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PURPOSE: To guide users of the CHPS unit of the necessary steps of protocol application.

SCOPE: Principal Investigators and Clinical Study Teams.

PROCEDURE:

1. Submit your protocol to the Institutional Review Board (IRB) through HSERA.
2. Submit an application to the Center for Human Phenomic Science (CHPS). This is done through HSERA, on the left side bar/menu there is an option for “my CTRC requests” and then “create”.
3. Submit a CHPS budgeting spreadsheet to Tracey Caputo (Financial Officer), caputot@upenn.edu. This spreadsheet can be accessed on the CHPS website (www.med.upenn.edu/CHPS) under CHPS Budgeting and Funding Opportunities > CHPS Process and Budgeting Tool. Please refer to the PCAM Infusion inclusion/exclusion criteria SOP prior to submitting the budgeting request to Tracey Caputo.
4. If your study will be using study-provided equipment (ex. an infusion pump provided by the sponsor), communicate this on this application and contact CHPS Nursing Leadership at the time of application to begin discussion of this equipment.
5. Your protocol will be placed on the review agenda for the next CHPS Protocol Review Meeting held the second Tuesday of every month.
6. The CHPS nursing team may reach out to your team to discuss feasibility and visit logistics prior to CHPS approval of the protocol.
7. After the CHPS meeting and after the protocol receives IRB approval, Carl Shaw (Research Facilitator) shawcarl@pennmedicine.upenn.edu will e-mail the CHPS approval documents to the Principal Investigator and the Clinical Study Team. Within these documents is an Investigator/Coordinator Agreement with the CHPS that needs to be read and approved.
8. Before the first participant presents to the CHPS unit, all paperwork needs to be completed and an in-service must be given to CHPS staff to inform them of the study’s purpose and the CHPS’ staff responsibilities during each visit. Contact the CHPS Nurse Practitioner at least three weeks before the projected first participant visit for information on nursing worksheet development and in-service scheduling. Refer to CHPS SOP #2 Nursing Worksheets and SOP #3 In-services for more information.

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9. Once the in-service is completed, your CHPS # will be available for use to schedule appointments in the CHPS Scheduler. Please see CHPS SOP#4 CHPS Scheduler for more information.

Supersedes Study Application, 11/2017, 11/2018, **6/14/2019, 11/21/2021**

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