

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

See **Step 5** at [Electronic Submissions | Institutional Review Board | Office of Research Administration | SUNY Downstate](#) for details.

**Q1:** Is this for **multi-site** research that requires **sIRB review** as required by Federal Regulations, such as?  
 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 details and sIRB exceptions, see:**  
 · [Single IRB for Multi-Site or Cooperative Research | grants.nih.gov](#)  
 · [NOT-OD-16-094: Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research](#)  
 · [Single IRB Exception Determinations | HHS.gov](#)  
 · [Engagement of Institutions in Human Subjects Research \(2008\) | HHS.gov](#)  
 · [FDA Proposed Rules for Harmonization and sIRB.](#)

**Q6:** Is Downstate the Primary Awardee?

Obtain a quote for IRB fees from the WCG IRB and use the WCG IRB as the Reviewing IRB.  
  
*Reminder: Include applicable WCG IRB fees & Downstate Local IRB Review fees in the research budget.*

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 follow the policies of their Institution and the Reviewing IRB.

Whenever possible, use the **WCG IRB**; however, the Primary Awardee, Overall PI, or Sponsor decides which IRB to use. When required, Downstate Investigators may use the **BRANY IRB** or **NCI CIRB**, for which master IRB Reliance Agreements are in place. To establish an **IRB Reliance Agreement (IRA)** with a Reviewing IRB not otherwise listed above, use **SMART IRB Online Reliance System** process when possible.  
**Notes:**  
 1) When using an External IRB, obtain an IRB Fee Quote and include applicable Reviewing IRB fees & Downstate Local Review fees in the research budget.  
 2) Qualifications to be an eligible Reviewing IRB: a) member of SMART IRB, or b) AAHRPP accredited, or c) Quality Assessment within last 5 years.  
 3) Follow the Relying IRB's process for establishing the IRA. A paper based, IReX, or other electronic reliance agreement may be established for eligible Reviewing IRBs, when they are not a member of SMART IRB.  
 4) 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.  
 5) Exceptions may apply to Tribal and non-U.S. IRBs.

**Q2:** Is this for **Industry Sponsored human research**?

**Q3:** Is this for **multi-site** research overseen by an **External Reviewing IRB** (not the Downstate IRB)?

**Q4:** Is this for other human research (not described above), which requires **Full Board** or **Expedited** or **Exempt** IRB review?

**Q5:** Is an **IRB Determination** needed to document an activity is **not research**, **not human research** or that the institution is **not engaged in human research**?

**Q7:** Will Investigators from the **Downstate Workforce** be overseen by an IRB other than the Downstate IRB?

Use the **Downstate IRB** to 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, provided the research is NOT federally funded, NOT multi-site industry sponsored, and NOT exempt  
 5) Investigators from an institution willing to execute a **Downstate IRB Reliance Agreement** for **NON-EXEMPT** research.  
 6) Investigators who are **NOT** 'Investigators for the purposes of COI' and willing to execute a **Downstate Individual Investigator Agreement (IIA)**. Typically the investigator is at an institution that does not have an IRB and the Investigator acts independently of their institution (e.g., moonlighting resident) or their institution allows an IIA.

**Notes:**  
 1) For an institution to be eligible to establish an IRA with Downstate, the external institution must: a) have an FWA, b) have a local IRB or HRPP Office to confirm local research requirements, b) be a HIPAA covered entity, c) have a PHS/NIH Conflict of Interest compliant policy, d) have a compliance (audit or QA) program in place.  
 2) Multiple IRBs may be used when sIRB oversight is not required.  
 3) Include IRB fees in research budget, if Industry sponsored. See Downstate IRB Guidance on Fee Schedules.  
 4) Investigators not covered by an IRA nor IIA with Downstate **MUST** use another IRB (as determined by their institution) and should be described in the protocol and informed consent materials, if applicable; however, these investigators should not be listed in the Downstate IRB Application.  
 5) Describe data and specimen sharing plans, & privacy and security protections in the protocol or Downstate IRB application.  
 6) Establish any necessary agreements, including Data Agreement (DA), Data Use Agreement (DUA) for sharing Limited Data Sets (LDS), Clinical Trial Agreement (CTA), Material Transfer Agreement (MTA), Facilities Use Agreement (FUA), Confidentiality Agreement (CA), IRA, IIA, etc.  
 7) For additional guidance see the IRB website or contact [IRB@downstate.edu](mailto:IRB@downstate.edu)