

Guidance for Mass General Brigham Investigators: The IRB Approach for Reviewing TWIN Research Protocols

What is a TWIN research protocol?

A "twin" research protocol is when two or more Mass General Brigham investigators submit separate but identical research protocols in which the sponsor's Detailed Protocol is exactly the same. These are almost always industry- sponsored multi-site protocols. Ideally, the sponsor communicates to Investigators that this research will be conducted at both (or more) Mass General Brigham sites, but this is not always the case.

While the IRB acknowledges the autonomy of each separate entity within the Mass General Brigham network, we wish to unify TWIN submissions to a degree that facilitates consistent implementation of an identical protocol across Mass General Brigham. Prior to approval, the IRB will work with Investigators to ensure that Mass General Brigham documents such as the Mass General Brigham Protocol Summary and Mass General Brigham IRB-approved Consent Forms are identical (with the exception of site-specific differences/logistics).

How do I know if I am submitting a TWIN?

If you have agreed to be the PI for an industry-sponsored, multi-site protocol, we encourage Mass General Brigham Investigators to ask the sponsor if they have concurrent plans to approach other prospective investigators elsewhere across Mass General Brigham sites. If the sponsor confirms that they will be approaching/implementing a twin study at a Mass General Brigham sibling institution, then you are strongly encouraged to reach out to the twin investigator and submit ONE cohesive protocol (with 2 Site-PIs). If you opt to move forward with two separate protocol numbers as individual twins, each submitting PI should notify the IRB of the twin status at the time of submission.

How does the IRB review process work for TWIN submissions?

Sometimes the PI/study team is not aware that their protocol submission is a twin. The IRB also "screens" for twin studies as part of the Intake process.

- Once a twin study has been identified, the workflow for YOUR twin protocol submission will depend on a few factors, such as: (1) whether you are the first (i.e. "Twin A") or second ("Twin B") submission; and/or (2) If you are identified as Twin B, how far along Twin A is already in the review process.
- The IRB will e-introduce both Twin A and Twin B study teams to one another, delineate the specific workflow for your twin set, and will request your collaboration with each other as needed. Even if Twin A has already been approved by the IRB, please note that Twin B must still be reviewed by a fully convened panel of the Committee if it is a greater than minimal risk study.

NOTE: The earlier the twin set is 'flagged' to the IRB, the less amount of coordination between teams is required. Ideally, both twins are captured during the Intake process and the IRB can coordinate unification of submission documents before assigning to the Initial Review panel for Committee review.