Selection for Review

Who, or what, can be selected for review?

Any human subject research activity that is overseen by the UAMS IRB is subject to review. Individual studies are most commonly selected. Most often, we look at studies that are reviewed by the full convened IRB, but studies that qualify for exempt or expedited status also may be chosen.

All types of studies – behavioral, biomedical, industry-sponsored, investigator-initiated, grantfunded, unfunded, investigational drug/device, survey or focus group only, and any other types we may have missed in this list – are subject to review.

Broader areas involved in research, such as a lab or a department, can also undergo review, including the UAMS IRB. In fact, whenever we look at a study, we routinely look at how the IRB reviewed that study. We also can perform more general audits of the IRB.

How do we select research activities for review?

If a Principle Investigator requests a review, we are happy to come look at the study and give feedback. In addition to these requested reviews, we perform both routine and targeted audits.

Our most common type of review is what we call “routine.” We choose research activities for this type of review by compiling a list of all open studies and then selecting some using a random number table.

We try to focus on studies that have been open for no more than 12 months, because we like to provide feedback relatively early in a study’s course. However, sometimes we’ll find that many of the studies on our list haven’t enrolled any subjects yet, or never got started for one reason or another. Then we’ll have to select more studies to add to the list.

In any event, if a study is a) open and b) subject to UAMS IRB oversight, it’s subject to routine review. We typically won’t review a PI’s study if that same PI has had another study routinely audited within the previous 12 months and the first review showed no significant problems. However, if multiple studies are funded by the same funding source, more than one of them may be audited within a single 12-month timeframe, if they have different PIs.

We also do what we call targeted reviews. For example, we may want to look at studies that involve higher risk. Factors that may increase a study’s risk include (but are not limited to): higher-risk research procedures, such as gene therapy or phase 1 drug studies; the involvement of vulnerable populations; or a study the IRB has determined requires continuing review more often than annually. If we get a subject, employee, or whistleblower complaint, chances are good that we’ll come take a look at any study that’s involved.