

IRBMED is expanding its informed consent template options. Traditionally, a standard comprehensive informed consent template has been available for researchers to use as a starting point when developing their informed consent documents. The standard template's twelve sections prompt consent authors to address all federally required elements of informed consent, as well as some additional elements, such as eligibility criteria and the number of the subjects a researcher expects to enroll. The standard template is designed to accommodate the broadest possible range of research scenarios.

More recently, IRBMED has begun to offer shorter *specialty templates*, tailored for use in some common and specific study situations. Given their narrow focus, specialty templates may help researchers quickly develop consent documents that correspond to just the type of study they plan to conduct.

In 2012, the very first specialty template—designed for use with humanitarian use devices—became available.

IRBMED now offer two additional specialty templates:

- a template for one-time blood or tissue sample collection
- and another template for eligibility screening

Unlike the standard template, these specialty templates are not divided into numbered sections; they instead address all required elements of informed consent within a series of short paragraphs. Since specialty templates are customized for particular study scenarios, much of the text has been prepared in advance, leaving consent authors to supply details specific to their study where brackets appear in the template.

The first new specialty template is designed for research involving a single study visit, during which researchers collect a sample of a subject's blood or tissue. Researchers may use this template for studies

- whose only intervention is a single blood or tissue sample
- and that pose no more than minimal risk to subjects

They *may not* use this template

- if they plan to conduct genetic analysis on subjects' samples
- or if they plan to send subjects' materials or data to a biorepository or data repository

The second new specialty template may be useful to researchers who wish to obtain consent to screen potential subjects before enrolling them in the main study—for example, in order to avoid administering

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Specialty Informed Consent Templates

a lengthy informed consent process with individuals who are likely to be ineligible for the research. The eligibility screening template may be used

- solely for determining whether individuals are eligible to take part in a study
- and only when screening procedures present no more than minimal risk to subjects

As with the blood or tissue sample template, researchers *may not* use the eligibility screening template

- if screening procedures will involve genetic analysis of subjects' samples
- or if they plan to submit subjects' materials or data to a repository

Where they're appropriate, specialty informed consent templates may offer some advantages over the more elaborate standard template. Because much of their text is prepared in advance—undergoing repeated revision, as well as vetting by IRB Chairs and Leadership—researchers using specialty templates may save time in the consent writing process. And specialty templates' narrower focus and streamlined structure mean subjects will ultimately read shorter consent documents.

On the other hand, specialty templates' specificity makes them less adaptable than the standard template, and their shorter, simpler structure may not accommodate more complex and higher-risk research. For these reasons, the standard informed consent template remains in many instances the appropriate tool.

IRBMED will continue developing specialty templates tailored to common study scenarios. Please direct your recommendations for new specialty templates to the IRBMED office.

Contact the IRB for more information about informed consent template options.

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