

Submission Guidance for studies utilizing single IRB (sIRB)

Action	TJU is Reviewing IRB	TJU is Relying IRB
Start Up of a New Study	<p>Meet with the reliance team prior to submission. Start a <i>New Study Application</i>.</p> <p>Submit an initial study application as you would for a non-sIRB protocol.</p> <p>Once the study is approved, you can submit an Amendment to Protocol to add external sites.</p> <p>Be sure to include:</p> <ul style="list-style-type: none"> ⇒ Statement of Work ⇒ Site-specific consent form ⇒ Local Context Questionnaire ⇒ Certification of Local Context form ⇒ Protocol ⇒ Ancillary Approvals ⇒ SMART LOA or Jefferson IAA ⇒ PI Checklist (signed) 	<p>WCG or Advarra: Submit a <i>New Study Application</i> and complete an abbreviated Master Application. Be sure to include:</p> <ul style="list-style-type: none"> ⇒ Authorization Form ⇒ Consent Form ⇒ Protocol ⇒ Ancillary Approvals <p>CIRB: Submit a <i>New Study Application</i> and complete an abbreviated Master Application. Be sure to include:</p> <ul style="list-style-type: none"> ⇒ Site Specific Worksheet approval ⇒ Continuing Review Approval <p>Other Academic Institution: Meet with the Reliance Team prior to submission (<i>optional</i>). Submit a <i>New Study Application</i> and complete an abbreviated Master Application. Be sure to include:</p> <ul style="list-style-type: none"> ⇒ Statement of Work ⇒ Local Context Questionnaire (if required by IRB of record) ⇒ Protocol ⇒ IRB of Record Initial Approval Letter ⇒ IRB of Record Approved Master Consent Form ⇒ Jefferson Site-specific consent form ⇒ Ancillary Approvals ⇒ Reliance Agreement ⇒ PI Checklist (signed)
Addition or removal of staff	Utilize the personnel change form for Jefferson study personnel additions/removals. <i>External study</i>	Utilize the personnel change form.

	<p>team changes are not submitted via a Jefferson personnel change form. External key personnel changes should be reported to the local IRB.</p>	
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Change of PI	Utilize the <i>Amendment to Protocol</i> form. There is no need to submit a <i>Personnel Change</i> form.	Utilize the IRB Reliance Follow-Up form. Please include the approval letter from the external IRB, revised ICF, and any other documents as applicable.
Amendment to Protocol, ICF, etc.	Utilize the <i>Amendment to Protocol</i> form.	No submission is needed. You will be asked to itemize all amendments during the annual check-in.
Addition of a Site	<p>Late onboarding of participating sites: Utilize the <i>Amendment to Protocol</i> form. Be sure to include:</p> <ul style="list-style-type: none"> ⇒ Statement of Work ⇒ Site-specific consent form ⇒ Local Context Questionnaire ⇒ Certification of Local Context form ⇒ Protocol ⇒ Ancillary Approvals ⇒ SMART LOA or Jefferson IAA 	<p>Addition of a Jefferson enterprise site: Utilize the IRB Reliance Follow-Up Form. Forms that may be needed include:</p> <ul style="list-style-type: none"> ⇒ Statement of Work ⇒ Site-specific consent form ⇒ Local Context Questionnaire ⇒ Reliance Agreement
Applying for Continuing Review	<p>Utilize the Continuing Review Form. Please be sure to report enrollment data and status for all sites.</p> <p>Please include:</p> <ul style="list-style-type: none"> ⇒ Clean copies of all ICFs, if applicable. ⇒ Certification of Local Context form (<i>one per site</i>). 	<p>Utilize the External Check-In form. Please include:</p> <ul style="list-style-type: none"> ⇒ CR Report provided to IRB of Record for the Jefferson site(s). (<i>Not required for WCG/Advarra</i>) ⇒ CR approval letter from the external IRB.
Research with Nemours	<p>Utilize the <i>Amendment to Protocol</i> form. Be sure to include:</p> <ul style="list-style-type: none"> ⇒ Statement of Work ⇒ Site-specific consent form ⇒ Local Context Questionnaire ⇒ Certification of Local Context form ⇒ Protocol ⇒ Ancillary Approvals ⇒ SMART LOA 	<p>Utilize the <i>Nemours Authorization</i> form and submit via Qualtrics. The following conditions must be met:</p> <ul style="list-style-type: none"> ⇒ There are no research activities to occur at Jefferson ⇒ No Jefferson patients will be enrolled in the study

		<ul style="list-style-type: none"> ⇒ No Jefferson patient data will be used in the study ⇒ There is no data-sharing between Jefferson and Nemours
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Research with Wills Eye	<p>Submit an Amendment to Protocol to add Wills Eye as a site.</p> <p>Be sure to include:</p> <ul style="list-style-type: none"> ⇒ Addendum to IRB Authorization Agreement with Wills Eye Hospital ⇒ Statement of Work ⇒ Site-specific consent form ⇒ Local Context Questionnaire ⇒ Certification of Local Context form ⇒ Protocol ⇒ Ancillary Approvals 	<p>Submit an Initial Study Application to utilize Wills Eye as the IRB.</p> <p>Be sure to include:</p> <ul style="list-style-type: none"> ⇒ Addendum to IRB Authorization Agreement with Wills Eye Hospital ⇒ Statement of Work ⇒ Site-specific consent form, if applicable ⇒ Protocol ⇒ Wills Eye Approval
Updating a Reliance Agreement	Utilize the <i>Amendment to Protocol</i> form.	Utilize the IRB Reliance Follow-up Form.
Change the IRB of Record	Utilize the <i>Amendment to Protocol</i> form. Please be sure to include the documents listed above under Start-up of New a Study . <i>Documents will vary based on new IRB of Record.</i>	Utilize the IRB Reliance Follow-up Form. Please be sure to include the documents listed above under Start-up of New a Study . <i>Documents will vary based on new IRB of Record.</i>
Updating a Local Context Questionnaire / Certification of Local Context	N/A	Utilize the IRB Reliance Follow-up Form.
IRB of Record review requests (i.e. NIH ICF stamp)	N/A	Utilize the IRB Reliance Follow-up Form.