College of Medicine
Office of Research

About the College of Medicine's Clinical Research New Study Checklist

Regulatory requirements for clinical trials and other forms of clinical research are complex, and non-compliance can negatively impact study participants, investigators, the College of Medicine, and the University. The College of Medicine developed a New Study Checklist as a tool to support regulatory compliance by compiling the various requirements and associated resources into one document. The Principal Investigator is responsible for maintaining all required documentation for clinical studies conducted. The Clinical Research Support Office (CRSO) will distribute the checklist and designate a place in OnCore for the completed checklist to be uploaded and stored.

Frequently Asked Questions:

Why do we need a new study checklist?

There are many clinical research-related regulatory requirements, and it can be challenging to identify the steps needed or the resources available to ensure compliance. The checklist's content does not represent new requirements; rather, the purpose is to compile the various elements of regulatory compliance into one convenient document that includes links and resources to assist investigators and study teams.

Who should use the new study checklist?

All study teams conducting clinical research in the College of Medicine can utilize the checklist as a resource to ensure regulatory compliance for new studies.

When do study teams begin using the new study checklist?

All clinical research teams working with the CRSO to build a new research study in OnCore will receive the new study checklist as part of the study submission and review process; however, you do not need to wait for the CRSO to provide you with the checklist to get started. A current copy can be obtained from the Office of Research by emailing medicineresearch@uky.edu.

Not all parts of the new study checklist apply to my research; do I still need to complete it?

Only complete the sections that apply to your particular clinical research study, and mark the non-applicable sections appropriately.

Where do I get the new study checklist?

The CRSO will provide the new study checklist to you as part of building a research study in OnCore. A current copy can also be obtained from the Office of Research by emailing medicineresearch@uky.edu.

What do I do with the new study checklist?

The Investigator or designee can upload the checklist into OnCore as part of your study documents. Click here for directions on where to store the checklist in OnCore.

It would likely be more efficient if this new study checklist were offered in an electronic format, rather than a fillable PDF.

We are working on an internal electronic process for the checklist; however, this could take months to build, test, and implement. In the interim, investigators and research teams have asked for regulatory compliance guidance, and this PDF version is an immediate way to provide that support.

What if I have additional questions?

Please email any questions to medicineresearch@uky.edu