

BCH Oakland IRB – UCSF IRB Study Transfer Matrix

Use this guide to determine how to submit/transfer your BCH Oakland study to the UCSF IRB. Based the type of study you have (e.g., brand new study, approved study that is not in iRIS yet, approved study that is in iRIS as a reliance, or study approved by an external IRB), this table provides guidance about what forms to submit and how to answer specific questions in iRIS, the UCSF IRB’s online submission system.

	New Studies • Not approved by BCH Oakland or UCSF IRB	Transfer Studies • Already approved by BCH Oakland IRB • Not in iRIS yet Note: Exempt studies which are already approved by the BCH Oakland IRB will not be transferred into iRIS. If you want to continue your exempt research, submit as a NEW exempt study in iRIS.			Transfer Studies: UCSF Reliance on BCH Oakland • Already approved by BCH Oakland IRB • Already in iRIS as a reliance study Note: Exempt studies which are already approved by the BCH Oakland IRB will not be transferred into iRIS. Instead, if you want to continue your exempt research, submit as a NEW exempt study in iRIS.			Transfer of Outside Reliance Studies
Review Level	Full Committee, Expedited, & Exempt	Full Committee & Expedited			Full Committee & Expedited			Full Committee & Expedited (Reliance acknowledgment procedure)
Renewal/Expiration date	N/A	Renewed by BCH Oakland IRB between Jan 1- April 30, 2020	Requires renewal between May1- July 31, 2020	Requires renewal on/after August 1, 2020	Renewed by BCH Oakland between Jan 1- April 30, 2020	Requires renewal between May1- July 31, 2020	Requires renewal on/after August 1, 2020	Regardless of expiration date, all studies in this category must be transferred into iRIS by Dec 4, 2020
How to submit in iRIS	New Study	New Study	New Study	New Study	Continuing Review	Continuing Review	Continuing Review	New Study
Submit in CYBER before initiating transfer into iRIS?	No	No	Yes Before transferring into iRIS, submit your continuing review in CYBER and receive IRB approval. Then, transfer into iRIS within 120 days of approval.	Yes Before transferring into iRIS, submit your continuing review in CYBER and export the e-signed PDF of the continuing review form. The CR form will document the study status for the transfer process. You may be able to keep your current expiration date.	No	Yes Before transferring into iRIS, submit your continuing review in CYBER and receive IRB approval. Then, transfer into iRIS within 120 days of approval.	Yes Before transferring into iRIS, submit your continuing review in CYBER and export the e-signed PDF of the continuing review form. The CR form will document the study status for the transfer process. You may be able to keep your current expiration date.	No
Word versions of the consent and assent forms and/or information sheets	Use the UCSF templates Full Committee studies: Include the BCH Oakland Treatment and Compensation (T&C) for Injury statement until further notice. Expedited studies: Include the BCH Oakland T&C statement only if the study involves biomedical risk, like blood draws.	Submit Word.doc versions of the currently approved forms You may choose to update to the UCSF template format . The Oakland format can be used through December 31, 2021. After that date, all studies that are actively recruiting must use the UCSF consent template. IRB Staff are working to reconcile a difference in the consent injury language. If you choose to use the UCSF template, retain the Oakland injury language until this matter is resolved by the legal department.			Submit Word.doc versions of the currently approved forms You may choose to update to the UCSF template format . The Oakland format can be used through December 31, 2021. After that date, all studies that are actively recruiting must use the UCSF consent template. IRB Staff are working to reconcile a difference in the consent injury language. If you choose to use the UCSF template, retain the Oakland injury language until this matter is resolved by the legal department.			Submit PDFs of the currently approved forms

Integration Consent Addendum for Ongoing Studies	N/A	Complete the Integration Consent Addendum with study-specific details and upload to IRIS. Note: If your study has a complete HIPAA and consent waiver, this form is not required.	Complete the Integration Consent Addendum with study-specific details and upload to IRIS. Note: If your study has a complete HIPAA and consent waiver, this form is not required.	Complete the Integration Consent Addendum with study-specific details and upload to IRIS. Note: If your study has a complete HIPAA and consent waiver, this form is not required.
UCSF Health – BCH Oakland HIPAA Authorization Form	If applicable	If applicable Submit the version currently in use	If applicable Submit the version currently in use	Update HIPAA form.
Sponsors Protocol / Scientific Protocol	Required for Full Committee studies	Required for Full Committee studies Submit the version currently approved by BCH Oakland IRB	Required for Full Committee studies Submit the version currently approved by BCH Oakland IRB	Required for Full Committee studies
Investigator Brochures/ device instructions/ inserts for all investigational drugs, biologics and devices	If applicable Note: UCSF does not require submission of 1572 Form	If applicable Submit the version currently approved by BCH Oakland IRB Note: UCSF does not require submission of 1572 Form	If applicable Submit the version currently approved by BCH Oakland IRB Note: UCSF does not require submission of 1572 Form	N/A
Recruitment materials, handouts, non-standard surveys/ instruments	As applicable	Submit materials currently approved by BCH Oakland IRB	Submit materials currently approved by BCH Oakland IRB	N/A
PDFs of materials from CYBER	N/A	<u>For Studies renewed between Jan 1- April 30, 2020, submit:</u> 1. Original CYBER IRB application 2. Most recently approved CYBER IRB Continuing Review Form 3. BCH Oakland IRB approval letters: Initial approval and most recent Continuing Review approval <u>For studies that require renewal between May1- July 31, 2020, submit:</u> 1. Original CYBER IRB application 2. Most recently approved CYBER IRB Continuing Review Form 3. BCH Oakland IRB approval letters: Initial approval and most recent Continuing Review approval <u>For studies that require renewal on/after August 1, 2020, submit:</u> 1. Original CYBER IRB application 2. CYBER IRB Continuing Review Form that you just generated as part of the transfer process 3. BCH Oakland initial approval letter only	<u>For Studies renewed between Jan 1- April 30, 2020, submit:</u> 1. Original CYBER IRB application 2. Most recently approved CYBER IRB Continuing Review Form 3. Current CYBER IRB approval letter (i.e. initial or CR approval letter, not an amendment approval) <u>For studies that require renewal between May1- July 31, 2020, submit:</u> 1. Original CYBER IRB application 2. Most recently approved CYBER IRB Continuing Review Form 3. Current CYBER IRB approval letter (i.e. initial or CR approval letter, not an amendment approval) <u>For studies that require renewal on/after August 1, 2020, submit:</u> 1. Original CYBER IRB application 2. CYBER IRB Continuing Review Form that you just generated as part of the transfer process 3. BCH Oakland initial approval letter only	1. Original CYBER IRB application 2. Original BCH Oakland IRB acknowledgment letter. 3. Executed IAA or other reliance agreement.
Instructions for the iRIS “Initial Review Submission Form” (Form question, followed by how you should answer)	Q) Is BCH Oakland the PRIMARY SITE: A) Yes -- Q) Has this study been approved already by the BCH Oakland IRB A) No	Q) Is BCH Oakland the PRIMARY SITE: A) Yes -- Q) Has this study been approved already by the BCH Oakland IRB A) Yes	N/A	

<p>Instructions for the iRIS Continuing Review Form</p> <p>(Form question, followed by how you should answer)</p>	<p>N/A</p>	<p>N/A</p>	<p>Q) This is a:</p> <p>A) Check button for “Continuing review and minor modification”</p> <p>--</p> <p>Q) Types of changes being made:</p> <p>A) Check button for “Other changes including...”</p> <p>—</p> <p>Q) Describe each modification...</p> <p>A) Write “This BCH Oakland study is being transferred to the new UCSF Oakland IRB committee”</p> <p>--</p> <p>Note: Please do NOT incorporate additional, non-transfer-related changes to your study at this time. Once the transfer is complete, you may submit an amendment (modification).</p>	
<p>Instructions for the iRIS Study Application</p> <p>(Form question, followed by how you should answer)</p>	<p>Q) Section 6, UCSF AND AFFILIATED SITES:</p> <p>A) Check “UCSF Benioff Children’s Hospital Oakland” (and any other sites, if applicable)</p>	<p>Q) Section 6, UCSF AND AFFILIATED SITES:</p> <p>A) Check “UCSF Benioff Children’s Hospital Oakland” (and any other sites, if applicable)</p>	<p>Q) Section 6, UCSF AND AFFILIATED SITES:</p> <p>A) Check “UCSF Benioff Children’s Hospital Oakland” (and any other sites, if applicable)</p> <p>—</p> <p>Q) Section 6, RELYING ON AN EXTERNAL IRB:</p> <p>A) Change from Yes to No, then click the “Save and Continue to Next Section” button throughout the remainder of the application, answering all new questions that appear.</p>	<p>Follow UCSF guidance for Reliance Applications.</p> <p>Q) Section 6, UCSF AND AFFILIATED SITES:</p> <p>A) Check “UCSF Benioff Children’s Hospital Oakland” (and any other sites, if applicable)</p> <p>--</p> <p>Q) Section 6, RELYING ON AN EXTERNAL IRB:</p> <p>A) Yes</p> <p>--</p> <p>Q) Section 6, RELIANCE AGREEMENT TYPE:</p> <p>A) Check “Other” and then write “IAA” in the text field.</p> <p>--</p> <p>Q) Section 6, EXTERNAL IRB:</p> <p>A) List the IRB of Record</p> <p>Note: You do NOT need to list any other outside sites (institutions).</p>
<p>Additional requirements</p>	<p>N/A</p>	<p>N/A</p>	<p>N/A</p>	<p>Submit the current Reviewing IRB approval letter</p>