**New Key Information Section FAQ**

**Tell me about the new Key Information section of the Consent Document:**

It is a new regulatory requirement under the [Revised Common Rule](https://www.einstein.yu.edu/docs/administration/institutional-review-board/new-rule-summary-of-changes-for-research-community.pdf) that potential subjects be first presented with, “a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.” Sample Key Information sections are available [here](https://www.einstein.yu.edu/administration/institutional-review-board/forms.aspx#key-info). The section is also integrated into our Full Board (Greater than Minimal Risk) and Expedited (Minimal Risk) consent templates.

**Do I have to begin a consent document and presentation with a concise summary of Key Information?**

Full Board and Expedited studies approved after 1/20/2019 are required to include a Key Information Section (unless your study is MINIMAL RISK (expedited) and your consent form is five pages or shorter (including the Signature blocks)).[[1]](#footnote-1) The Key Information Section is required for all studies submitted after 12/15/2018 for Full Board review and after 12/20/2018 for Expedited review.

**Is this required for all consent documents?**

No. If your study is MINIMAL RISK (expedited) and your consent form is five pages or shorter (including the Signature blocks) the new Key Information section is not required.

If your study is under one of the six Exempt Categories, the new Key Information section is not required.

**When does the new requirement go into effect?**

The new section is required for all studies approved by Full Board or Expedited review after 1/20/2019. Studies that received Full Board review prior to 1/20/2019, but did not receive final IRB approval until after 1/20/2019 are also subject to this requirement.

The Key Information Section is required for all studies submitted after 12/15/2018 for Full Board review and after 12/20/2018 for Expedited review.

**Do I need to revise my existing IRB approved consent documents?**

No. Any study that received final IRB approval prior to 1/21/2019 will not need to amend its consent documents to meet this requirement.

**Do you have any samples that I can review?**

Sample Key Information sections are available [here](https://www.einstein.yu.edu/administration/institutional-review-board/forms.aspx#key-info).

**Does the information provided in the Key Information section have to be exactly what is in the Einstein template?**

Not verbatim. The intent of the rule is to consider what key information a potential subject would need to know up front. *It is the most important information that would influence a potential participant to say “Yes” and the most important thing that would influence a potential participant to say “No” to participation.* This allows the individual to weigh the key pros and cons of volunteering early in the process.

**Isn’t the reason someone would or wouldn’t participate always going to be a risk or benefit?**

In some cases, it will, but it depends. The most significant deterrent could be a serious potential risk or a number of benign but unpleasant risks. In other cases, it may be merely inconvenience. The key reason to participate could be a personal gain or to help advance science. A proven alternative treatment may be considered more advantageous that an experimental treatment. The most influencing factor could be the implication of the risk. A breach of confidentiality may have minor repercussions for a survey study, while the same occurrence with genetic testing could affect family planning. The idea is not to present all considerations first, but start with the most influential pros and cons to participation.

**How do I know what information would be key to someone’s decision to participate or not?**

The choice may be based on the investigator’s experience with the study population. Support groups or associations may provide insight into participant perceptions. You may also search for empirical research (e.g., *Participant perception of risks and benefits of genetic research*; or P*articipant Perceptions on data sharing*). The patient-centered and participant-centered movements have prompted considerable research on subject perceptions of research consent.

1. This exception was clarified on January 17, 2019 to only include MINIMAL RISK (expedited) studies. [↑](#footnote-ref-1)