

TITLE:	How to File a New Federalwide Assurance (FWA)
SUMMARY:	Describes the steps, information and resources for filing a new Federalwide Assurance (FWA)
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1. When is an FWA needed?

A Federalwide Assurance (FWA) is used by institutions, clinics and others when they have received federal research dollars to conduct human subjects research. This includes directly receiving federal funding and also including when funding comes from a sub-award, sub-contract, or is a part of a federally funded initiative like the CTSA. In an FWA, institutions make commitments about how they will conduct the research, and they must honor those commitments to remain compliant with the Department of Health and Human Services regulations.

KUMC currently has an FWA. Rural Sites will need to complete the FWA process if they are participation on a study that receives federal dollars.

2. What is the process to submit an FWA?

Institutions must submit FWAs electronically using the submission system available through the Office of Human Research Protections ([OHRP website](#)), unless an institution lacks the ability to do so. If an institution believes it lacks the ability to submit its FWA electronically, it must contact OHRP by telephone or email (see [OHRP FWA Contact Information](#)) and explain why.

Institutions must update their FWA within 90 days after any changes are made to the legal name of the institution, the Human Protections Administrator (the main contact), or the Signatory Official.

The FWA is effective for 5 years and must be renewed every 5 years, even if no changes have occurred, in order to maintain an active FWA. Any renewal or update that is submitted electronically, and approved by OHRP, begins a new 5-year effective period.

3. Steps to Submitting an FWA:

- a. Obtaining a submission number is the first step to file a new FWA.
 - i. Go to the [FWA site](#).
 - ii. Scroll down to the bottom of the screen and click on “I need a submission number.”
 - iii. Enter
 - 1. Your e-mail
 - 2. a password created for the submission, and
 - 3. a password hint that cannot be the same as the password.

