Center for Children's Surgery
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Regulatory Process Guide

Last updated 4.20.20

This reference guide is designed to help CCS faculty and research staff navigate the regulatory processes needed when starting new research projects. Details regarding the steps and requirements for initiating common types of research projects are provided. Questions or assistance can be requested by contacting ROCS@childrenscolorado.org

Contents

Retrospective Chart Reviews

If you are planning on conducting a study that only consists of retrospective data, you will need to develop a protocol for your study. You will also need to have a list all the data fields you are interested in collecting included in your protocol. **It is recommended to consult with a biostatistician ahead of time to ensure you are collecting meaningful data**. If you need biostatistics support, you can submit a ROCS intake form here or contact us directly at ROCS@childrenscolorado.org.

Summary of required steps:

1. Develop study protocol
2. Create InfoEd protocol to receive COMIRB #
3. Complete COMIRB application
4. Submit to Human Subject Research Portal
5. Submit to COMIRB after receiving Human Subject Research Portal Clearance Letter

A step by step guide to create new research protocols in eRA InfoEd can be found here. Once you have the final version of your protocol and data fields, you can to create a new protocol in the *eRA InfoEd system*. **You will need to create a protocol in order to receive a COMIRB number and complete the Personnel Form which will be used for the Human Subject Research Protocol Submission Portal.**

The COMIRB application you will need to complete for a retrospective chart review is the *Secondary Research Application* which can be found here in the Forms tab on the COMIRB website.

The next step entails submission to the *Human Subject Research Protocol Submission Portal* (HSR Portal).

The following items are required for **all** HSR Portal submissions:

- COMIRB number
- COMIRB personnel form (completed in InfoEd; form should be downloaded for submission to the HSR portal)
- Protocol
    - Instructions – How to complete the COMIRB protocol template (Biomedical)
    - Instructions – How to complete the COMIRB protocol template (Social)

As you complete the HSR Portal Clinical Research Administration Protocol Assessment Form (HSR Portal Clinical Admin PAF), a list of documents required for your submission will populate at the bottom of the form. You will not be able to submit unless you have uploaded all the required documents to the application. If you do not have the documents the system is asking for and they are not applicable, please upload a document stating such. *You have the option to save and return later if you start the form and determine additional documents are needed to complete the application.*

After you submit the HSR Portal Clinical Admin PAF, you will receive an email of your submission confirmation. This confirmation email is your Clearance Letter to include in your COMIRB submission. Once you receive this clearance letter, you are ready to submit your research project to COMIRB. Some of the required documents can be found in the Forms tab on the COMIRB website, such as the Secondary Research Application, Protocol template, and PI Attestation form.

The following items are required for your COMIRB submission:

- Secondary Research Application
- Protocol (include list of data fields collecting)
- Personnel form (complete in InfoEd)
- PI Attestation form
- HSR Portal Clinical Admin PAF clearance letter

Retrospective Chart Reviews for Cancer-Related Protocols

If you are planning on conducting a study that only consists of retrospective data that is cancer-related, you will need to submit to HSR Portal, COMIRB, and Protocol Review & Monitoring System (PRMS) with the Cancer Center. All cancer-related protocols regardless of type of protocol (industry, cooperative group, chart review, etc.) are required to be reviewed by the PRMS.

You will initiate the same process as a Retrospective Chart Review but incorporate the PRMS submission. The PRMS and HSR Portal submissions are recommended to be submitted on the same day.

The required forms for the PRMS submission can be found on the PRMS website. The following items are required for the PRMS REDCap submission:

- Protocol
- PI Involvement Form
- PRMS Signature page

After you receive the PRMS approval letter and HSR Portal Clinical Admin PAF clearance letter, you are ready to submit your research project to COMIRB.

The following items are required for your COMIRB submission:

- Secondary Research Application
- Protocol (include list of data fields collecting)
- Personnel form (complete in InfoEd)
- PI Attestation form
- PRMS approval letter
- HSR Portal Clinical Admin PAF clearance letter

Prospective Studies

If you are planning on conducting a study that will be collecting prospective data, you will need to have consent forms for the eligible study subjects. **It is highly recommended to consult with a methodologist and a biostatistician to ensure the research design is thoroughly developed and you are collecting meaningful data**. If you need assistance in developing the research design of your study and/or need biostatistics support, you can submit a ROCS intake form here or contact us directly at ROCS@childrenscolorado.org.

Summary of required steps:

1. Develop study protocol
2. Create InfoEd protocol to receive COMIRB #
3. Complete COMIRB application
4. Submit to Human Subject Research Portal
5. Scientific Advisory & Review Committee (if needed)
6. Submit to COMIRB after receiving Human Subject Research Portal Clearance Letter
7. Submit Epic Use Plan to CAS
8. Complete OnCore signoffs

The COMIRB application you will need to complete for a prospective study is the *COMIRB Application Form* that can be found here in the Forms tab on the COMIRB website.

You will need to develop a protocol and consent form and these templates can be found in the Forms tab on the COMIRB website. If needed, assent templates are also found in the same place.

Once you have the final version of your protocol, consent form, and assent form (if applicable), you will create a new research protocol in *eRA InfoEd system* and a step by step guide to create new research protocols in eRA InfoEd can be found here. **You will need to create a protocol in order to receive a COMIRB number and complete the Personnel Form which will be used for the Human Subject Research Protocol Submission Portal.**

Before submitting study documents to COMIRB for approval, you will need to submit to the *Human Subject Research Protocol Submission Portal* (HSR Portal).

The following items are required for HSR Portal submission:

- COMIRB number
- COMIRB personnel form
- Protocol
    - Instructions – How to complete the COMIRB protocol template (Biomedical)
    - Instructions – How to complete the COMIRB protocol template (Social)
- Consent form
- Assent form (if applicable)
- Survey(s) (if applicable)

As you complete the HSR Portal Clinical Research Administration Protocol Assessment Form (HSR Portal Clinical Admin PAF), a list of documents required for your submission will populate at the bottom of the form. You will not be able to submit unless you have uploaded all the required documents to the application. If you do not have the documents the system is asking for and they are not applicable, please upload a document stating such. *You have the option to save and return later if you start the form and determine additional documents are needed to complete the application.*

Scientific Advisory & Review Committee (SARC)

What is SARC?

The Scientific Advisory and Review Committee (SARC) serves as the scientific review board for the Colorado Multiple Institutional Review Board (COMIRB) to review non-oncology, investigator-initiated trials (IITS). The SARC performs scientific and feasibility reviews of new research protocols for investigator-initiated clinical research at CU Denver Anschutz, UCHealth, CHCO or DHHA that has not had an independent review for scientific merit.

Which protocols require SARC review?

Investigator-initiated protocols that meet any of the following conditions will receive a SARC review:

- More than minimal risk with no previous independent review of scientific merit
- Previous independent review of scientific merit, but protocol has undergone substantial change since the time of review (e.g., change in the aims, hypotheses, experimental design, or sample size)
- Protocol supported by a Career Development Award or other mentored mechanism (e.g. NIH K award)
- Protocol requesting a CTRC Microgrant

The COMIRB reserves the right to send any IIT through SARC review, even if the protocol does not meet the above criteria.

What does SARC review?

The review process is designed to ensure quality research according to the following criteria:

- Scientific merit, including scientific premise, testable hypotheses, appropriate experimental approach, sample size justification, and appropriate data analysis plan
- Study design feasibility
- Realistic accrual rate for completion within a practical time frame

What is the SARC review process?

When a protocol is submitted to the HSR Portal, the portal team reviews the protocol to determine if a SARC review is required prior to COMIRB submission. If a SARC review is required, the protocol is routed to the SARC Coordinator who will schedule the protocol for review and contact the study team regarding the review details. Once a protocol has received SARC approval, the study team issued an HSR portal clearance letter, permitting them to submit the protocol to COMIRB for review. Notification of SARC approval is sent to the study team via OnCore. SARC approved documentation is uploaded to OnCore and InfoEd.

SARC Process Overview

1. HSR Portal	• Study team submits protocol to HSR Portal • Portal team assesses protocol for SARC review and routes protocol to SARC if review required
2. SARC	• Protocol reviewed by SARC • PI revises protocol per SARC stipulations/recommendations • Revised protocol approved by SARC • SARC approval sent to study team via OnCore
3. COMIRB	• Portal team sends portal clearance email to study team • Study team submits SARC approved protocol to COMIRB for review

After you submit the HSR Portal Clinical Admin PAF (whether you need a SARC review or not), you will receive an email of your submission confirmation. If the email states it is a Clearance Letter, you will need to include it in your COMIRB submission. Once you receive this clearance letter, you are ready to submit your research project to COMIRB. Some of the required documents can be found in the Forms tab on the COMIRB website, such as the COMIRB Application form, Protocol template, PI Attestation form, Consent form, and Assent form.

The following items are required for your COMIRB submission:

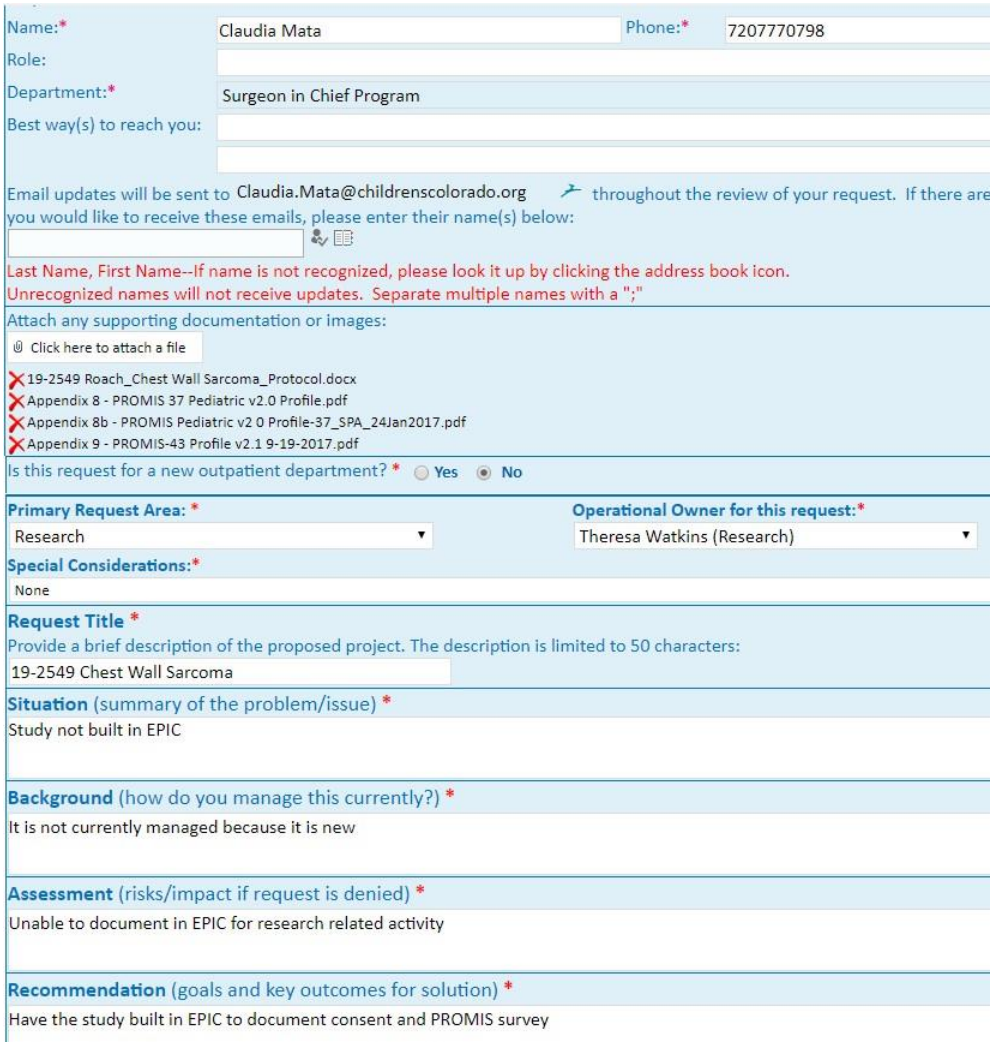
- COMIRB Application form
- Protocol (include list of data fields collecting)
- Consent form
- Assent form (if applicable)
- Survey(s) (if applicable)

- Personnel form (complete in InfoEd)
- PI Attestation form
- HSR Portal Clinical Admin PAF clearance letter

Since you will be consenting study subjects at Children's Hospital Colorado, you will need to submit an **Epic Use Plan (EUP) and Epic Protocol/Smartset Request Form** to CAS. To submit your EUP and Epic protocol/Smartset Request form, you will complete a *CAS Work Request*. The Smartset Request form can be found on the CAS Work Request Form page.

CHCO intranet homepage → Quick Links → CAS Work Request Form

Be sure to include the COMIRB number in Request Title. You will need to attach the study protocol, the personnel form, and Epic Protocol/Smartset Form to the EUP form and select *Research* as the Primary Request Area and *Theresa Watkins* as the Operational Owner for this request. Below is an example of the CAS Work Request Form.


Name:* Claudia Mata Phone:* 7207770798
Role:
Department:* Surgeon in Chief Program
Best way(s) to reach you:
Email updates will be sent to Claudia.Mata@childrenscolorado.org throughout the review of your request. If there are you would like to receive these emails, please enter their name(s) below:
Last Name, First Name--If name is not recognized, please look it up by clicking the address book icon.
Unrecognized names will not receive updates. Separate multiple names with a ";"
Attach any supporting documentation or images:
Click here to attach a file
19-2549 Roach_Chest Wall Sarcoma_Protocol.docx
Appendix 8 - PROMIS 37 Pediatric v2.0 Profile.pdf
Appendix 8b - PROMIS Pediatric v2 0 Profile-37_SPA_24Jan2017.pdf
Appendix 9 - PROMIS-43 Profile v2.1 9-19-2017.pdf
Is this request for a new outpatient department? * Yes No
Primary Request Area: * Research
Operational Owner for this request:* Theresa Watkins (Research)
Special Considerations:* None
Request Title *
Provide a brief description of the proposed project. The description is limited to 50 characters:
19-2549 Chest Wall Sarcoma
Situation (summary of the problem/issue) *
Study not built in EPIC
Background (how do you manage this currently?) *
It is not currently managed because it is new
Assessment (risks/impact if request is denied) *
Unable to document in EPIC for research related activity
Recommendation (goals and key outcomes for solution) *
Have the study built in EPIC to document consent and PROMIS survey

Epic Protocol/Smartset Request Form
You can find the template on the CAS work request page

- Tabs along the bottom

- Read Me tab
    - Includes instructions on how to complete each tab
- General Information tab
    - General study information for the build and training in Epic
- Arms tab
    - Populate with orders and tasks needed for each arm
    - Only 1 arm, only complete the Arm 1 tab

***CAS Work Requests Tips:**
Items the study teams can do to help move requests along faster

- Put the IRB number in the request title description
- Indicate where the study will take place whether it is Inpatient, Outpatient, or both
- Attach the completed Epic Protocol/Smartset Request form and confirm accuracy
- Attach the personnel form for all requests
- **Provide Detail!** The more information that is provided, the faster we can assign the request to an analyst
- **Submit EUP the same week as IRB submission as it may take up to 4-6 weeks to be reviewed**

You will receive an email from the CAS Research Team after your request has been reviewed to set up a phone call with the team and discuss any required documents they may need for the call.

If you have questions, you can contact the CAS Research Team at CASResearchTeam@childrenscolorado.org or at 720-777-2856.

OnCore
OnCore is mandatory for **all** studies conducted at CHCO. Study recruitment of study subjects cannot begin until it has been approved by COMIRB, CAS, and is in "Open in Accrual" status in OnCore.
OnCore is a clinical trial management system (CTMS) that enables users to manage all protocols and subjects in one place; it supports clinical research billing compliance; simplifies data management and monitoring; easily tracks biospecimens throughout the entire lifecycle; improves patient recruitment and tracks outcomes; as well as automates the flow of information between systems.

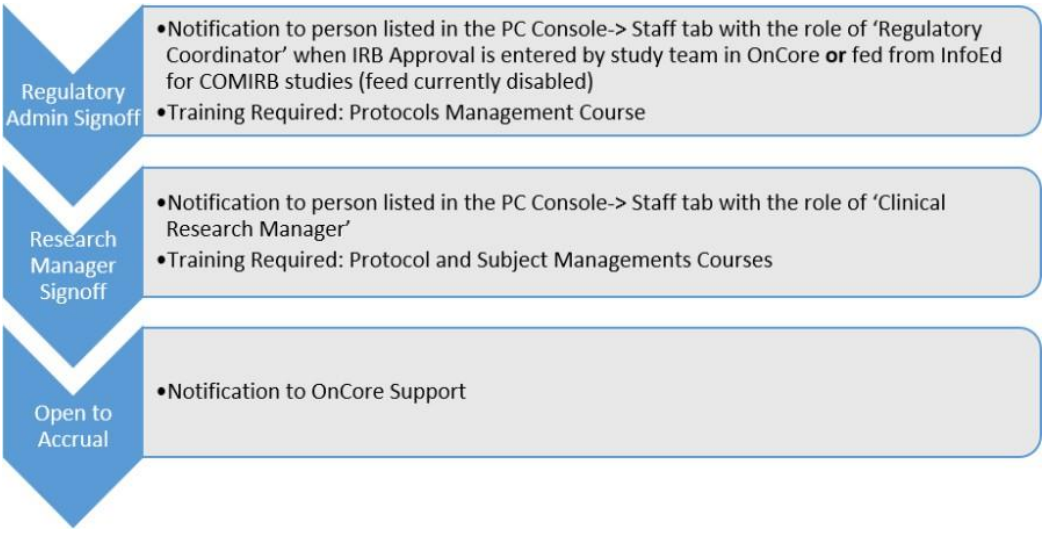
OnCore's purpose is to help research coordinators and administrators manage the day-to-day operational activities of clinical studies. These activities include committee reviews, budgeting, tracking protocols and enrollments including individual patient visits, billing for services, managing biospecimen inventories, and reporting to regulatory agencies.

To help you manage OnCore, you will need to identify a Regulatory Coordinator and Research Manager. If you need assistance in identifying these roles, you can contact ROCS at ROCS@childrenscolorado.org. A Regulatory Coordinator and Research Manager will complete the required steps to get a protocol open to accrual in OnCore and manage the system throughout the duration of the study, including recruitment of study subjects and study closure. Below is the timeline and the steps involved to move the protocol into "Open to Accrual" status.

How to get a protocol open to accrual in OnCore
Step 1: A request for a protocol build is received through one to three channels

- New protocol submitted through the Human Subject Research Portal
- Amendment submitted through Amendment Portal (protocols are assessed for OnCore Calendar and Financials requirements per participating department and/or hospital(s))
- Existing studies needing to move the into OnCore submitted through the OnCore Build Request Form

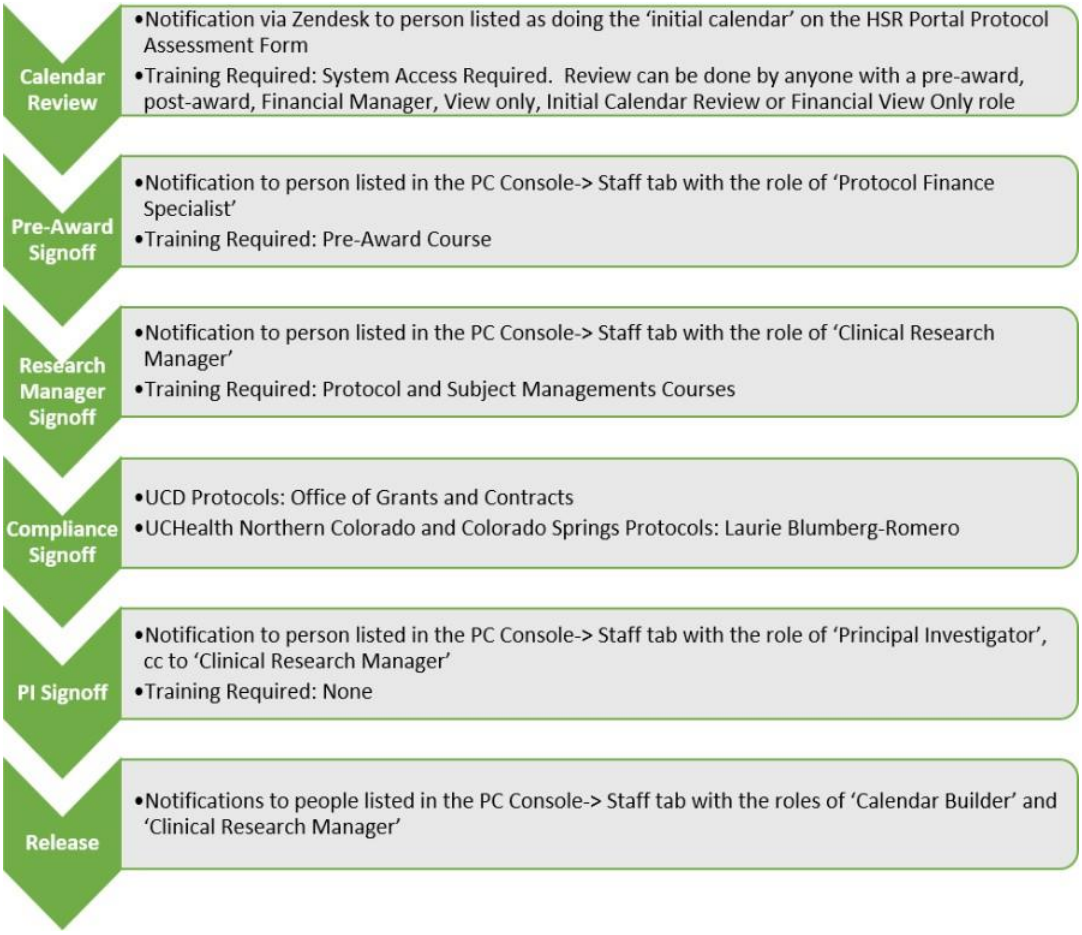
Step 2: The UCDenver Portal Administrator builds the protocol shell in the OnCore PC Console (OnCore Path: Menu → Protocol → PC Console)



Step 3: The Study Team should enter IRB Review Information in the PC Console (access and training required). Entering IRB Approval will start the Protocol Signoffs with an email notification to the Regulatory Coordinator:

Step 4: The OnCore Support Calendar Builder begins building the protocol calendar with procedures (collectively call the 'Specifications')

- The Calendar Builder will reach out to the study team with questions during the build
- The status of this build can be viewed using **these instructions**
- If applicable the appropriate Hospital Research Specialist performs the Coverage Analysis in OnCore
    - For an overview of the CHCO Startup process **click here**
- Hospital Research Specialist email the study team when the Coverage Analysis is complete with instruction to review (1) Coverage Analysis and (2) calendar structure
- The Calendar Builder enters financial and billing information
    - If applicable the fully executed contract and finalized internal budget should be sent to OnCoreSupport@UCDenver.edu when received
- When all financials information has been entered the Calendar Builder 'completes' the specifications and starts the **specification signoff process.** Each signoff is triggered by completion of the previous signoff and the responsible person (notification sent of) receives and email with instructions on how to complete their signoff



Step 5: When both the PC Console Clinical Research Manager Signoff is complete and the Specifications have been released OnCore Support will open the protocol to accrual and Hospital Research Administration will EPIC Activate. An email notification is automatically sent to the study team.

Delegation of Authority Log

A Delegation of Authority Log (DOA) is important for prospective studies. It is created at the beginning of the study and should be filed with other study documents. It is a tool to ensure that all research members fully understand their roles and duties for the study. Each research member will write in their name on a line and fill in the numbers corresponding their designed responsibilities from the Responsibilities Legend. The PI reviews the DOA with each research member and signs the document at the bottom of the page. A DOA is also used to document change of personnel and can be submitted to CAS to update those changes for the Epic Use Plan. Below is an example of a DOA and you can access this template from ROCS.

Signature and Delegation of Authority Log

Principal Investigator:	Jonathan Roach, MD	Site:	University of Colorado/Children's Hospital Colorado
Protocol Title:	19-2549 Functional and Oncologic Outcomes of Chest Wall Sarcoma Treatment in Children and Young Adults	Department:	Department of Pediatric Surgery

Complete one line for each individual of the study team. Use the legend at the bottom of the page to complete the Delegated Responsibilities column.

Name	Delegated Responsibilities*	Initials	Signature	Start Date (MM/DD/YYYY)	End Date (MM/DD/YYYY)	PI initial/date

By initialing above, I, the PI, declare that during the conduct of the above study, I have delegated the following study-related activities:

*Responsibilities Legend		
1. Assess Inclusion/Exclusion Criteria	4. Send QoL Survey	7. Follow-up Phone Calls
2. Determine Eligibility	5. REDCap Data Entry	8. Regulatory Correspondent
3. Obtain Informed Consent	6. Complete Study Forms	9. Regulatory Document Maintenance

Signature of Principal Investigator: _____ Date: _____

Prospective Studies for Cancer-Related Protocols

If you are planning on conducting a prospective study that is cancer-related, you will need to submit to HSR Portal, COMIRB, and Protocol Review & Monitoring System (PRMS) with the Cancer Center. All cancer-related protocols regardless of type of protocol (industry, cooperative group, chart review, etc.) are required to be reviewed by the PRMS.

You will initiate the same process as a Prospective Study but incorporate the PRMS submission. The PRMS and HSR Portal submissions are recommended to be submitted on the same day.

A new protocol submission to PRMS requires both hard copies and copies uploaded within the REDCap link. Hard copies must be received before 12:00pm on the Friday prior to the next Scientific Review Committee meeting. You can see the submission due dates at the PRMS website. Hard copies are to be delivered to Building 500, 6th floor North Wing hallway, in PRMS in-basket.

The required forms for the PRMS submission can be found on the PRMS website. The following items are required for the PRMS REDCap submission:

- Protocol
- PI Involvement Form
- PRMS Signature page

After you submit your documents through the PRMS REDCap form, you will need to drop off the hard copies to the PRMS in-basket in Building 500, 6th floor North Wing Hallway. The following items are required hard copies:

- Protocol
- PI Involvement Form
- PRMS Signature page

After you receive the PRMS approval letter and HSR Portal Clinical Admin PAF clearance letter, you are ready to submit your research project to COMIRB.

The following items are required for your COMIRB submission:

- COMIRB Application Form
- Protocol (include list of data fields collecting)
- Consent form
- Assent form (if applicable)
- Survey(s) (if applicable)
- Personnel form (complete in InfoEd)
- PI Attestation form
- PRMS approval letter
- HSR Portal Clinical Admin PAF clearance letter

You will follow the same process for OnCore and the Epic Use Plan as described above.

Maternal and Fetal/Neonate Studies

If you have a study involving maternal and/or fetal/neonate study subjects, you will need to receive additional approvals from Perinatal Research Advisory and Facilitation Committee (PRAFC) and/or Colorado Fetal Care Center Review Committee.

Perinatal Research Advisory and Facilitation Committee

Pregnant women, their fetuses and newborn infants, especially preterm infants in neonatal intensive care units, represent a unique and limited population of families who would like to participate in clinical research. There is considerable potential for competition among studies that begin at these unique stages of the life cycle, which is a burden to studies recruiting from these limited subject populations.

The PRAFC to assist investigators whose studies involve:

- Pregnant women
- Placenta, umbilical cord or cord blood samples
- Neonates (0-30 days) admitted to the NICU or well-baby nursey at UCH, or the NICU, CICU, or PICU at CHCO

All potential perinatal research projects must be reviewed by the Committee prior to the initiation of any study. Upon completing protocol submission in the HSR portal and indicating that your protocol meets one of the above requirements, the PRAFC questionnaire and review process will be initiated.

Primary goals of the facilitation process:

- Determine the feasibility of the proposed research
- Identify overlap with existing studies
- Foster collaboration among overlapping research investigators
- Establish priorities for protocols
- Assure that investigators are fully aware of existing data and biobank resources already available
- When necessary, direct investigators to alternative resources and/or research sites

Colorado Fetal Care Center Review Committee

If your research study will be recruiting patients in the Colorado Fetal Care Center (CFCC), you will need to complete an additional form so it can be reviewed by the CFCC Review Committee. You can find the online form here and once you submit the form, you will be contacted by the CFCC coordinator to set up a meeting with the reviewing committee.

Multisite Studies

If you are planning on conducting a study with another institution or institutions, you will need to determine if you will request local IRB approval or rely on another institution's IRB.

If you are going to request local IRB approval through COMIRB, you will complete the same process above, whether it is retrospective chart review or a prospective study. You will need to have a Data Use Agreement (DUA) to share data with the other institution. The process of a DUA will be talked about in more details in Step 3 in the SMARTIRB section below.

If you are going to rely on another institution's IRB and go through SMARTIRB, the process is slightly different. You will need to receive all study documents from the lead institution which includes:

- Protocol
- Data collection form
- Consent form (if applicable)
- Assent form (if applicable)
- Survey(s) (if applicable)
- Data Use Agreement Template
- Other Party contact information
    - Name
    - Email
    - Phone number

How to begin a SMARTIRB:

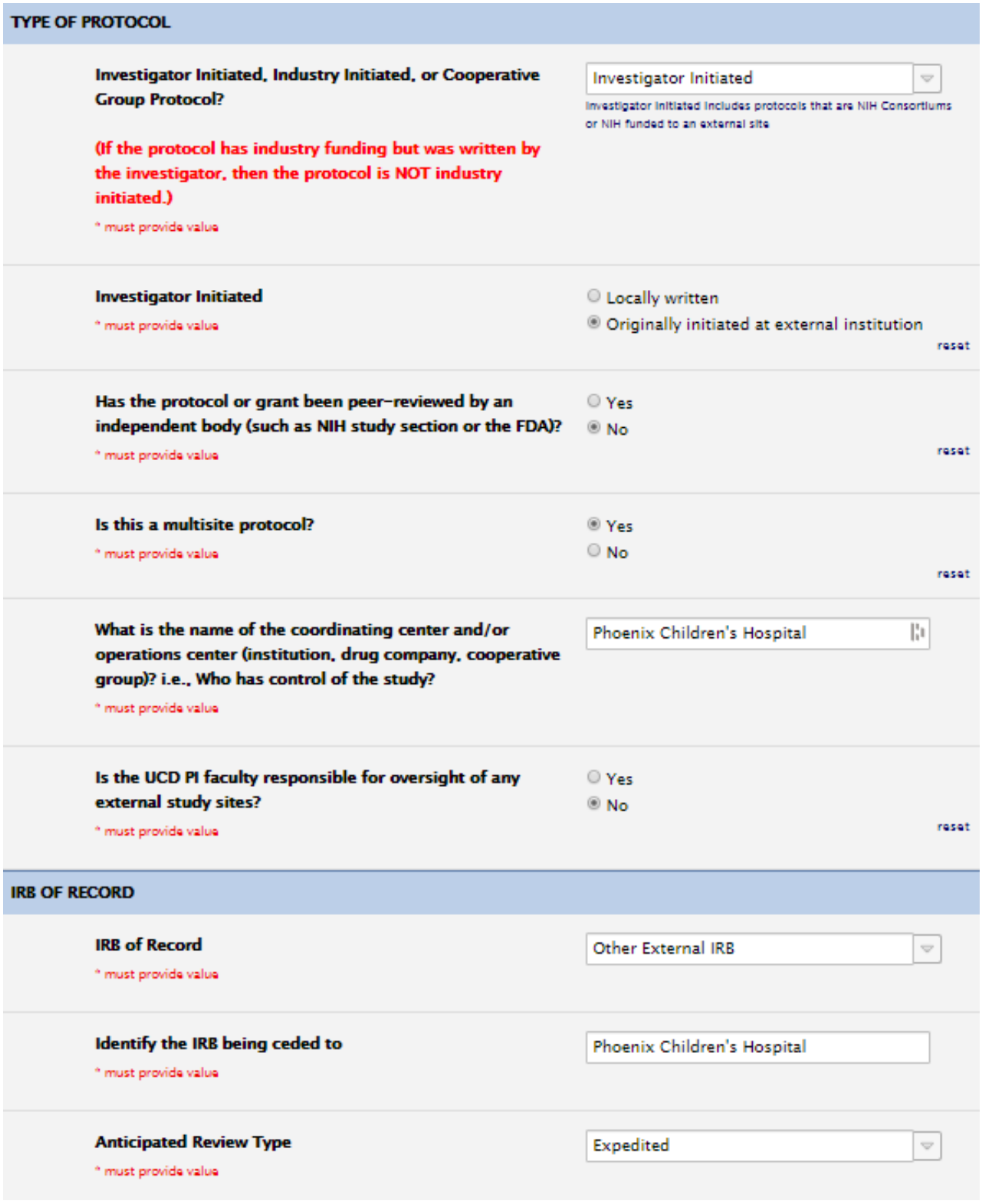
Step 1: Create a protocol in InfoEd to receive a COMIRB number

Create a new research protocol in *eRA InfoEd system* and a step by step guide to create new research protocols in eRA InfoEd can be found here. **You will need to create a protocol in order to receive a COMIRB number and complete the Personnel Form which will be used for the Human Subject Research Protocol Submission Portal.**

Step 2: **Submit to Human Subject Research Portal (HSR Portal)**

Complete the form in the *Human Subject Research Protocol Submission Portal* as you would for any other protocol, but there are certain answers that are selected in order to notify External IRB of this study. External IRB is a group that works with the Clinical Research Support Center and OnCore to review and approve the IRB ceding process. External IRB can be contacted at externalirb@ucdenver.edu if you have any questions.

As you are completing the form, you will select **Yes for *Is this a multisite protocol*** under the *Type of Protocol* section. Under the same section, enter the name of the institution that will be the coordinating center for the study. Under the *IRB of Record* section, select *Other External IRB* in the drop-down menu and enter the institution who will be the IRB of Record. Below is an example of these sections filled out.



As you complete the form, a list of documents required for your submission will populate at the bottom of the form. You will not be able to submit unless you have uploaded all the required documents to the application. If you do not have the documents the system is asking for and they are not applicable, please upload a document stating such. *You have the option to save and return later if you start the form and determine additional documents are needed to complete the application.*

Step 3: Submit intake form to Research Agreements for a Data Use Agreement

For multisite studies, a Data Use Agreement (DUA) is needed in order to share data with the lead institution. Once you receive IRB approval from the lead institution, you will complete the intake form here and below is the form and all of the information you will need to know to fill it out. **Please note that after you press submit, you will be taken to another page to enter the information for the Other Party in the agreement.** *If you have any questions, you can contact Research Agreements.*

Agreement Intake Form

Resize font:

Please complete the Agreement Intake form for the agreements required for your project.

Note that one form should be completed per agreement needed, unless you need an agreement with a single party for multiple purposes (e.g. network participation and data transfer) or if you need the same agreement with mutliple insitutions (e.g. Data Coordinating Center).

If you have questions about completing this form, please contact researchagreements@childrenscolorado.org

Thank you!

If you are interested in learning more about agreements that may be required for data transfer, check out the CU HIPAA Forms and Resources or the CHCO HIPAA Glossary of Terms

Contact & Project Information

Name of person completing form
* must provide value

Who should be contact for questions about this agreement request?

Preferred email address for contact
* must provide value

Last Name of Local Principal Investigator (or project lead, if not research)
* must provide value

First Name of Local Principal Investigator (or project lead, if not research)
* must provide value

Project name ***(for IRB approved projects, please enter the whole protocol name)***
* must provide value

Is this agreement related to a research project?
* must provide value

Yes No I am not sure

reset

What is the IRB status?

Please indicate what you are trying to accomplish with this agreement (select all that apply)

- ☐ Transfer **Data** between Children's Hospital Colorado and another, outside institution (receiving and/or sending data)
- ☐ Transfer **Materials** (e.g. specimens) between Children's Hospital Colorado and an outside institution (sending or receiving)
- ☐ Payment (Vendor agreement, etc. *Do not use this for grants, Work Orders under the MSA or Clinical Trial Agreements*)
- ☐ Participation/Collaboration/Consortium
- ☐ Use/Receive a Device
- ☐ Other

If you are unsure, please see defintions below.

Definitions
Data: may include protected health information, personally identifiable information, genomic information, etc.
Materials: may include specimens derived human or animal origin, such as blood, serum, tissue, sputum, etc.
Payment: includes vendor agreement, remuneration agreements, fixed billing agreements, etc. This does not include Clinical Trial Agreements (CTAs), grants or work orders under the MSA (for more information on the MSA check out the MSA training page).
Participation/Collaboration: includes collaborations, consortiums, research networks, registries, among others. These are used to establish participation and outline requirements for participating. These are not always required for participation, and the language may be included in another agreement type. If you have questions, please contact Research Agreements
Outside of Children's Hospital Colorado: outside of the Children's Colorado network. This includes university servers, labs, freezers, as well as off campus and outside of Children's Colorado. If the data or materials are staying within the Children's Colorado system, then they are not leaving Children's Colorado.

In your own words, describe what you intend to accomplish with this agreement.

Expand

e.g. we need to transfer full PHI data to a registry at X instute; We need to be paid for the work to process samples for X project; the data coordinating center told us we needed to get this agreement signed so that we can transfer data

Will any patients from the European Union be enrolled in this study?

○ Yes ○ No ○ I am not sure

reset

Will Children's Hospital Colorado be acting as a data coordinating center for this project or will mutliple similar agreements be needed for this project with different entities?

○ Yes ○ No ○ I am not sure

reset

Only choose yes if mutliple of the same type of agreement is needed for this project with different institutions. e.g. you need the same DUA with 3 different institutions

Other Considerations

Do you need authorship addressed in this agreement? ○ Yes ○ No ○ I am not sure reset

Are there any other agreements already in place for this project or related to the agreement you are currently requesting? ○ Yes ○ No ○ I am not sure reset

includes agreements for participation, vendors, payment, grants, MSA Work Order

Please provide any additional information that you feel may be important to this agreement.

Expand

Please provide any relevant deadlines

Related Documents

Please upload the documents listed below. Omission of a necessary document may delay review, as review may not begin until all necessary documentation has been received.

Please upload the most recent Protocol for this project. If this is not a research project, please include the project Charter, or similar document that provides an overview of the project. Upload file

* must provide value

Do you have multiple versions of the IRB approval letter that are relevant to this agreement? ○ Yes ○ No reset

Please upload a Data Flow Diagram that shows the flow of data between entities, including the identifiers that may be transferred. Upload file

Please include if there is more than one transfer, or if there are complexities that are difficult to describe.

Please upload any templates or draft agreements for the requested agreement. Upload file

After you press submit, you will be taken to another page to enter the information for the Other Party in the agreement. *If you do not see a new page, please contact Research Agreements*

Submit

Save & Return Later

This request may take up to 5 weeks to be reviewed and fully executed so it is recommended to submit this form as soon as you receive IRB approval.

****You are NOT able to share or collect any data until the agreement has been signed by both parties and all OnCore and Epic Use Plan requirements have been completed and the study is in "Open in Accrual" status.****

Resources & Contact Information

Resource	Website	Email	Phone
ROCS		rocs@childrenscolorado.org	720-777-0798
COMIRB	https://research.cuanschutz.edu/comirb	comirb@ucdenver.edu	303-724-0155
Clinical Research Support Center (CRSC)	http://www.ucdenver.edu/research/CRSC/Pages/default.aspx	clinicalresearchsupportcenter@ucdenver.edu	303-724-1111
Colorado Clinical & Translational Sciences Institute (CCTSI)	https://cctsi.cuanschutz.edu/		720-848-7100
Regulatory Compliance	https://research.cuanschutz.edu/regulatory-compliance		
OnCore Support	http://www.ucdenver.edu/research/ResearchAreas/OnCore/Pages/OnCoreHome.aspx	oncoresupport@ucdenver.edu	303-724-4111
SARC	http://www.ucdenver.edu/research/Pages/SARC.aspx	SARC@ucdenver.edu	
Research Start-Up		researchstartup@childrenscolorado.org	
CHCO Research Institute		researchinstitute@childrenscolorado.org	
External IRB		externalirb@ucdenver.edu	
PRMS	https://medschool.cuanschutz.edu/colorado-cancer-center/clinical-trials/protocol-review-and-monitoring-system	Prmc.uchsc@ucdenver.edu	303-724-8832
Research Agreements		researchagreements@childrenscolorado.org	
REDCap Administration	https://cctsi.cuanschutz.edu/resources/informatics/redcap	redcap@ucdenver.edu	
Clinical Application Services (CAS)		casresearchteam@childrenscolorado.org	720-777-2856

FAQs

Q1. How do I add/remove people to/from my IRB protocol?
If you need to add/remove people to/from your protocol, you will need to submit an Amendment to COMIRB. The required documents needed are Change form, updated Personnel Form, and Cover Letter. The change form can be found on the forms tab on the COMIRB website. The personnel form is updated in InfoEd. A cover letter is needed to state the reason for updating personnel in your study. You will upload the change form and the cover letter to InfoEd and the personnel form populated in InfoEd is to be updated with the changes.

Q2. How do I close out a study?
To close out your study, you will need submit a Study Closure in InfoEd. The required documents to close a study are Continuing Review Form, Change Form, and Cover Letter. The Continuing Review form will be information specific to the study and you will select option 6 (closing) for Current Status. The Change Form is used to lay out the changes happening in the study (i.e., study closure) and itemizes what documents you will be submitting. The Cover Letter is to describe the reason for closing your study. You usually close out your study when you have completed all data analysis and only working on final versions of manuscripts. Below are examples of a **Continuing Review Form and Change Form**.

Colorado Multiple Institutional Review Board

Continuing Review Form

Approval Stamp

Complete and return 45 days prior to expiration of the protocol

Protocol

Protocol #: Initial Approval: Expires:

Title:

Principal Investigator

☐ Check here if PI is a student/resident/fellow/trainee

Current PI: Department:

E-Mail: Phone:

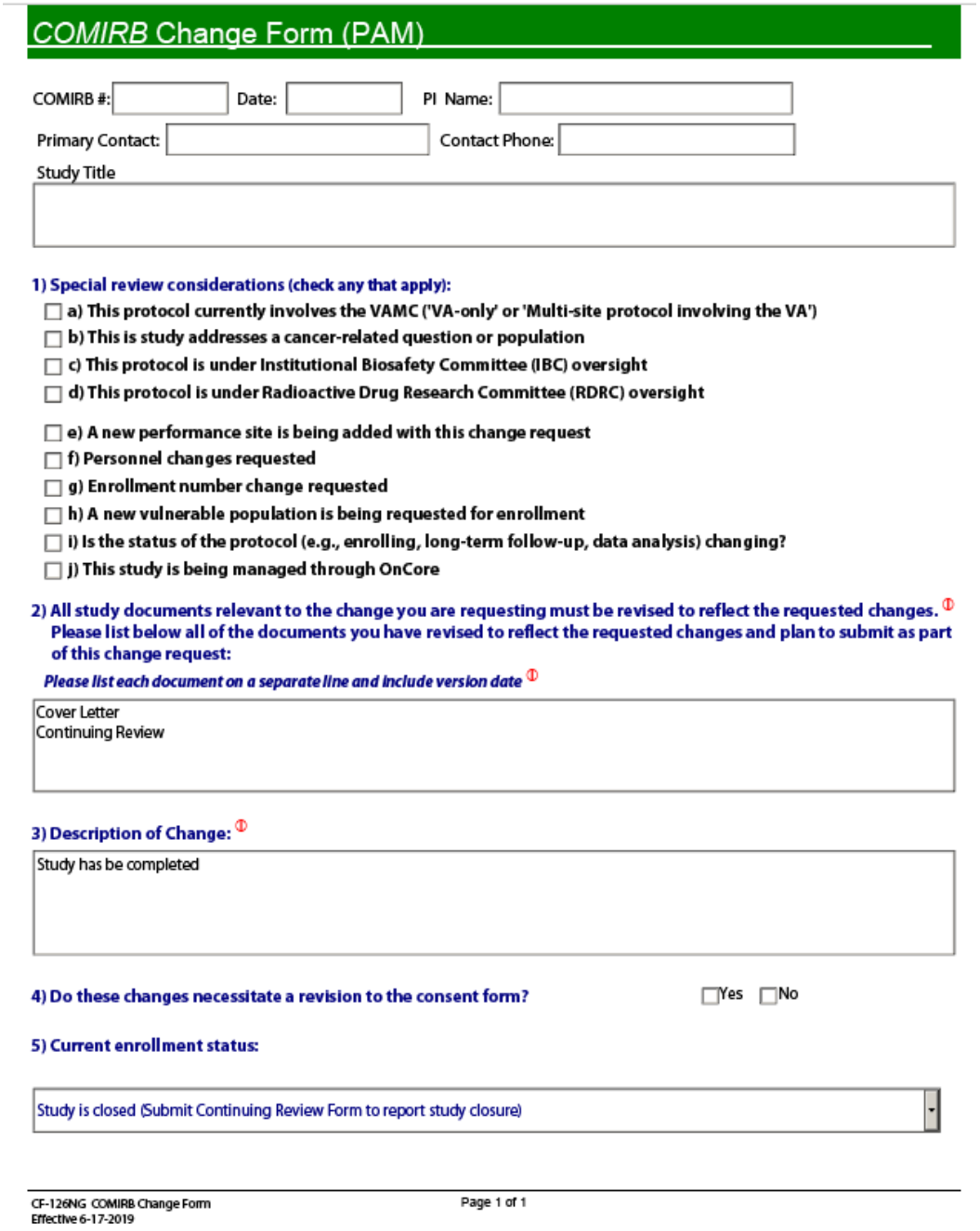
Indicate VA involvement in this study

☐ VA only study (check if any **one** true)	☐ Multi-site involving VA	☐ Non-VA study (**all** must be true)
> Funding solely from the VA OR > All procedures performed on VA property, with VA patients, or using VA equipment/resources OR > All investigators and study personnel working solely on VA time	> Both VA and non-VA funding OR > Some procedures performed on VA property, with VA patients, or using VA equipment/resources OR > Some investigators and study personnel working on VA time	> No VA funding AND > No procedures performed on VA property, with VA patients, or using VA equipment/resources AND > No investigators or study personnel working on VA time

Select the option below that best describes the status of your study: ☐ Check here also if you are re-opening the study

Current Status:

○ 1) Not Yet Started	No subjects have ever been enrolled into this study
○ 2) Project Still Active	Enrollment of participants continues
○ 3) Project Still Active	Enrollment is **complete**, but participants are still receiving research related **Interventions** (e.g. blood draws, still receiving treatment, etc.)
○ 4) Project Still Active	Enrollment is **complete** and research activities are limited to **Long-Term follow-up** of participants
○ 5) Project Still Active	Enrollment is **complete** and participants have completed all research related interventions and long-term follow-up is complete. Research activities are limited to **data analysis** only
○ 6) Closing	Enrollment is **complete,** all research procedures and data analysis are **complete**. May possibly be accepted for publication.



COMIRB Change Form (PAM)

COMIRB #: Date: PI Name:

Primary Contact: Contact Phone:

Study Title

1) Special review considerations (check any that apply):

- a) This protocol currently involves the VAMC ('VA-only' or 'Multi-site protocol involving the VA')
- b) This is study addresses a cancer-related question or population
- c) This protocol is under Institutional Biosafety Committee (IBC) oversight
- d) This protocol is under Radioactive Drug Research Committee (RDRC) oversight
- e) A new performance site is being added with this change request
- f) Personnel changes requested
- g) Enrollment number change requested
- h) A new vulnerable population is being requested for enrollment
- i) Is the status of the protocol (e.g., enrolling, long-term follow-up, data analysis) changing?
- j) This study is being managed through OnCore

2) All study documents relevant to the change you are requesting must be revised to reflect the requested changes. Please list below all of the documents you have revised to reflect the requested changes and plan to submit as part of this change request:

Please list each document on a separate line and include version date

Cover Letter
Continuing Review

3) Description of Change:

Study has be completed

4) Do these changes necessitate a revision to the consent form? Yes No

5) Current enrollment status:

Study is closed (Submit Continuing Review Form to report study closure)

CF-126NG COMIRB Change Form
Effective 6-17-2019

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Q3. When are IRB amendments required?

Amendments are required when you have any substantial changes to your study such as increase enrollment numbers, collect additional data fields, personnel changes, or changes to recruitment methods. When you have these kinds of changes to your study, you will need update your IRB application and protocol, complete a Change Form, and write a Cover Letter. As part of the amendment submission, you will upload track changed and clean versions of your updated protocol as well as other necessary study documents (flyers, consent/assent form).

Q4. Who do I contact if I need information from EPIC for my study?

If you are needing more information about using EPIC data in your study, you may submit a DASH request: https://dash.childrenscolorado.org/. or contact Sara.DeakyneDavies@childrenscolorado.org. You must be connected to CHCO VPN to access the DASH request form.

Q5. What does it mean if my study is deemed IRB exempt?

Exempt IRB protocols involve research activities that are minimal risk. Exempt research is subject to Institutional Review as determined and approved by COMIRB. Although exempt research is not covered by the federal regulations, this research is not exempt from UCD or the appropriate Affiliate's policies on responsible conduct of research or the ethical guidelines of the Belmont Report. For more information, you can review the Exempt Research Guidance on the COMIRB Guidance and Policies website found here. If you have more questions, you can contact COMIRB.