

Flexibility Coalition Luncheon: Streamlining Review of Consent

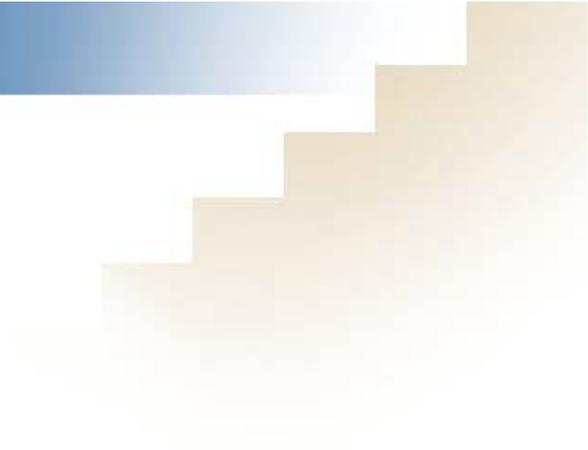
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Overview

- Assessing our Flexibility
- Our Approach
- Your Homework

How Flexible Are We?

Proposal # 1

Tomorrow you will return to your IRBs and remove all template consents from your website. You will also no longer allow your IRB members to reference the “template” during their reviews.

How flexible are you feeling?

- A. I am ready – I hate our template consent
- B. No way- We live by our template.
- C. I'm feeling a little excited, but a bit nervous

Proposal 2

On Monday you will send out a memo to all IRB members informing them that you will no longer accept marked consent forms. All substantive issues related to the consent form, including text changes will be raised in the meeting, therefore marked consent documents are no longer needed.

How flexible are you feeling?

- A. I am ready – Marked consent documents are impossible to work with after the meeting
- B. No way- How will members communicate their consent edits to us?
- C. I'm feeling a little excited, but a bit nervous

Proposal # 3

When you return from the conference you will propose a new policy to your boss that requires IRB members to provide a rationale each time they wish to mandate that an “optional” element of consent be included in a consent document. You will train members on this requirement and provide tip sheets for how they can include this rationale in their review notes.

How flexible are you feeling?

- A. I am ready – I am so tired of writing stipulations asking investigators to include the targeted number of subjects to be enrolled at my site in the consent form
- B. No way- It is more protective if the optional elements of consent are included in the consent form, especially for greater than minimal risk research.
- C. I’m feeling a little excited, but a bit nervous

Our Approach

Adopting Flexibility in Consent Review

The Problem:

- Our consent “requirements” were unwieldy and were leading to complaints related to IRB review

The Evaluation:

- We performed a quality review of our consent-related stipulations
- Several Items were identified as “required” changes that were unrelated to a required consent elements and were not contributing in a meaningful way to subject comprehension

The Solution:

- Forced a discussion of all substantive consent issues at the convened meeting
- Non-substantive issues became recommendations [Created a distinction between stipulations/recommendations]
- Provided member education on the difference between substantive/editorial changes

Your Homework

Your Homework: Search for Flexibility

- Identify your “problem” areas
 - Perform a QA of your consent stipulations- Are you overreaching? Are you substantively contributing to subject understanding? What are the most common “errors”? Are you holding onto old practices that may need to be re-visited?
- Consider adopting one [or more] strategies to introduce flexibility into the consent review process
 - Piloting innovations often works best prior to full implementation- People need time to adjust to change!
- Develop a plan to evaluate the impact of your change



Contact Information

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