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When an IRB is Responsible for Facilitating Recruitment Material Compliance with Institutional Branding Standards

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In 2011, Wake Forest Baptist Medical Center unveiled a new brand — Wake Forest Baptist Health® — and a new triple helix logo, that encompassed the School of Medicine, the graduate school, the physician's assistant program, and both the inpatient and outpatient services provided by its physicians.

Branding is the process by which an organization seeks to make itself and/or its products and services distinctive and memorable to its customers and other constituencies. The primary responsibility of an institutional review board (IRB) is to protect the safety and welfare of human research subjects, not marketing. However, since IRBs review subject recruitment materials for regulatory compliance (and no other department routinely reviews them), our institution assigned responsibility for branding compliance of these materials to our IRB, as well.

Communicating the New Brand Standards

Traditionally, study teams at our institution had been given a great deal of creative freedom regarding layout, color and font selection in the preparation of recruiting materials. However, they would now have to comply with strict guidelines, as set forth in a 27-page branding guide. The expectation was that the research program would benefit from the reputation of the institution's brand and the institution's brand would benefit from the reputation of the research program.

The IRB used several communication techniques to educate investigators and their research teams on the application of the new branding standards to research advertisements:

- Emailing the study coordinators with a link to the "Brand Center" website, which was created by the Marketing Department to provide guidance on the standards and templates for advertisements
- Handing out hard copies of the new branding standards at regularly scheduled IRB educational meetings
- Announcing the new policy on the IRB webpage
- Creating a guidance document on how to apply the standards to recruitment materials
- Holding a face-to-face meeting with the research community, at which the IRB Director and Marketing explained the standards, guidance and template materials.

Plan A: The First Review Model

The new standards included very specific elements of graphic design, such as the appropriate picture resolutions and formats needed for different media presentations, the proper layout and size of the new set of logos, and color schemes. It was obvious that the IRB and study teams lacked the requisite design expertise to meet all of the new branding standards. Nevertheless, the IRB and Marketing jointly developed a plan to implement the new policies with minimal disruption of the existing workflow.

Study teams were given the choice of either applying the branding requirements to recruitment materials and advertisements themselves, or submitting them to Marketing for assistance with design after the IRB had first reviewed them for appropriate content and wording. Marketing would then alter the design of an advertisement if necessary but would not change any of the content or wording.

Despite these efforts, recruitment materials that did not meet the new standards continued to appear. Non-compliance likely occurred because study teams attempted to meet the complex branding standards themselves, without seeking assistance from the Branding Team.

The IRB office was thus tasked with developing another review model to ensure compliance with the branding standards.

Plan B: The Second Review Model

The IRB at Wake Forest Baptist Health uses eIRB, an electronic submission and review system, to manage the workflow of its research protocol portfolio. Part of the process for new applications already involved simultaneous ancillary review by the Radiation Safety Committee, the Clinical Research Unit, and other committees before the application was scheduled for a Board meeting. For example, a protocol that involves radiation exposure is routed automatically to the Radiation Safety Committee for review and approval prior to IRB review.

In the second review model, we simply added Marketing to the list of committees that review protocols. Study teams could upload recruiting materials to the eIRB system or deliver them personally or by email to Marketing. Ideally, approval by Marketing would be obtained before an application was reviewed in a Board meeting. However, if Marketing required any changes, they would record them in the eIRB system, where the IRB and study team could see them. The IRB's conditional approval letter would require these changes to be made before final approval. All changes required by Marketing would be included, along with IRB-required changes, in stipulation letters. Revisions to recruiting materials required by Marketing would then cycle back to Marketing for its approval, and then on to the IRB for final review of responses to stipulations. If Marketing accepted the changes and IRB stipulation responses were appropriate, the IRB could then grant approval. Marketing agreed to try to turn around initial and subsequent reviews in 48 hours or less.

Results

Since we implemented the second review model in November 2012, 30 submissions have gone through the process. Thirteen of these were new applications, and 17 were amendments that involved additions or changes to recruitment materials. Marketing approved 19 (63%) of these submissions within 48 hours or less, and five (17%) within one week. Six (20%) took longer than a week to receive approval from Marketing. These turn-around times reflect calendar days, not just business days, and include study-team response time to requests by Marketing change requests.

Of the 30 submissions, study teams elected not to work with Marketing prior to its review in 17 of these cases. For new applications, turn-around time for Marketing review was 70% greater when the study team did not work with Marketing ahead of time than when it did. For amendments, turn-around time was 400% greater.

An analysis of cases requiring more than one week for Marketing approval revealed that study teams often spent more time reworking their material in response to Marketing change requests than was required for regulatory approval, such as IRB review. Thus, not

seeking expert branding advice while developing the material often explained why final IRB approval was delayed by Marketing approval.

Conclusions

The second review model is an easy and efficient way to help researchers comply with institutional branding standards. Although branding compliance is not within the federal charge of IRBs, processes can be implemented within the human research protection workflow to assist investigators in meeting these standards, as well as minimize the diversion of the IRB from its primary responsibilities. The same processes can be applied to other ancillary reviews.

It is too soon to analyze quantitative data on the impact of uniform branding on the public's interest in research at our institution. However, an analysis of enrollment data before and after this change can be performed in the future.

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