IRB Processes for Reconciling Consent form Injury Language with Executed Sponsor Contracts
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Background: IRBs are required to ensure that, when appropriate, the informed consent form details coverage available for the costs that may result from research-related injuries. For industry-sponsored research protocols, coverage for injuries is negotiated through the clinical trial agreement. Since contract negotiations are often pending when IRB review initially occurs, the coverage outlined in the consent document at the time of initial review may not be representative of the final negotiated coverage.

Methods: To address this problem, the IRB, in collaboration with the institutional contract office, developed a process to ensure that the IRB does not release a final approved consent form until the contract is executed and a final review of the consent form language has been completed. This process includes the following key components: Reconciliation of injury language in the consent form with any applicable master clinical trial agreements by IRB staff as part of the initial pre-screening process prior to IRB review; early identification of consent form language that is inconsistent with the coverage for subject injury the institution requires for sponsored research; withholding of the final stamped consent form for any studies where a study-specific clinical trial agreement is pending; real-time dissemination of executed agreements from the contracting office to the IRB; prompt reconciliation of the language in the final contract with the consent form by the IRB staff.

Findings: The primary challenge with the implementation of this process was communicating this procedural change to the research community and sponsoring agencies. To address this issue the IRB adopted standardized language to communicate the progress of the review of the subject injury language in IRB correspondence and hosted educational sessions for the research community to explain the process change. Additionally, to avoid delays in study initiation a 24 hour deadline for contract/consent language reconciliation was imposed.

Conclusions: Other HRPPs may consider implementing a similar procedure to facilitate reconciliation of the language detailing coverage for research subject injury in the contract and consent. Future plans at this Institution include development of a guidance document to explain how the Institution handles the review of language pertaining to research-related injury coverage in consent forms for sponsored research. This document will be designed to better communicate the Institution’s expectations and procedures to the research community and to sponsors.