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| --- | --- | --- | --- | --- | --- | --- | --- |
| **RefNo** | **Protocol Version Number / Date** | **Date of (s)(c)IRB Approval** | **Date Provided to the Site** | **Did the Protocol Require Local IRB Submission / Approval?** | **\*\*If Yes, Date of Local IRB Approval / Acknowledgment Or N/A** | **Did the (s)(c)IRB Require Reconsent from Participants?** | **Brief Summary of Changes** |
|  |   |   |   |  [ ]  Yes\*\* [ ]  No |   [ ]  N/A |  [ ]  Yes [ ]  No |     |
|  |   |   |   |  [ ]  Yes\*\* [ ]  No |   [ ]  N/A |  [ ]  Yes [ ]  No |     |
|  |   |   |   |  [ ]  Yes\*\* [ ]  No |   [ ]  N/A |  [ ]  Yes [ ]  No |     |
|  |   |   |   |  [ ]  Yes\*\* [ ]  No |   [ ]  N/A |  [ ]  Yes [ ]  No |     |
|  |   |   |   |  [ ]  Yes\*\* [ ]  No |   [ ]  N/A |  [ ]  Yes [ ]  No |     |

**Local IRB Submission Guidelines:**

In general, amended protocols approved by an sIRB or cIRB do not need to be submitted locally. Items designated for local review can include but are not limited to:

* Updates to Conflict of Interest (COI) management plans for investigators with an active COI
* Addition of a pediatric population to the trial
* Changes that require review from another University group (RDRC, CTSI, HCI, etc.)

If you are unsure whether an sIRB approved amendment needs to be submitted locally, please contact the IRB as irb@hsc.utah.edu

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| **RefNo** | **Consent Version Date** | **Date of (s)(c)IRB Approval** | **Date Provided to the Site** | **Did the Consent Require Local IRB Submission / Approval?** | **\*\*If Yes, Date of Local IRB Approval / Acknowledgment Or N/A** | **Did the (s)(c)IRB Require Reconsent from Participants?** | **Brief Summary of Changes** |
|  |   |   |   |  [ ]  Yes\*\* [ ]  No |   [ ]  N/A |  [ ]  Yes [ ]  No |     |
|  |   |   |   |  [ ]  Yes\*\* [ ]  No |   [ ]  N/A |  [ ]  Yes [ ]  No |     |
|  |   |   |   |  [ ]  Yes\*\* [ ]  No |   [ ]  N/A |  [ ]  Yes [ ]  No |     |
|  |   |   |   |  [ ]  Yes\*\* [ ]  No |   [ ]  N/A |  [ ]  Yes [ ]  No |     |
|  |   |   |   |  [ ]  Yes\*\* [ ]  No |   [ ]  N/A |  [ ]  Yes [ ]  No |     |

**Local IRB Submission Guidelines:**

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* If your consent form has a Utah-specific section that is reviewed and approved by the local IRB (e.g. a “Master” ICF with an addendum specific to our site)
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| **RefNo** | **Consent Type** | **Consent Version Date** | **Date of (s)(c)IRB Approval** | **Date Provided to the Site** | **Did the Consent Require Local IRB Submission / Approval?** | **\*\*If Yes, Date of Local IRB Approval / Acknowledgment Or N/A** | **Did the (s)(c)IRB Require Reconsent from Participants?** | **Brief Summary of Changes** |
|  | [ ]  ICF[ ]  PPF[ ]  Assent |   |   |   |  [ ]  Yes\*\* [ ]  No |   [ ]  N/A |  [ ]  Yes [ ]  No |     |
|  | [ ]  ICF[ ]  PPF[ ]  Assent |   |   |   |  [ ]  Yes\*\* [ ]  No |   [ ]  N/A |  [ ]  Yes [ ]  No |     |
|  | [ ]  ICF[ ]  PPF[ ]  Assent |   |   |   |  [ ]  Yes\*\* [ ]  No |   [ ]  N/A |  [ ]  Yes [ ]  No |     |
|  | [ ]  ICF[ ]  PPF[ ]  Assent |   |   |   |  [ ]  Yes\*\* [ ]  No |   [ ]  N/A |  [ ]  Yes [ ]  No |     |
|  | [ ]  ICF[ ]  PPF[ ]  Assent |   |   |   |  [ ]  Yes\*\* [ ]  No |   [ ]  N/A |  [ ]  Yes [ ]  No |     |

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