

## How to Open a BCHO Study to Accrual in OnCore

### How to Add an Institution that Uses Research Center IRB

*This set of instructions is necessary to designate the institution(s) using the research center IRB so that the institution is correctly associated with any IRB Reviews that are documented to a protocol in OnCore. By selecting this option for a given protocol you are indicating in OnCore that the IRB of the research center (BCHO, UCSF or an affiliated site) is the IRB of record. Complete this set of instructions so when you reach the step to “Document an Initial IRB Review”, the institution is pre-populated in that section of OnCore.*

1. Navigate to **PC Console > Institution**
2. Click **“Update”** button
3. Select **“Uses Research Center IRB”** checkbox next to **UCSF Benioff Children’s Hospital**
4. Click **“Submit”** button
5. Click **“Close”** button

**★ PC Console** ?

Protocol No.: [REDACTED]
Library: BCHO
PI: [REDACTED]
Sponsor: [REDACTED]

Protocol Target Accrual: 70
Accrual To Date: 0
Protocol Status: IRB INITIAL APPROVAL

UCSF Total Accrual Goal (Upper): 70
IRB Expiration: 01/31/2021

**Select Protocol**

Type here to search

**Main**

**Treatment**

**Institution**

**Accrual**

**Status**

**Reviews**

**Documents/Info**

**Eligibility**

**Notifications**

**Deviations**

**New Protocol**

Participating Institutions
+
Add

Institution	Coordinating Center	Uses Research Center IRB	IRB Initial Approval Date	IRB Last Renewal Date	IRB Next Review Date	Current Status	Status Date	Calendar Version	Delete
<ul style="list-style-type: none"> <li>• <a href="#">Study Sites</a></li> <li><a href="#">UCSF Benioff Children's Hospital Oakland</a></li> </ul>	<input type="checkbox"/>	<input checked="" type="checkbox"/>						0	<input type="checkbox"/>

Participating Networks
+

Description	Delete
No information entered	

Select

Submit
Clear
Close

Lock Protocol

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**How to Add a Participating Study Site**

*This set of instructions is one of the steps required to enable to functionality to register a study subject at a given study site. You will be choosing participating study sites under which study subjects can be enrolled within the CRA console.*

1. Navigate to **PC Console > Institution**
2. Click the hyperlink for **UCSF Benioff Children’s Hospital**
3. Click **“Update”** button
4. Click on Study Site link that you want to update as a participating study site under **“Participating Institutions”** and a new menu opens with new tab options on the left hand side of the page.

Protocol Institution: UCSF Benioff Children’s Hospital Oakland ?				
Protocol No.: 2019-033	Library: BCHO	PI: Lalefar, Nahal	Sponsor: Pediatric Blood & Marrow Transplant Consortium (PBMTC)	
Protocol Target Accrual: 165		Accrual To Date: 0	Protocol Status: IRB INITIAL APPROVAL	
UCSF Total Accrual Goal (Upper): 165	Short Title:			
<b>Staff</b>	Protocol Staff			
	Name	Role	Contact Info	Staff Regulatory
Regulatory Items	<a href="#">Moriarty, Marci</a>	Study Contact	Phone: E-mail: mmoriarty@mail.cho.org	Online Subject Management for Affiliates & Monitors date: 06/05/2015
IRB Reviews	<a href="#">Lalefar, Nahal</a>	Principal Investigator	Phone: E-mail: Nahal.Lalefar@ucsf.edu	
Consent Forms				<input type="button" value="Update"/>
Documents				
Task Lists				
<b>Study Sites 4</b>				
Status				
PC Console				
Admin > Organizations				

5. Click **“Study Sites”** from menu on left hand side of page
6. Click **“Update”** button

- Click **“Study Participant”** checkbox for study site that will be enrolling subjects and to which study team will be registering subjects.

**Protocol Institution: UCSF Benioff Children's Hospital Oakland** ?

Protocol No.: 2019-033      Library: BCHO      PI: Lalefar, Nahal      Sponsor: Pediatric Blood & Marrow Transplant Consortium (PBMTC)

Protocol Target Accrual: 165      Accrual To Date: 0      Protocol Status: IRB INITIAL APPROVAL

UCSF Total Accrual Goal (Upper): 165

Short Title:

Code	Name	Study Participant?	Registered	Accrued
BCHO	UCSF Benioff Children's Hospital Oakland	<input checked="" type="checkbox"/>	0	0

Submit Close

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- Click **“Submit”** button
- Click **“Close”** button
- The study site you just selected should now show **“Y”** under Study Participant field.

**Protocol Institution: UCSF Benioff Children's Hospital Oakland** ?

Protocol No.: 2019-033      Library: BCHO      PI: Lalefar, Nahal      Sponsor: Pediatric Blood & Marrow Transplant Consortium (PBMTC)

Protocol Target Accrual: 165      Accrual To Date: 0      Protocol Status: IRB INITIAL APPROVAL

UCSF Total Accrual Goal (Upper): 165

Short Title:

Code	Name	Study Participant?	Registered	Accrued
BCHO	UCSF Benioff Children's Hospital Oakland	Y	0	0

Update

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**Update Status Tab within Protocol Institution**

*This set of instructions is one of the steps required to enable to functionality to register a study subject at a given study site. You will be setting a given study site’s status to “Open to Accrual”.*

1. **PC Console > Institution**
2. Click on the link to the Institution to be updated (if multiple institutions are added to a protocol)

The screenshot shows the 'PC Console' interface for protocol 2019-033. The header includes protocol details: Protocol No.: 2019-033, Library: BCHO, PI: Lalefar, Nahal, and Sponsor: Pediatric Blood & Marrow Transplant Consortium (PBMTC). It also shows Protocol Target Accrual: 165, Accrual To Date: 0, Protocol Status: NEW, and UCSF Total Accrual Goal (Upper): 165.

The main content area is divided into two sections: 'Participating Institutions' and 'Participating Networks'. The 'Participating Institutions' table has the following columns: Institution, Coordinating Center, Uses Research Center IRB, IRB Initial Approval Date, IRB Last Renewal Date, IRB Next Review Date, Current Status, Status Date, Total Accrual, Pending Amendment, Expired Items, and Calendar Version. One institution is listed: 'UCSF Benioff Children's Hospital Oakland' with a status of 'OPEN TO ACCRUAL' and a status date of '02/12/2020'. This row is highlighted with a red box.

The 'Participating Networks' section shows 'No information entered'. On the right side, there are buttons for 'Pending Amendments', 'View PDF', and 'Update'. At the bottom right, there is a 'Lock Protocol' button.

3. The “Protocol Institution” page will open.

4. Click **“Status”** on the left hand side menu.

**Protocol Institution: UCSF Benioff Children's Hospital Oakland** ?

Protocol No.: [REDACTED] Library: BCHO PI: [REDACTED] Sponsor: [REDACTED]

Protocol Target Accrual: 165 Accrual To Date: 0 Protocol Status: **NEW**

UCSF Total Accrual Goal (Upper): 165 Institution Status: **OPEN TO ACCRUAL**

Short Title:

Staff	Protocol Staff			
Regulatory Items	Name	Role	Contact Info	Staff Regulatory
IRB Reviews	[REDACTED]	Study Contact	Phone: [REDACTED] E-mail: [REDACTED]	Online Subject Management for Affiliates & Monitors date: 06/05/2015
Consent Forms	[REDACTED]	Principal Investigator	Phone: [REDACTED] E-mail: [REDACTED]	

[Update](#)

Documents

Task Lists

Study Sites

**Status**

PC Console

Admin > Organizations

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5. Click **“Update”** button
6. Under **“Add Status”** complete the following fields:
7. Select **“Open to Accrual”** from **“Status”** drop-down menu
8. Enter a status date in **“Status Date”** field
9. Select the correct option from the drop-down menu **“Initiator”**
10. Click **“Add”** button
11. Click **“Close”** button to return to **“Protocol Institution”** page.

**Protocol Institution: UCSF Benioff Children's Hospital Oakland** ?

Protocol No.: 2019-033 Library: BCHO PI: Lalefar, Nahal Sponsor: Pediatric Blood & Marrow Transplant Consortium (PBMTC)

Protocol Target Accrual: 165 Accrual To Date: 0 Protocol Status: **NEW**

UCSF Total Accrual Goal (Upper): 165

Short Title:

Staff	Add Status <b>6</b>					
Regulatory Items	Status <b>7</b>	Status Date <b>8</b>	Initiator <b>9</b>	Change Reason	Comments	
IRB Reviews	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<b>10</b> <a href="#">Add</a>
Consent Forms	Protocol Institution Status					<a href="#">History</a>
Documents	Status Date	Status	Initiator	Change Reason	Comments	Last Changed By
Task Lists	No information entered					
Study Sites						<b>11</b> <a href="#">Close</a>

PC Console

Admin > Organizations

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## How to Document an Initial IRB Review in OnCore

*This is one of the steps required before you can open a study to accrual. Documenting this information in OnCore is required to indicate that the IRB has performed and approved the initial review of a protocol.*

1. Navigate to **PC Console > Reviews > IRB**
2. Click **“Add”** button

The screenshot shows the OnCore PC Console interface. At the top, there is a navigation bar with '★ PC Console' and a help icon. Below this, there are fields for Protocol No., Library (BCHO), PI, and Sponsor. Further down, there are fields for Protocol Target Accrual (70), UCSF Total Accrual Goal (Upper) (70), Accrual To Date (0), Protocol Status (NEW), and IRB Expiration.

The main content area is divided into several sections:

- Select Protocol:** A search box with the text 'Type here to search'.
- Navigation Tabs:** Summary, PRC, DSMC, IRB (selected), LTFU Transfer, and Other External Committee Actions.
- IRB Review Reason Counts Table:**

	Adverse Event Reporting Form	Change	Continuing Review	Initial Review	Migrated Consent	Modification Form	Protocol Violation / Incident Report Form	Reporting Form	Safety Reporting	Single Patient Exception	Study Closeout Report
Pending	0	0	0	0	0	0	0	0	0	0	0
Total	0	0	0	0	0	0	0	0	0	0	0
- IRB Action History (\* denotes a global amendment):** No Records Found.
- Buttons:** 'Add' (highlighted with a red box) and 'Submit' buttons.

At the bottom of the interface, there is a copyright notice: Copyright© 2001-2020 Forte Research Systems. All rights reserved.

Fill in the following fields:

3. **Review Date** – enter IRB meeting date (date format: 02/01/2020)
4. **Submit Date** – enter date initial study application was submitted to IRB for review
5. **Committee** – select appropriate IRB review committee from drop-down menu
6. **Review Reason** – select “Initial Review” from drop-down menu
7. **Review Type** – select “Exempt”, “Expedited” or “Full” for level of review
8. **Action** – select “Approved”
9. **Action Date** – enter date initial review was approved by IRB committee
10. **Expiration Date** – enter expiration date of IRB review
11. **Summary** – use this field to enter any notes/comments specific to this initial review (as needed)
12. Click **“Submit”** button
13. **Institution** – Click “Edit” link and a new window will pop-up
14. **Review Institutions** – select checkbox for UCSF Benioff Children’s Hospital

15. Click “Submit” button in pop-up window

**Update IRB Review** ?

Protocol No.: [REDACTED] Library: BCHO PI: [REDACTED] Sponsor: [REDACTED]  
 Protocol Target Accrual: 70 Accrual To Date: 0 Protocol Status: IRB INITIAL APPROVAL  
 UCSF Total Accrual Goal (Upper): 70 IRB Expiration: 01/31/2021

**Review Information**

3 Review Date: 01/01/2020 4 Submit Date: 12/01/2019 5 Committee: BCHO 6 Review Reason: Initial Review 7 Review Type: Full  
 8 Action: Approved 9 Action Date: 02/01/2020 10 Expiration Date: 01/31/2021 Review No.: [REDACTED]

Summary 11  
 4000 character(s) remaining

Yes Votes: [REDACTED] No Votes: [REDACTED] Abstain Votes: [REDACTED] Institution: University of California San Francisco [Edit](#) 13

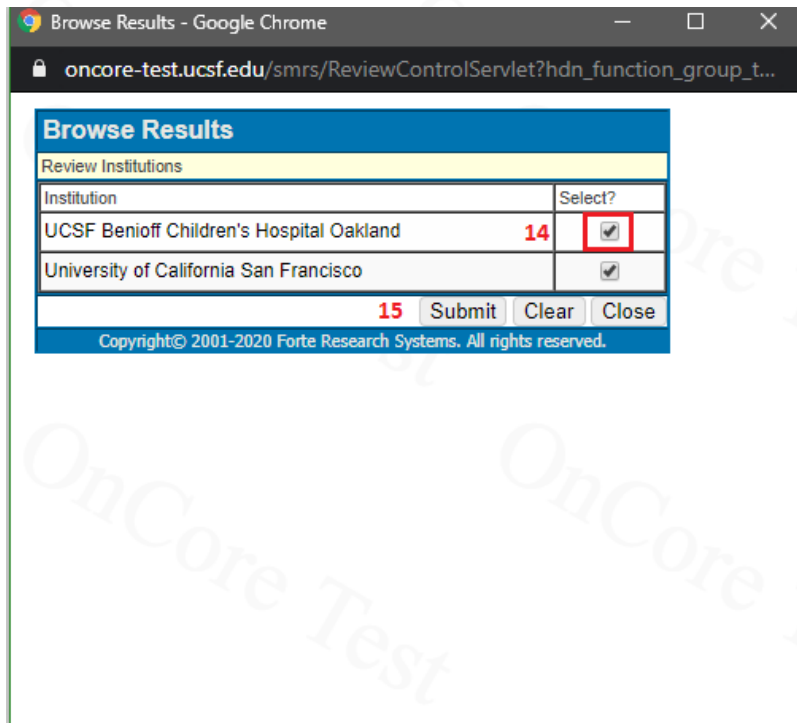
Details (0) Reviewers (0) Communications (0) Notes

Details Add Select Previous Details/Docs

Type	Amend-ment No.	Received Date	Version Date	Description	Comments	Global?	Reconsent Required?	Delete?
No records found								

[IRB Approval Notice](#) [To Meeting Agenda](#) Create Follow-Up Review 12 Submit Submit and Close Clear Close

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**How to Add a Reviewed Consent Form**

A consent form with version number and date is required to be documented in OnCore in this section. When registering subjects to a research study in the CRA Console, the consent version signed by the subject must be selected before the subject’s status can be updated to “On Study” (assuming the subject is eligible).

1. Navigate to **PC Console > Reviews > IRB**
2. Click **“Edit”** link under **“Details”** next to the corresponding IRB Initial Review entry (some studies have multiple IRBs)

★ PC Console
?

Protocol No.: [REDACTED]      Library: BCHO      PI: [REDACTED]      Sponsor: [REDACTED]

Protocol Target Accrual: 70      Accrual To Date: 0      Protocol Status: IRB INITIAL APPROVAL

UCSF Total Accrual Goal (Upper): 70      IRB Expiration: 01/31/2021

Select Protocol

Summary   PRC   DSMC   **IRB**   LTFU Transfer   Other External Committee Actions

**IRB Review Reason Counts**

	Adverse Event Reporting Form	Change	Continuing Review	Initial Review	Migrated Consent	Modification Form	Protocol Violation / Incident Report Form	Reporting Form	Safety Reporting	Single Patient Exception	Study Closeout Report
Pending	0	0	0	0	0	0	0	0	0	0	0
<b>Total</b>	0	0	0	1	0	0	0	0	0	0	0

**IRB Action History** ( \* denotes a global amendment)

Filter by Review Reason:

University of California San Francisco											Add
	Review Date	Submit Date	IRB Committee	Review Reason	Review Type	Review No.	Action	Action Date	Expiration Date	Delete?	
1.	01/01/2020	12/01/2019	UC Reliance	Initial Review	Full		Approved	02/01/2020	01/31/2021	<input type="checkbox"/>	<a href="#">Details</a> <a href="#">Edit</a>

Add

Submit



3. Under **Details** click “**Add**” button and complete the following fields:
4. **Type** – Select “Consent” from drop-down menu
5. **Amendment No.** – enter the version number of the consent form being entered
6. **Received Date** – enter the date the consent form was submitted to the IRB
7. **Version Date** – Enter the Version Date corresponding to the version number.
8. **Description** – Enter Description of Consent form (Ex. Main ICF, Imaging Consent, Retreatment Consent, etc.)
9. Click “**Save**” link at bottom right of page
10. Hit “**Submit and Close**” or “**Submit**” button

**Update IRB Review** ?

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Protocol No.: ██████████ Library: BCHO PI: ██████████ Sponsor: ██████████

Protocol Target Accrual: 70 Accrual To Date: 0 Protocol Status: IRB INITIAL APPROVAL

UCSF Total Accrual Goal (Upper): 70 IRB Expiration: 01/31/2021

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**Review Information**

Review Date	<input type="text" value="01/01/2020"/>	Submit Date	<input type="text" value="12/01/2019"/>	Committee	<input type="text" value="BCHO"/>	Review Reason	<input type="text" value="Initial Review"/>	Review Type	<input type="text" value="Full"/>
Action	<input type="text" value="Approved"/>	Action Date	<input type="text" value="02/01/2020"/>	Expiration Date	<input type="text" value="01/31/2021"/>				

Summary

4000 character(s) remaining

Yes Votes	<input type="text"/>	No Votes	<input type="text"/>	Abstain Votes	<input type="text"/>	Institution	University of California San Francisco <a href="#">Edit</a>
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**Details** 3 **Add** | [Select Previous Details/Docs](#)

Type <b>4</b>	Amendment No. <b>5</b>	Received Date <b>6</b>	Version Date <b>7</b>	Description <b>8</b>	Comments	Global?	Reconsent Required?	Delete?
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	N/A	<b>9</b> <a href="#">Save</a> <a href="#">Cancel</a>
No records found								

[IRB Approval Notice](#) 10  
[To Meeting Agenda](#) [Create Follow-Up Review](#) [Submit](#) [Submit and Close](#) [Clear](#) [Close](#)

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**Open the Study to Accrual**

Once an Initial IRB Review and Consent are documented in OnCore, the option to open the study to accrual will be available. A study’s status must be set to “Open to Accrual” before you can register a subject to the study in the CRA Console.

1. **PC Console > Status**
2. Click **“Open”** button
3. **Status Date** – enter date study was opened to accrual
4. Click **“Submit”** button

★ PC Console ?

Protocol No.: [REDACTED]      Library: BCHO      PI: [REDACTED]      Sponsor: [REDACTED]

Protocol Target Accrual: 165      Accrual To Date: 0      Protocol Status: IRB INITIAL APPROVAL

UCSF Total Accrual Goal (Upper): 165      IRB Expiration: 01/31/2021

Select Protocol

Status
Task Lists
ClinicalTrials.gov

Protocol Status History

Status Date	Status	Initiator	Change Reason	Comments	Last Changed By
02/01/2020	IRB INITIAL APPROVAL				Andrews,Blakely
01/23/2020	NEW				Andrews,Blakely

On Hold
Open
Abandon
Update

[PRC Submission Form](#) |

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