WORKSHEET: Criteria for DH-H to Cede IRB Review		
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The purpose of this worksheet is to provide information on criteria that the Dartmouth-Hitchcock Health and the HRPP will evaluate when considering requests for the DH-H IRB to serve as sIRB, to outsource to a commercial IRB, or to require a pSite's accredited IRB to serve as sIRB.

1 General Exclusion Criteria. The following are circumstances in which the Dartmouth-Hitchcock Health will not cede IRB review for a multisite study.

- ☐ The institution does not maintain an OHRP-approved Federalwide Assurance (FWA)
- ☐ The study activities involve only medical chart reviews
- ☐ The study is determined to be Exempt

2 Criteria to Cede IRB Review to Dartmouth College. Dartmouth-Hitchcock Health will evaluate on a case-by-case basis ceding IRB review. The following characteristics of the study will be evaluated to determine whether the sIRB and study team can adequately support and oversee the research.

- ☐ The Principal Investigator is NOT employed by D-H.
  Comments: Click or tap here to enter text.
- ☐ The study does NOT utilize any 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 does NOT enroll patients from D-H or recruit 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 does NOT utilize 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.

3 Criteria to Cede IRB Review to a Commercial IRBs. Dartmouth-Hitchcock Health will evaluate on a case-by-case basis ceding IRB review. The following characteristics of the study will be evaluated to determine whether to cede IRB review to a Commercial IRB (e.g. Advarra, WIRB, etc.)	
☐	The project is commercially sponsored research
☐	D-HH IRB lacks sufficient expertise to conduct the IRB review
☐	D-HH is the lead site of a multi-site project and the IRB lacks sufficient resources to provide oversight of the project
3 General Considerations for ceding IRB Review. The following are additional considerations for evaluating the institution's willingness to cede IRB Review	
☐	IRB maintains a valid OHRP-approved Federalwide Assurance (FWA) Comments: Click or tap here to enter text.
☐	Ceding IRB review is mandatory or optional. Comments: Click or tap here to enter text.
☐	The reviewing IRB has sufficient expertise and experience reviewing and overseeing research of similar nature to the proposed study. Comments: Click or tap here to enter text.
☐	The risks to participants when ceding IRB review. Comments: Click or tap here to enter text.
☐	The reviewing IRB has sufficient expertise with certain features of the protocol or the participant population that may pose special concerns. (e.g. recruitment of socially or economically disenfranchised populations, local cultural mores or unique clinical circumstances) Comments: Click or tap here to enter text.
☐	Whether if ceding IRB could create or mitigate unique institutional risks, such as conflicts of interest
☐	The financial implications of the decision—this includes: a) analysis of lost research opportunities (i.e. unwillingness of a sponsor or funder to allow local, non-ceded IRB review) b) the additional administrative time and costs associated with establishing authorization agreements
☐	Resources needed by the study team to learn and adhere to the policies and procedures of the reviewing IRB