



WORKSHEET: Criteria for D-HH as sIRB		
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The purpose of this worksheet is to provide information on criteria that the Dartmouth-Hitchcock Health (D-HH) IRB will evaluate when considering requests for the D-HH IRB to serve as single IRB of record for multi-site or collaborative research.

1 General Exclusion Criteria. The following are circumstances in which the Dartmouth-Hitchcock Health may not serve as the sIRB for a multisite study.

- D-HH is not listed as the prime awardee of federal grant.
 - D-HH is not the prime awardee, the lead PI/site will be responsible for identifying the sIRB, such as an accredited IRB from a designated pSite or a commercial IRB.
 Comments: [Click or tap here to enter text.](#)
- The study is not federally funded (PI does not anticipate NIH or federal funding)
- The study is Small Business Innovation Research (SBIR)
- The study is industry sponsored
- The study activities involve only medical chart reviews
- The study includes internationally-based sites

2 Collaboration with Dartmouth College: If any of the following are true, Dartmouth-Hitchcock IRB will serve as the IRB of Record for studies in which Dartmouth College is engaged.

- The Principal Investigator is employed by Dartmouth Hitchcock.
Comments: [Click or tap here to enter text.](#)
- The study utilizes D-H data or specimens. Examples include:
 - Data from the D-H EDH (electronic medical record), Clinical Trials Management System (CTMS), PeopleSoft, pathology system
 - Specimens from D-H pathology, biorepositories or clinical labs
 - D-H data that is part of a national dataset
 - D-H healthcare/clinical data included in registries
 - Oncology Research Information Exchange Network (ORIEN)
 - Etc.
 Comments: [Click or tap here to enter text.](#)
- The study enrolls D-H patients and/or recruits from D-H sites. Sites include:
 - DHMC-Lebanon
 - DH – Bedford
 - DH – Concord
 - DH – Hudson
 - DH – Keene
 - DH – Manchester
 - DH – Merimack
 - DH – Milford
 - DH – Nashua
 - DH – Psychopharmacology Research Group
 - NCCC – Lebanon
 - NCCC – Keene
 - NCCC – Manchester
 - NCCC – Nashua
 - NCCC –St. Johnsbury
 - Brattleboro Memorial Hospital
 - Cottage Hospital
 - Littleton Regional Hospital
 - Monadnock Community Hospital
 - New London Hospital
 - North Country Hospital
 - Speare Memorial Hospital
 - Springfield Hospital
 - SW Vermont Medical Center
 - Valley Regional Hospital
 - Weeks Medical Center
 Comments: [Click or tap here to enter text.](#)
- The study utilizes any D-H resources. This includes any study procedures taking place at a D-H location, using D-H equipment or shared resources.
Comments: [Click or tap here to enter text.](#)



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<input type="checkbox"/>	The College has requested the oversight of a project that includes clinical research activities, in which: a) None of the previous criteria are true; and b) The HRPP Director and/or Institutional Official has determined that the D-HH IRB should provide oversight of the project
3	Study Criteria for Serving as sIRB for all other institutions. Dartmouth-Hitchcock Health will evaluate on a case-by-case basis serving as the sIRB. The following characteristics of the study will be evaluated to determine whether the institution and study team can adequately support and oversee the research.
<input type="checkbox"/>	Complexity of protocol/risk level of study Comments: Click or tap here to enter text.
<input type="checkbox"/>	Number, type and location of participating sites Comments: Click or tap here to enter text.
<input type="checkbox"/>	Study is Investigator initiated, Business and Industry, or Other Comments: Click or tap here to enter text.
<input type="checkbox"/>	D-HH PI experience Comments: Click or tap here to enter text.
<input type="checkbox"/>	Study team is adequately resourced and prepared to facilitate the multi-site study. Comments: Click or tap here to enter text.
<input type="checkbox"/>	Participating site(s) are adequately resourced and prepared to participate in the multi-site study. Comments: Click or tap here to enter text.
<input type="checkbox"/>	FDA regulated research activities are included in the study. Comments: Click or tap here to enter text.
3	Additional Considerations for Serving as sIRB. The following are additional considerations for evaluating the Institution's ability to serve as the sIRB for a multisite study.
<input type="checkbox"/>	D-HH IRB has sufficient expertise to conduct the IRB review Comments: Click or tap here to enter text.
<input type="checkbox"/>	D-HH HRPP Stakeholders (Sponsored Projects Administration, Quality Assurance Program, etc.) have adequate resources to support or monitor the research activities. Comments: Click or tap here to enter text.
<input type="checkbox"/>	Ability for D-HH to comply with the relevant local context considerations of the participating site(s) Comments: Click or tap here to enter text.
<input type="checkbox"/>	Preference to outsource sIRB function to a commercial IRB (Advarra, WIRB) Comments: Click or tap here to enter text.
<input type="checkbox"/>	Other relevant considerations (e.g., vulnerable populations, conflicts of interest, costs, etc.) Comments: Click or tap here to enter text.