IRB Streamlining

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IRB Streamlining

- IRB streamlining = identifying ways to improve the IRB review and approval process
- Wide spectrum of opportunity:
  - The larger the change → the longer and more complex the effort
  - Varies for research study type:
    - Simple: De-identified data query
    - Complex: Multi-site Randomized Clinical Trial (RCT)

UC BRAID Example

DRAFT Guidance for Requesting Data from UC ReX

Purpose: Guidance for researchers and staff using UC ReX data services

- This document has been reviewed by and includes input from the IRB Directors at UCD, UCI, UCLA, UCSD, UCSF, and UCOP General Counsel

Guidance Matrix for Requesting Data from UC ReX			
Type of Data Request	**IRB Approval**	**HIPAA Waiver of Authorization**	**Data Use Agreement (DUA) or Other Agreement**
De-identified data (UC ReX Data Explorer)	• **Not required**; Not human subjects research • Note: Data Stewards confirm data elements do not contain patient identifiers (e.g., PHI).	**Not required**	***Depends on Individual Campus Requirements***
Limited data	• **Not required**; not considered identifiable per OHRP guidelines) therefore not human subjects research • Additional approvals might be required if there are further plans for re-use/sharing of data	**Not required**	**DUA Required by Regulation**; only the researcher requesting data is required to sign*; researcher may need to sign DUAs with multiple campuses*
Personally identifiable data	• **Required**; at minimum required at one site. • May use IRB reliance process • Local facilitators may be required if using information for recruitment-only purposes (i.e., site not engaged in research)	**Required**; only at one site (e.g., obtained by "lead" PI from "reviewing" IRB when using IRB reliance process)	***Depends on Individual Campus Requirements***
Note: Use of participant recruitment services: o These entities are not engaged in human subjects research if they: inform prospective subjects about the availability of the research; provide information about the research (which may include a copy of the relevant informed consent document and other IRB approved materials) but do not obtain consent or act as representatives of the investigators; provide information about contacting investigators for information or enrollment; and/or seek or obtain the prospective subjects' permission for investigators to contact them. o These entities may be considered Business Associates under HIPAA and therefore require a Business Associate Agreement.			

UC BRAID IRB Advisory Committee v. 7/20/15

University of California Biomedical Research Acceleration, Integration and Development

IRB Approach by Type

- Learning from experience
  - Discussions with Rachael at UC BRAID
  - Harmonization is still hard for them!
- Evaluating best way to incorporate IRB processes for pSCANNER
  - Suggests ap
  - Can dovetai

Type of Request	IRB Approval	DSA/Other Agreement
Aggregate	Not Required: Not human subject research	pSCANNER DSA
De-identified	Not Required: Not human subject research BUT local IRB must approve exemption	Site-specific DSA (Researcher) pSCANNER DSA
Limited Data	Not Required: Same approach as de-identified but additional approvals may be required if further plans for re-use/sharing of data	Site-specific DSA (Researcher) Multi-site DSA (if shared) pSCANNER DSA
PII	Required: Details TBD Would include recruitment	TBD

pSCANNER IRB Streamlining

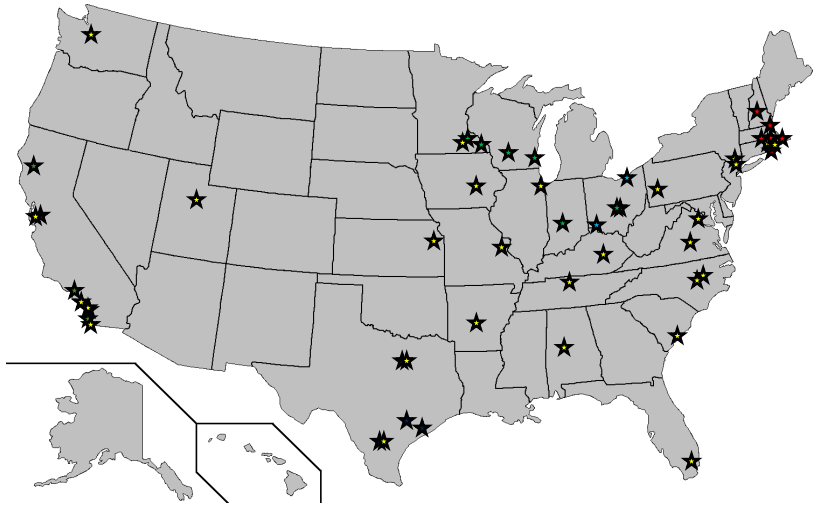
- For pSCANNER, we can provide specific guidance on IRB form completion on our portal to help researchers with data requests
  - Example: de-identified data queries:
    - Provide partially completed IRB human subject determination forms
    - Include templated pSCANNER language
    - Note: This language will be approved internally before being deployed on the pSCANNER portal

PCORnet SMART IRB

Development of a Cross-CTSA IRB Reliance Agreement – Toward a National System

Funded by NCATS: September 2014-April 2016; additional funding currently being sought

Successful regional IRB reliance networks came together to develop a national solution.



Participating Institutions
Case Western Reserve University
Dartmouth College
Harvard Medical School
MetroHealth Medical Center Cleveland
The Ohio State University
University of California – Davis
University of New Mexico
University of Texas Southwestern
University of Wisconsin – Madison
Vanderbilt University

Principal Investigator	Alan I. Green, Dartmouth College
Sr. Reliance Advisor	Barbara Bierer, Harvard Medical School
Regulatory Leads	Sabune Winkler, Harvard Medical School & Nichelle Cobb, Univ. Wisconsin-Madison
Informatics Lead	Amarendra Das, Dartmouth College

SMART IRB Webinars

- PCORnet is partnering with NCATS to help Network partners sign the SMART IRB agreement and expect SMART IRB will be widely implemented by January 2017.
- Nichelle Cobb with SMART IRB will lead informational webinars for PCORnet on October 17th at 2:00PM EST and October 27th at 4:00PM EST.
- All Network members and their study teams should plan to attend one of these webinars.

SMART IRB Webinars

- Additional webinars will be scheduled. If you have not received a calendar invitation, please email Carl at cstepnowsky@ucsd.edu.
- October 17th Meeting Information:
  - Time: 2-3pm ET
  - Call-in: 1-855-244-8681
  - Access Code: 737 187 705
  - It will be a WebEx Meeting

Questions?