IRB REVIEW DURATION
CHANGE PACKAGE

Protect the rights and welfare of human research subjects
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Section 1 | Introduction & Background

The Clinical and Translational Sciences Awards (CTSA) Consortium, led by the National Center for Advancing Translational Sciences (NCATS), is charged with accelerating and improving clinical and translational research. So far, the potential of the CTSA Program is only partially realized. In order to maximize the Consortium’s impact, NCATS has implemented the Common Metrics Initiative, which employs a set of common metrics for use in collaborative management based on the principles of the Results-Based Accountability (RBA) framework. The Common Metrics Initiative is using a set of common metrics for three initial topics, IRB Duration, Pilot Funding Publications and Grants, and Careers in Clinical and Translational Research, to help to focus activities as a network and at the individual CTSA hubs on making significant improvements in research translation and workforce development. This change package outlines potential strategies for hubs to use as they begin or advance strategic management efforts for IRB Duration.

What is a Change Package?
A change package is a concise and practical document that includes ideas and inspiration for teams seeking to apply methods to increasing the effectiveness and efficiency of their processes and outcomes. Change packages focus on a specific metric or process, and generally include background material; a summary of evidence or best practices; and specific strategies, tools and examples that can be applied to the work.

How Was This Change Package Developed?
This initial change package was informed by research findings when available, as well as strategies implemented or planned by Pilot and Implementation Group 1 and Group 2 hubs participating in the Common Metrics Initiative. It will be revised as additional learning surfaces.
Strategic Management Method

The work of hub teams participating in the Common Metric Initiative is guided by the Results-Based Accountability framework. Developed by Mark Friedman and described in his book *Trying Hard is Not Good Enough*, RBA is used by organizations to improve the performance of their programs or services. RBA starts with ends and works backward, towards means. RBA provides a step-by-step process to get from ends to means. This process is called “Turn the Curve” thinking.

Hubs in the Common Metric Initiative use Scorecard software to enter and graph their common metric results and facilitate their Turn the Curve planning process.
Section 2 | IRB Duration Driver Diagram

An initial driver diagram for the IRB Duration metric is depicted on the next page.

A Driver Diagram is a visual depiction of the theory behind an improvement effort—a roadmap of sorts. It illustrates the linkages between an overall aim (in this case, improving the median number of days from IRB receipt to final approval), drivers (facilitating factors that, if present, can help achieve the aim), and the strategies that can help you get there (like those included in this change package).

Five drivers were identified during work with the hubs participating in Implementation Groups 1 and 2 in the Common Metrics Initiative who elected to work on IRB duration as their initial metric. They are:

1) Engaging and supporting investigators to create high-quality IRB applications and respond to inquiries in a timely manner
2) Providing appropriate IRB staffing and review committees and optimizing their workloads
3) Eliminating waste and redundancy from the IRB review and approval process
4) Optimizing the use of appropriate technology, and
5) Using feedback to continually improve IRB processes.

Over time, the initiative will likely identify additional drivers and strategies that will lead to improvement and the driver diagram will be updated.
**Median IRB Review Duration**

**Driver Diagram v1.0**

**Drivers**

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

**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

**Strategies**

- Increase investigator awareness of available hub support services (faculty meetings, symposia/fields/cope, 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

- 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.
Strategies

Starting on the next page are specific examples for a number of the strategies in the driver diagram that may yield to improvement at the level of a CTSA hub. These strategies are organized around the drivers outlined above.

A Strategy answers the question “What are we going to do?” [to Turn the Curve].

--Phil Lee, Clear Impact
**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 be also be affected by investigator responsiveness to IRB requests for information or changes.

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**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.

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"Prolonged IRB reviews are most likely when inexperienced researchers prepare and submit their completed applications in a vacuum, without consulting their committee."

--Bluestein et al
**Rationale:**
Proper staffing is crucial to the effective operation of an IRB. Regulatory authorities (e.g., FDA, OHRP) require infrastructure support for the IRB, and the development and dissemination of policies and procedures.

**EXAMPLE STRATEGIES**
- **Tip Sheets** to help organizations write Human Research Protection Program (HRPP) policies and procedures*
- HRPP **Operations Manual** to serve as a reference for staff, reviewers and others
- **Revise** the review committee meeting schedule and duration (and a presentation by the Wake Forest CTSI about this initiative)
*these reference accreditation standards but may also be helpful models when accreditation is not being sought

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**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
Rationale:
Transparent disclosure of IRB duration metrics can help build will for improvement efforts and manage researcher expectations for outcomes.

EXAMPLE STRATEGIES

A dashboard of metrics to enable tracking and monitoring of IRB performance

Reporting of Number of Days to IRB Approval

Rationale:
Researcher feedback can provide a valuable source of information about ways in which performance can be improved and the researcher community be better served.

EXAMPLE STRATEGIES

Positive and negative feedback elicited from the researcher community.
REFERENCES


Blustein J, Regenstein M, Siegel B, Billings J. Notes from the field: jumpstarting the IRB approval process in multicenter studies. Health Serv Res. 2007;42(4):1773-82.
