Determining which IRB to Use, which Agreements are required, and which IRB fees to budget.


Q1: Is this multi-site research that requires siIRB review as required by Federal Regulations?

Examples:
1) NIH funded non-exempt research that uses a single protocol to conduct research at multiple sites
2) Other studies as required by other Federal Department/Agency (contact funding Department/Agency for determination)
3) Multiple sites are engaged (as determined by where the investigator is an employee or agent per OHRP guidance) in non-exempt federally funded Human Research
4) **FDA regulated Clinical Investigation with multiple US site participation** (**pending FDA implementation, included here for planning purposes**)

For more details and siIRB exceptions, see:
- Single IRB for Multi-Site or Cooperative Research | grants.nih.gov
- Single IRB Exemption Determinations | HHS.gov
- FDA Proposed Rules for Harmonization and siIRB.

Q2: Is this Industry Sponsored human research with multi-site participation?

Q3: Is this a multi-site research project that is overseen by an External Reviewing IRB (not the Downstate IRB)?

Q4: Is this a Non-Exempt human research project that involves only the following investigators?
- Investigators from the Downstate workforce (see Step 4)
- Investigators from institution with a fully executed Downstate IRB Reliance Agreement (IRA). Current IRAs are executed with:
  - *University Physicians of Brooklyn (UPB),
  - *NYC Health + Hospital, Kings County, and
  - *Maimonides, when the qualified Principal Investigator is a member of the Downstate workforce, providing the research is NOT federally funded, NOT multisite industry sponsored, and NOT exempt.
- Investigators from an institution that is willing to execute a Downstate IRB Reliance Agreement (includes identification language for NON-EXEMPT research. To be eligible, the external institution must: 1) have an FWA, 2) have a local IRB or HRPP Office to confirm local research requirements, 3) be a HIPAA covered entity, 4) have a PHS/NIH Conflict of Interest compliant policy, 5) have a compliance (audit or QA) program in place.
- Investigators who are NOT: Investigators for the purposes of COI and willing to execute a Downstate Individual Investigator Agreement (IA). The Investigator may independently of their institution (e.g., nursing resident) or their institution may allow an IIA.

Q5: Is this an EXEMPT human research project?
Note: This research may include funded projects, multiple sites, and Investigators from multiple institutions.

For other situations: E-mail IRB@downstate.edu for guidance.

Q6: Is Downstate the Primary Awardee?

Whenever possible, use the **WCG IRB**; however, primary Awardee, Overall PI, or Sponsor decides which IRB to use.

Include applicable Reviewing IRB fees & Downstate Local Review fees in research budget. See Downstate IRB Guidance on Fee Schedules.

Q7: Will Investigators from the Downstate Workforce be overseen by a Commercial IRB, or another IRB for a Non-Federally funded/Non-Industry sponsored study?

Use the Downstate IRB and ONLY include:
1) Investigators from the Downstate Workforce (see step 4),
2) UPB Investigators,
3) Kings County Investigators,
4) Maimonides Investigators, when the qualified Principal Investigator is a member of the Downstate workforce, providing the research is NOT federally funded, NOT multisite industry sponsored, and NOT exempt.
4) Investigators covered by an IRA or IIA executed with Downstate.

Notes:
1) Multiple IRBs may be used.
2) Investigators not covered by an IRA or IIA with Downstate MUST use another IRB, as determined by their institution. The Institution of the external investigators should be described in the protocol and informed consent materials, but must not be listed in the Downstate IRB Application.

Use the Downstate IRB and ONLY include:
1) Investigators from the Downstate Workforce,
2) UPB Investigators, and
3) Kings County Investigators.
4) Investigators with an IIA with Downstate who do not have an IRB at the institution from where they are employed.

Notes:
1) Include IRB fees in research budget, if Industry sponsored.
2) All other Investigators use their own site's IRB.

After the Reviewing IRB approves the study (or for "pre-review" requests), submit Form 11-A3 to the Downstate IRB to confirm local research context.
1) Downstate IRB Acknowledgment is required to activate the research at Downstate for ONLY Investigators from the Downstate workforce.
2) All other Investigators must have an IRA or IIA or similar agreement with the Reviewing IRB. If from an institution (i.e. not an independent), they must also follow their Institution’s local procedures, and their institution must have an FWA with OHRP.

Establish IRB Reliance Agreement with the Reviewing IRB via *SMART IRB* whenever possible. (See Step 5E.)
Downstate Investigators may use the ‘BRANY’ IRB or ‘NCI CIRB, when applicable.

Notes:
1) The IRB Reliance Agreement with the Reviewing IRB and Downstate covers Investigators from the Downstate workforce. Additional IRAs must be established by all other investigators with their institution.
2) Contact the Downstate IRB if Reviewing IRB is not a member of SMART IRB.
3) Follow the Relaying IRB’s process for establishing the IRA. A paper based, IRA*, or other electronic reliance agreement may be established for eligible Reviewing IRBs.
4) Qualifications to be an eligible Reviewing IRB: a) member of SMART IRB, or b) AAHRPP accredited, or c) Quality Assessment within last 5 years. 5) Exceptions may apply to Tribal and non-U.S. IRBs.

10/28/2022