Yale eReg Protocol Import/ Creation Guide

1.0 Overview

Protocols requiring International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) compliance are automatically imported from OnCore into eReg by the Yale Center for Clinical Investigation (YCCI) eReg Support staff for those departments which are exclusively using eReg to maintain their regulatory files. For all other departments, protocol import is requested via the eReg Protocol Import Request Form.

2.0 Timing of Protocol Import

The timing of protocol import depends on whether or not the department managing the regulatory binder is exclusively using eReg to maintain its regulatory files.

2.1 For departments exclusively using eReg to maintain their regulatory files, protocols are imported once a protocol risk assessment has been completed by the Yale Center for Clinical Investigation (YCCI). A protocol risk assessment is completed once the protocol record is in OnCore. All protocols in OnCore will have a risk assessment performed.

2.2 For departments that are not exclusively using eReg to maintain their regulatory files, and/or for protocols that will not be in OnCore, protocols are imported upon request via the eReg Protocol Import Request Form.

3.0 eReg Protocol Import Request Form

Only those departments not exclusively using eReg to maintain their regulatory files should request a protocol import.

To request an eReg protocol import, complete the following form:
https://redcapynh.ynhh.org/surveys/?s=N7WE3EW984WRWMMP

A protocol import request form must be completed for each protocol needing to be imported into eReg.

4.0 Regulatory Templates

The YCCI eReg Support staff will select the regulatory template to be used for an imported protocol based on the study attributes and management type listed in OnCore or provided in the eReg Protocol Import Request Form.

5.0 Protocol Staff

Users in eReg with a role of Yale Regulatory Manager who are assigned to the same department as the imported protocol will automatically have access to the protocol once it has been imported/created in eReg. Yale 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. A protocol's department/Yale Cancer Center (YCC) disease team designation is taken from OnCore and added to the eReg protocol record upon import.

The following rules will be followed if a staff member needs to be added to the staff section of the eReg binder, to ensure someone on the study team has access to the record:

5.1. Yale Cancer Center (YCC) studies:

For YCC studies, staff will not be added to the eReg protocol by the eReg Support team. YCC Regulatory Managers have access to view and edit all YCC protocols upon import.

5.2. Non-Yale Cancer Center studies:

For non-YCC studies in departments that are not exclusively using eReg, the requestor listed on the Protocol Import Request Form will be added as staff to the imported protocol. The requestor will have access to view and edit the protocol upon import.

For non-YCC studies in departments exclusively using eReg, staff will not be added to the eReg protocol by the eReg Support team. The Regulatory Manager(s) designated for the department have access to view and edit all protocols associated with their department upon import.

6.0 Automatic Protocol Import

Protocols requiring ICH GCP compliance are automatically imported from OnCore into eReg by YCCI eReg Support staff for departments who are exclusively using eReg to maintain their regulatory files. If your department is interested in exclusively managing and maintaining your protocols' regulatory documents in eReg moving forward, please reach out to eReg Support at eReg.Support@yale.edu.