When do you need to submit a separate biorepository study protocol and separate consent form to the DUHS IRB?

Under the HRPP Database and Specimen Repository (DSR) policy, external repository sites are handled differently than internal, Duke-controlled repository sites. Specifically, a Duke biorepository site requires a separate IRB protocol submission and a separate consent form.

When data/samples are stored for use in future research studies and Duke researchers control access to the specimens, whether the physical location of the biorepository is at Duke or elsewhere (such as when Duke has obtained storage space off-campus for the samples), under the HRPP Database and Specimen Repository (DSR) policy, this is considered an internal Duke repository site.

A noteworthy example of this is the biorepository in Greenfield, Indiana at a Covance facility. Duke has obtained space in this facility for storage of samples obtained for future research. This space is used for storing samples collected for future research under a number of IRB approved protocols, some of which are coordinating center protocols from DCRI, including protocols where Duke is not a site for subject enrollment and/or interventions. Even though the site itself is external to Duke, for protocols under which Duke researchers collect and/or control access to the samples, this biorepository would be considered an internal Duke biorepository, requiring a separate IRB protocol submission and separate consent form.

When protocols are submitted to the IRB involving storage of samples for future research, please state not only the location of the storage site, but also whether or not Duke researchers will control access to the stored samples.

Please note that waiver of consent/authorization for samples stored in a Duke biorepository is possible, but would generally require that the samples were not collected for the purpose of storage for future research (i.e., they were collected in the past for other research studies, for clinical purposes, or for quality improvement purposes). For the IRB to approve such a waiver, the study must meet the criteria for waiver of consent [45 CFR 46.116(d)] and waiver of authorization [45 CFR 164.512(i)(1)and(2)].