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.
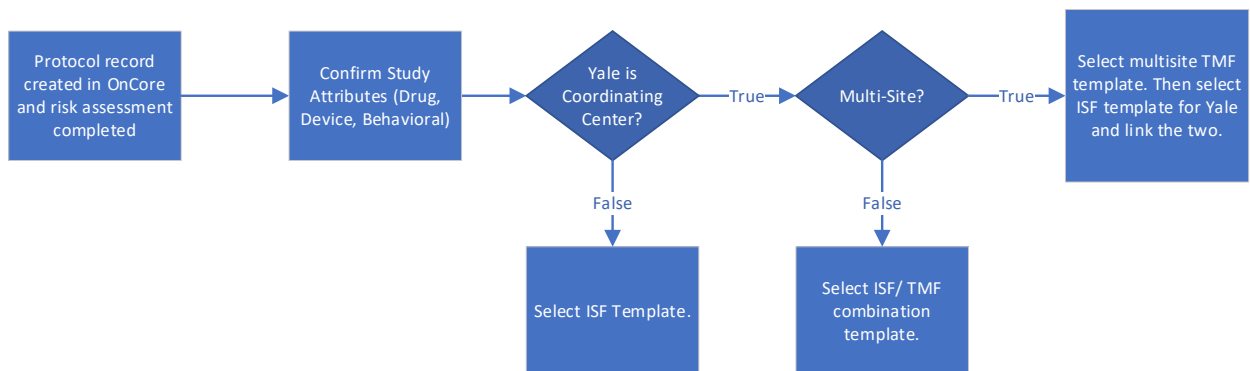
What will happen to my existing studies?
Existing protocols will not be affected by this change. The regulatory template used for a protocol is noted in the Protocol Outline.

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.