Tufts CTSI
Common Metrics Implementation

Learning Session 4
December 13, 2016
• Learning Session 3 evaluation

• Funding innovation in clinical and translational science: what predicts return

• IRB duration metric Change Package

• Shout-out
Evaluation of Learning Session 3

Q2 Please rate the Learning Session overall:

Answered: 27  Skipped: 0

Response rate = ~42%
“I like the ability to speak and not just type in the box”

“I really liked having open discussions on the call”
Funding innovation in clinical and translational science: what predicts return in a large multi-institutional CTSA

Pamela Davidson, PhD
UCLA Clinical and Translational Science Institute
Funding innovation in clinical and translational science: What predicts return in a large multi-institutional CTSA?

Pamela Davidson, PhD
UCLA CTSI-Evaluation
NCATS Common Metrics Initiative
December Learning Collaborative 2016
Acknowledgements

UCLA CTSI PI
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Doug Bell, MD, PhD
Marianne Zachariah

CTSI-Evaluation
Terry Nakazono
LeeAnna Bowman-Carpio
Jachael Gardner
Nicole Makowka
Jim Morrison
1. **Preliminary Results**: Funding Innovation in the CTSA Program

2. Study Aims, Data Sources, Variables

3. Pilot Grants/Voucher Awards

4. Analytic Framework/Dependent Variables/Significant Predictors

5. Implications
   a. Hub/Turn-the-Curve
   b. NCATS CTSA Program
1. Funding Innovation

- One of the primary goals of the CTSA Program is to advance discovery and accelerate clinical research processes.
- Pilot grants and core voucher awards are critical CTSI resources and services that support and promote discovery and innovation.
1. Funding Innovation

- Our review yielded a few studies in the research literature on critical success factors for launching and refining a pilot grant or core voucher program to stimulate collaborations, innovations and scientific achievement.

- Scientific achievement – a critical CTSA outcome, e.g.,
  - % of Pilot Research Projects having at least one publication
    - Yes/No (0,1)
    - # Publications, Impact Factor
  - % of Pilot Research Projects having at least one subsequent research award
    - Yes/No (0,1)
    - $$$ Amount
1. Conduct novel evaluation research to examine the significant predictors of CTSA return on pilot grants and voucher awards
   - Having at least 1 subsequent research award
   - Total dollar amounts yielded

2. Use findings to optimize investments, scientific achievement
2. Data Sources

I. Administrative Databases
   i. Administrative records of all pilot and voucher awards, primary HUB institution of the investigator, dollar amount, date of funding

II. Faculty Database and Partner Websites
   i. Gender
   ii. Faculty Rank

III. UCLA CTSI Longitudinal Scientific Achievement Survey LSAS:
   i. Modelled after the Rockefeller University’s Graduate Tracking Survey System (Romanick, et al., 2014)
   ii. In use at Rockefeller University since 2011
   iii. Adapted by other CTSA Hubs
### 3. CTSI Pilot Projects Funded¹

<table>
<thead>
<tr>
<th>Pilot Mechanism</th>
<th>Award Description</th>
<th>#Pilot Projects Funded (2011-12)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CTSI Prototype Grant</strong></td>
<td>Awarded faculty-student teams working on novel technologies through the UCLA Business of Science Center.</td>
<td>2</td>
</tr>
<tr>
<td><strong>Supplement award</strong></td>
<td>Partner site award (CDU in 2011).</td>
<td>6</td>
</tr>
<tr>
<td><strong>CTSI Catalyst Award</strong></td>
<td>Support team-building activities that advance translational science and promote collaborations across disciplines and CTSI institutions.</td>
<td>35</td>
</tr>
<tr>
<td><strong>CTSI Novel Translational Technology and Methodologies (NTTM) Grant</strong></td>
<td>Foster the development of any research tool, technique, or resource with the potential of bridging critical gaps in the conduct of translational biomedical science.</td>
<td>2</td>
</tr>
<tr>
<td><strong>CTSI Seed Grant</strong></td>
<td>Foster pilot studies that use CTRC facilities and staff with the goal of developing these into larger, successful, extramurally funded projects.</td>
<td>82</td>
</tr>
<tr>
<td><strong>CTSI Team Science Award</strong></td>
<td>Intended to catalyze team science among CTSI partner and affiliate institutions to plan for submission of large extramural grants.</td>
<td>14</td>
</tr>
<tr>
<td><strong>Community Engagement Research Program (CERP) Pilot</strong></td>
<td>Funding and technical assistance to community-based organizations (CBOs) to build capacity and skills to conduct research in collaboration with academic researchers.</td>
<td>3</td>
</tr>
<tr>
<td><strong>CTSI Junior Faculty Mentored Award</strong></td>
<td>Junior Faculty Mentored-Research Awards are available for junior faculty in any series within their first three years of appointment to support mentored training in translational research in all areas of investigation.</td>
<td>24</td>
</tr>
<tr>
<td><strong>KL2</strong></td>
<td>Supports highly qualified junior faculty to conduct mentored, interdisciplinary, patient-oriented research.</td>
<td>1</td>
</tr>
<tr>
<td><strong>Totals</strong></td>
<td></td>
<td>169</td>
</tr>
</tbody>
</table>
3. Voucher Awards

- UCLA CTSI awards vouchers worth up to $10,000 to defray cost of accessing laboratory and other scientific core resources and technologies
  - 7 Core Areas: Animals, Cells, Computations, Genetics, Humans, Images, and Molecules
  - Currently 74 cores within 7 Core Areas
  - 79 vouchers were awarded in Year 1 (2011)
  - 61 vouchers were awarded in Year 2 (2012)
  - Total of 140 voucher awards

The slide presents number of mutually exclusive investigators who received vouchers in 2011-2012; some investigators received more than one voucher, also in two cases one voucher award had two PIs.
## CTSI Survey Pilot and Voucher Awardees (PIs)

<table>
<thead>
<tr>
<th></th>
<th>Totals</th>
<th>Pilot only</th>
<th>Voucher only</th>
<th>Pilot &amp; Voucher</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong># Pilot and Voucher Awardees (PIs)</strong></td>
<td>313</td>
<td>168</td>
<td>131</td>
<td>14</td>
</tr>
<tr>
<td><strong>Survey Respondents (n, %)</strong></td>
<td>259 (83%)</td>
<td>136 (81%)</td>
<td>111 (85%)</td>
<td>12 (86%)</td>
</tr>
</tbody>
</table>
## 4. Analytic Framework/ Domains

- Contextual
- CTSI Support
- Incubation period
- Collaborations/Research Support
- Special Populations
- Clinical Trials/Community Research
- Barriers/Facilitators to Conducting Research
- Research Products
- Self-Reported Impact

Incubation period: Start date of award to close date of LSAS survey cycle 3 11/28/16
### 4. Analytic Framework: Domains/Variables

#### CTSI Longitudinal Scientific Achievement Survey, 2011-2012 (n=259)

<table>
<thead>
<tr>
<th>Domain/Variables</th>
<th>N</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Contextual</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Institution</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• UCLA</td>
<td>189</td>
<td>(73)</td>
</tr>
<tr>
<td>• Cedars-Sinai</td>
<td>18</td>
<td>(7)</td>
</tr>
<tr>
<td>• Harbor</td>
<td>41</td>
<td>(16)</td>
</tr>
<tr>
<td>• Charles Drew</td>
<td>11</td>
<td>(4)</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Male</td>
<td>149</td>
<td>(58)</td>
</tr>
<tr>
<td>• Female</td>
<td>110</td>
<td>(42)</td>
</tr>
<tr>
<td><strong>Staff/Faculty Appointment</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Non-faculty</td>
<td>38</td>
<td>(15)</td>
</tr>
<tr>
<td>• Assistant professor</td>
<td>69</td>
<td>(27)</td>
</tr>
<tr>
<td>• Associate professor</td>
<td>53</td>
<td>(20)</td>
</tr>
<tr>
<td>• Professor</td>
<td>99</td>
<td>(38)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Domain/Variables</th>
<th>N</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CTSI Support</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>User group</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Pilot¹</td>
<td>148</td>
<td>(57)</td>
</tr>
<tr>
<td>• Voucher</td>
<td>123</td>
<td>(47)</td>
</tr>
<tr>
<td>• Biostatistics consultation</td>
<td>50</td>
<td>(19)</td>
</tr>
<tr>
<td>• CTRC²</td>
<td>45</td>
<td>(17)</td>
</tr>
<tr>
<td>• Salary support</td>
<td>25</td>
<td>(10)</td>
</tr>
<tr>
<td><strong>Incubation period, in months (from date of award to SAS survey close date)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• 12.9 to 25.1 mos.</td>
<td>63</td>
<td>(24)</td>
</tr>
<tr>
<td>• 25.2 to 26.3 mos.</td>
<td>71</td>
<td>(27)</td>
</tr>
<tr>
<td>• 26.6 to 30.4 mos.</td>
<td>61</td>
<td>(24)</td>
</tr>
<tr>
<td>• 30.8 to 65.8 mos.</td>
<td>64</td>
<td>(25)</td>
</tr>
</tbody>
</table>

-Preliminary analysis updates scientific productivity and incubation period in the 3rd survey cycle, the final analysis will need to update responses to other IV, e.g., barriers to research. Incubation period is underestimated due to attrition in longitudinal survey responses; additional data sources will be used to obtain more robust measures of scientific productivity and we will recalculate incubation period.
### 4. Analytic Framework: Domains/Variables (cont’d)

**CTSI Longitudinal Scientific Achievement Survey, 2011-2012 (n=259)**

<table>
<thead>
<tr>
<th>Domain/Variables</th>
<th>N</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Collaborations/Research Support</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Collaborations with another NIH Institute</td>
<td>109</td>
<td>(42)</td>
</tr>
<tr>
<td>• Collaborations with other CTSAs</td>
<td>41</td>
<td>(16)</td>
</tr>
<tr>
<td>• No. of collaborations with other UCLA CTSI Hub partners</td>
<td>135</td>
<td>(52)</td>
</tr>
<tr>
<td>• None</td>
<td>100</td>
<td>(39)</td>
</tr>
<tr>
<td>• One</td>
<td>24</td>
<td>(9)</td>
</tr>
<tr>
<td>• Industry/not-for-profit support</td>
<td>43</td>
<td>(17)</td>
</tr>
<tr>
<td><strong>Special Populations - Is your research related to:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pediatrics</td>
<td>31</td>
<td>(12)</td>
</tr>
<tr>
<td>HIV</td>
<td>16</td>
<td>(6)</td>
</tr>
<tr>
<td>Rare diseases</td>
<td>22</td>
<td>(8)</td>
</tr>
<tr>
<td><strong>Clinical Trials/Community Research</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Any research related to clinical trials?</td>
<td>25</td>
<td>(10)</td>
</tr>
<tr>
<td>• Any community partnered research?</td>
<td>35</td>
<td>(14)</td>
</tr>
</tbody>
</table>

**Barriers/Facilitators to Conducting Research**

<table>
<thead>
<tr>
<th>Domain/Variables</th>
<th>N</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Any barriers or challenges reported?</td>
<td>160</td>
<td>(62)</td>
</tr>
<tr>
<td>• Any facilitators enabling advances reported?</td>
<td>155</td>
<td>(60)</td>
</tr>
</tbody>
</table>

**Research Products**

<table>
<thead>
<tr>
<th>Domain/Variables</th>
<th>N</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• One or more publications attributed to CTSI</td>
<td>52</td>
<td>(20)</td>
</tr>
</tbody>
</table>

**Self-Reported Impact**

<table>
<thead>
<tr>
<th>Domain/Variables</th>
<th>N</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total no. of impacts (scientific, health, community) from CTSA support</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>75</td>
<td>(29)</td>
</tr>
<tr>
<td>1</td>
<td>131</td>
<td>(51)</td>
</tr>
<tr>
<td>2</td>
<td>42</td>
<td>(16)</td>
</tr>
<tr>
<td>3</td>
<td>11</td>
<td>(4)</td>
</tr>
</tbody>
</table>

*Preliminary analysis* updates scientific productivity and incubation period in the 3rd survey cycle, the final analysis will need to update responses to other IV, e.g., barriers to research. Incubation period is underestimated due to attrition in longitudinal survey responses; additional data sources will be used to obtain more robust measures of scientific productivity and we will recalibrate incubation period.
### Preliminary Results

<table>
<thead>
<tr>
<th>Investigators having at least one subsequent research award (DV-1)</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>0, no</td>
<td>211</td>
<td>81.5</td>
</tr>
<tr>
<td>1, yes</td>
<td>48</td>
<td>18.5</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>259</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

Slide reports combined awards for pilot grants and core vouchers, 2011-2012. Preliminary results include survey respondents only and therefore underestimate the dependent variable (DV); Additional data sources will be used to construct more robust measures. Incubation Period: 2011 through 2016.
Investigators having at least one subsequent research award (DV)

**significant predictors:**

- **Longer incubation period** compared to those investigators whose projects had less time to incubate (OR=5.1, p < .01)

- **Collaborating with another NIH institute** were more than twice as likely to report at least one subsequent research award (OR= 2.4, p< .05)

- Investigators engaged in **Pediatrics research** were more than 3 times as likely to report at least one subsequent research award (OR= 3.3, p< .05)

- Investigators who reported **Publications attributed to CTSI support** were 3 times more likely to report a subsequent research award (OR=3.1, p< .05)

- Investigators who reported **scientific, health and/or community impact** from their research were about twice as likely to report at least one subsequent research award (OR=1.9, p< .05)
Investigators funded, 2011-2012 (n=259)

**Preliminary Results**

<table>
<thead>
<tr>
<th>Subsequent research awards in $ dollar amount quartiles (DV-2)</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>211</td>
<td>81.5</td>
</tr>
<tr>
<td>(1) $30,000-$246,221</td>
<td>12</td>
<td>4.6</td>
</tr>
<tr>
<td>(2) $266,178-$615,000</td>
<td>12</td>
<td>4.6</td>
</tr>
<tr>
<td>(3) $661,605-$1,762,515</td>
<td>12</td>
<td>4.6</td>
</tr>
<tr>
<td>(4) $1,894,000-$13,145,465</td>
<td>12</td>
<td>4.6</td>
</tr>
</tbody>
</table>

Slide reports combined awards for pilot grants and core vouchers, 2011-2012.

*Preliminary results* include survey respondents only and therefore underestimate the dependent variable (DV); Additional data sources will be used to construct more robust measures. Incubation Period: 2011 through 2016.
Subsequent research awards in $ dollar amount quartiles

Significant predictors:

- **Longer incubation period** (0.413, p<.05)

- **Collaborating with another NIH institute** (0.378, p<.01)

- **Community partnered research** (-0.580, p<.01)

- **Publications attributed to CTSI support** (0.550, p<.01)

- **Scientific, health and/or community impact** (0.189, p=0.05)
5. Implications

- Using a periodic survey to track scientific productivity, we conducted novel evaluation research to examine significant predictors of having at least one subsequent research award and total dollar amounts yielded.

- Every CTSA PI will want to generate the evidence-base for predicting factors that significantly contribute to: (a) return on investment in innovation, and (b) a successful research trajectory.

- However, in our turn-the-curve analysis we need to apply a SYSTEMS PERSPECTIVE.
Steps in Turn-the-Curve (TTC) Thinking

1. How are we doing?

2. What is the story behind the curve?

3. Who are partners that might have a role to play in turning the curve?

4. What would work to turn the curve?

5. What is our strategy to turn the curve?
Pilot and Voucher Awards:
Having at least one subsequent research award

- Hyper-competition for limited federal research dollars
- Demand for research dollars outstrips supply
- Declines in success rates for NIH grant applications, especially for junior investigators
- K-Award Workshops, K to R and Bridge funding to support high potential scholars
- Are we training too many biomedical researchers for limited academic appointments?
- Should we raise the bar on selection and recruitment?
- Biomedical research in US academic medicine is contracting
- Over the past decade the expansion has stalled and even reversed
- Federal funding continues on a downward trajectory (includes Research and Facilities)
- "System is under tremendous strain, which threatens the vitality of science in the US"
- Biomedical Industry is robust

Turn the Curve Thinking
• The political and economic picture for federal research funding is on an uncertain trajectory and the direction will substantially effect the biomedical research structure in the academic medical centers

• Recent passage of the Cures Legislation may turn this around – President Obama expected to sign into law

• To improve long-term scientific productivity, senior scientists in consultation with NIH leaders have suggested
  – Structural changes in research staffing and training postdoctoral fellows,
  – Improving the goals and mechanisms for scientific grants,
  – Improving evaluation criteria to guide reviewers,
  – Strengthening grant review panels, and
  – A more critical review of program funding at the federal level (Alberts, et al., 2014).
Publications/ Triangulate data from 3 data sources to construct most robust metric
• Scientific Achievement Survey (SAS)
• Pubs generated using investigator names
• Pubs generated by Biomed Librarian using NCATS grant #

Subsequent Research Awards
• Augment LSAS data
• NIH reporter to include SAS non-respondents
• Internet-based search to identify NFP/Foundation Funding
• Access to Office of Contracts and Grants Administration (OCGA) or other administrative data sources on campus


Bernard, G. R. (2012). Preparedness of the CTSA’s structural and scientific assets to support the mission of the National Center for Advancing Translational Sciences (NCATS). *Clinical and translational science, 5*(2), 121.


IRB Review Duration Change Package

Laura E. Peterson
Tufts Common Metrics Implementation Team
I would like to find ways to share more across hubs about TTC plans and to see what others are doing

--Bill Trochim
Weill Cornell CTSC
“Harvest” best and promising practices that could help turn the curve
IRB REVIEW DURATION
CHANGE PACKAGE

Respect for Persons
Beneficence  Justice

Protect the rights and welfare of human research subjects
“Start with the end in mind”

Common Metric Aim

Improve the median number of calendar days from the official IRB application receipt date to the official IRB final approval date for fully reviewed protocols
Turn the Curve Plans

• Positive/facilitating factors from Story Behind the Curve

• What Works

Existing Evidence

Change Package

“Drivers”
Drivers for IRB Duration

1. Engaged and supported investigators create high-quality applications and respond to inquiries in a timely manner

2. IRB staff and review committees are sufficient and appropriate with optimized workloads

3. Waste and redundancy are identified and eliminated

4. Use of appropriate technology is optimized

5. Processes are improved based on feedback from researchers and system metrics
Turn the Curve Plans

• What Works

• Strategies

Existing Evidence

Change Package

Strategies
Driver: Identify and eliminate waste and redundancy

Strategies

• Use QI tools (process workflow mapping, root cause analysis, LEAN / Six Sigma) to understand steps in the process

• Set targets for the duration of specific steps in the process

• Identify & remove redundant & non-essential questions from the IRB application

• Avoid process stagnation by engaging in parallel reviews
Aim + Drivers + Strategies = Driver Diagram
Increase investigator awareness of available hub support services (faculty meetings, symposia/fairs/expo, optimize web site, partner with marketing)

Provide investigators with:
- Application templates
- Frequently Asked Questions (FAQs)
- Flowchart depicting the IRB process
- Tip sheet on how to improve an application
- Submission checklists
- Exemplar protocols and consent forms
- Periodic updates and tips, e.g., in a newsletter
- Conduct training in the IRB application process for investigators and staff
- Provide support during application preparation (drop-in clinics, consultation services)
- Provide pre-screening/pre-review services
- Provide feedback on rejected submissions

Conduct training in the IRB application process for investigators and staff

Provide support during application preparation (drop-in clinics, consultation services)

Provide pre-screening/pre-review services

Provide feedback on rejected submissions

Assess for staff member training needs and provide appropriate training

Assign a single coordinator to support a study through the entire process

Develop and follow Standard Operating Procedures for each step of the process

Increase the number of review panels/committees (and/or frequency of meetings)

Increase meeting frequency during high-demand periods

Use quality improvement tools to clearly understand steps in the process and identify potential waste or bottlenecks (Process workflow mapping, Root cause analysis, LEAN/Six Sigma)

Set targets for the duration of specific steps in the process

Identify & remove redundant & non-essential questions from the IRB application

Avoid process stagnation by engaging in parallel reviews

Utilize an electronic IRB submission and tracking system

Improve online instructions at the time of data entry

Program electronic reminders for outstanding responses to inquiries

Post turnaround time metrics on a public-facing website

Elicit feedback from investigators on their experience with the process at the time of each IRB approval

Hold focus groups with small groups of investigators

Assess protocols with particularly long TAT for commonalities, potential remedies

Additional drivers and strategies will be identified as the Common Metrics Initiative continues

1. Engaged and supported investigators create high-quality applications and respond to inquiries in a timely manner

2. IRB staff and review committees are sufficient and appropriate with optimized workloads

3. Waste and redundancy are identified and eliminated

4. Use of appropriate technology is optimized

5. Processes are improved based on feedback from researchers and system metrics

6. Common Metric Aim
   - Improve the median number of calendar days from the official IRB application receipt date to the official IRB final approval date for fully reviewed protocols

Drivers

Strategies

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5. Processes are improved based on feedback from researchers and system metrics

6. Processes are improved based on feedback from researchers and system metrics

Drivers

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- Provide pre-screening/pre-review services
- Provide feedback on rejected submissions

Strategies

- Assess for staff member training needs and provide appropriate training
- Assign a single coordinator to support a study through the entire process
- Develop and follow Standard Operating Procedures for each step of the process
- Increase the number of review panels/committees (and/or frequency of meetings)
  - Increase meeting frequency during high-demand periods

- Use quality improvement tools to clearly understand steps in the process and identify potential waste or bottlenecks (Process workflow mapping, Root cause analysis, LEAN/Six Sigma)
- Set targets for the duration of specific steps in the process
  - Identify & remove redundant & non-essential questions from the IRB application
  - Avoid process stagnation by engaging in parallel reviews

- Utilize an electronic IRB submission and tracking system
  - Improve online instructions at the time of data entry
  - Program electronic reminders for outstanding responses to inquiries

- Post turnaround time metrics on a public-facing website
  - Elicit feedback from investigators on their experience with the process at the time of each IRB approval
  - Hold focus groups with small groups of investigators
  - Assess protocols with particularly long TAT for commonalities, potential remedies

Additional drivers and strategies will be identified as the Common Metrics Initiative continues
1. Engaged and supported investigators create high-quality applications and respond to inquiries in a timely manner

- Increase investigator awareness of available hub support services (faculty meetings, symposia/fairs/expo, optimize web site, partner with marketing)
- Provide investigators with:
  - Application templates
  - Frequently Asked Questions (FAQs)
  - Flowchart depicting the IRB process
  - Tip sheet on how to improve an application
  - Submission checklists
  - Exemplar protocols and consent forms
  - Periodic updates and tips, e.g., in a newsletter
- Conduct training in the IRB application process for investigators and staff
- Provide support during application preparation (drop-in clinics, consultation services)
- Provide pre-screening/pre-review services
- Provide feedback on rejected submissions
- Assess for staff member training needs and provide appropriate training
- Assign a single coordinator to support a study through the entire process
- Develop and follow Standard Operating Procedures for each step of the process
- Increase the number of review panels/committees (and/or frequency of meetings)
- Increase meeting frequency during high-demand periods

2. IRB staff and review committees are sufficient and appropriate with optimized workloads

- Assess for staff member training needs and provide appropriate training
- Assign a single coordinator to support a study through the entire process
- Develop and follow Standard Operating Procedures for each step of the process
- Increase the number of review panels/committees (and/or frequency of meetings)
- Increase meeting frequency during high-demand periods

3. Waste and redundancy are identified and eliminated

- Use quality improvement tools to clearly understand steps in the process and identify potential waste or bottlenecks (Process workflow mapping, Root cause analysis, LEAN/Six Sigma)
- Set targets for the duration of specific steps in the process
- Identify & remove redundant & non-essential questions from the IRB application
- Avoid process stagnation by engaging in parallel reviews

4. Use of appropriate technology is optimized

- Utilize an electronic IRB submission and tracking system
  - Improve online instructions at the time of data entry
  - Program electronic reminders for outstanding responses to inquiries

5. Processes are improved based on feedback from researchers and system metrics

- Post turnaround time metrics on a public-facing website
- Elicit feedback from investigators on their experience with the process at the time of each IRB approval
- Hold focus groups with small groups of investigators
- Assess protocols with particularly long TAT for commonalities, potential remedies

6. Additional drivers and strategies will be identified as the Common Metrics Initiative continues
Hub example strategies, by driver

**DRIVER: IDENTIFY AND ELIMINATE WASTE AND REDUNDANCY**

**Rationale:**
- It is important to look beyond symptoms to uncover the true causes of delays
- Minimizing non-value added activities and reducing variation can eliminate rework and bottlenecks and improve satisfaction

**EXAMPLE STRATEGIES**

An example from the Indiana CTSI of using process mapping to identify potential waste in IRB processes

A tutorial on Cause and Effect diagrams – a method for conducting a root cause analysis
**Driver: Engage and Support Investigators to Create High-Quality Applications**

Rationale:
Applications with inadequate, incomplete or insufficient information are a top reason for IRB approval delay.

These problems may be particularly acute in junior investigators, or those who do not avail themselves of existing support services and other resources.

Turnaround time can also be affected by investigator responsiveness to IRB requests for information or changes.

**Example Strategies**

- Create [Frequently Asked Questions](#) about the IRB process to share with investigators.
- Develop a [flowchart](#) of the process to aid in a shared understanding of what will happen and when.
- Provide updates and tips in a monthly [newsletter](#).
- Provide [pre-review services](#) for new investigators.
- Rockefeller University [Navigation Program](#): a structured protocol development and educational program.

**IRB Checklist**

Tufts CTSI Tufts Clinical and Translational Science Institute

Common Metrics Implementation
**DRIVER: ENGAGE AND SUPPORT INVESTIGATORS TO CREATE HIGH-QUALITY APPLICATIONS**

**EXAMPLE STRATEGIES**

Create **Frequently Asked Questions** about the IRB process to share with investigators.

Develop a **flowchart** of the process to aid in a shared understanding of what will happen and when.

Provide updates and tips in a monthly **newsletter**.

Provide **pre-review services** for new investigators.

Rockefeller University’s **Navigation Program**:

- Structured protocol development and educational program

**IRB Checklist**

Common Metrics Implementation

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Rationale:

Applications with inadequate, incomplete or insufficient information are a top reason for IRB approval delay.

These problems may be particularly acute in junior investigators, or those who do not avail themselves of existing support services and other resources.

Turnaround time can be also be affected by investigator responsiveness to IRB requests for information or changes.
Some drivers don’t have as many strategies. Many strategies don’t have examples.
Some drivers don’t have as many strategies. Many strategies don’t have examples.

Median IRB Review Duration Driver Diagram v1.0
Even so, there are quite a few Strategies listed. Are we expected to do all of them?!
Even so, there are quite a few Strategies listed. Are we expected to do all of them?!
Our hub isn’t working first on the IRB Duration metric. When will there be a Change Package for Careers / Pilots?
Our hub isn’t working first on the IRB Duration metric. When will there be a Change Package for Careers / Pilots?

Pilot publications metric – Learning Session 5

Careers metric – Learning Session 6
Share Seamlessly, Steal Shamelessly
Shout-out
Mon. October 3, 2016, 4:00-5:15 p.m. – Foster Auditorium, Paterno/Pattee Library

SEMINAR | Everyone Needs an Elevator Pitch: Strategies to Engage Non-Technical Audiences on Technical Research Topics

Andy Gustafson
Smeal College of Business

Skilled scientists and engineers must be equipped with not only technical expertise, but also with communication skills that can get others interested in their areas of research. This could mean the difference between success or failure in launching a new business, gaining a grant, or garnering support from the community at large regarding why your work matters. Learn strategies from a business communications expert to condense your key message into a “pitch” that can be given in the duration of a typical elevator ride. Seminar is 1hr 15min.
• Applies to more than one metric
• Partnership beyond the CTSI
Next Learning Session

Tuesday Jan. 10, 2017
3pm – 4pm ET