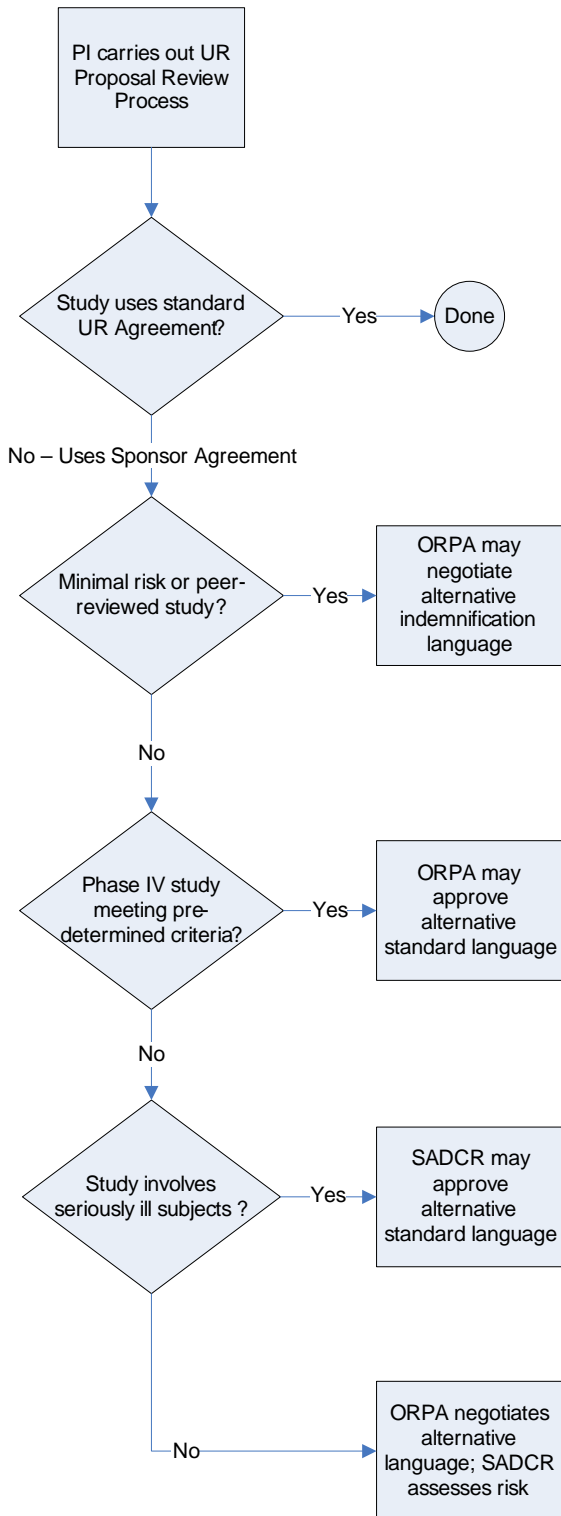


Institutional Review of Investigator Initiated Externally Sponsored Clinical Trial Agreements

7/20/2005



See ORPA Guide – Guidance for University Approval of Sponsored Clinical Trials
<http://www.rochester.edu/ORPA/OGUIDES/guidect.pdf>

See UR Standard Clinical Trials Agreement
<http://www.rochester.edu/ORPA/Agreements/CLINTRIrev1.pdf>

See Institutional Risk Assessment Process for Principal Investigator Initiated Externally Sponsored Clinical Studies
http://www.rochester.edu/ORPA/policies/risk_%20assessment.pdf

See Policy Regarding Exceptions to Indemnification Provisions for Phase IV Clinical Studies and Process for Evaluation
<https://intranet-secure.urmc.rochester.edu/Policy/ClinicalResearch/PhaseIVStudyIndemnificationPolicy.pdf>

See Policy for Granting Exceptions to Indemnification Provisions for Selected Clinical Studies Involving Seriously Ill Patients
<https://intranet-secure.urmc.rochester.edu/Policy/ClinicalResearch/IndemnificationExceptionPolicy.pdf>

See Institutional Risk Assessment Process for Principal Investigator Initiated Externally Sponsored Clinical Studies
http://www.rochester.edu/ORPA/policies/risk_%20assessment.pdf