VCU Office of the Vice President for Research and Innovation

eTMF Study Roles Guideline

Security profile: Please indicate which of the following roles using the role table below:

- Study Manager
- CTA
- Study Document Contributor
- Study Document Viewer
- External Inspector: Please reach out to the contacts below directly for this type of account

Study Staff Roles and Functions:

Each time an individual is added to a study, they will need to be assigned one of the below roles

Role	Functions	Blinded/unblinded Role (Can vary per study)
Study Manager	• Permissions to manage Global Directory • Permissions to create studies, countries, sites and products • Can manage their assigned studies, countries and sites and all necessary related study data (milestones, expected documents, personnel, communications, etc.) • Can create, modify and participant in workflows for documents in their assigned study • Can assign personnel and grant access as study persons	Can be either blinded or unblinded

	• Can view and run reports and create their own • Ability to archive studies • Full document contribution permissions: create and edit documents, participate in workflows, track quality issues, manage expected documents	
CTA	• Same roles as study manager except can't change life cycle states of study, country and sites or archive studies; or can't grant user access	Can be either blinded or unblinded
Study Document Contributor	• Permissions to view studies, countries, sites and milestones related to specific studies • Full document contribution permissions: create and edit documents, participate in workflows, track quality issues, manage expected documents • Can view and run reports and has ability to create their own • Can be designated as	Can be either blinded or unblinded

	quality control reviewer	
Study Document Viewer (may be used for internal monitors)	• Permissions to view study documents and data but cannot make updates • Can participate in document workflows as needed	Can be either blinded or unblinded
External Inspector (reserved for external monitors/auditors/inspectors such as for the purpose of a FDA inspection)	• Assigned to an inspector of a study and provides them with access to the TMF. This will provide permissions to view the approved study documents and some key study data.	

Contact

Please contact either of the following for questions regarding this document:

Lauren Wallace, MS
Director of Clinical Research Regulatory Affairs
kanigherl@vcu.edu

Jim Ward, MS, MBA
Assistant Vice President of Research Computing
jhward@vcu.edu

Document History

Version	Effective Date	Brief Description of Change
1.0	**01/05/2023**	Initial