RSNA Clinical Trials Methodology Workshop

Template For
Basic Elements of Informed Consent
Federally Funded Research (HHS): 45 CFR Part 46.116(b)(c)
FDA-Regulated Research: 21 CFR 50.25

The requirements for research consent form are mandated by federal regulations (45 CFR Part 46.116(b)(c) for federally funded research and 21 CFR 50.25 for FDA-regulated research) and institutional policies. Your institution is likely to have a consent form template available on the IRB website and you can use it to create the consent form for this workshop. If you prefer, you can use the brief template we've provided below.

Prior to implementation of the revised Common Rule by HHS, HHS and FDA had the same consent form requirements. Effective January 21, 2019, the revised Common Rule requires additional consent information. Although FDA has not adopted these requirements, FDA will allow these additional requirements to be added to consent forms for FDA-regulated research.

Under the revised Common Rule, there are 9 basic elements of consent (which are required) and 9 additional elements (to be included when appropriate). In addition, there is a new Common Rule requirement that the informed consent must begin with "key information", which should be a concise and focused presentation of information that is most likely to assist a subject in understanding why they might or might not want to participate. Generally, it should include information about the purpose, the risks, the benefits, and alternatives, and it should explain to the person how to think about these pieces of information in terms of making a decision. In this workshop, we will focus on the key information and the first 4 basic elements of informed consent, which are specific to your protocol. The remaining basic and additional elements are generally boilerplate language and options provided by your institution and are not required for this workshop, but may be included if desired.

The consent form should be written in language understandable by the potential subjects for your clinical trial. To the extent possible, use lay language, shorter sentences, and bulleted items to break down the content and make it more understandable to the lay reader. Diagrams and drawings may also be helpful.

RSNA CONSENT FORM TEMPLATE:

1. **Key Information**: A brief explanation of the study purpose, risks, benefits, alternatives and why a participant might or might not want to participate in the research. *(Note: This information is also required in the basic elements that follow. The key information should provide a brief description with expanded information under the relevant element; there is no need to duplicate the information in its entirety.)*

2. **Basic Element 1:** Statement that the study involves research; explanation of the purpose(s) and expected duration of participation; description of procedures and identification of experimental procedures.

3. **Basic Element 2:** Description of reasonably foreseeable risks or discomforts to subject.

4. **Basic Element 3:** Description of benefits to subject or to others that may reasonably be expected from the research.

5. **Basic Element 4:** Disclosure of alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

Basic and Additional Elements not required in the submitted consent form:

Basic Elements: *Your institutional consent form template should contain boilerplate language for the remaining basic elements and you do not need to include these elements in your submitted consent form. For your information, the other basic elements are (the new basic element under the revised Common Rule is marked):*

- Description of the extent to which confidentiality will be maintained;
- For research involving more than minimal risk, explanation as to whether compensation and medical treatments are available if injury occurs;
- Explanation of whom to contact if questions arise about the research or the subjects' rights or whom to contact if research-related injury occurs;
- Statement that participation is voluntary, that refusal to participate involves no penalty or loss of benefits, and that subject may discontinue at any time;
- ***(NEW)*** For studies involving collection of identifiable private information or identifiable biospecimens, (i) a statement that identifiers may be removed and the information or biospecimens used for future research without further consent, or (ii) a statement that the information or biospecimens will not be used or distributed for future research, even if deidentified.

Additional Elements: *Your institutional consent form template should also contain information on the additional elements of consent to be included when appropriate for the study; you do not need to include these in your submitted consent form. For your information, the additional elements are (the new additional elements under the revised Common Rule are marked):*

- A statement that the particular treatment or procedure may involve risks to the subject (or the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
- Any additional costs to the subject that may result from participation in the research;
- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject;
- The approximate number of subjects involved in the study;
- ***(NEW)*** Whether the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will share in that profit;
- ***(NEW)*** Whether clinically relevant research results, including individual results, will be disclosed to subjects and, if so, under what conditions;
- *(NEW)* For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing.