Chart 5: Does Exemption for Existing Data Documents and Specimens Apply?

From Chart 2

Does the research involve only the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens? *

("Existing" means existing before the research is proposed to an institutional official or the IRB to determine whether the research is exempt.)

YES

Does the research involve a vulnerable population such as: prisoners, children, decisionally impaired, pregnant women, fetuses, neonates?

Yes → Go to Chart 12

No → No

Are the sources publicly available?

YES → Go to Chart 13

NO

Will information be recorded by the investigator in such a manner that the subjects cannot be identified, directly or through identifiers linked to the subjects?

YES → Research is exempt

NO → Research is not exempt