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| **If an amendment involves …** | **Then the amendment submission should include:**  *References to the main smartform use version 3 (e.g. the consent form view is view 7.4). For older studies, the corresponding view should be updated (e.g. consent form view is 16.8).* |
| * Revised IB(s) with change to risk(s) | * Indicate “Change in risks” in view 1.2 of amendment * Consider whether current subjects need to re-consent and complete views (1.3.1, 1.3.2) of amendment to confirm any re-consent that will occur * Modify main AURA smartform view 5.1 to reflect the new or revised risks * Upload revised consent form in view 7.4 of main AURA smartform |
| * Revised consent form | * If there is no currently approved consent form, explain in the amendment summary of changes in view 1.2 that enrollment is re-opening and why * Consider whether previous subjects need to re-consent and complete views (1.3.1, 1.3.2) of amendment to confirm any re-consent that will occur * Upload clean and tracked change version of ALL revised consent form (s) in main AURA smartform view 7.4 |
| * Change in PI | * Revise view 1.1 of the modified study smartform to name the new PI * Upload memo from new PI indicating agreement to assume responsibility for the study in main AURA smartform view 8.1, question 2 * Go through entire current smartform and change PI name wherever else it is listed * Update consent form(s) in view 7.4, if applicable * Update advertisements in view 3.1, if applicable * Update protocol in view 8.1, if it is a UChicago protocol |
| * Adding “sponsor-requested” text to consent form | * Provide regulatory or other justification for new text within amendment summary of changes, if new text does not clearly relate to the changes described in the amendment |
| * Sharing data/samples | * Explicitly state in the amendment form summary of changes in view 1.2 that data (and/or samples) will be shared * Specify if data/samples will be coded/de-identified/identifiable (see FAQ entitled “Identifiable, Coded, and De-Identified Data/Samples: When are these definitions appropriate?” at <https://biologicalsciences.uchicago.edu/irb-faqs-and-guidance>) (see also CR\_POL\_117 as well) * If sharing with another site, and data/samples are identifiable, confirm outside site has IRB approval upload in view 8.1 of modified smartform as applicable * Update view 5.2 (and 3.11 for samples) of modified smartform and provide a description of data/samples to be shared (e.g. will it be clinical data? Just coded samples or data along with samples?) * If sharing identifiers, upload updated consent form (and specify what PHI will be shared) in modified smartform view 7.4 * If there is an internal U of C protocol, upload revised protocol document in view 8.1 to specify what will be shared with each site * If new elements of PHI will be shared, amendment should specify if previously-enrolled subjects’ PHI will be shared, and if so, will subjects be asked to re-consent? (and obtain authorization for sharing of PHI) |
| * If electronic consent is proposed | * Clearly describe consent process AND how consent will be documented in modified smartform view 7.1 * Provide method (e.g. electronic program) used in amendment summary of changes and view 7.1 of modified smartform (See OCR e-consent guidance “Information on Use of Electronic Informed Consent - 4-21-2020”) * Provide sign off from IT Security, as applicable, for any new program to be utilized for e-consent |
| * Changes requested by IRB | * Specify in amendment form summary of changes in view 1.2 who requested the change and when (e.g. continuing review) |
| * Change in funding | * If the funding change involves new data sharing with a new funder, update any data sharing views/consent form (see above on sharing data/samples) * Specify in view 1.2 of the amendment how the new funding relates to the approved study (e.g. is this the same aim or is a new aim being added to the protocol) and in particular, if applicable, explain in the amendment summary of change why the new grant title does not match approved study * If the PI or any co-Is have an outside financial interest with the newly identified funding, include a memo in view 8.1 of the modified smartform to provide details and update the consent form (if there is a consent form) to describe the outside interest |