

## Consent guidelines

Consent Form: The IRB consent template form is an outline of the minimum requirements.

1. PLEASE PROOFREAD before submitting the consent. We recommend that you run a spell check program and have another party review the consent to find obvious typographical mistakes. Consent forms must be in language understandable to the subjects or their representative at an 8th grade reading level.
2. Please provide a telephone number with 24-hour availability for the “Who do I call?” research contact.
3. If financial compensation is paid to research subjects, include schedule for payment on the consent form - schedule should not be coercive, i.e. only if the trial is completed, but should be paid for each separate study period.
4. Pages of the consent form should be clearly identified by including the title of the project at the top of each page. Pages of the consent form should be numbered inclusively, i.e. Page 1 of 3, Page 2 of 3, etc.
5. Not all the sections of the consent template are applicable to each study. For example, include the language on a data safety monitoring board only if there is such a board for the study. Be careful to indicate on the application form whether there is a data safety monitoring board to correspond to the section in the completed consent form:
6. On the last page of the consent template, there is an optional signature line for a legally authorized representative to sign for the patient. This section should not be included unless the investigator provides specific information in the application form to justify its inclusion. The IRB has determined that nearly all projects it oversees are not appropriate for someone other than the patient to provide consent.
7. The avoidance of pregnancy language is required by Georgetown University. Specifically, there can be no reference to birth control or contraception
8. Since many studies come with model consent documents, it is important that the IRB consent template be used carefully. Much of the consent template contains boilerplate language that must be in the final submitted consent. When the template asks for a risks section, it is appropriate to cut and paste the risk section from the model consent. It is not appropriate, however, to substitute sponsor language in any of the sections beginning with “What about confidentiality.” Be certain to include an introduction at the beginning of the consent that contains either the template language or a comparable substitute. If there are conflicts between the model consent language and the template language, the template always takes precedence. It is the responsibility of the investigator to submit the consent to the sponsor for review, if applicable. If the sponsor demands language that is different from required text in the consent template, the investigator should so inform the IRB office which will then have an appropriate university official review the proposed language.
9. Be sure to complete the consent template completely. There are too many instances where sections like “(investigator name)” are left verbatim in the submitted consent. The IRB cannot approve a consent containing such oversights and it is certainly more efficient to carefully proofread the submitted consent to catch such errors.