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Regulatory Placemats: A Simple Solution to a Significant IRB Problem

By David Vulcano

In a recent study of institutional review board (IRB) regulatory compliance, the investigators audiotaped meetings of 10 of the top NIH-funded academic medical center IRBs to see if they discussed the required regulated criteria for study approval when such information was not adequately addressed in the study application.[1] Despite the full knowledge and consent of the members, the study found that the IRBs often did not conduct the necessary discussions pursuant to Common Rule (and FDA) criteria:

- 21% did not address risk minimization.
- 57% did not address risk/benefit comparison.
- 60% did not address equitable subject selection.
- 54% did not address data monitoring to ensure safety.
- 25% did not address privacy protection and confidentiality.

We can assume that the members of these IRBs are competent and well-meaning professionals, so what can explain this lapse? Perhaps they simply did not recall the pertinent regulations.

It is not practical for IRB members to memorize the regulations. Nor is it practical for them to constantly open binders and look up the pertinent regulations. IRB members need a simple and easily accessible tool to put the pertinent regulations literally at their fingertips. Table 1 presents the criteria for the ideal tool:[2]

Table 2: Criteria for Quality Improvement Tools

Common Contributing Problems	Solution Requirements
Details of training are forgotten over time.	Training reminders should be "fresh," even "just-in-time."
Regulations, policy binders, and checklists may be brought to meetings but remain unopened.	References should be "open" for instant access by anyone at any time.
Criteria checklists are typically used by only one or two IRB members.	Open access to criteria checklists should be available to all members during the meeting.
Some members fear challenging or questioning other members, who either have or exude more authority.	All members should be empowered through reference to the regulations.
IRBs have limited financial resources.	Tools should be inexpensive.
Members do not have time for recurrent training.	Training should be integrated into the workflow.
It is costly and time-consuming to update training materials when regulations, guidance and policies change.	Updates should be quick and easy to implement.
Many meeting rooms are multi-purpose, so the IRB cannot put informational posters on the walls.	Any physical tool should be easily portable.

A Simple Solution: Regulatory Placemats

Children might use a placemat displaying, for example, a map the world, as a learning aid. However, educational placemats are rarely found in an adult environment. Nevertheless, they have unique advantages in IRB meetings, including their use as actual placemats when food is consumed.

The author created a set of 14 laminated, 11”x17” placemats printed with the regulations most commonly relevant to IRB deliberations. Each placemat contains information on one topic, e.g., “Waiver of Consent” or “Criteria for a HIPAA De-Identified Data Set.” It cost $20 to print and laminate a complete set. When a regulation changes, a new guidance is published, or clarification is required, it is a simple matter to update a placemat.

At each meeting, each member receives a different placemat, typically not the same one from the previous meeting. Since there are typically more placemats than members, an IRB coordinator selects those most appropriate for the studies to be addressed at the meeting.

With the placemats literally at hand, members do not have to remember the details of the regulations, take the time to look them up, or defer to a member who asserts expertise.

Results

The regulatory placemats appear to meet all of the criteria in Table 1. In response to a survey of 300 IRB members of 32 IRBs conducted nine months after implementation, 28% of IRB members said the placemats greatly enhanced discussions and criteria-based decision making, 57% said they somewhat enhanced discussions and criteria-based decision making, 15% said they had no effect, and 0% said they weakened discussions and criteria-based decision making.[3] Additionally, 83.7% of respondents said they preferred using the placemats, 9.3% of the members said they did not want them, and 7.0% said they were indifferent.

Since initial use two years ago, IRBs at other institutions also have started using the regulatory placemats. In addition, a European government agency has implemented the concept in its own ethics boards. Recently, the placemats won the Health Improvement Institute’s 2012 Best Practice Award for Excellence in Human Research Protection. Further, as the tool itself is content agnostic, other hospital committees are using similar placemats for work unrelated to research review.

The placemats are available at www.firstclinical.com/journal/2013/1302_HCA_Placemats.pdf.

References

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