1. Is the University of Pittsburgh’s instance of Advarra eReg 21 CFR Part 11 Compliant?

Yes. Validations were performed and Standard Operating Procedures have been developed, and the system is compliant.

1. Which studies can use Advarra eReg?

The eReg system is optionally available now for all clinical trials. However, starting January 1, 2026, the following types of studies will be required to use Advarra eReg:

* New studies conducted under a faculty held Investigational New Drug (IND) or Investigational Device Exemption (IDE) application; and
* Single site studies meeting the [National Institute of Health (NIH) definition of a clinical trial](https://grants.nih.gov/policy-and-compliance/policy-topics/clinical-trials/definition).
* Multi-center studies meeting the [NIH definition of a clinical trial](https://grants.nih.gov/policy-and-compliance/policy-topics/clinical-trials/definition), where Pitt is the Coordinating Center (i.e., lead site).
1. How do I request access to Advarra eReg?

Complete the request form at this link [User Access Form](https://redcap-std.hs.pitt.edu/redcap/surveys/?s=4CR9F8HA4J947743). A separate request form needs to be submitted for each user. A central person may submit requests on behalf of study team members, or each individual study team member may submit their own request. All users will be added to the contacts list.

1. Will I be required to complete training?

Yes. All users (including investigators) will be required to complete training before being granted access to Advarra eReg. The required training is dependent on the user role. The required training modules will be set up for users based on user role. There is also a [training video](https://rescdn.hs.pitt.edu/clinical-research-content/eReg/Advarra%20eReg%20Protocol%20Training.mp4) available on setting up a protocol which is optional for users.

1. What if I’ve already completed Advarra eReg training for another study?

Upon proof a training module has been completed, such as a certificate, that training will not be required to be repeated.

1. Where do I direct my Advarra eReg questions?

All questions should be submitted to hs.appsupport@pitt.edu. Technical questions will be answered by the Health Sciences Information Technology. Compliance questions will be triaged to the Education and Compliance Support for Human Subjects Research for response.

1. How will non-Pitt employees gain access to Advarra eReg?

All users will need a Pitt e-mail account to access Advarra eReg. A sponsored account will need to be requested from Pitt Information Technology. The ‘sponsor’ will need to have a primary account and submit a request to [Technology Help Desk](https://services.pitt.edu/TDClient/33/Portal/Requests/TicketRequests/NewForm?ID=itE6fP3hNtM_&RequestorType=Service).

[Sponsored Accounts General Information](https://services.pitt.edu/TDClient/33/Portal/KB/ArticleDet?ID=801)

1. I need to add an organization to my protocol, and it’s not listed in the dropdown selection. How do I request new Organizations (e.g., IRBs or Laboratories) to be added to Advarra eReg?

If the Organization should also be listed in Advarra OnCore, submit the request to CTOHelp@pitt.edu. If the Organization is specific to Advarra eReg submit the request to hs.appsupport@pitt.edu.