IRB Streamlining

Carl Stepnowsky
Barbara Filkins
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)
### Guidance Matrix for Requesting Data from UC ReX

<table>
<thead>
<tr>
<th>Type of Data Request</th>
<th>IRB Approval</th>
<th>HIPAA Waiver of Authorization</th>
<th>Data Use Agreement (DUA) or Other Agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>De-identified data (UC ReX Data Explorer)</td>
<td>- Not required; Not human subjects research &lt;br&gt; Note: Data Stewards confirm data elements do not contain patient identifiers (e.g., PHI).</td>
<td>Not required</td>
<td>Depends on Individual Campus Requirements</td>
</tr>
<tr>
<td>Limited data</td>
<td>- Not required; not considered identifiable per OHRP guidelines &lt;br&gt; therefore not human subjects research &lt;br&gt; Additional approvals might be required if there are further plans for re-use/sharing of data</td>
<td>Not required</td>
<td>DUA Required by Regulation; only the researcher requesting data is required to sign, researcher may need to sign DUAs with multiple campuses</td>
</tr>
<tr>
<td>Personally identifiable data</td>
<td>- Required; at minimum required at one site. &lt;br&gt; May use IRB reliance process &lt;br&gt; Local facilitators may be required if using information for recruitment only purposes (i.e., site not engaged in research)</td>
<td>Required; only at one site (e.g., obtained by “lead” PI from “reviewing” IRB when using IRB reliance process)</td>
<td>Depends on Individual Campus Requirements</td>
</tr>
</tbody>
</table>

### Note:
- Use of participant recruitment services:
  - 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.
  - These entities may be considered Business Associates under HIPAA and therefore require a Business Associate Agreement.
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 approach for pSCANNER
  - Can dovetail with Portal development

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