

Templates

Protocol Templates and Forms

1) Protocol Submission and Review

- [NCI-CCR Protocol Template and Guidelines](#) (Word)

Precis:

- [Precis Format](#) (Word)
- [Precis Example 1](#) (Word)
- [Precis Example 2](#) (Word)

2) Protocol Deviations and Unanticipated Problems

Definitions:

Protocol Deviation (PD): Any change, divergence, or departure from the IRB-approved research protocol.

Unanticipated Problem (UP): Any incident, experience, or outcome that meets **all** of the following criteria:

- **Unexpected** (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
- **Related or possibly related** to participation in the research (**possibly related** means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- Suggests that the research places subjects or others at a **greater risk of harm** (including physical, psychological, economic, or social harm) than was previously known or recognized.

Deviations and Unanticipated Problems are reported to the NCI IRB via iRIS.

- [CCR Reportable Event Form](#) (Word)

3) Informed Consent/Assent

- [NCI-CCR Consent Form Template](#) (Word)
- [Model Consent Language - Genomic Sequencing](#) (Word)
- [Assent Template](#) (Word)
- [NCI CIRB Approved Consent Boilerplate Template](#) (Word)

Non-English Speaking Research Subjects:

- [Short Written Consent Forms for Non-English Speaking Research Subjects](#) (*NIH Access Only*)
- [NCI Short Form Addendums version 1](#) - using optional studies language that was approved **prior** to April 2012. *Please be sure that the Addendum that you select matches your protocol.*
- [NCI Short Form Addendums version 2](#) - using optional studies language that was approved **after** April 2012 and **prior** to May 2015. *Please be sure that the Addendum that you select matches your protocol.*
- [NCI Short Form Addendums version 3](#) - using optional studies language that was approved **after** April 2015 and **prior** to November 2015. Please be sure that the Addendum that you select matches your protocol.
- [NCI Short Form Addendums version 4](#) - using optional studies language that was approved **after** October 2015. Please be sure that the Addendum that you select matches your protocol.
- [NCI Addendum to Short Form](#) - blank form for translating portions of the consents with yes/no questions for those consents where the questions can not be removed.

4) Exemption from IRB Review

- All new requests for determinations must be submitted through OHSRP's web-based request for determination system. No email or paper submissions will be accepted. The system can only be accessed using Mozilla Firefox, Google Chrome, or Safari (not Internet Explorer). NIH login required. <https://federation.nih.gov/Determination/start.php>
- Amendments to all existing projects, which received determinations through the old paper-based system, will have to be submitted as new projects in the system. After that point, amendments can be made within the system.
- If you need assistance submitting an exemption request, please contact your Protocol Support Office team member.
- [FAQs about Requests for Determination of whether IRB Review is Required.](#)
- [How to Use the Web-Based OHSRP Request for Determination System.](#)

5) Report Templates

- [Planned Enrollment Report](#)
- [Cumulative Inclusion Enrollment Report](#)