CENTER FOR CLINICAL AND TRANSLATIONAL SCIENCE

# CONSENT CHECKLISTS: REGULATORY CRITERIA

**For consent documents on studies that fall under convened or expedited IRB review.**

## UIC SPECIFIC CONSENT REQUIREMENTS

**Applies to UIC consents**

- ☐ UIC consent template used (recommended)
- ☐ Consent written in the second person, except for the final section (agreement to participate).
- ☐ If applicable: The consent includes the sponsor / funding agency's name and statement that they are providing funds (or test article or other support) for the conduct of the research.
  - ☐ N/A – research is not funded
- ☐ If applicable: The consent describes any conflicts of interest disclosed following the UIC COI disclosure agreement (SFI-DMP), and cleared by the UIC COI office.
  - ☐ N/A – no COI identified
- ☐ If a Certificate of Confidentiality has been granted or obtained, the associated consent template language added.
  - ☐ N/A – the research is not federally funded and no Certificate of Confidentiality will be sought
- ☐ Statement of subject's responsibilities during the study.
- ☐ Name, department and contact information for investigator.
- ☐ Process to obtain and document consent process is described in detail in the initial review application form

## OTHER CONSENT REQUIREMENTS

**Include if applicable to the research. Refer to OPRS website for text under the Consent Form Template, Additional Informed Consent Template Language, or HIPAA Drop-In Language**

- ☐ Research that involves the use / disclosure of protected health information (PHI): Add HIPAA drop-in text
  - ☐ N/A
- ☐ Optional components of the research are identified in the consent, and the consent includes checkboxes where participants can indicate their choice. (Note, these commonly involve consent for future contact, retaining data or samples for future research within a repository or biobank, and/or genetic testing)
  - ☐ N/A
- ☐ Confidentiality risks: Add text from the Additional Informed Consent Template language specific to the following populations:
  - Focus Group or Group Discussions
  - Online Survey Research
  - Abuse / Neglect of a Child, Disabled or Elderly Adult

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| • Studies involving HIV/STD, TB, or HCV testing<br>• Chicago Public Schools<br>• Certificate of Confidentiality (automatically applies to federally funded research)<br>• Funding by National Institute of Justice or Department of Justice<br>☐ N/A |
| ☐ Prisoners: Add text from the Additional Informed Consent Template language "Benefits"<br>☐ N/A |