Welcome to the CTTI Informed Consent Project Expert Meeting

March 10-11, 2015
Housekeeping

- Please remember to turn your phones on vibrate or silent
- Please state your name and organization prior to speaking so others know who is talking

- Parking
- Restrooms
- Lunch
- Reception
Clinical trials in crisis

The changing structure of industry-sponsored clinical research: pioneering data sharing and transparency.
Kuntz RE.
Addressing This Need

To identify and promote practices that will increase the quality and efficiency of clinical trials

Public-Private Partnership involving all stakeholders
60+ members
Collaboration Towards Solutions

- Better
- Streamlined
- Fit for purpose

Clinical Trials

- Government and regulatory agencies
- Industry: pharma biodevice CRO
- IRBs
- Clinical investigators
- Patients / Patient advocacy groups
- Academia
- Industry trade / Professional organizations
Better, Streamlined, Fit for Purpose Clinical Trials

- Change
- Build consensus
- Gather evidence
- Formulate recommendations
- Identify solutions
- Identify Research Impediments
# Portfolio of CTTI Projects

<table>
<thead>
<tr>
<th>Completed projects</th>
<th>Investigational plan</th>
<th>Study start-up</th>
<th>Study conduct</th>
<th>Analysis and dissemination</th>
<th>Specialty areas</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Large simple trials</td>
<td>• Central IRB</td>
<td>• Adverse event reporting</td>
<td>• Long-term opioid data</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Uses of electronic data</td>
<td>• Site metrics</td>
<td>• IND safety</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Central IRB</td>
<td>• Monitoring</td>
<td>• Monitoring</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Site metrics</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current projects</td>
<td>• Patient groups and clinical trials</td>
<td>• Central IRB advancement</td>
<td>• Safety case studies</td>
<td>• Streamlining HABP/VABP trials</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Pregnancy testing</td>
<td>• GCP training</td>
<td>• IND safety advancement</td>
<td>• Pediatric Antibiotic trials</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• QbD</td>
<td>• Informed consent</td>
<td>• State of clinical trials</td>
<td>• Unmet need in Antibiotic development</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Trials based on registries</td>
<td>• Investigator turnover</td>
<td>• DMCs</td>
<td>• HABP/VABP pilot study</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Remote Clinical Trials</td>
<td>• Recruitment and retention</td>
<td>• HABP/VABP trials</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Introduction to the CTTI Informed Consent Project

Michele Kennett, University of Missouri

March 10, 2015
Issue

Informed consent documents are lengthy and may be difficult for patients to comprehend.

Current informed consent process is often not meeting the needs of research participants.
Why Improve Informed Consent?

Patients

Ethicists

Regulators

Sponsors

Patients
**Project Objectives**

- Understand previous and current efforts, whether successful or not, to improve informed consent documents and the informed consent process, including alternatives to the traditional paper informed consent document.

- Understand barriers and identify potential remedies to concisely communicating the required elements of informed consent.

- Propose a more effective process, including informed consent documentation, for ensuring research participants’ understanding of critical informed consent elements, taking into account variability among research settings and participants.

- Identify potential strategies and opportunities for pilot testing the informed consent process improvement recommendations.

*Re-consent of research participants, assent and consent in the learning health care system are outside the scope of this project.*
Project Methods

Project Initiation

Literature Review

Expert Interviews

Develop Draft Recommendations

Expert Meeting

Finalize Recommendations
Project Team Members

TEAM LEADERS
- Michele Kennett, University of Missouri
- Jennifer Lentz, Eli Lilly and Company
- Jane Perlmutter, Patient Advocate

EXPERT INTERVIEW WORKGROUP LEADERS
- Beverly Lorell, King & Spalding
- Steve Mikita, Patient Advocate

CISCRP STAFF
- Annick Anderson
- Zachary Hallinan

CTTI STAFF
- Annemarie Forrest, CTTI Project Manager
- Kimberley Smith, Project Assistant
Project Team Members

- Fred Bloom (CDC)
- Steve Cummings (UCSF)
- Molly Flannery (FDA)
- Julia Gorey (OHRP)
- Jayvant Heera (Pfizer)
- Kevin Hudziak (Eli Lilly)
- Hallie Kassan (North Shore-LIJ)
- Kathy Kopnisky (NIH)
- Ross McKinney (Duke)
- Marsha Melvin (FDA)
- Linda Morgan (Patient Advocate)
- Seth Schulman (Pfizer)
- Sheila Young (GSK)
- Rose Tiernan (FDA)
Meeting Objectives

- Present findings and conclusions from the project literature review and expert interview series
- Solicit feedback and develop consensus on proposed recommendations to enhance the informed consent process
Meeting Agenda – Day 1

- Presentation of the literature review and expert interview findings
- Presentation and discussion on proposed recommendations related to
  - The Informed Consent Process
  - Training on Conducting the Informed Consent Process
  - Use of E-Consent Technology
Meeting Agenda – Day 2

- Presentation and discussion on proposed recommendations related to
  - The Tiered Consent Model for the Informed Consent Document
- Discuss actionable opportunities for transformative change in informed consent