JOURNAL OF CLINICAL RESEARCH BEST PRACTICES
Vol. 12, No. 7, July 2016 "Happy Trials to You"

# Reducing Waste in the Process for Preparing IRB Minutes

**By Michelle Grienauer**

## Introduction

The Toyota Production System (TPS), along with its management philosophies and practices, is an international model for businesses seeking to increase efficiency, reduce waste, and improve quality. Over the past decade, many hospitals and healthcare systems adopted TPS methods with impressive results, such as reduced medication error rates, reduced hospital stays, and shorter appointment waiting times.[1] These successes have been noticed by human research protection programs (HRPPs), and several HRPPs have implemented TPS methodology to improve the quality and speed of Institutional Review Board (IRB) review while also reducing administrative burden.[2]

This article focuses on one such example of the application of TPS methodology by HRPPs: eliminating waste from the process for preparing IRB meeting minutes. This article will outline common steps in the minutes process, along with the associated types of waste and discuss methods to eliminate unnecessary steps and reduce waste.

## TPS and Lean Production

TPS is a system based on the Toyota Way, the managerial and production philosophy of the Toyota Motor Corporation. At its core, the Toyota Way is a workplace culture of continuous improvement and respect for people.[3] Every employee, from executives "up to" shop floor workers, is trained and encouraged to identify effective ways to improve processes and to implement changes that reduce waste.[4] This culture, as demonstrated by the phenomenal success of the Toyota Motor Corporation, can create large gains in productivity and quality, and can generate a stable and skilled workforce.

TPS is the basis for "lean manufacturing" methods and their core objective of eliminating system waste.[5] TPS defines "waste" more broadly than materials or products that can be thrown away. Instead, waste is considered from a system level and, therefore, "system waste" is found in process steps that are unnecessary or do not provide value to the customer. Wasteful steps add cost and time to a process and can also reduce quality, since they divert attention from essential steps and create opportunities for error. Lean methodology eliminates unnecessary steps and streamlines steps that are necessary but do not provide value to customers.[6] This "lean" approach has been proven to generate extraordinary improvements in productivity, quality and process times.[7]

### Identifying Process Steps and Defining Value

The first stage in eliminating waste within a process is to identity all the steps in the process and determine which ones provide customer value. Value can be assessed by understanding what a customer wants from a process or service.[8] To make this assessment, it is important to understand that most processes involve both internal "customers" (e.g., departments or teams responsible for a subsequent production step) and external customers (e.g., the final recipient(s) of the product or service).

The next stage is determining which steps are necessary, regardless of customer value. If a costly or time-consuming step is necessary but provides only a small value, it cannot be eliminated but is a prime target for streamlining.


© 2016 First Clinical Research and the Author(s)

Table 1 outlines common steps in a conventional process for preparing IRB minutes, along with whether each step adds value for a customer and whether the step is necessary.

**Table 1. Process for Preparing IRB Minutes before Applying Lean Methods**

| Actor | Action | Adds Value? | Necessary? |
|---|---|---|---|
| IRB Staff I* | Record IRB discussion and actions. | Yes | Yes |
| IRB Staff I | Enter attendance and vote information into a minutes template document. | Yes | Yes |
| IRB Staff I | Circulate template to IRB Staff II. | No | No |
| IRB Staff I | Wait for response. | No | No |
| IRB Staff II* | Enter board determinations, bases for requiring changes, summaries of controverted issues, etc., into template and send back to IRB Staff I. | Yes | Yes |
| IRB Staff I | Compile responses into a draft version of the minutes. | No | Yes |
| IRB Staff I | Circulate draft minutes to each board member present at the meeting. | No | No |
| IRB Staff I | Wait for response. | No | No |
| IRB Members | Review draft minutes and provide revisions (if any). | No | No |
| IRB Staff I | Save and store all communication and draft versions. | No | Yes |
| IRB Staff I | Compile board member edits into a new draft version. | No | No |
| IRB Staff I | Send draft minutes to the IRB Chair. | No | No |
| IRB Staff I | Wait for response. | No | No |
| IRB Chair | Review draft minutes and provide revisions or a statement that the minutes are acceptable. | No | No |
| IRB Staff I | Create final version of minutes. | Yes | Yes |
| IRB Staff I | Send final version of minutes to IRB Chair for signature. | No | No |
| IRB Staff I | Wait for response. | No | No |
| IRB Chair | Sign minutes and send back to IRB staff. | No | No |
| IRB Staff I | Circulate approved minutes to all IRB members and other individuals, as required by institutional policy. | No | Yes |
| IRB Staff I | Store finalized minutes and destroy draft minutes. | Yes | Yes |

* "IRB Staff I" refers to clerical functions (e.g., Board Secretary role). "IRB Staff II" refers to functions that require regulatory expertise (e.g., IRB Analyst role).

In this process, internal customers include the "actors" in column one. External customers include IRB members not present at the meeting, institutional officials, compliance officers, and federal agency representatives. Under the independent IRB model, external customers might also include the institution where the research is conducted and study-sponsor auditors.

As Table 1 demonstrates, there are very few value-added steps in a conventional process for preparing IRB minutes. In fact, only the last activity in the table provides direct value to an external customer. For example, an Office for Human Research Protections (OHRP) or Food and Drug Administration (FDA) investigator would likely be concerned only that adequate final minutes are available for inspection and copying, not how the minutes were drafted.


© 2016 First Clinical Research and the Author(s)

## Eliminating System Waste

As discussed above, the goal of lean methodology is to eliminate waste by removing unnecessary steps and minimizing the time spent on steps that are necessary but do not add value. Once all the steps in a process have been identified, along with their value and necessity, the next phase is to determine how to eliminate or streamline wasteful steps.

According to TPS, seven major types of waste exist in most processes: overproduction, waiting, unnecessary transport, overprocessing, excess inventory, unnecessary movement, and defects.[9] In lean methodology, unused employee creativity is considered to be an eighth type of waste.[10]

The main types of waste in a conventional process for preparing IRB minutes are: waiting, unnecessary transport, and overprocessing.

### Waiting

A very common form of waste is waiting for a previous step to be completed, for a tool or supply to become available, or for a capacity bottleneck to clear.

In a conventional IRB minutes process, too much time is spent waiting for drafts to be prepared, reviewed and edited. Depending on the turnaround times and whether reviews are done sequentially or in parallel, waiting can delay completion of the process by weeks or even months.

From the customer perspective, waiting almost never adds value. But since no process is instantaneous, there will always be some necessary lag time. In TPS and lean methodology, the goal is therefore to reduce or remove all *unnecessary* waiting time. Unnecessary waiting time in the IRB minutes process can be reduced by limiting the number of individuals reviewing draft minutes, by setting deadlines, or by using software that allows simultaneous editing by multiple reviewers.

For example, HRPPs often employ IRB staff members (often called IRB Administrators or IRB Analysts) to draft IRB meeting minutes and consolidate edits by reviewers. These staff members usually have extensive training in human subjects protection regulations and often have qualifications such as Certified IRB Professional (CIP) certification. Under this model, an IRB staff member with the requisite expertise ensures that the minutes include required IRB determinations and adequate supporting information, such as summaries of controverted issues. If the staff member attends the meeting or can obtain a transcript or recording, he or she should be able to draft the minutes without review by board members. Instead, an IRB member could be consulted when a specific question arises, e.g., if a recording is indistinct or a comment is ambiguous. After the final minutes are published, board members should still be able to notify IRB staff if the minutes are inaccurate and to propose a correction. If this scenario is common, board member review of the draft minutes probably cannot be eliminated.

Regardless of the number of reviewers, unnecessary waiting time can often be eliminated by setting deadlines. For example, if a board member does not respond within the expected timeframe, IRB staff can assume the reviewer had no edits and the process can move forward. As above, the delinquent board member would still have the opportunity to correct the final minutes.

Technology can also be harnessed to reduce waiting. Some IRBs use software that allows centralized online storage with cooperative editing of, and commenting on, a single meeting minutes document, including an audit trail of the edits. Information about the meeting, such as attendance, voting and discussion, can be entered directly into a virtual workspace. The final minutes can easily be produced for regulators and auditors. Such software applications


© 2016 First Clinical Research and the Author(s)

are designed to ensure adequate privacy and confidentiality of IRB records and are compliant with applicable regulations, such as the Health Insurance Portability and Accountability Act (HIPAA) Security Rule and FDA electronic record requirements.

### Unnecessary Transport

Another form of system waste, related to waiting, occurs due to unnecessary transport or movement of people or work product.

In a conventional IRB minutes process, unnecessary transport waste is incurred in multiple rounds of emailing draft minutes to the people involved in the review process. While the direct cost of email transport is essentially free, it does require attention from senders and receivers and is prone to error as draft copies proliferate. Given the existence of technology for centralized online document storage and cooperative editing, the email process is very wasteful.

Even without sophisticated software, draft minutes can be stored in a network folder, provided there is secure remote access for reviewers not employed by the institution.

### Overprocessing

Waste is generated in producing a higher quality product than the customer wants because unneeded steps are taken to produce that product or service.

Federal regulations require only that IRBs prepare and maintain "adequate documentation" of IRB activities, including IRB meeting minutes.[11] However, as shown above, IRB processes often require each board member attending a meeting to review the draft minutes. Many IRBs also require a written signature from the IRB Chair approving the final version.

Adequate documentation requires the minutes to include sufficient detail to meet the regulatory requirements related to *content* (e.g., attendance, vote, basis for requiring changes or disapproval, and summary of controverted issues). The regulations do not require the minutes to be prepared in any particular manner. In fact, recent draft guidance issued jointly by OHRP and FDA confirms that the regulations provide institutions and IRBs with the flexibility to choose procedures for preparing and maintaining minutes that best suit a particular organization.[12] Interestingly, the same guidance also recommends that institutions and IRBs decide who is responsible for preparing and maintaining minutes and that, *if* there is a process for "acceptance or approval" of the meeting minutes, this process is covered in written procedures.[13] This recommendation implies that there is no regulatory requirement that the minutes be accepted or approved, only that they be adequately prepared and maintained.

In other words, the regulations do not require IRB board members (or anyone else) to review a draft version of the minutes. Nor do they require approval by the IRB chairperson. Thus, from the perspective of the OHRP and FDA customers, these steps do not add value. Rather, regulatory requirements are satisfied if one person, working alone, can produce adequate minutes. However, if producing adequate minutes requires review by board members and the IRB Chair, these non-value-added steps will still be necessary.

There are several ways to reduce overprocessing waste in the preparation of IRB minutes. In the most efficient process, experienced IRB staff members compile meeting notes into a template to create a final version of the minutes.[14] Alternatively, IRB staff can prepare a tentative final version for IRB Chair review and approval, or this version can accompany the agenda for the next IRB meeting, with acceptance by default if no objection is raised by the end of the meeting.[15]


© 2016 First Clinical Research and the Author(s)

No matter the process, mistakes might be discovered after the minutes are approved, finalized, or accepted. The IRB meeting minutes policy should therefore include a process for correcting errors found in the final minutes.

Importantly, both TPS and lean methodology promote applying the scientific method to process improvements. Thus, before implementing system changes, institutions should compare the results of different processes to find the one that produces adequate minutes with the least waste. The results of any revised process should also be analyzed for impact on productivity, quality and process times

## Conclusion

The example of reducing waste in the IRB minutes process demonstrates the power of lean methodology, which is based on TPS philosophy. By eliminating process steps that do not add value, the time required to produce IRB minutes can be reduced from months to days. Preparing meeting minutes is just one of many IRB processes. It might be tempting for an HRPP to pick and choose various TPS tools and to achieve quick results by targeting "low-hanging fruit" processes. However, adopting TPS tools without the underlying Toyota Way principles will likely result only in short-term and unsustainable improvements.[16]

The fundamental TPS philosophy is to create a workplace culture in which each individual has the training, ability and support to continuously improve their processes. An HRPP functioning in a true lean culture can thoroughly take advantage of TPS tools to move beyond simple process changes to significant improvements over the entire IRB review process. Sustaining such improvements is not possible without the input, buy-in and support of each individual involved in the system. Thus, HRPPs should consider embracing TPS philosophies and practices to improve the quality of IRB review while reducing administrative burden.

## References


1. See, e.g., Julie Weed, Factory Efficiency Comes to the Hospital, N.Y. Times, July 10, 2010, at BU1; Seattle Children's Hospital, Continuous Performance Improvement (CPI), http://www.seattlechildrens.org/about/continuous-performance-improvement/ (last visited March 24, 2016).
2. See, e.g., Ross A. Hickey & Elizabeth Tioupine, "Lean" Thinking for IRB Process Improvement (November 2015) (presentation, Public Responsibility in Medicine and Research (PRIM&R) Advancing Ethical Research Conference); Stanford University Human Research Protection Program, Continuous Quality Improvement (CQI), http://researchcompliance.stanford.edu/hs/new/cqi/index.html (last visited March 24, 2016).
3. Jeffrey K. Liker, The Toyota Way: 14 Management Principles from the World's Greatest Manufacturer 10-14 (McGraw-Hill 2004)
4. Id.
5. Id. at 7.
6. Id. at 31.
7. See, e.g., Weed, supra note 1.
8. Liker, supra note 3, at 7.
9. Id.
10. Id.
11. 45 CFR 46.115 and 21 CFR 56.115.



© 2016 First Clinical Research and the Author(s)

12. OHRP and FDA Draft Guidance, Minutes of Institutional Review Board (IRB) Meetings: Guidance for Institutions and IRBs (November 2015) http://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/draft-guidance-minutes-2015/index.html.
13. Id.
14. See, e.g., University of Washington, Human Subjects Division, Standard Operating Procedures, IRB Meeting Minutes (January 30, 2015), https://www.washington.edu/research/hsd/docs/1731; Seattle Children's Research Institute, Institutional Review Board, IRB Policy, Meeting, Minutes and Quorum (January 29, 2014) http://www.seattlechildrens.org/pdf/8.pdf.
15. Id.
16. Liker, supra note 3, at 10-14.

**Author**

Michelle Grienauer is a Senior Regulatory Attorney at Quorum Review IRB. Contact her at 1.206.902.3362 or mgrienauer@quorumreview.com.


© 2016 First Clinical Research and the Author(s)