

The American Society for Investigative Pathology requested clarification from NIH regarding biospecimen research and the updated clinical trials definition. Michael Lauer, Deputy Director for Extramural Research, NIH has indicated that the following case study is NOT an example of a clinical trial:

A research study is being conducted comparing fluorescence in situ hybridization probe (FISH probe) type A with FISH probe type B to determine which probe is better able to detect mutations associated with a specific gene. Identifiable biospecimens will be used (for purposes of this example it does not matter whether the sample is from previously consented archived biospecimens or whether the sample is gathered under the appropriate consent with the specific intent to use it in this research study). The identifiable biospecimens are randomly assigned to be either type A or type B. For comparison, the same gene region is analyzed using direct DNA sequencing. Conclusions are drawn as to the accuracy of each type of FISH probe.

X Per Dr. Lauer, this is not a clinical trial.

ASIP is seeking to work with NIH on the development of a case study that would be posted on the NIH [clinical trials website](#). Previously, NIH provided case studies of research involving the [secondary use of biospecimens](#) (Case #10b) and [use of de-identified samples](#) (Case #10a), indicating that both such cases are NOT clinical trials.

Please let Jennifer Dreyfus, ASIP Science Policy Consultant, know should you have examples of research that appear to meet NIH's definition of a [clinical trial](#) but where such categorization isn't logical or appropriate from a researcher's point of view.