# DRAFT POINTS TO CONSIDER:

## Summary Requirement for Informed Consent Documents

*Not official guidance — subject to change in accordance with regulatory requirements*




Standard Templates Working Group of the
SMART IRB Harmonization Steering Committee

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*For review only; document is not finalized.*

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# DISCLAIMER

**Draft Report: April 2018 — *not official guidance*:** These draft points to consider were developed by a working group of the SMART IRB Harmonization Steering Committee to assist the research community in meeting new requirements for informed consent described in the revised Common Rule. Please note that this document will be modified to conform to official guidance or regulatory clarifications as they become available. Until then, we welcome comments on the draft document.

# BACKGROUND

## On Informed Consent Requirements in the Revised Common Rule

In accordance with the revised Common Rule published on January 19, 2017, the federal Office for Human Research Protection (OHRP) and 15 other federal agencies will require, upon the effective date, significant changes to the structure and content of informed consent documents. A crucial element of these changes is the requirement that consent forms begin with a "concise summary of key information" to assist a prospective participant in understanding the reasons why one might or might not want to join the research. Regulations further specify that this section of the consent form must be organized in a way that facilitates the potential participant's understanding of what study participation would entail.

In making these changes, the authors of the revised Common Rule expressed their goal to empower decision-making by effectively addressing the growing concern over the length and complexity of informed consent documents. Ultimately, this new section of the consent form will advance core ethical principles that promote autonomy and understanding of the proposed research. Furthermore, it serves to re-establish the original purpose of the consent document as a teaching tool to educate individuals about research, in general, and the current options with which they are being presented, in particular.

While the IRB community awaits guidance from OHRP, questions have arisen on the best approach to implement this new requirement. At the same time, the new NIH requirement for single IRB review of multisite studies presents implementation challenges when an IRB reviews informed consent documents on behalf of multiple institutions.

## On the Development of this Document

The SMART IRB Harmonization Steering Committee (HSC) tasked the Standard Template Working Group with developing standard templates and guidelines to support investigators and IRBs as they adapt to the new responsibility of entering into reliance arrangements for multisite research. The group chose to focus on the requirement for a concise summary of the informed consent document because it represents a new and unfamiliar standard for which formal guidance is not available.

The discussion below represents the group's results through December 2017. These ideas may provide a starting point for further discussion and contribute to formulation of best practices. As a community, IRBs and investigators are in the discovery stage of evaluating this new federal requirement, and we welcome input and commentary. If official guidance is put forward, this document will be appropriately revised.

### Methods Employed

To develop these draft points to consider, the Standard Templates Working Group consulted regulators, the regulated community, and patient advocacy groups. In addition, members of SMART IRB's HSC, Ambassador team, and "Enable" Working Group provided valuable input, as did members of the Harvard Catalyst Regulatory Committee. The working group also consulted members of the broader IRB community during the 2017 PRIM&R AER conference.





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### Input from OHRP

Conversations with representatives of OHRP coupled with information presented by OHRP at the 2017 PRIM&R AER conference suggest that the intent for this new section of the consent form is to promote a different approach to the informed consent process. The initial section of the revised informed consent document should contain protocol-specific language that focuses on key points an individual would need to assess their interest in participating in the study and to synthesize the information in a way that highlights the potential benefits and drawbacks of participation.

The new section of the consent form should not be an "executive summary" that simply lifts, restates, and reformats required elements of informed consent that are presented later in the document. Representatives of OHRP encourage a flexible approach, which could include a combination of text, graphics, tables, and other communication tools.

During the development of these draft points to consider, several examples of study-specific concise summaries were submitted to representatives of OHRP for comment. While OHRP was unable to comment on these examples, the representatives expressed appreciation for and interest in the work.

### Advice from Patient Advocates and Representatives

Two patient groups convened by external organizations provided input on the working group's draft materials. These included members of the Research Participant Advisory Council at Cincinnati Children's Hospital Medical Center who provided feedback and attendees of an October 2017 Learning Engagement Conference which was convened by the Greater Plains Collaborative, a PCORI-funded Clinical Data Research Network (CDRN). The CDRN critiqued the group's work to date and helped to refine their approach.

Several comments from patient advocates and representatives were noteworthy. Patient advisors were not convinced that the proposed regulatory change would be of value when consent documents were already lengthy. Opinions differed on the appropriate length of the new section (from one paragraph to two pages), level of detail regarding risk, and whether payment information and disclosures about financial conflicts of interest should be included. They also expressed concern for study staff burden and preparation time required to help potential participants shift their focus from the longer document to the concise summary.

These discussions deepened the working group's understanding of the desire to present potential participants with both research and non-research options; to present serious risk, pain, or significant lifestyle burdens; and to highlight the long-term impact of the decision at the outset of the consent conversation. Commenters expressed a desire for clear communication about the distinct purpose of the proposed concise summary, coupled with reassurance that detailed information would be presented later in the document and not be compromised. They encouraged a user-friendly format with headers and other visual aids, and some suggested the use of a separate pamphlet or brochure.

Despite efforts to present examples in plain language, advocates critiqued apparent reliance on medical terminology and assumptions about the potential participant's knowledge of their disease. Advocates requested clearer explanations of randomization, when applicable, as it is frequently misunderstood. While commenters recognized the importance of presenting arguments both for and against participation in a particular study, they expressed concerns about dissuading individuals from considering research participation. Terms such as "pros and cons" were deemed preferable to "why or why not," and commenters suggested using statements such as "You might want to consider not participating if ___." Finally, commenters appreciated the written emphasis on taking one's time to choose and removing time pressure to make a decision.





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# POINTS TO CONSIDER

As of March 1, 2018, there is no guidance from OHRP regarding strategies to fulfill the anticipated requirement for a concise summary of key elements to initiate the informed consent document. Below, we present a draft of points to consider, which have been gleaned from regulatory study, conversations, and input from the SMART IRB HSC, as described above. We consider our efforts to be a work-in-progress that will benefit substantially from additional review by the regulated community.

In approaching the anticipated requirement, institutions should decide which studies should comply with the new standard. As a starting point, institutions may elect to limit this new consent requirement only to studies that fall under the purview of the revised Common Rule and/or to wait until its effective date. Institutions might opt to apply the requirement to all greater-than-minimal-risk studies, to avoid differing standards and potential confusion for IRBs and study staff. Or, they might opt to apply the requirement to complex research projects such as those that employ a consent form longer than eight pages.

## Overall Principles

- The concise summary should focus on protocol-specific information that is predicted to facilitate the potential participant's comprehension of the study.
- The concise summary should be written in the investigator's voice, using a conversational tone.
- The content should reflect what a reasonable person would need to know in order to weigh research and non-research options.
- Plain language and brevity are essential.
- Investigators should consider a variety of formats, depending on the needs of the participant population.
- Investigators and IRBs should optimize the flexibility provided by the new standard since currently there are no "required elements."
- IRBs should rely on the expertise of investigators to articulate the strategy for presenting research options to potential participants.
- Investigators and IRBs may find it helpful to think of this section as "the top ten things you should know about this research study."
- The concise summary should direct the reader to the details presented in the remainder of the full consent document.

## Options for Implementation

A. **Until official guidance is issued by OHRP (and timing to coincide with the effective date of the revised Common Rule), investigators and IRBs may wish to limit this section to include only the topics or questions reflected in the preamble to the Common Rule.**

Information could be structured around questions such as:

- What problem is the study trying to solve?
- Why might someone consider joining the study?
- What are the pros and cons of being in the study?





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- What is the difference between being in this study and continuing with usual care?
- What else should I consider?

B. **A broader approach might include the use of questions and headers, as recommended by patient advocates:**

- Why is this research being done?
- What will happen to me during the study?
- For how long will I participate?
- How is the research different from my standard care?
- Will I benefit from the study?
- Will taking part expose me to risks?
- Do I have other options?
- Will it cost me anything to participate?
- Will I be paid?
- What else should I consider?

C. **IRBs could adopt the suggestion by SMART IRB HSC members and others to provide investigators with a detailed list of themes or "points to consider" that would be adapted as relevant to a particular study, including:**

- The voluntary nature of research.
- The reason the individual is being invited to participate.
- The reason for the study: facts or prior data that support the rationale for the trial.
- As applicable, a statement about the FDA status of the test article.
- As applicable, a description of how the test article differs from what is already approved for the patient population.
- If the study involves randomization or another group assignment, an explanation that not everyone will receive the same intervention, and a description of the study groups.
- Benefits/advantages to study participation that would not otherwise be available.
- A study-specific description of what participation entails:
    - The overall duration of the study.
    - Non-routine tests or procedures that might be required in order to determine eligibility.
    - Brief description of the main procedures, interventions, or tests being done for research purposes.
    - A reference to optional studies that would be available if the participant agrees.
- A summary of the key risks a potential participant should consider, particularly as compared to the key risks of other options such as standard of care. These risks would include those minor risks that are most likely to occur, as well as the most serious, but uncommon risks.





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- How risks will be monitored and mitigated (e.g., dose adjustments, additional medications, or withdrawal from the study).
- Significant differences/asymmetry between study arms, if applicable.
- Noteworthy effects on quality of life, major time commitments, uncomfortable procedures, special precautions, or required lifestyle adjustments that should be considered before deciding to participate in the study.
- Brief description of the key benefits that may be associated with participation.
- A statement summarizing alternative courses of action if the person decides not to join the study.
- Assurances that further information is available, conversation and questions are encouraged, and a hastily made decision is not being requested.





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