COLUMBIA|RESEARCH
Human Research Protection Office
Institutional Review Boards

Date:	20 August 2024
Re:	Policy on Resolution of Queries After Study Closure

Applicable regulations, state or local laws, contractual obligations or Columbia University (Columbia) policy may require storage of research data for a specific period after study procedures are completed. Maintaining individually identifiable private information from a completed study without using, studying, or analyzing such information is not human subjects research and, thus, does not require continuing oversight by the IRB.

A sponsor, monitoring entity, or oversight agency may occasionally request clarifications or raise queries on data originally collected as specified in an IRB-approved protocol and permitted per the Informed Consent Form signed by a subject, even after study closure and completion of oversight by the Columbia or other designated IRB of Record and after any applicable close-out activities.

For such occasional clarifications related to existing data in research records including electronic case report forms or the Medical Record, researchers do not need to re-open the study with the Columbia or previously designated IRB of Record to provide or clarify data initially collected or available during the period when the protocol had IRB-approval and access to such information was consistent with informed consent provided by the subject.

However, any queries related to new research questions, or queries that will generate new data, or new source documents, must be routed through an official IRB review and approval process.

This policy pertains to all research studies, regardless of sponsor or IRB of Record.

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