RESEARCH COMPLIANCE
Division of Research

CU-IRB Office Checklist for Clemson's Prisma SEED Grant Recipients

- Submit provisional application to CU-IRB Office within 10 business days of receiving the award notice. The steps to submit the provisional application is available on the IRB webpage, https://www.clemson.edu/research/division-of-research/offices/orc/irb/forms.html.

  Note: The provisional application will be granted for 60 days to allow the study team time to submit their complete human subjects protocol/application to the designated reviewing IRB office for approval.

- Submit site clearance to Prisma if the CU-IRB Office is the designated reviewing IRB for the study. Prisma's site clearance is required before submitting your application to the CU-IRB Office. Refer to the site clearance guidance in the addendum for more information.

  Note: You will be notified if CU-IRB Office is your designated reviewing IRB during the Clemson's administrative review process.

- Submit CU-IRB application within 45 days of receiving the CU-IRB conditional determination for the provisional application.

- If Prisma is the designated reviewing IRB for the study, submit your CU-IRB application to register the study at Clemson within 14 business days of receiving Prisma's IRB final determination. Refer to the CU-IRB forms webpage for more information about registering multi-institutional research projects, https://www.clemson.edu/research/division-of-research/offices/orc/irb/forms.html.

  Note: You must have a CU-IRB "approved" record on file to purchase incentive cards through Clemson's procurement system.

Contact the CU-IRB Office at IRB@clemson.edu if you have any questions about the IRB process at Clemson or you may attend one of our office hour sessions through Zoom. Office hours information available at https://www.clemson.edu/research/division-of-research/offices/orc/irb/index.html.

Prisma Health Seed Grant Program
Frequently Asked Questions from Clemson University Investigators

Getting Started

How do I get started with my seed grant?

For the 2025 Seed Grant Program, Prisma Health will host onboarding drop-in sessions on January 13, February 12, and March 10 as well as a kickoff meeting on December 16 to facilitate successful launch of awarded seed grant projects. Please reference the timeline.

Institutional Review Board (IRB)

Which IRB should approve my seed grant, Prisma Health or Clemson? And who do I contact?

Faculty should seek compliance approvals from their individual home institutions. If you are not familiar with how to initiate an IRB review request, please contact your IRB office. For Prisma Health, contact irb@prismahealth.org. For Clemson, contact irb@clemson.edu.

If I am from Clemson and was notified to use Prisma Health's IRB, what do I need to do for Clemson?

You will submit a provisional application in InfoEd to CU-IRB when you receive the award notice and then submit the multi-institutional request form to register the study at Clemson after you receive Prisma Health IRB's determination. Refer to the checklist on the CU-IRB website for timelines.

Do I add the Prisma Health personnel to the CU-IRB application?

If CU-IRB is the designated reviewing IRB for the study, then yes, include all study personnel on the application and upload their CITI training documents.

If Prisma Health's IRB is the designated reviewing IRB and you are only registering the study with CU-IRB, then you DO NOT have to list the Prisma Health personnel on the application. Only list the CU team members and upload their CITI training documents.

Do I add the Clemson personnel to the Prisma Health application?

If Prisma Health is the designated reviewing IRB for the study, then yes, include all study personnel on the application and link for CITI training documents.

When do I need Prisma Health local site approval?

Prisma Health local site approval is required when a protocol is approved by an IRB other than the Prisma Health IRB and the study requires the use of Prisma Health services for their project (i.e., billable lab test or X-ray, engagement of use of employee time to support the project, etc.). For more information, please visit the IRB website or contact irb@prismahealth.org.

Data Access / Data Use Agreements

When do I need approval from the Data Support Core (DSC)?

- Requests for list of eligible patients for a project require DSC engagement and a Partial HIPAA Waiver to access potential participant contact information.
- Projects that require data for retrospective analysis of previously collected data require a DSC consult. Data that is collected through direct intervention with a study participant(s) do not require a DSC consult.

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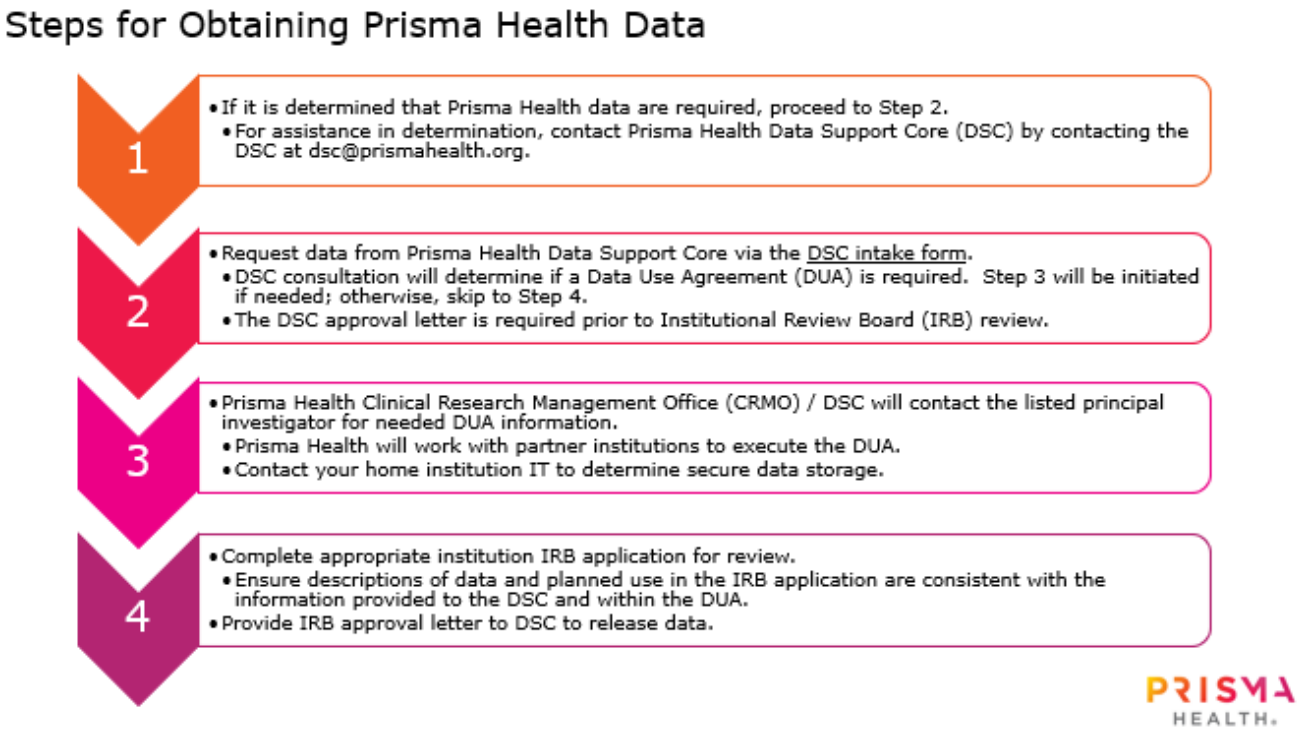
- Investigators should contact the Prisma Health Data Support Core (DSC) as soon as possible to discuss their project. DSC contact is made through the Consultation and Approval Request, or DSC@Prismahealth.org

When is a Data Use Agreement or Material Transfer Agreement required and who do I contact?
A Data Use Agreement is required prior to the exchange of patient data between organizations. Clemson investigators should contact the Clemson Office of Sponsored Programs to initiate the agreement process.

A Material Transfer Agreement may be required if you are obtaining tissue, blood, etc., for the purposes of your research. Requirements for an MTA can be obtained from the Prisma Health Clinical Research Management Office: CRMO@PrismaHealth.org

For seed grants that require it, executed DUA and MTA documents will be completed and provided attached to award agreements.

What are the steps for obtaining Prisma Health data?



<u>Financial Administration</u>
How do I access my seed grant funds?
If the seed grant related expenses are to be incurred at Clemson University, a sponsored project agreement will be issued to that institution defining the project title, project period, funding amount, and terms and conditions. Upon full execution of the agreement, Clemson's Grants and Contracts Administration office will then set up a grant account from

which the funds can be accessed. If you have questions about your project once it is set up, contact Abbey Anderson (anshepp@clemson.edu).

What do I do if I need a budget revision?
Contact your assigned Grants and Contracts Administrator (Abbey Anderson (anshepp@clemson.edu)) who will obtain approval from Prisma Health, if required.

What do I do if I need a no cost extension?
Prisma Health will not approve any no cost extensions for seed grants awarded in the 2025 cycle.

Facilitating Research in the Health System

Who can I contact for questions on accomplishing the research objectives at Prisma Health?
Prisma Health's clinical departments are served by a Clinical Research Unit (CRU) structure. The CRUs function as the research arm for departments and service lines to support industry-funded, grant-funded, and investigator-initiated studies. The CRU Directors serve as a resource for identifying partners, determining study feasibility, and defining appropriate research methods to be successful in conducting research in the clinical environment. In addition to the CRU Directors, each CRU consists of a variety of research managers, research coordinators, research nurses, and regulatory coordinators. These teams can be of assistance in all aspects of conducting clinical studies including budgeting, IRB submissions, data collection, patient enrollment, and follow-up. Please reach out to the CRU Director if your proposal will involve any patient or team member interaction or any patient data requests at Prisma Health.

For non-clinical departments, please contact Research-Assist@prismahealth.org.

Clinical Research Unit Name	Departments Served	Contact
CRU–Upstate	Upstate only - Anesthesia, Surgery, Neuroendovascular Surgery, Orthopedics, Radiology, Rehabilitation, OB/GYN, Pediatrics, Pediatric Hematology and Oncology	Stephanie Tanner, Director stephanie.tanner@prismahealth.org
CRU–Department of Medicine (Upstate)	Upstate only - Cardiology, Endocrinology, Infectious Disease, Gastroenterology, Neurology, Stroke, and Pulmonology	Harvey Shrum, Director ann.shrum@prismahealth.org
CRU–Midlands	Midlands only – Pediatrics, cardiology, infectious disease, pulmonology, rheumatology, and neurology (Baptist campus only)	Julia Adams, Director julia.adams@prismahealth.org

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Addiction Medicine Center	Cross department center serving Upstate and Midlands in areas	Dr. Claire Stam, Director claire.stam@prismahealth.org
Cancer Institute	Cancer Institute (Upstate and Midlands), Center for Cancer Prevention and Wellness, Center for Integrated Oncology Survivorship	Dr. Julie Martin, Director julie.martin@prismahealth.org
Neurology (Midlands)	Midlands only - Neurology	Phil Fleming, Manager phil.fleming2@prismahealth.org
Orthopedics (Midlands)	Midlands only - Orthopedics	Harley Davis pamela.davis2@PrismaHealth.org

What clearance do I need to perform research, including data collection, on site at Prisma Health?
Clearance to be on site at Prisma Health depends on the type of work to be performed and the role of person being cleared.

- For faculty investigators requiring on site clearance, the process begins by having a department that will be hosting you, presumably your seed grant partner investigator's department, and completing this onboarding request form: https://academics.prismahealth.org/academics/student-affairs/instructors-staff-and-scholars.
- If students will be engaging in the research process, the process begins by having a department that will be hosting you. Student clearance begins with this form: https://sa.prismahealth.org/student-research-enrollment/. Clearance questions may be directed to the Office of Student Affairs Administration via email to student.affairs@prismahealth.org or by phone at 864-455-1178.

How can I compensate research participants at Prisma Health?
There are two options for research participant compensation:

- Prisma Health uses reloadable cards called ClinCards. The fees associated are a per card fee plus a load fee for each payment that must be budgeted in addition to the payment(s). Ex. If you need plan to have only one participant and you will provide a $50 payment at consent and another $50 payment after the intervention, you must budget $4.95 for the card plus $3.50 ($1.75*2) for the load fees plus the $100 for cost of the payments, totaling $108.45. The Prisma Health research partner can contact their department research manager/director to obtain ClinCards. ClinCards are administered through the Clinical Research Management Office: crmo@prismahealth.org.
- Clemson payments are issued through gift cards when included in a grant budget and approved by the CU-IRB. Cards must be purchased through buyWAY$ in accordance with the institutional policy found here. Investigators should contact their college post-award office and departmental business manager to obtain payments.

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Can I pay a Prisma Health clinician or employee/team member for participating in my seed grant research as a research participant?

A Prisma Health clinician or employee/team member can participate in a research project ONLY during out of office/off hours.

- Compensation for Prisma Health clinicians can only be through a gift card secured by Clemson and cannot be through a ClinCard or other form of payment issued by Prisma Health (i.e., gift card).
- Compensation for Prisma Health employee/team members (non-clinicians) can be either through a gift card secured by Clemson or can be through a ClinCard, which becomes a taxable event.

Additional questions? Contact seedgrants@prismahealth.org.

Office of Human Research Protection
Institutional Review Board
701 Grove Rd
ESC158
Greenville, SC 29605

DFFGY6. 4Institutional Approval – GUIDANCE

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 HIPPAA 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