

Yale eREG Notice re: Contact Credentials and Action Required by 22-Nov-2021

Dear eReg Users,

The eReg Support Staff in the Yale Center for Clinical Investigation (YCCI) have made changes to required staff credentials reflected in the following regulatory templates:

- Investigator Site File for Device Studies
- Investigator Site File for Drug Studies
- Participating Site File for Device Studies
- Participating Site File for Drug Studies
- Trial Master File and Investigator Site File Combination for Drug Studies

The following credentials are required within these regulatory templates:

Role	Curriculum Vitae	Good Clinical Practice Training	Medical License	Signature Sample
Clinical Research Assistant		✓		✓
Clinical Research Coordinator		✓		✓
Pharmacist (Drug only)		✓		✓
Pharmacy Technician (Drug only)		✓		✓
Principal Investigator	✓	✓	✓	✓
Protocol Coordinator		✓		✓
Regulatory Coordinator		✓		✓
Regulatory Manager		✓		✓
Research Laboratory		✓		✓
Sub-Investigator	✓	✓	✓	✓

What will happen to my existing studies?

Protocols that were not set up using the regulatory templates outlined above will not be affected by this change. The regulatory template used is noted in the Protocol Outline.

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YSM-GENERAL

Regulatory Template [Investigator Site File for Drug Studies](#)

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Consent Documents and HIPAA Aut

The regulatory templates noted above will be used starting 22-Nov-2021 so existing studies will be largely unaffected by the change.

What will happen to my contact record?

Until your signature sample credential is uploaded to your contact record, your record will not be impacted by this change at the contact level. However, any staff member listed on a protocol using the new regulatory templates will show as having an incomplete status until a signature sample has been uploaded to the contact record.

What do I need to do?

Review the credential requirements for your staff role(s) and ensure your most up to date credentials are on file. Email eReg.Credentials@yale.edu to provide any missing credentials.

Curriculum vitae, Good Clinical Practice training and medical licenses were previously required in prior regulatory templates that are now retired. Signature samples were not required. All users will complete the attached (or equivalent document used by a department and/ or sponsor) signature sample document and return it to eReg.Credentials@yale.edu. Please return the completed signature sample document by 22-Nov-2021 to ensure your contact credentials are complete when the new regulatory templates begin to be used.

Who do I contact with questions?

Please contact eReg Support (eReg.Support@yale.edu) with any questions.