HUMAN RESEARCH PROTECTION

Criteria for external IRB reliance

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Resource type GUIDANCE

Required criteria for reliance — **ALL** must be checked

- ☐ Hennepin Healthcare is engaged in Human Subjects Research
- ☐ The research is non-exempt
- ☐ A reliance agreement or SMART IRB Master Reciprocal Agreement is in place with the proposed external IRB under which the research falls or a Reliance Agreement has been/will be established for the research.
- ☐ The proposed external IRB is AAHRPP-accredited (or is able to document comparable standards) and is willing to serve as the IRB of record
- ☐ The proposed external IRB maintains and OHRP-approved Federalwide Assurance (FWA)
- ☐ The principal investigator does not have unresolved or unmitigated compliance concerns
- ☐ The principal investigator and/or any study team members have no substantive conflicts of interest
  OR
  A COI management plan has been established and will be communicated to the sIRB
- ☐ The research does not involve human embryos or embryonic stems cells, gene transfer, fetal tissue, review and oversight by the biosafety committee or other high-profile research otherwise subject to additional institutional policy

Additional criteria — at least **ONE** must be checked (check all that apply)

- ☐ The research is a multi-site **industry-sponsored clinical research** study:
  - The study is multi-site (more than 2 sites) and initiated by a for-profit business or industry sponsor;
  - The protocol was designed and written solely by the business or industry sponsor;
  - The business or industry sponsor is the sole holder of any applicable IND/IDE;
  - The research does not involve prisoners or other participants subject to additional protections afforded under Subpart C of the regulations
- ☐ The principal investigator and/or study team members play a limited role in the study, e.g., data analysis, consultation, etc.
- ☐ A funding agency or organization, i.e., NIH, requires use of an external IRB
- ☐ The research involves no greater than minimal risk to subjects
- ☐ The IRB Chair/Vice Chair has determined (in consultation with other institutional stakeholders as appropriate) that use of an external IRB is appropriate for the research even if none of the other considerations in this section apply