STEP 5 FLOW CHART

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 **Single IRB (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 sIRB requirements & 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.*

YES → **Q8: Is Downstate the Primary Awardee?**

Q8: YES → **9: Obtain a quote for IRB fees from the WCG IRB when using the WCG IRB and use the WCG IRB as the Reviewing IRB.** *Reminder: Include applicable WCG IRB fees & Downstate Local IRB Review fees (for Industry funded research) in the research budget.*

9: → **10:** 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** (see step 4a).*
2) All other Investigators follow the polices of their Institution and the Reviewing IRB.

Q8: NO → **11.** Whenever possible, use the **WCG IRB**; however, the Primary Awardee, Overall PI, or Sponsor decides which IRB to use. 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 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, c) CARE-Q certified, or d) 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.

Q1: NO → **Q2:** Will Downstate receive **Industry Sponsor funding** for human research (exempt or non-exempt) that is conducted at Downstate or conducted by the the Downstate Workforce?

Q2: YES → **Q12:** Will the Downstate Workforce *(see step 4a)*, be overseen by an (external) Reviewing IRB?

Q2: NO → **Q3:** Is this for **multi-site** non-exempt research **overseen by an (External) Reviewing IRB (not the Downstate IRB)**?

Q3: YES → **Q12:** Will the Downstate Workforce *(see step 4a)*, be overseen by an (external) Reviewing IRB?

Q3: NO → **Q4:** Is this for other human research, not described above, which requires **Full Board** or **Expedited** IRB review?

Q4: YES → **Q12:** Will the Downstate Workforce *(see step 4a)*, be overseen by an (external) Reviewing IRB?

Q4: NO → **Q5:** Is this for other human research, not described above, which qualifies for **Exempt** IRB review?

Q5: YES → **Q13:** Will the Downstate Workforce *(see step 4a)*, be overseen by an (external) Reviewing IRB?

Q5: NO → **Q6:** 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**?

Q6: YES → **Q13:** Will the Downstate Workforce *(see step 4a)*, be overseen by an (external) Reviewing IRB?

Q6: NO → **7:** Contact the Downstate IRB for guidance.

Q12: YES → **11.** (above)

Q12: NO → **14.** Submit **applicable Forms** to the **Downstate IRB** to include:
1) Investigators from the Downstate Workforce *(see step 4a)*, including Research Volunteers approved by the SVPR Office.
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 eligble institution with an executed **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.*

Q13: NO → **14.** (above)

Q13: YES → **15.** Submit **Form 11-10** to the **Downstate IRB** to include ONLY the Investigators from the Downstate Workforce *(see step 4a)*.
NOTES: 1) This form is typically used when an investigator has a joint role or appointment with Downstate or when a Downstate student or trainee is conducting activities at their employer's institution and seeks approval by their institution's IRB or HRPP for multi-site activities which includes Downstate. 2) Verify (External Reviewing IRB will review the Downstate workforce. 3) External investigators follow policies of their institution's IRB.

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Notes For Step 5 Flow Chart:

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 the research budget when the research is funded by an Industry sponsor. 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, agreements, and privacy and security protections in the protocol or Downstate IRB application. When the research design permits it, do not plan to share Downstate identifiable data (including identifiers about specimens) outside of Downstate.

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) "Multi-site" means multiple institutions with separate legal entities or institutions with separate Federal Wide Assurances (FWAs). Multisite does NOT mean multiple sites within the Downstate, which are covered under a single FWA.

8) Students and Trainees who are NOT in a Downstate academic program MUST go through the Senior VP or Research (SVPR) Office to become Downstate Research Volunteers to become members of the Downstate workforce to be included on a Downstate IRB application.

9) External investigators who are NOT otherwise covered by an Individual Investigator Agreement or an IRB Reliance Agreement must become a Downstate *Research Volunteers* if they are conducting human research on a Downstate site or if they will have access to Downstate Protected Health Information or Downstate private identifiable information.

10) For additional guidance refer to the IRB website or contact IRB@downstate.edu