

BSPH IRB Guidance: Key Information for Informed Consent

General Requirement for Informed Consent: Informed Consent must begin 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. 45 CFR 46.116(a)(5)(i)

As PI of the study, you must provide Key Information to introduce your study to participants. The Revised Common Rule describes this requirement as follows (important concepts highlighted):

Definitions from *Oxford English Dictionary*:

Concise: Giving a lot of information clearly and in a few words; brief but comprehensive.

Focused: Directing a great deal of attention, interest, or activity towards a particular aim.

Drafting key information takes time and thought on the part of the investigator. “Key Information” varies study to study, and involves consideration of the context of the study. In general, you may want to include:

- A statement that your project involves research
- Why you are doing the study
- Why you are asking me
- How joining the study will affect me personally (e.g., what are you asking me to do)
- Participation is voluntary; I don’t have to join the study

Investigators must think about the key information section and put themselves in the shoes of their potential participants. Think about what your study population would **want** to know, and what they **need** to know to help them make their decision. Include information that a reasonable person would want to know about why she might want to join a study, and why she might not want to join a study. For example,

- If a pharmacokinetics study (no benefit) requires women to go off hormonal contraception, that’s important information that might cause someone not to join the study and it should be included in “key information”;
- If a survey study requires people to travel to the study site and it will provide travel reimbursement, that information might help inform a decision;
- If the study offers no direct personal benefit, but does offer a payment to participants, that factor may be important to potential participants and should be included;
- If a study will ask an adolescent highly sensitive personal questions, tell them whether or not answers will be shared with parents/guardians;
- If a therapeutic study offers potential benefit, but requires that participants risk randomization into a placebo group, or will change a participant’s future treatment options, that information could be “key”;
- If a study involves observing mosquitoes and use of bed-nets in a person’s home, the fact that a study team member needs to be present in a house overnight is likely an important factor in decision-making.

Much of this is common sense; do take some time and think it through.