's FWA.
Is your institution a covered entity under HIPAA for research activities?
Yes
No
If applicable, provide any institution-specific details regarding HIPAA activites that may be relevant to the Reviewing IRB.
I acknowledge that my responses will be available on the SMART IRB website for anyone to download and view.
Preview
Submit
Download Institutional Profile

FYIs

A recording of this talk will be posted on the SMART IRB website

A link to the talk will be sent to those who registered for the talk when it is posted

If you have any questions for the panelists, please use the chat function or Q&A function to submit them

Exception from Informed Consent (EFIC) & Single IRB

SMART Talk

February 17, 2021

What is EFIC?

Research in emergency settings may not allow for a timely consent process prior to initiating research interventions.

When these procedures are more than minimal risk, a waiver of consent cannot be applied.

An Exception from Informed Consent allows an investigator to initiate research interventions without first obtaining consent.

Specific criteria must be met to qualify for EFIC.

** This is *not* for the emergency use of a test article. This is *planned emergency research.*

EFIC Criteria Summarized

21 CFR 50.24

Federal Register, Vol. 61, pp. 51531-51533

1. The human subjects are in a life-threatening situation…*as determined by several criteria.*
2. Obtaining informed consent is not feasible…*as determined by several criteria.*
3. Participation in research holds out the prospect of direct benefit to the subjects…*as determined by several criteria.*
4. An informed consent process must be conducted when reasonable feasible with the participant, LAR, or family member…*according to several criteria.*
5. Researchers are required to complete community consultation and public disclosure activities prior to beginning the study…*according to much federal guidance.*
6. Public disclosure must occur after the trial has concluded.
7. Use of an independent DSMB.
8. Obtain and IND or IDE from the FDA (for drug and device studies).

What is the purpose of community consultation?

Community consultation means providing the opportunity for discussions with, and soliciting opinions from, the community in which the study will take place and the community from which the study subjects will be drawn. These communities may not always be the same; when they are not the same, both communities should be consulted.

The goals of community consultation are to:

- show respect for persons by informing the community about the study in advance;
- inform community members about the trial in advance and provide a means for affected communities to provide meaningful input to the IRB before its decision to approve, require modifications to, or disapprove the study;
- show respect for the community by allowing representatives of the community to identify potential community-level concerns and effects of the research; and
- show respect for subjects' autonomy. Respect may be shown by including in community consultation activities individuals who may have, or be at risk for, the condition under study (and thereby obtain input from a group that is expected to be similar to the eventual study subjects).

What is the purpose of public disclosure?

Public disclosure means dissemination of information (i.e., one-way communication) to the community(ies), the public, and researchers about the emergency research.

The goal of public disclosure prior to initiation of the study is to provide sufficient information to allow a reasonable assumption that the broader community is aware of the plans for the investigation, its risks and expected benefits, and the fact that the study will be conducted without obtaining informed consent from most study subjects.

The goal of public disclosure after the study is completed is to ensure that the communities, the public, and scientific researchers are aware of the study's results. Disclosure to researchers of the results, both positive and negative, of studies conducted under 21 CFR 50.24 is particularly important because such disclosure may help FDA and researchers learn from these studies involving vulnerable subjects who are unable to consent.

Dear Single IRB,

Who is my community?

And how do I know they have been consulted?

And how do I know they have received the information I sent out in public disclosure?

Sincerely,
The Investigators all over the country
who want to do this study really badly

THE UNIVERSITY OF UTAH

Top 5 Things a Single IRB Needs

1. A standard set of elements the SIRB expects in a site investigator's community consultation and public disclosure plan.
2. An in depth profile of the site's population and community characteristics, and the likelihood of sub-population inclusion.
3. A site HRPP vetting process for the plan and the community profile, as well as potential ad hoc reviewer involvement with the SIRB.
4. A standard set of elements the SIRB expects when the site investigator reports back the results of the community consultation.
5. Be ready to do a lot of advising.

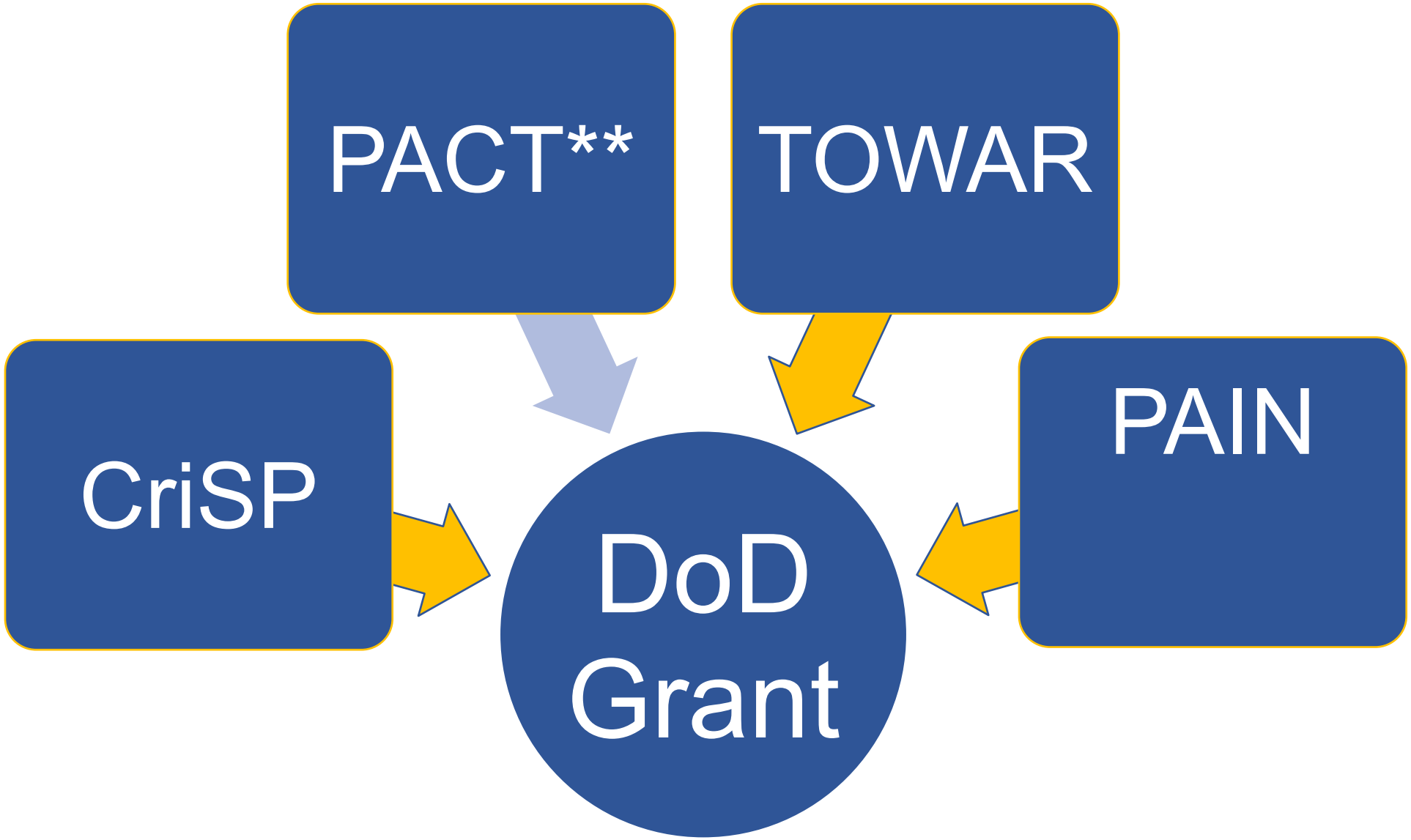
sIRB Issues Related to Planned Emergency Research

SMART Talk

February 17, 2021

Pitt Research

Human Research Protection
Office of Research Protections


PACT**
TOWAR
CriSP
PAIN
DoD Grant

Considerations

- FWAs and Agreements
  - Which sites are “engaged”
  - Do they fit in another institution’s legal structure
  - Who do you ask

- Inability to connect
  - How many attempts should be made
  - Can the IRB determine site is not a good fit
  - Who communicates decision

Considerations

- Community Consultation
  - Is it hitting the right “community”
  - Multiple hospitals within same catchment area
  - COVID challenges
  - Populations with no internet access
  - Populations with different languages and cultures
- Training of EMS crews

Considerations

- Prisoners
- Limited or inaccurate eligibility information
  - Children who look like adults
  - Prisoners
    - Status unknown at time of intervention
    - Arrested after intervention
  - Pregnant Women

Strategies at Pitt

- “On-demand” committee
- HRP staff effort written into grant
- Dedicated research management staff
- Weekly touch base meetings
- Review of Manual of Operations
  - Education/re-education plan

Planned Emergency Research

Single IRB (SIRB) Review

Lizbeth Adams PhD CIP

Executive Vice Chair, Advarra

Top Five Points

1. Initial Review- Process
2. Initial Review Criteria- CC/PD
3. Initial Review-Individual Site Plans
4. Site Plans-Common Feedback
5. Continuing Review Criteria

Initial Review Process

- Designated panel meets bi-monthly
- Chair(s) work closely with sites/coordinating centers to communicate expectations
- Developed guidance materials for research sites

Initial Review Process

- Protocol, Consent Form, EFIC Plan
- Individual site plans for CC/PD; approve with modifications but do not release ICF until final CC/PD report is reviewed
- Review final CC/PD report via expedited process, approve or escalate to FB
- Final approval documents and ICF to site

Initial Review Criteria- EFIC Plan

- **Community Consultation- who?**
  - Broad and multi-faceted approach based on demographics
  - Communities most affected are informed and can provide input
  - A priori identification of population most at risk for study condition
  - Activities designed to provide opportunities for community discussion

Initial Review Criteria- EFIC Plan

- **Community Consultation- what?**

A (Interactive Events)	B (Surveys/Social Media)
A presentation and Q&A by an investigator at a meeting of an existing group (e.g., Zoom meeting with religious or community interest group)	Telephone survey
Formal focus group (small group session with trained moderator)	Online survey
In-person interviews with community leaders (e.g., church leaders, community organizers politicians, etc.)	Social media messaging, with opportunity for interaction (e.g., online post of Facebook live event with comments enabled)
A booth or table at community events involving conversation and dialogue (not just handing out flyers)	In-person survey (e.g., waiting room survey)
Meetings convened by the investigators inviting the targeted audience (e.g., invited meeting of elderly/assisted housing residents)	A booth/table at community events handing out study materials/surveys with limited interaction

6 events total with at least 2 from Column A and one from Column B

Initial Review Criteria- EFIC Plan

Public Disclosure: 6 total with at least 2 from A, 1 from B, 1 from C

A (networking)	B (paid advertising)	C (conventional outlets)
Website	Newspaper advertisement	Press release
Social media postings	Television and radio ads	News stories, interviews (print, radio, or television)
Mailings (including e-mail circulars/listservs and direct paper mailings)	Outdoor advertising (e.g., bus ads, billboards, etc.)	Newsletters (articles or informational ads, print or electronic)
Booth/table community event	Paid online advertisements (banner, block, or video ads purchased from Google, Facebook, YouTube, etc.)	Brochures, flyers, handouts, bulletin boards
		Radio or television PSA (public service announcements)

Initial Review Process- Individual Sites

- SIRB will require detailed local context information for **each** site. Local IRB may provide additional local context to SIRB

- Information to be provided includes: demographics of local population, additional or unique population variables (homeless population? specific religions represented?), unique factors about local institution and culture (past animosity toward research enterprise?), institutional resources available (community advisory board?)

Initial Review Process- Individual Sites

- Suggestions are made to the site and the site EFIC plan is approved with modifications
- Final report from site after CC/PD activities should include: type and number of activities, number of community members who participated, the level of interaction between community members and study staff, and demographics of community members who participated.
- Any objections or concerns raised by community should be reported and consideration given to modifying protocol and/or engaging the community further to address their concerns.

Continuing Review

- Information requested from the sites:

1. Describe any ongoing CC/PD efforts undertaken since initial IRB approval at your site
2. Have there been any opt-outs, negative public feedback, or concerns since initial approval at your site
3. Please provide the summary of LAR contact information/attempts

Save the date for the next SMART Talk
March 17, 2021
2:00-3:30 pm ET

Harmonization Working Group Recommendations on Ancillary Reviews

Questions?
Contact help@smartirb.org

Register at smartirb.org

Sign up for our mailing list to be notified of future offerings