Templates

Protocol Templates and Forms

1) Protocol Submission and Review

- See the NIH IRBO website for institutional templates at Protocol Templates (nih.gov). You may also contact NCICCRPSOCentral@nih.gov for templates and guidance.

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

See the NIH IRBO website for institutional templates at Consent Templates and Guidance (nih.gov) and Assents and Assent Template (nih.gov). You may also contact NCICCRPSOCentral@nih.gov for templates and guidance.

4) Exemption from IRB Review

See the NIH IRBO website for institutional guidance and templates at Protocol Templates (nih.gov). For guidance on determinations and for assistance to CCR investigations for submission, please contact NCICCRPSOCentral@nih.gov.

5) Report Templates

- Planned Enrollment Report
- Cumulative Inclusion Enrollment Report