

Institutional Approval Requirement

The Institutional Approval Form is required for any research activity **that does not have** a formal contract or external grant award or subaward that will utilize any Prisma Health facility resources, engage Prisma Health patients or Prisma Health employees as research subjects, or engage Prisma Health employees or physicians in the conduct of the research.

This approval is also required for any proposed research that will utilize any ancillary department services. i.e. lab tests or imaging that is not covered by an existing contract or grant award.

Research that involves Prisma Health employees as research subjects, including surveys of employees may require Prisma Health Human Resources approval.

This approval form is not required for research that only requires access to Prisma Health Data. The Data Support Core Review processes provides approval for data use and identifies requirements for specific data use agreements or HIPAA waiver / partial waiver determinations.

Submission Procedures / Requirements

- Request for approval for any research activity not otherwise approved (Prisma Health IRB, Contract agreement or Grant award/ subaward) must be submitted prior to the initiation of any research activity.
- The Prisma Health Clinical Research Management Office (CRMO) provides oversight to this process and will provide final approval of the request.
- Identification of and approval by a Prisma Health Collaborator is required; however, the final approval must come from the Prisma Health CRMO Office.
- A copy of the proposed protocol and any data collection tools must be attached to this submission.
- If the proposed research has been approved by an IRB other than the Prisma Health IRB, please attach a copy of the Reviewing IRB approval letter. [IRB approval is not required prior to this submission.]
- Submit the completed form along with required attachments to: CRMO@PrismaHealth.org
 - Questions related to this process may be submitted to the CRMO Office: CRMO@PrismaHealth.org