Yale eReg Protocol Import/ Creation Guide

1.0   Overview

All protocols requiring International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) compliance will automatically be imported from OnCore into eReg by the eReg Support staff for those departments who are currently using eReg.

2.0   Protocol Risk Assessments

Protocols are imported once a protocol risk assessment has been completed by the Yale Center for Clinical Investigation (YCCI). A protocol risk assessment will be triggered once the protocol has been built in OnCore. All protocols built in OnCore will have a risk assessment performed.

3.0   Protocol Import

When imported into eReg, the following rules will be followed to add a staff member to the staff section of the eReg binder:

3.1.   Yale Cancer Center (YCC) studies:

For YCC Studies, the OnCore protocol creator will be added.

3.2.   Non-Yale Cancer Center studies:

For Non-YCC studies, we will add the staff member who has one of the following OnCore staff roles, in the order listed (only one person will be added in eReg—if no one has the first role listed, we will look for the second, etc.):

- o   Administrator Only
- o   Clinical Research Assistant
- o   Clinical Research Coordinator

4.0   Protocol Creation

If a protocol will not be built in OnCore, please reach out to eReg Support to have your protocol created in eReg.
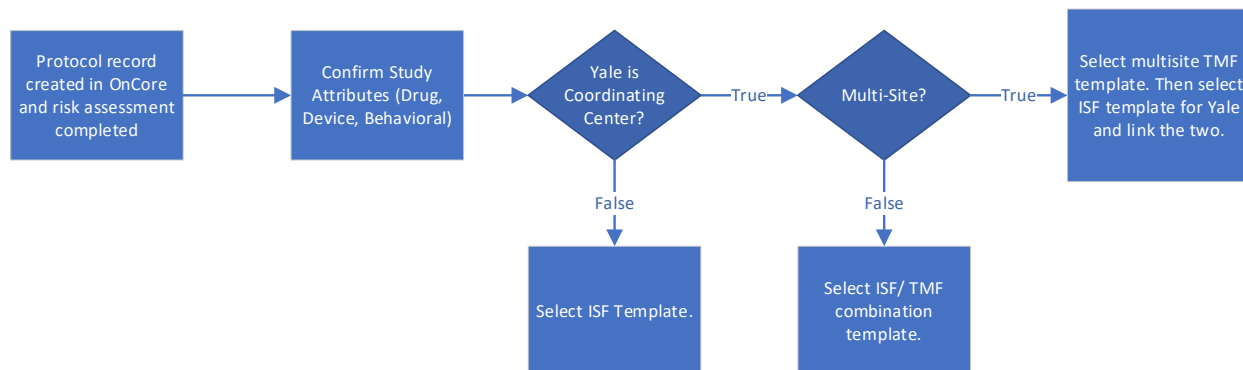
Yale Center for Clinical Investigation

5.0   Regulatory Templates

YCCI eReg Support staff will select the regulatory templates to be used for an imported protocol based on study attributes and management type. The risk assessment will confirm the study attributes and management type.

The diagram below details which regulatory template will be selected:

6.0   Protocol Access

The staff member added to the staff section in the eReg binder will have access to the protocol once it has been imported/created. They will be responsible for adding all additional study team members to the staff list.

Users in eReg with a role of Regulatory Manager who are assigned to the same department as the imported protocol will also have access to the protocol once it has been imported/created in eReg and a study team member has entered the department in the Protocol Details section of the eReg binder. Regulatory Managers can view and edit eReg binders for all protocols assigned to their department in eReg without being listed in the staff section of each protocol.