Chart 5: Does Exemption 45 CFR 46.101(b)(4) (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.)

** "Only" means that no non-exempt activities are involved. Research that includes exempt and non-exempt activities is not exempt.

YES

Are these sources publicly available?

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?

NO

Research is not eligible for exemption under 45 CFR 46.101(b)(4) from 45 CFR part 46 requirements.

YES

Research is eligible for exemption under 45 CFR 46.101(b)(4) from 45 CFR part 46 requirements.

Return to Chart 2 and consider whether 45 CFR 46.101(b)(5) exemption applies.

* Note: See OHRP guidance on research use of stored data or tissues and on stem cells at http://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-research-involving-stem-cells/index.html, and on coded data or specimens at http://www.hhs.gov/ohrp/regulations-and-policy/guidance/research-involving-coded-private-information/index.html for further information on those topics.

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