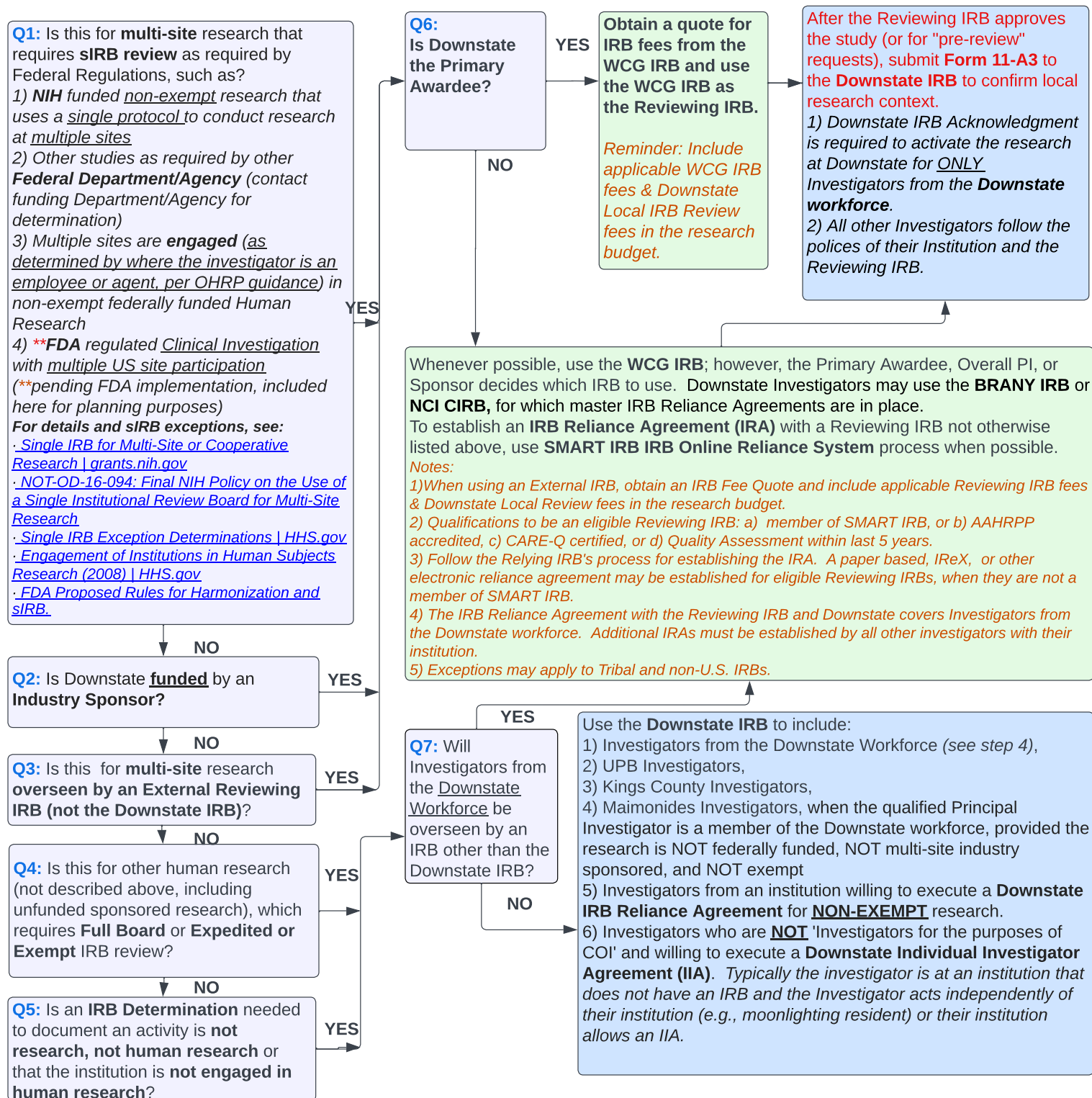


Determining which IRB to Use, which Agreements are required, and which IRB fees to budget.

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



Notes:

- 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 slrb 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, & 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