

Yale eREG Notice re: New Regulatory Templates for Social/ Behavioral Research

Dear eReg Users,

The eReg Support Staff in the Yale Center for Clinical Investigation (YCCI) have released regulatory templates to be used for social/ behavioral research studies:

- Investigator Site File for Social/ Behavioral Studies
- Participating Site File for Social/ Behavioral Studies
- Trial Master File for Social/ Behavioral Studies

The eReg Guidance Document for [Investigator Site File Regulatory Templates](#) has been updated to include the Investigator Site File for Social/ Behavioral Studies information.

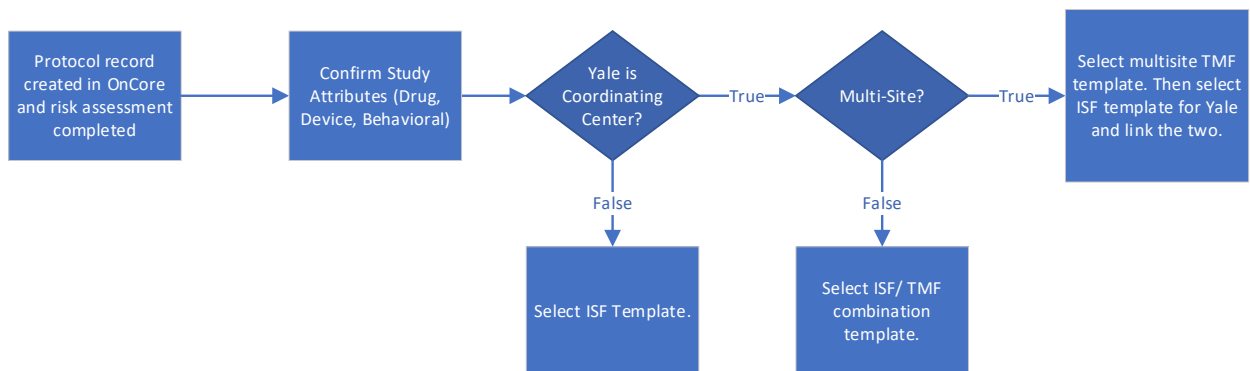
What will happen to my existing studies?

Existing protocols will not be affected by this change. The regulatory template used for a protocol is noted in the Protocol Outline.

The screenshot shows the eREG system interface. At the top, there is a navigation bar with 'eREG.', 'Menu', 'Protocols', 'Regulatory Templates', and 'Review'. Below this is a breadcrumb trail: 'Protocols > YSM-GENERAL > Protocol Outline'. The main heading is 'YSM-GENERAL'. Underneath, it says 'Regulatory Template: Investigator Site File for Drug Studies', with this text circled in red. Below that are links for 'Expand All | Collapse All' and a section titled 'Consent Documents and HIPAA Aut'.

What do I need to do?

If you have a new study that should utilize the social/ behavioral regulatory template(s), notify eReg Support (eReg.Support@yale.edu) when you are requesting protocol import. Decisions regarding the regulatory template to be used for a protocol are made according to study attributes, Yale's role in the study and whether it's multi-site.



Who do I contact with questions?

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