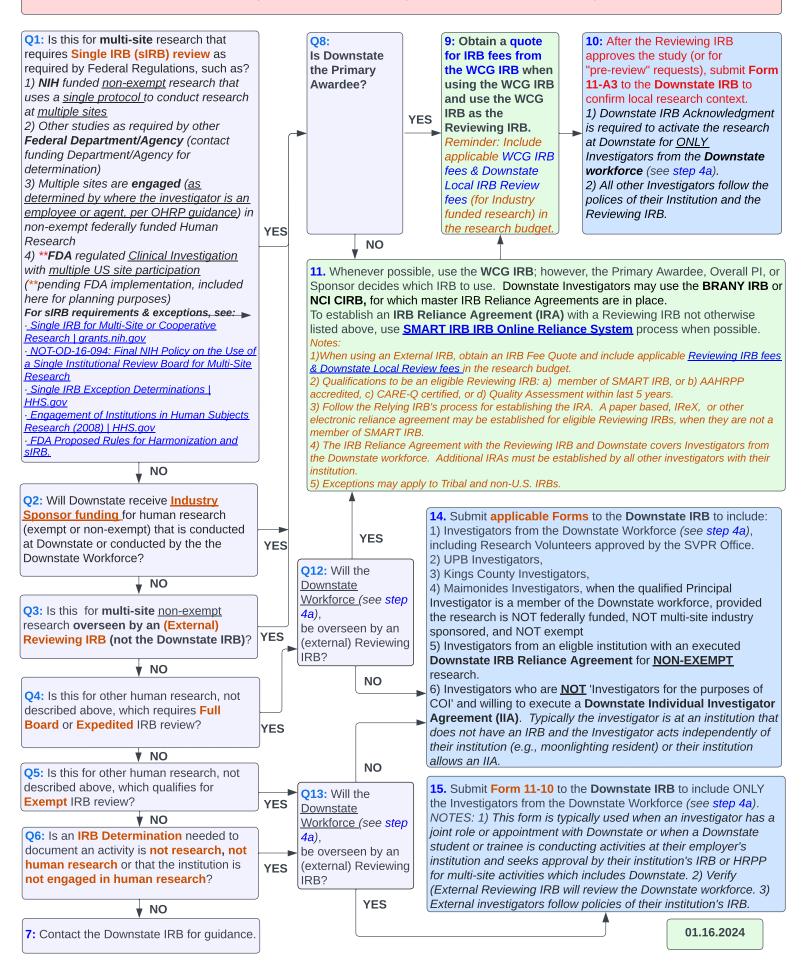
STEP 5 FLOW CHART

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.



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 <u>Research Volunteers</u> 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 <u>Research Volunteers</u> 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