REVIEW of THIRD PARTY VENDOR DOCUMENTS

Third party vendor documents are not under the purview of the Research Ethics Board (REB) to review since the REB does not have any formal jurisdiction over the third party service provider's documents and policies. As such, third party vendor documents (including but not limited to "end user license" agreements, "terms of use", reimbursement consent/agreement) are not reviewed by the UHN REB.

An agreement to use a service during a research study is between the participants and the vendor (i.e. service provider). While participants must be informed about the potential use of a service in the research consent form, (e.g. an optional method for providing reimbursement using a third party), the consent form should only present a basic statement, in simple, non-biased language, about the use of the service. All other details should be presented in the third party vendor document.

Although ICH GCP suggests that the REB should obtain "written information to be provided to subjects," the applicability of the ICH GCP to the documents from third party vendors has currently not been defined. These documents are typically outside of the scope of research, are not considered consent documents as described by research regulations, and thus are not subject to REB's review.

A consent form referring to a third party service provider, where the service is **absolutely** necessary to conduct the study (for example, home visits by a nurse), would need to be appropriately assessed by the REB to determine if it *may or may not* require REB review.

Therefore, as per the above, the UHN REB does not review third party vendor documents that will be used during a research study. This also includes UHN "authored" documents that contain vendor document language.