



eRegulatory Confidentiality Document Agreement

As an Advarra eRegulatory (eReg) user with the University of Arizona Health Sciences (UAHS), you may have access to private information. Before using this system, be sure that you understand your responsibilities regarding confidentiality of private information.

An eReg user is anyone who has access to the eReg system with a user ID and password. Your user ID is equivalent to your signature. Do not share or disclose your user ID or password with anyone. When leaving your workstation, you must log out of eReg or lock your workstation. As part of your duties, you may be required to collect information about a patient's medical condition, history, medication, and family illness. You must realize the sensitive nature of the information and be committed to maintaining confidentiality. You agree to not release or discuss patient-specific information with others unless it is necessary to serve the patient, or required by law, unless the patient has consented to such disclosure.

Measures must be taken so that all information captured, maintained, and/or utilized by UAHS and any of its subsidiaries, affiliates, sponsors, and medical partners can be accessed only by authorized users. UAHS has a legal and ethical responsibility to safeguard the privacy of all patients and to protect the confidentiality of their health information and all other types of confidential information. Patient information is confidential regardless of how it is obtained, stored, utilized, or disclosed. As an authorized user of eReg, I agree to adhere to the above requirements. Failure to do so may result in the revocation of my privileges.

New users are responsible to enroll and complete required trainings on EDGE Learning: CITI, HIPAA and ISA (visit [CTapps website](#) for more information). Once all trainings are completed, please complete this form and submit a ticket in [TicketCat](#) to request access. COM-ITS will assign required trainings on Advarra University after receiving the ticket.

Staff Information			
Print Name:		UA Email:	
Wet Signature:		UA NetID:	
Date of Signature:		College and Dept/Div:	
Staff Role			
Affiliate Access	Clinical Research Coordinator	Multi-Site Access	Principal Investigator
Regulatory Coordinator	Regulatory Manager	Reports	Reviewer
Signer	Other:		

Print Supervisor Name:

Supervisor Signature:

Signature Date:



Standard Roles Table

The following roles are created/customized based on Advarra's system roles. All roles that are modified will include the UAHS label in eReg. UAHS includes the following standard system roles:

Role Name	Allows Users To...
Affiliate Access	Intended for users from outside of the coordinating center organization to give them permission to log in, upload documents, and send copies of those documents to the coordinating center.
Clinical Research Coordinator	<ul style="list-style-type: none">• View contact records, including credentials and delegated tasks by staff role.• View assigned protocols, including multi-site protocols.• Create review sessions globally, and view, edit, and delete review sessions to which they are assigned.• View the Sign Documents page and electronically sign documents. <p>This role is intended to be a standalone role for a user.</p>
Multi-Site Access	<ul style="list-style-type: none">• View and edit contact records, including credentials and delegated tasks by staff role.• Manage assigned multi-site protocols, including staff, documents, and organizations.• Manage participating sites.• View the Sign Documents page and electronically sign documents. <p>This role is intended to be an additional role stacked on top of other roles for a user.</p>
Principal Investigator	<ul style="list-style-type: none">• View contact records, including credentials and delegated tasks by staff role.• View organization records and regulatory tracking documents in the system.• View assigned protocols, including multi-site protocols.• View and edit staff for assigned protocols, including multi-site protocols.• View the Sign Documents page and electronically sign documents.
Regulatory Coordinator	<ul style="list-style-type: none">• View, add, edit, and delete contact records, including credentials and delegated tasks by staff role.• View and edit organization records at the global level.• View, add, edit, and delete staff for protocols to which they are assigned, including importing staff.• View and edit protocol documents/URLs for protocols to which they are assigned, including importing documents from OnCore.• View, add, edit, and remove organizations for protocols to which they are assigned, including adding and editing organization details.• View and edit the outline for protocols to which they are assigned.



	<ul style="list-style-type: none">• Lock assigned protocols.• View and edit the Inbox Configuration for protocols to which they are assigned.• Run reports.• View regulatory templates.• Create review sessions globally, and view, edit, and delete review sessions to which they are assigned.• View the Sign Documents page and electronically sign documents.
Regulatory Manager	<ul style="list-style-type: none">• View application settings, delegated tasks by staff role at the system level, reference lists, and the help menu.• View, add, edit, and delete contact records, including credentials and delegated tasks by staff role.• View and edit organization records at the global level.• View, add, edit, and delete staff for protocols in their department, including importing staff.• View and edit protocol documents/URLs for protocols in their department, including importing documents from OnCore.• View, add, edit, and remove organizations for protocols in their department, including adding and editing organization details.• View and edit the outline for protocols in their department.• Lock and unlock protocols in their department.• View and edit the Inbox Configuration for protocols in their department.• Run reports.• View regulatory templates.• Create review sessions globally, and view, edit and delete review sessions to which they are assigned.• View the Sign Documents page and electronically sign documents.
Reports	<p>View reports for assigned protocols or for their department.</p> <p>This role is intended to be a standalone role OR an additional role stacked on top of other roles for a user.</p>
Reviewer	<p>View both protocol-based and SOP review sessions to which they have been assigned as a reviewer.</p>
Signer	<p>Review and sign documents.</p>