

IRB Workflow Diagrams

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This document presents the internals of the IRB module.
Use it to understand features and operation, and determine
how to customize the product to your needs.

Overview

[Icon Key](#)

[Roles](#)

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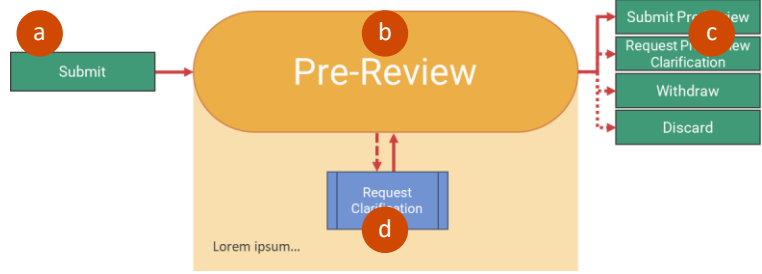
[Other Assignments](#)

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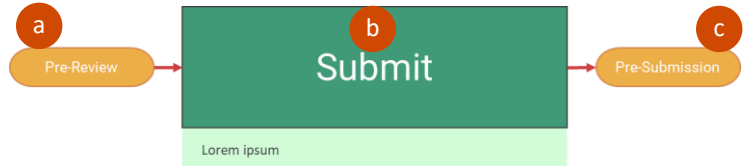


State Detail Pages



- a** Left side: **Actions** that lead to this state
- b** Center: **State** name
- c** Right side: **Actions** that are available from this state
(Note: dashed lines indicate alternate or optional actions)
- d** Optional **Loop** processes, such as Request Clarification

Action Detail Pages



- a** Left side: **States** that have this action
- b** Center: **Action** name
- c** Right side: Action can lead to these **States**
(Note: dashed lines indicate alternate or optional states)

Roles & Project Assignments Table

Each **State detail page** has a table that specifies who is allowed to do what.

Roles & Project Assignments			
IRB BA	✓	✓	✓
IRB Business Analyst	✓	✓	✓
IRB Committee Admin	✓	✓	✓
IRB Committee Chair	✓	✓	✓

Checkmarks in these columns indicate who can *view* or *edit* SmartForm content, and who will *receive tasks* on this state's SmartForm.

Review

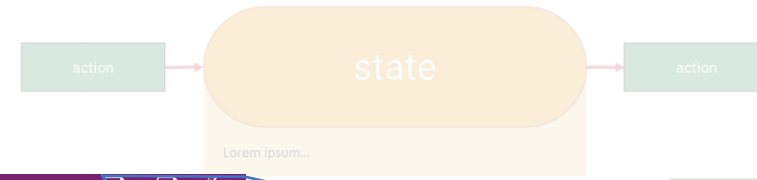
- [User Roles](#)
- [Project Assignments](#)

Every detail page has this icon – which links to this *Icon Key* page.



Workflow: Initial Study Submission

Description
TBD



Roles & Project Assignments			
IRB BA	✓	✓	✓
IRB Business Analyst	✓	✓	✓
IRB Committee Admin	✓	✓	✓
IRB Committee Chair	✓	✓	✓
IRB Coordinator	✓	✓	✓
IRB Director	✓	✓	✓
IRB General User	✓	✓	✓
IRB Principal Investigator	✓	✓	✓
IRB Registered User	✓	✓	✓
IRB Reliance Coordinator	✓	✓	✓
IRB Site Manager	✓	✓	✓
IRB Study Staff	✓	✓	✓
Ancillary Reviewer	✓	✓	✓
Assigned Coordinator	✓	✓	✓
Designated Reviewer	✓	✓	✓

View SmartForm content

Modify SmartForm content

User receives a **task**

Available Non-Workflow Actions

- Add Comment
 - Add Private Comment
 - Assign PI Proxy
 - Assign Primary Contact¹
 - Copy Submission
 - Manage Guest List
 - Manage Ancillary Reviews²
 - Submit Ancillary Review²
 - Assign Coordinator³
 - Add Related Grant
 - Add Participating Sites⁴
 - Manage Tags
- ¹ Available only for initial submissions
² Except: Closed and Discarded
³ Except: Pre-Submission
⁴ Only for MSS studies - available after PI History is submitted



IRB Roles

Role Name	Role Description
IRB General User	All users expected to access the IRB module must be assigned this role. Provides basic permissions to view and create IRB submissions. Can be assigned as a study team member and have certain other project assignments. Also used for system-executed actions.
IRB Principal Investigator	Conducts research at an institution, often funded with grants from government or other sponsors, to conduct human subject’s research. While others assist the PI in developing and editing a submission, only the PI (or designated PI proxies) can submit the study or follow-on submissions to start the IRB review process.
IRB Coordinator	Guides submissions through the review process. Reviews a newly submitted study for completeness, determines the level of review it needs, and ensures correspondence with the PI is completed in a timely manner. To perform these actions on a submission, the user must be assigned as the IRB coordinator for that submission.
IRB Director	<p>Responsible for overall IRB administration and oversight, but is typically less involved with the day-to-day processing of submissions than the IRB coordinator. The director can perform the same actions as an IRB Coordinator and more, typically without being assigned as the coordinator for the submission.</p> <p>To access and perform actions on a submission, the director must be listed as staff on the IRB Admin Office overseeing the submission.</p>
IRB Reliance Coordinator	Manages multi-site studies and their participating sites and collaborative research, and for studies that use an external IRB of record. This is similar to IRB Coordinator role but specific to multi-site studies and submissions.
IRB Global Viewer	Provides read-only access to all IRB submissions. This is typically granted to a user from another module, such as a COI administrator who needs to check the status of submissions.
IRB Business Analyst	Has system-wide access, including full permissions to system settings. Has full permissions to all data, workspaces, and actions in the system.

These are the system-defined user roles in IRB. They provide basic rights in the IRB module.

To work in a specific project (submission), often a *Project Assignment* must be given, in addition to the user having an underlying role that allows that assignment.

Note: Users with IRB Director and IRB Coordinator roles must be added to the appropriate IRB admin office to gain access to IRB submissions.

Also see:

- [Project Assignments](#)

Submission Assignments

Listed as	Description
Principal Investigator	A person with the <u>IRB Principal Investigator</u> role who is listed as the Principal Investigator on the specific submission. Submits the study or follow-on submissions to start the review process and responds to requests from the IRB.
PI Proxy	If assigned to the submission by the Manage Access action, can perform most of the duties of the Principal Investigator.
Primary Contact	Assists the PI with editing the submission. Person who creates the submission is automatically assigned as the Primary Contact and can reassign this duty using the Manage Access action.
Study Team Member	Involved in developing a study and listed in the submission as study team member. Assists the PI with editing the submission.
Assigned IRB Coordinator	This is a person with the <u>IRB Coordinator</u> role who has been assigned to the submission as a coordinator to guide it through the review process. To be assigned, the user must also be listed as staff on the IRB Admin Office overseeing the submission. Anyone with the IRB Coordinator role can assign themselves or other coordinators using the Assign IRB Coordinator action.
Designated Reviewer	A committee member who is pre-assigned as an eligible designated reviewer and is assigned as the designated reviewer for this submission. The Assign Designated Reviewer action assigns them to the submission.
Staff Reviewer	A person with <u>IRB Coordinator</u> or <u>IRB Director</u> role assigned as a staff reviewer on this submission. The Assign Staff Reviewer action makes this assignment.
Committee Reviewer	Person pre-assigned as a committee member of the committee that is assigned to the submission.
Ancillary Reviewer	An individual or organization assigned as an <u>Ancillary Reviewer</u> on the submission. An Ancillary Reviewer can view all areas of project to complete their review

Submission Assignments provide *project-specific rights* in order to perform specific tasks or job duties related to an IRB submission.

Rights can be conditional based on the Project Assignment.

Just like IRB Roles, *Project Assignments* contain permissions, however these permissions are specific to each study. They grant a user permission to view or edit a study submission's SmartForm (available at each state) or to execute actions. Examples:

- View the state of a submission
- Perform an action on a submission
- Provide organizational privileges; for example, being a department member
- Act in a particular capacity; such as a Principal Investigator, a Proxy or a committee reviewer

The IRB Coordinator and IRB Administrator can assign rights to users who are eligible to receive those rights. This prevents arbitrary assignments of rights. For example:

- A study team member can submit a study *if* assigned as a PI or PI proxy.
- A PI can delete ancillary reviews *if* assigned as PI/proxy to that study *and* the review is still in Pre-Submission.

The IRBA or IRBC can grant an IRB General User an assignment of a committee member or committee administrator.

Committee-Related Project Assignments

Listed on Committee as	Description and Rights
IRB Committee Administrator	Responsible for managing committee meetings
IRB Committee Chair	An IRB committee member assigned to chair the committee
IRB Committee Member	Part of an IRB committee, responsible for reviewing a submission

How To Create an IRB Committee

Creating a committee involves these steps:

- Assign the [IRB Committee Administrator](#)
- Assign the [IRB Committee Chair](#)
- Assign [IRB Committee Members](#)

To assign an [IRB Committee Administrator](#):

1. Assign the intended user with the role of [IRB Coordinator](#).
2. Depending on the user's responsibilities, also assign the user the [IRB Director](#) user role.
3. Assign the user as the [IRB Committee Administrator](#).

Note: There will be an [IRB Committee Manager](#).

To assign an [IRB Committee Chair](#):

- Assign the intended user as an [IRB Committee Member](#) *and* [IRB Committee Chair](#).

Also see:

- [Committee Actions by Role](#)

Non-Workflow Actions

Executing these actions does not affect the workflow. Hence, they are called *Non-Workflow Actions*. They are available in various states in IRB.

The [Reference](#) section shows which Non-Workflow Actions are available in each project state.

Action	Description
Add Participating Sites	Action is available only in MSS studies.
Add Review Comments	Available only in the Committee Review state.
Ancillary Review Actions	Create Ancillary Review: Create a review that is outside of the normal review workflow, such as for someone outside of the current organization. Bypass Ancillary Block: Allows users with applicable rights to bypass ancillary review if there is a blockage in the workflow established via Settings Submit Ancillary Review: Allows users to record ancillary review determination Not available in Closed and Discarded states.
Assign Coordinator	Assign a coordinator when the study is in pre-review state and when IRB coordinator has not yet been assigned. If a coordinator is already assigned to a study, this action is available in all the study states. (Also see Central Actions)
Assign IRB	Assigns the IRB submission to the correct IRB office. Action is available in the Pre-Review state.
Assign Responsible Party	Assigns a responsible party for an RNI.
Add Related Submission	Identify submissions related to the RNI.

Action	Description
Assign Reviewers	Select users authorized to participate in a committee review. Action is available in Committee Review state.
Assign to Meeting	Assigns the submission to a meeting for review
Copy Submission	Creates a copy of a submission. Action is available on Initial Submission and External SS/MSS in all states.
Create Related Project	Allows the user to create a related project for another module
Create Task	Allows the user to create an ad-hoc task
Edit Pre-Review	Allows the user to edit certain information recorded on the Submit Pre-Review action
Edit Updated Review	Allows user to edit certain information recorded on the Submit Update Review action
Finalize Document	Merges documents uploaded as part of the submission into a pdf document template, with a watermark, and prepares a final version of those documents

Action	Description
Manage Access	Manages: Assign Primary Contact, Assign PI Proxy, Manage Other Personnel.
Manage Editors	Manage list of users who get edit access to the RNI.
Manage Participating Sites	Add or delete (in applicable states) participating sites in a multi-site study . This action appears when an sIRB submission is created.
Manage Relationships	Action is available on Initial Submission & External SS/MSS. Allows user to manage relationships outside of the Smart Form, such as Add Related Grant.
Manage Tags	For reporting purposes, allows adding aggregating tags to a proposal.
Prepare Letter	Allows generation of correspondence letter with protocol specific information. Creates correspondence letter PDF, which is sent to the investigator and posted on the submission workspace.
Remove From Agenda	Removes the submission from the assigned meeting agenda.

Workflow: Initial Study

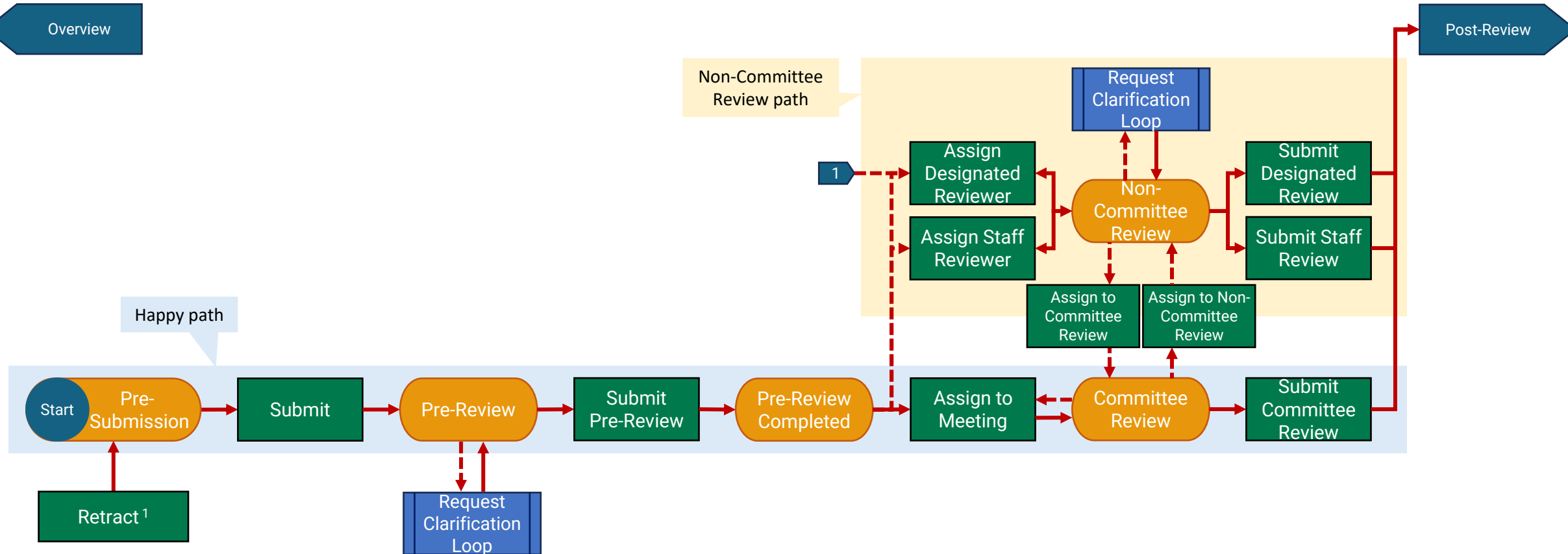
The **Initial Study (IS)** workflow creates a new, internal, single-site IRB study. This can be a research project or investigation that involves human participants.

Initial Studies can include various types of research, such as clinical trials, surveys, interviews, experiments, or observational studies.





Overview

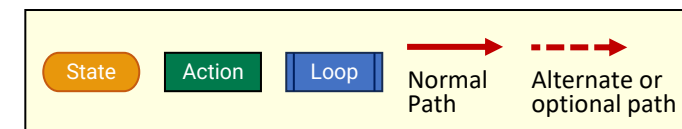
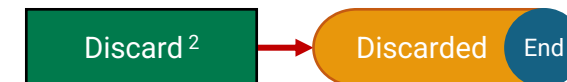
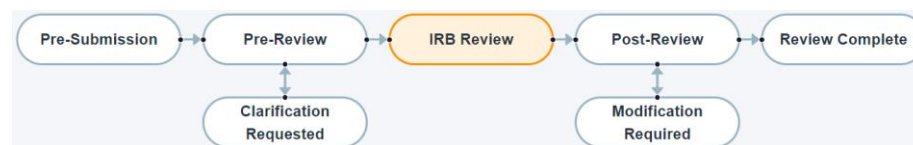


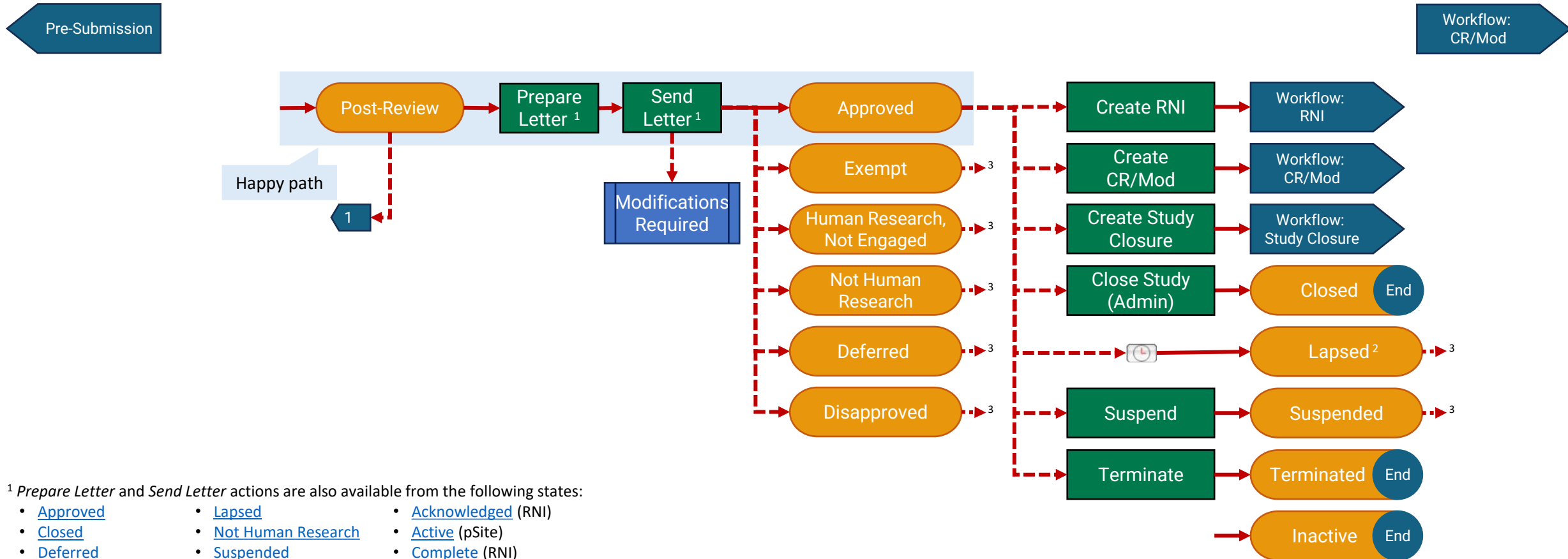
¹ *Retract* action is available in *all states prior to Post-Review*.

² *Discard* action is available in *all states prior to Post-Review*, and:

- [Disapproved](#)
- [Modifications Required](#)

Note: The term *IRB Review* implies both *Committee Review* and *Non-Committee Review* together. This term is used in the IRB app Workflow Map.





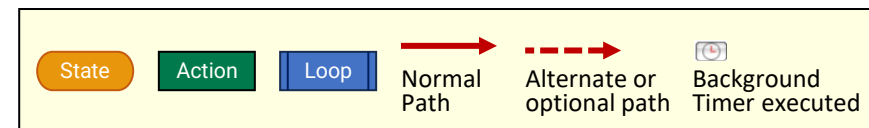
¹ Prepare Letter and Send Letter actions are also available from the following states:

- [Approved](#)
- [Closed](#)
- [Deferred](#)
- [Disapproved](#)
- [External IRB Approved](#)
- [Human Research, Not Engaged](#)
- [Lapsed](#)
- [Not Human Research](#)
- [Suspended](#)
- [Terminated](#)
- [Acknowledged](#) (RNI)
- [Active](#) (pSite)
- [Complete](#) (RNI)
- [Inactive](#) (pSite)




² The following states can automatically advance to [Lapsed](#) due to a lapsed deadline:

- [Approved](#)
- [Human Research, Not Engaged](#)
- [Suspended](#)

³ These states have *optional actions* that change the state or start another workflow.





Assignments			
Principal Investigator	✓	✓	✓
PI Proxy	✓	✓	✓
Primary Contact	✓	✓	✓
Study Team Member	✓	✓	
IRB Coordinator	✓	✓	
IRB Director	✓	✓	
Ancillary Reviewer	✓		✓

Start

Pre-Submission

Pre-Submission is entered through:

- Initial Submission (Study)** - Created from project creator link on the IRB page. This workflow is only for internally reviewed submissions.
- Modification / Continuing Review (Mod/CR)** - Created from project creator link on the study workspace for internally reviewed studies that have been approved. Available to study team members.

- ### Actions Available at This State
- [Submit for Review](#)
 - [Discard](#)

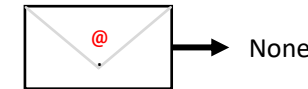
- ### Available Non-Workflow Actions
- Create Related Project
 - Create Ancillary Review
 - Copy Submission
 - Submit Ancillary Review
 - Manage Access
 - Manage Relationships
 - Discard
 - Create Task
 - Bypass Ancillary Block
- Note:** Some actions are dependent upon a related pending task or require specific user credentials.





Who can execute this action

- Principal Investigator
- PI proxy
- MSS PI
- MSS PI proxy (for Multi-Site Submission)
- IRB Coordinator (any user with IRBC role)

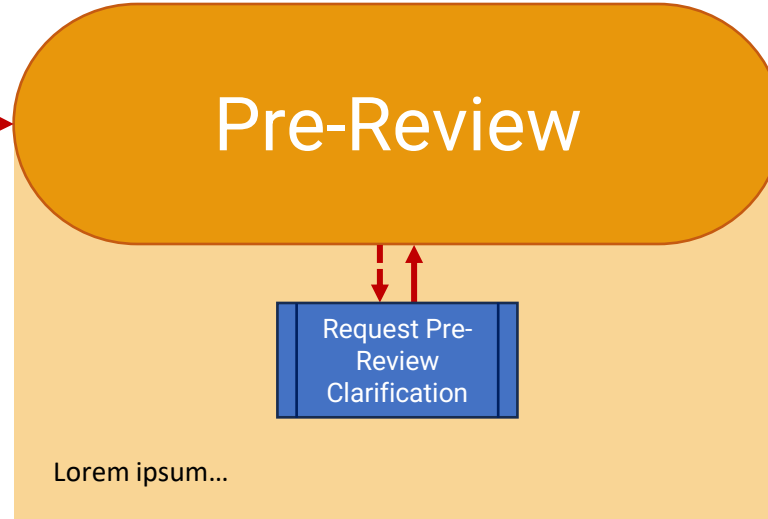
Notifications Generated





Roles & Project Assignments			
			
✓	✓	✓	
T	B	D	

Submit for Review



Actions Available at This State

- [Submit Pre-Review](#)
- Request Pre-Review Clarification
- [Confirm External IRB Reliance](#)
- Discard
- Retract

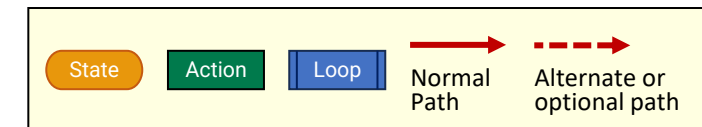
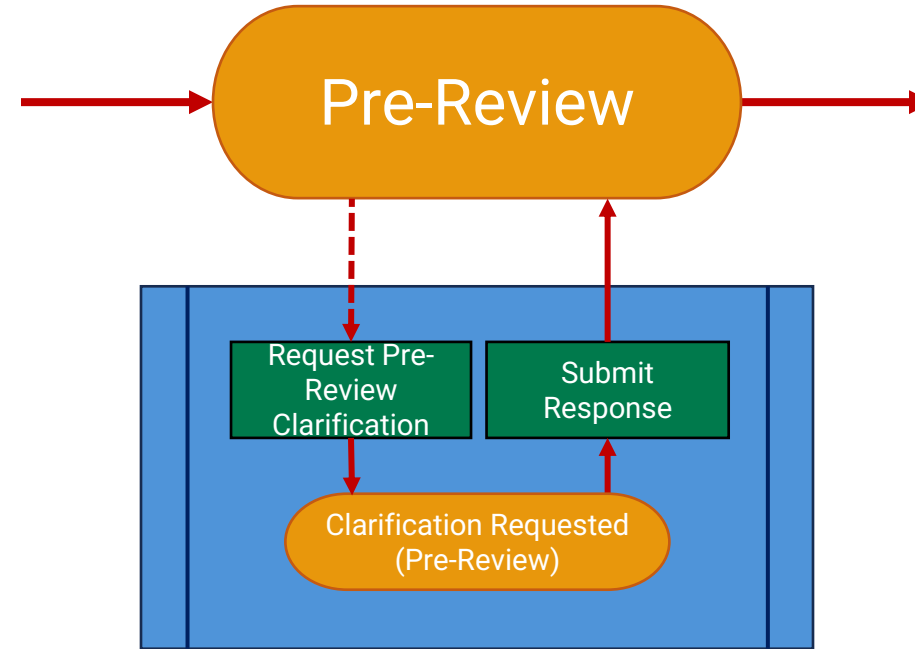
Available Non-Workflow Actions

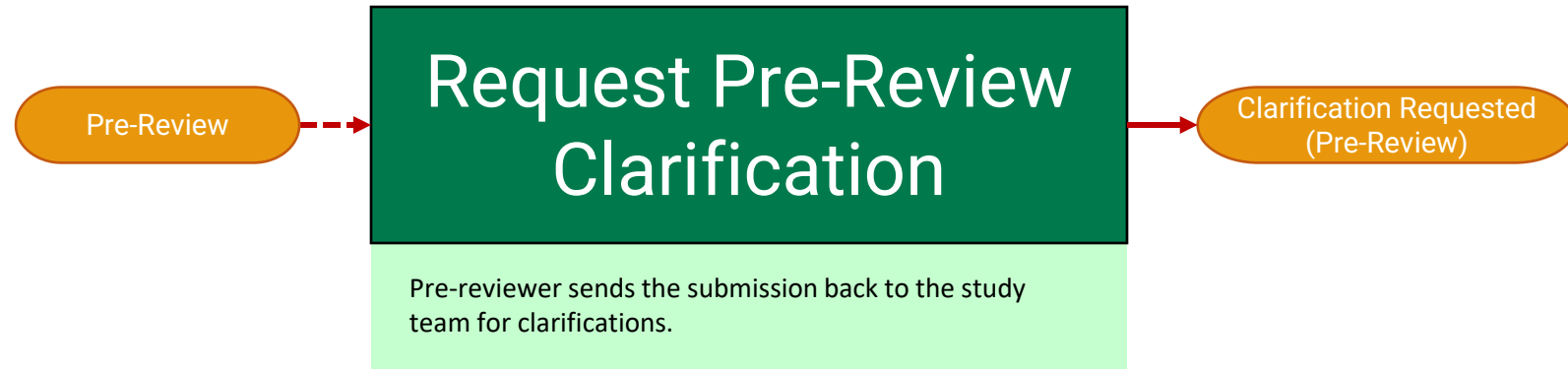
- Create Related Project
- Create Ancillary Review
- Copy Submission
- Assign Coordinator
- Submit Ancillary Review
- Assign IRB
- Manage Access
- Manage Relationships
- Create Task
- Bypass Ancillary Block
- Correspond with External IRB¹
- Manage Participating Sites²

Note: Some actions are dependent upon a related pending task or require specific user credentials.

¹ Applies to External IRB submissions

² Applies to sIRB submissions.





Who can execute this action

- IRB Director
- Assigned IRB Coordinator

Notifications Generated



Principal Investigator
Primary Contact
PI Proxies






Request Pre-Review
Clarification

Clarification Requested (Pre-Review)

Lorem ipsum...

Actions Available at This State

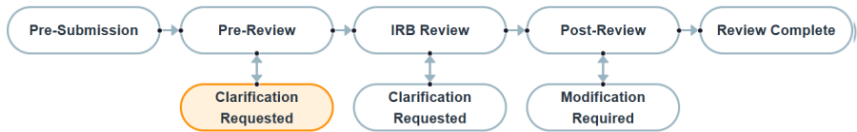
- [Submit Response](#)
- [Discard](#)
- [Retract](#)

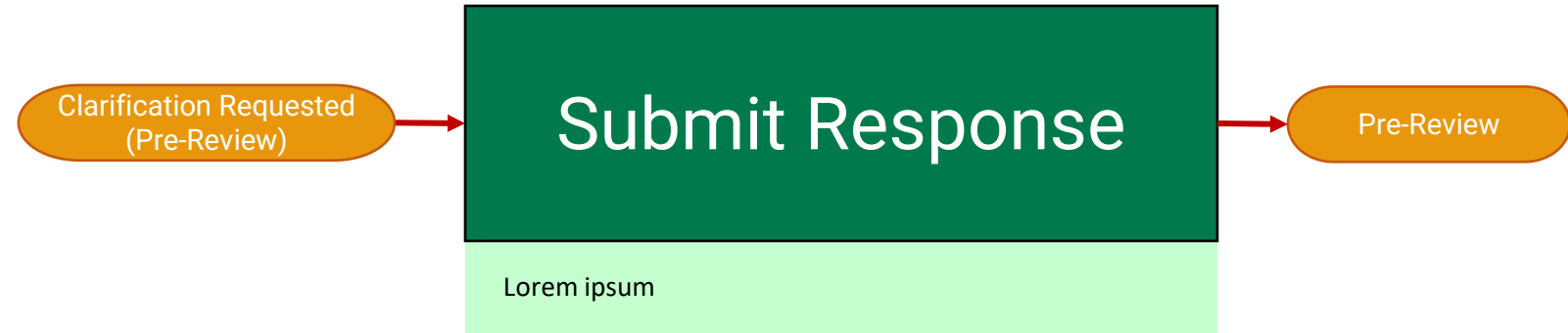
Roles / Project Assignment			
Principal Investigator	✓	✓	✓
PI Proxy	✓	✓	✓
Primary Contact	✓	✓	✓
Study Team Member	✓	✓	
Assigned IRB Coordinator	✓		
IRB Director	✓		
Ancillary Reviewer	✓		✓

Available Non-Workflow Actions

- Create Related Project
- Create Ancillary Review
- Copy Submission
- Assign Coordinator
- Submit Ancillary Review
- Manage Access
- Manage Relationships
- Create Task
- Bypass Ancillary Review Block

Note: Some actions are dependent upon a related pending task or require specific user credentials.

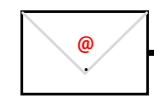




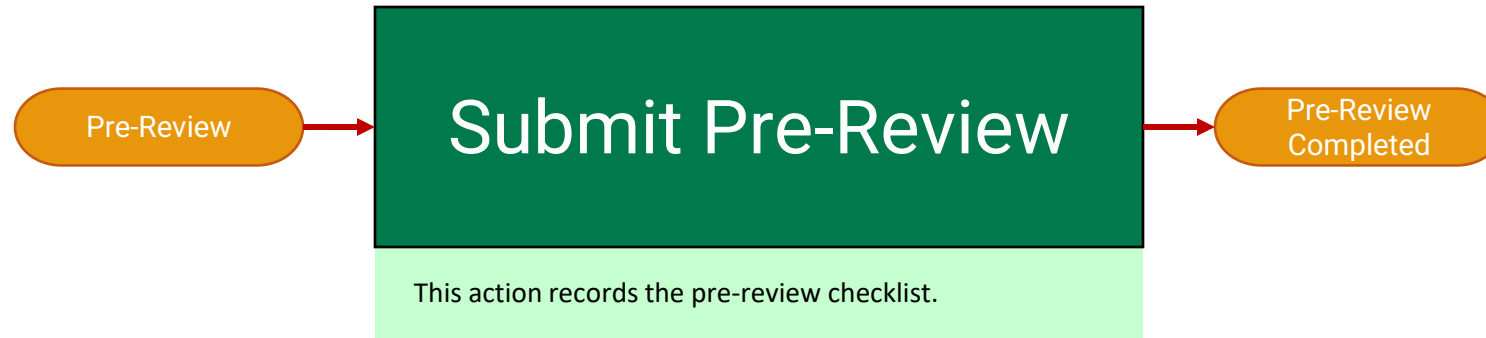
Who can execute this action

- Investigator
- PI Proxy

Notifications Generated



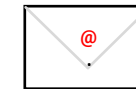
Assigned IRB Coordinator



Who can execute this action

- IRB Director
- Assigned IRB Coordinator

Notifications Generated



None



Submit Pre-Review

Pre-Review Completed

Lorem ipsum...

Actions Available at This State




- [Assign Designated Reviewer](#)
- [Assign Staff Reviewer](#)
- [Assign to Meeting](#)
- [Discard](#)
- [Retract](#)

Available Non-Workflow Actions

- Create Related Project
- Create Ancillary Review
- Copy Submission
- Assign Coordinator
- Manage Participating Sites¹
- Edit Pre-Review
- Manage Access
- Manage Relationships
- Create Task

¹ Applies to sIRB studies

Note: Some actions are dependent upon a related pending task or require specific user credentials.

Roles / Project Assignment			
Principal Investigator	✓	✓	✓
PI Proxy	✓	✓	✓
Primary Contact	✓	✓	✓
Study Team Member	✓	✓	
Assigned IRB Coordinator	✓		
IRB Director	✓		
Ancillary Reviewer	✓		✓

Assign Coordinator

This action selects an IRB user as a coordinator for an IRB study. A coordinator can be assigned if one has not yet been assigned.

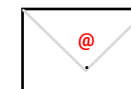
Note: This action is a non-workflow action (does not change the submission state) and is available in all states after [Pre-Submission](#).

While this action does not change the state of the submission, it is crucial for enabling an IRB Coordinator to take further actions.

Who can execute this action

- IRB Director
- IRB Coordinator

Notifications Generated



Assigned IRB Coordinator (when assigning someone other than yourself)

States where this action is found

- [Modifications Submitted](#)
- [Non-Committee Review](#)

Assign to Committee Review

Committee Review

This action is available when a submission is in the Non-Committee Review and the reviewer decides the submission needs Committee Review.

Note: As a follow-up action, the submission will need to be assigned to a meeting.

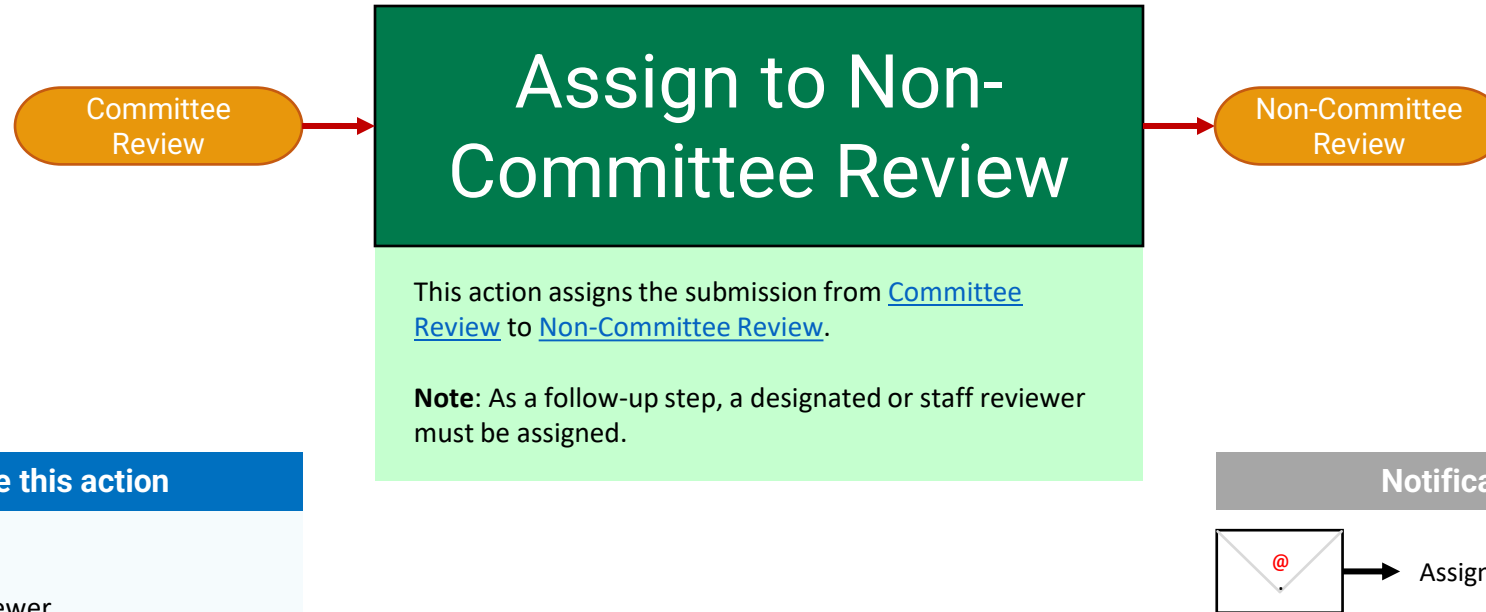
Who can execute this action

- Designated Reviewer
- Assigned IRB Coordinator
- IRB Director

Notifications Generated



Assigned IRB Coordinator



States where this action is found

- [Action Submitted \(RNI workflow\)](#)
- [Clarification Requested \(Non-Committee Review\)](#)
- [Deferred](#)
- [Modifications Submitted](#)
- [Non-Committee Review](#)
- [Pre-Review](#)
- [Pre-Review Completed](#)

Assign Designated Reviewer

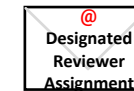
This action assigns and sends the submission to a designated reviewer, which can be selected from members of all IRB committees.

Non-Committee
Review

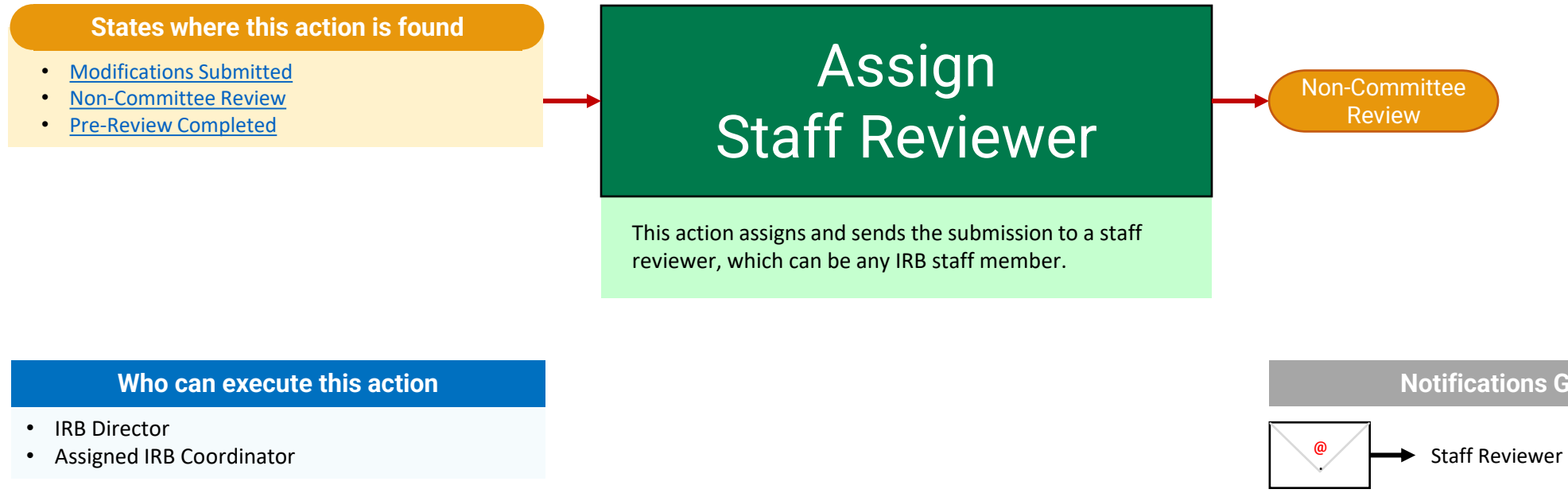
Who can execute this action

- IRB Director
- Assigned IRB Coordinator

Notifications Generated



Designated Reviewer



States where this action is found

- [Pre-Review Completed](#)
- [Committee Review](#)
- [Deferred](#)

Assign to Meeting

Committee
Review

Who can execute this action

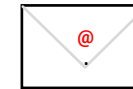
- IRB Director
- Assigned IRB Coordinator

This action assigns a submission to a meeting.

If a meeting has already been assigned, this action is not available. To re-assign a meeting, user must first select *Remove From Agenda* action.

If action is selected from Committee Review state, there is no state change.

Notifications Generated



None



Key

Actions Leading to This State

- [Assign Designated Reviewer](#)
- [Assign Staff Reviewer](#)
- [Assign to Non-Committee Review](#)

Non-Committee Review

Request
Clarification
Loop

Staff Review Determinations:

- Exempt
- Human Research, Not Engaged
- Modifications Required
- Not Human Research

Designated Review Determinations include all the above and "Approved."

The determination affects the state change that occurs when [Send Letter](#) action is selected.

Conditions for available actions at this state:

- *Submit Staff Review* action is available if state was entered from *Assign Staff Reviewer*.
- *Submit Designated Review* action is available if state was entered from *Assign Designated Reviewer*.

Actions Available at This State

- [Submit Staff Review](#)
- [Submit Designated Review](#)
- [Assign to Committee Review](#)
- [Assign Designated Reviewer](#)
- [Assign Staff Reviewer](#)
- [Review Required Actions](#) (RNI workflow)
- [Discard](#)
- [Retract](#)




Available Non-Workflow Actions

- Create Related Project
- Create Ancillary Review
- Copy Submission
- Add Related Submission¹
- Assign Coordinator
- Assign Designated Reviewer
- Assign Staff Reviewer
- Edit Pre-Review
- Manage Access
- Manage Relationships
- Manage Editors¹
- Manage Participating Sites²
- Create Task

¹ Applies to RNI workflow

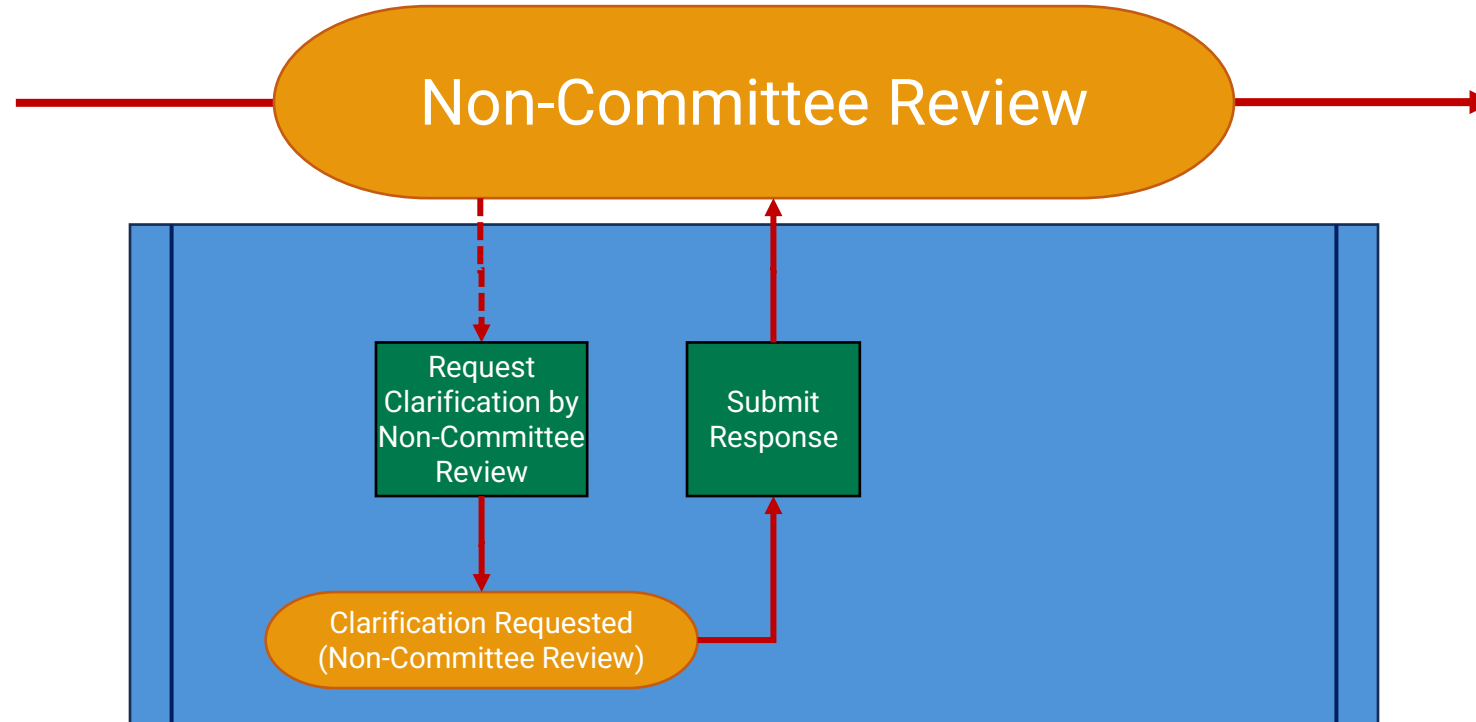
² Applies to sIRB workflow

Note: Some actions are dependent upon a related pending task or require specific user credentials.

Roles / Project Assignment			
Principal Investigator	✓	✓	✓
PI Proxy	✓	✓	✓
Primary Contact	✓	✓	✓
Study Team Member	✓	✓	
Assigned IRB Coordinator	✓		
IRB Director	✓		
Ancillary Reviewer	✓		✓

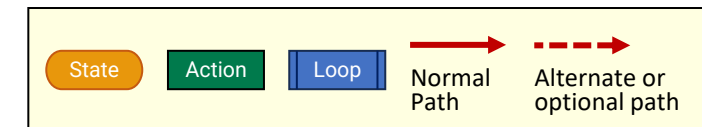


While in the Non-Committee Review state, the reviewer can *Request Clarification by Non-Committee Review*. This action changes the state to Clarification Requested (Non-Committee Review).



While in the Clarifications Requested (Non-Committee) state, the reviewer can *Submit Response* (if the clarification can be submitted by the PI or PI proxy)

Any of these actions changes the state to Non-Committee Review.



**Who can execute this action**

- Designated Reviewer
- Staff Reviewer
- Assigned IRB Coordinator
- IRB Director

Notifications Generated

Principal Investigator
Primary Contact
PI Proxies



Request Clarification by
Non-Comm Review

Clarification Requested (Non-Committee Review)

Note: *Assign Designated Review* and *Assign Staff Reviewer* actions do not change the state when executed from CR NC Rev.

Actions Available at This State

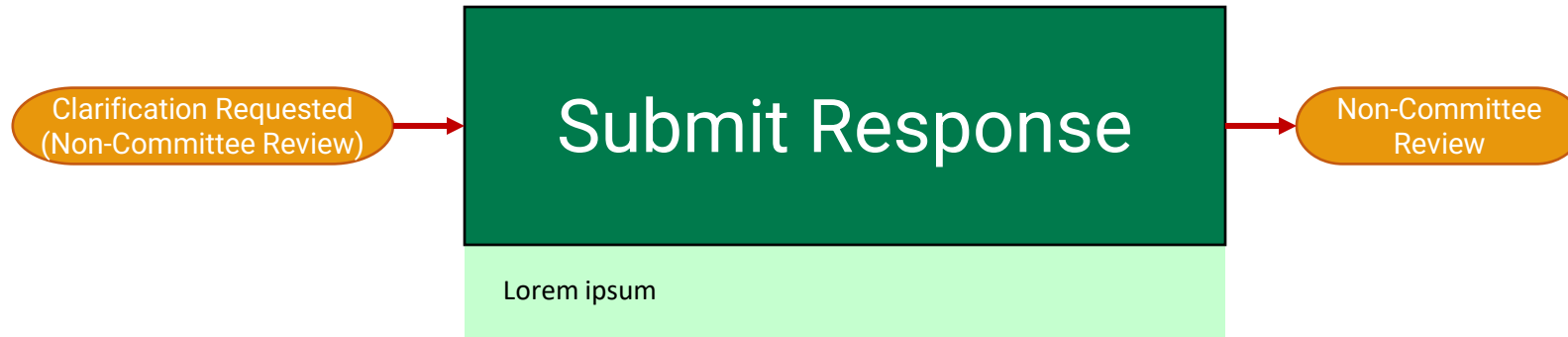
- [Submit Response](#)
- [Assign Designated Reviewer](#)
- [Assign Staff Reviewer](#)
- [Discard](#)
- [Retract](#)

Available Non-Workflow Actions

- Assign Coordinator
- Assign Staff Reviewer
- Copy Submission
- Correspond with External IRB
- Create Ancillary Review
- Create Task
- Create Related Project
- Edit Pre-Review
- Manage Access
- Manage Participating Sites
- Manage Relationships
- Submit Ancillary Review

Note: Some actions are dependent upon a related pending task or require specific user credentials.

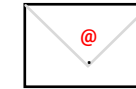
Roles & Project Assignments			
Principal Investigator	✓	✓	✓
PI Proxy	✓	✓	✓
Primary Contact	✓	✓	✓
Study Team Member	✓	✓	
Assigned IRB Coordinator	✓		
IRB Director	✓		
Designated Reviewer	✓		
Staff Reviewer	✓		
Ancillary Reviewer	✓		✓



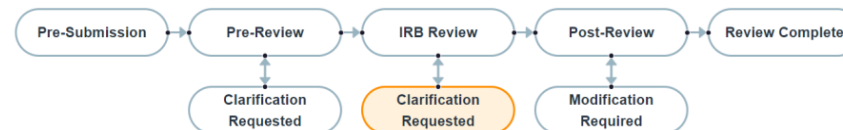
Who can execute this action

- Principal Investigator
- PI Proxy

Notifications Generated



- One of these persons will receive a notification depending on the path of the submission:
- Assigned IRB Coordinator
 - Assigned Designated Reviewer
 - Assigned Staff Review



States where this action is found

- [Approved](#)
- [Not Human Research](#)
- [Human Research, Not Engaged](#)
- [Non-Committee Review](#)
- [Post-Review](#)
- [Terminated](#)
- [Suspended](#)

Who can execute this action

- IRB Director
- Assigned IRB Coordinator
- Committee Administrator
- Assigned Designated Reviewer

Submit Designated Review

This action records the designated review of the submission.

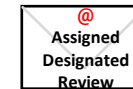
This action is available when a designated reviewer has been assigned.

Determinations: This action lets the user select a submission determination, which affects the state change after Post-Review.

- Exempt
- Human Research, Not Engaged
- Modifications Required
- Not Human Research

Post-Review

Notifications Generated



Assigned Designated Reviewer





Key

Actions Leading to This State

- [Assign to Committee Review](#)
- [Assign to Meeting](#)

Committee Review

From *Submit Committee Review* action, the **Committee Review Valid Determinations** are:

- Approved
- Modifications required to secure approval
- Human Research, Not Engaged
- Not Human Research
- Deferred
- Disapproved

Outcome can also be “Tabled”

Submit Committee Review action is available once the review has been assigned to a meeting.

Note: Committee Review does not have a *Request for Clarification* loop.

Actions Available at This State

- [Assign to Meeting](#)
- [Assign to Non-Committee Review](#)
- [Discard](#)
- [Retract](#)
- [Submit Committee Review](#)

Available Non-Workflow Actions

- Add Related Submission
- Add Review Comments¹
- Assign Coordinator
- Assign Reviewers
- Assign to Meeting
- Copy Submission
- Create Ancillary Review
- Create Related Project
- Create Task
- Edit Pre-Review
- Manage Access
- Manage Participating Sites²
- Manage Relationships
- Remove from Agenda¹
- Submit Ancillary Review

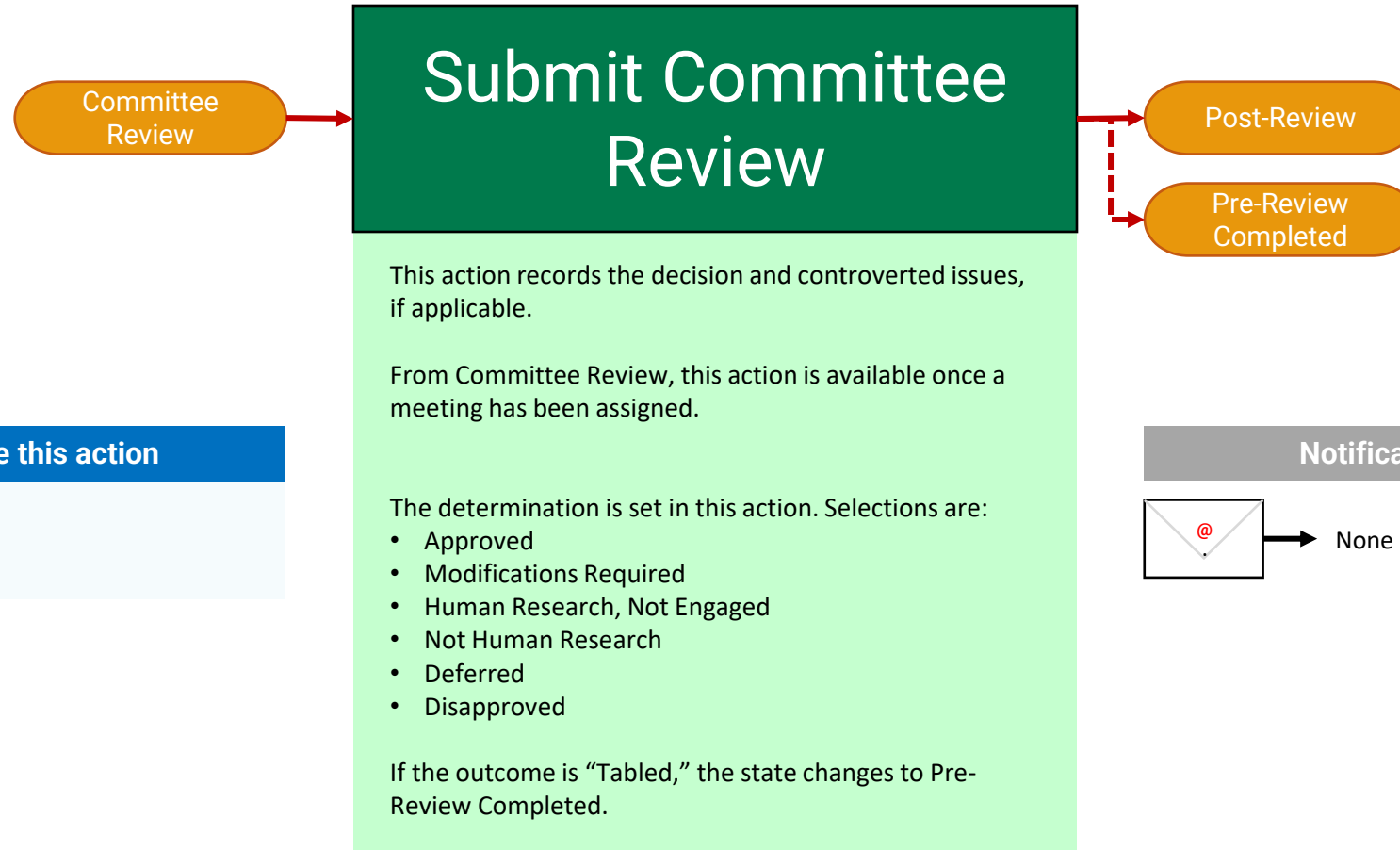
¹ Available only after the submission is assigned to a meeting

² Applies to sIRB submissions

Note: Some actions are dependent upon a related pending task or require specific user credentials.

Roles & Project Assignments

			
Principal Investigator	✓		✓
PI Proxy	✓		✓
Primary Contact	✓		✓
Study Team Member	✓		
Assigned IRB Coordinator	✓		
IRB Director	✓		
Designated Reviewer	✓		
Staff Reviewer	✓		
Ancillary Reviewer	✓		✓



Who can execute this action

- IRB Director
- Assigned IRB Coordinator
- Committee Manager



Actions Leading to This State

- [Review Required Modifications](#)
- [Submit Committee Review](#)
- [Submit Designated Review](#)
- [Submit Staff Review](#)

Post-Review

Note: The *Review Required Actions* action is available if the determination is “Modifications Required”.

Actions Available at This State

- [Submit Committee Review](#)
- Submit Designated Review
- Submit Staff Review
- Send Letter

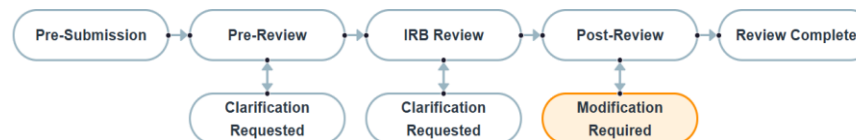
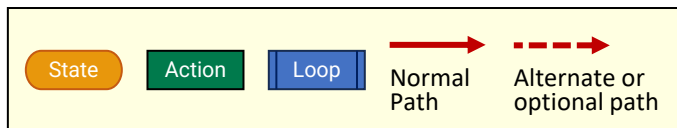
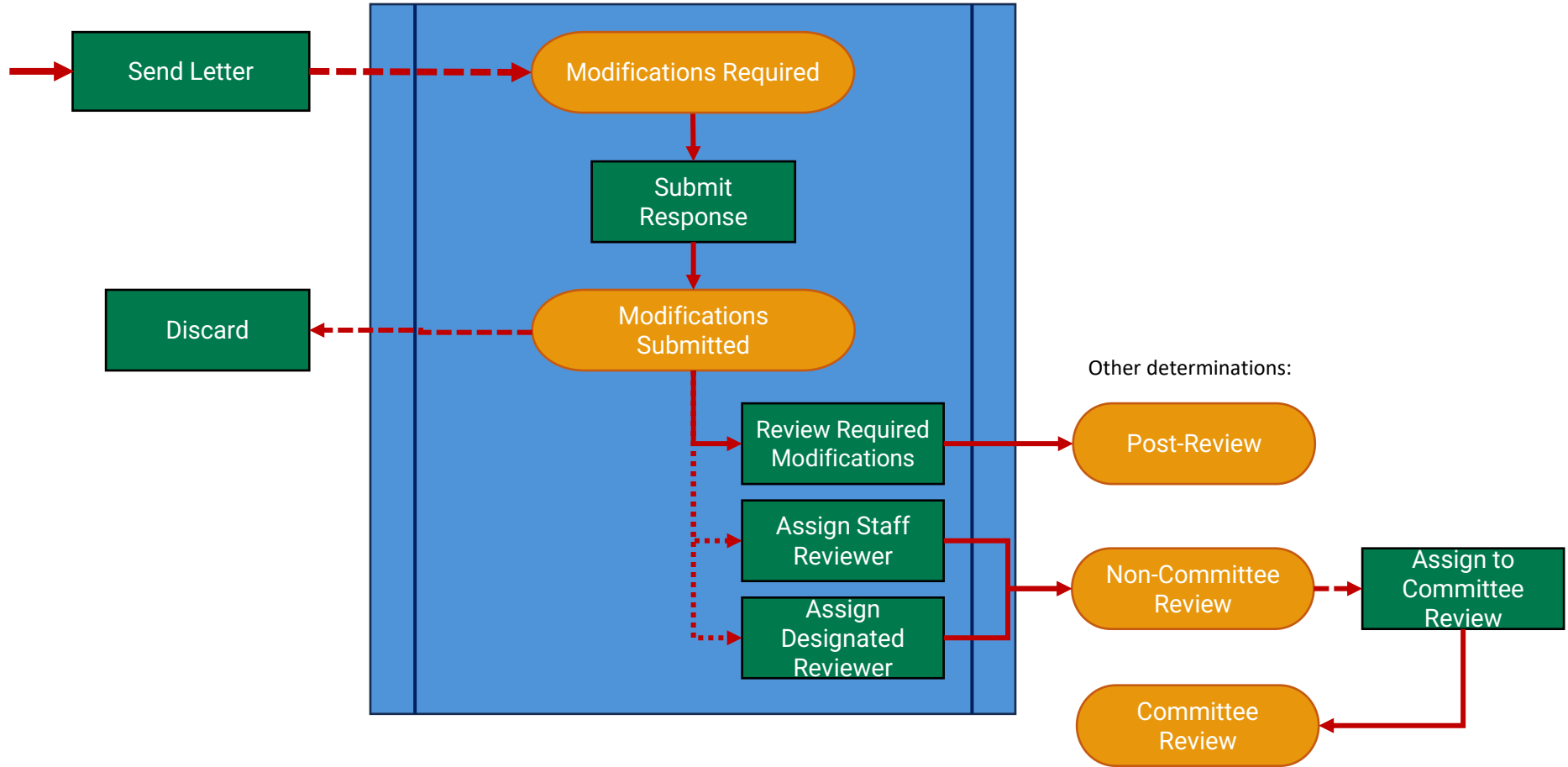
Roles / Project Assignment

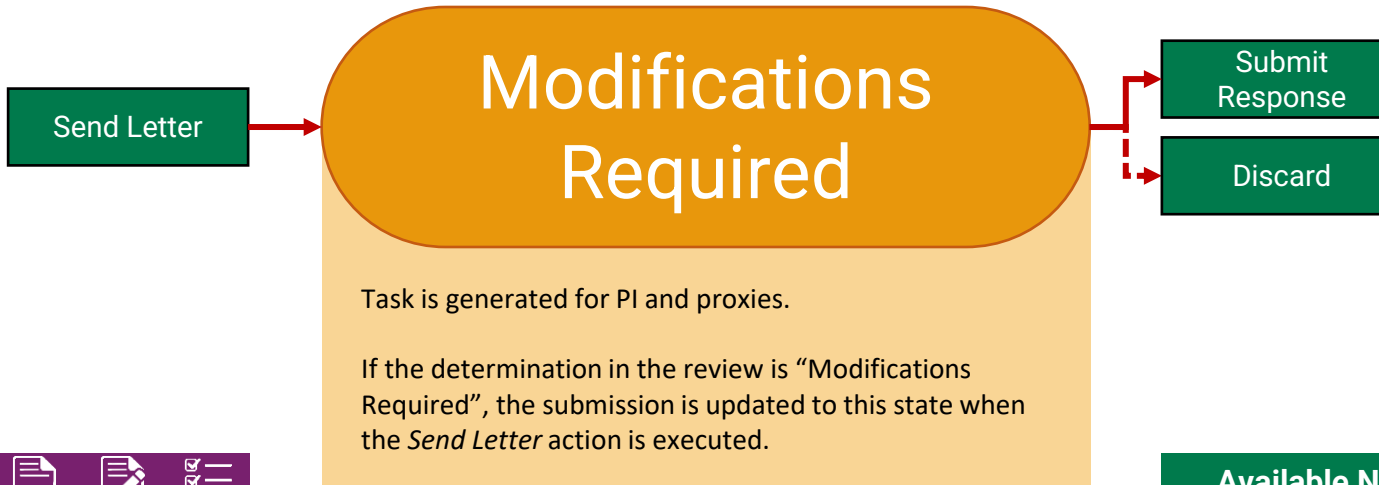
Principal Investigator	✓	✓	✓
PI Proxy	✓	✓	✓
Primary Contact	✓	✓	✓
Study Team Member	✓	✓	
Assigned IRB Coordinator	✓		
IRB Director	✓		
Ancillary Reviewer	✓		✓

Available Non-Workflow Actions

- Add Related Submission (*RNI workflow*)
- Assign Coordinator
- Bypass Ancillary Block
- Copy Submission
- Create Ancillary Review
- Create Related Project
- Create Task
- Edit Pre-Review
- Finalize Documents
- Manage Access
- Manage Participating Sites (sIRB submissions only)
- Manage Relationships
- Prepare Letter
- Submit Ancillary Review

Note: Some actions are dependent upon a related pending task or require specific user credentials.



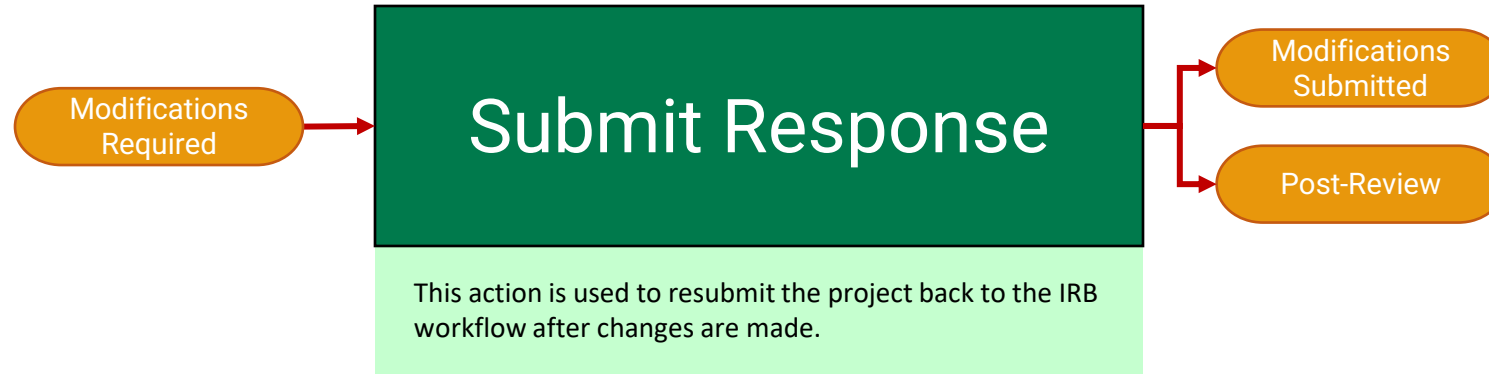


<u>Roles & Project Assignments</u>			
Principal Investigator	✓	✓	✓
PI Proxy	✓	✓	✓
Primary Contact	✓	✓	✓
Study Team Member	✓	✓	
Assigned IRB Coordinator	✓	✓	
IRB Director	✓	✓	
Designated Reviewer	✓		
Staff Reviewer	✓		
Ancillary Reviewer	✓		✓

Available Non-Workflow Actions

- Assign Coordinator
- Copy Submission
- Create Ancillary Review
- Create Related Project
- Create Task
- Edit Pre-Review
- Manage Access
- Manage Participating Sites
- Manage Relationships
- Submit Ancillary Review

Note: Some actions are dependent upon a related pending task or require specific user credentials.



Who can execute this action




- Principal Investigator
- PI Proxy
- Primary Contact
- Additional Editor

Notifications Generated

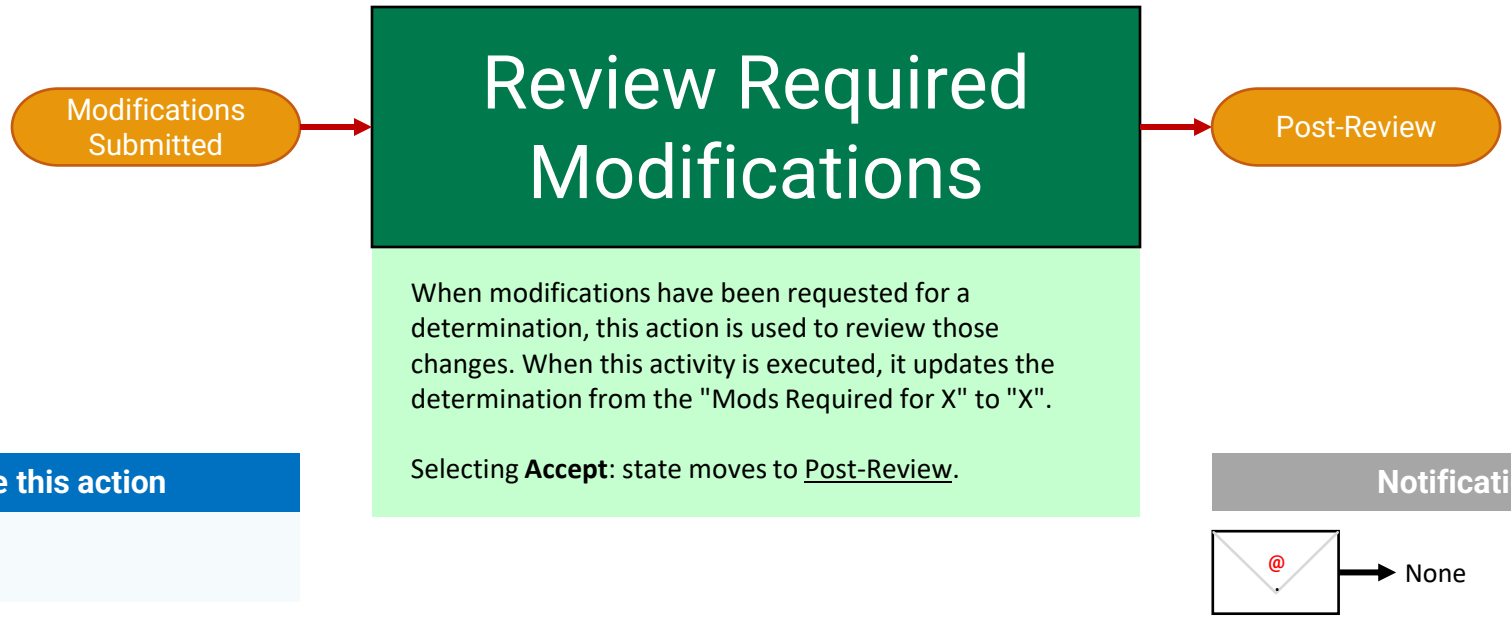


→ Committee Chair
Assigned IRBC



<u>Roles & Project Assignments</u>			
Principal Investigator	✓		✓
PI Proxy	✓		✓
Primary Contact	✓		✓
Study Team Member	✓		
Assigned IRB Coordinator	✓		
IRB Director	✓		
Designated Reviewer	✓		
Staff Reviewer	✓		
Ancillary Reviewer	✓		✓

<u>Available Non-Workflow Actions</u>
<ul style="list-style-type: none"> Assign Coordinator Copy Submission Create Ancillary Review Create Related Project Create Task Edit Pre-Review Manage Access Manage Participating Sites Manage Relationships Submit Ancillary Review
<p>Note: Some actions are dependent upon a related pending task or require specific user credentials.</p>



States where this action is found

- [Acknowledged](#)
- [Active](#)
- [Approved](#)
- [Closed](#)
- [Complete](#)
- [Deferred](#)
- [Disapproved](#)
- [External IRB Approved](#)
- [Inactive](#)
- [Human Research, Not Engaged](#)
- [Lapsed](#)
- [Not Human Research](#)
- [Post-Review](#)
- [Suspended](#)
- [Terminated](#)

Send Letter

This action sends the correspondence letter to the study team with the official IRB decision.

This action must be preceded by the *Prepare Letter* action.

The IRB determination configures the follow-on state and the automated notification.

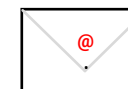
If Continuing Review (CR) is given an approval determination and the first four research milestones are met, the parent study transitions to [Closed](#).

Who can execute this action

- IRB Director
- Assigned IRB Coordinator

Determination & State Transition	Notification sent to:
Acknowledged	PI, PI Proxy
Approved	PI, PI Proxy, Primary Contact
Complete	PI, PI Proxy, Primary Contact
Deferred	PI, PI Proxy
Disapproved	Assigned IRB Coordinator
Exempt	PI, PI Proxy
Human Research, Not Engaged	PI, PI Proxy, Primary Contact
Modifications Required	Committee Chairs, Assigned IRB Coordinator
Not Human Research	PI, PI Proxy, Primary Contact
Retracted	PI, PI Proxy
Tabled (Pre-Review Completed)	PI, PI Proxy




Notifications Generated



Recipient depends on the determination

End States

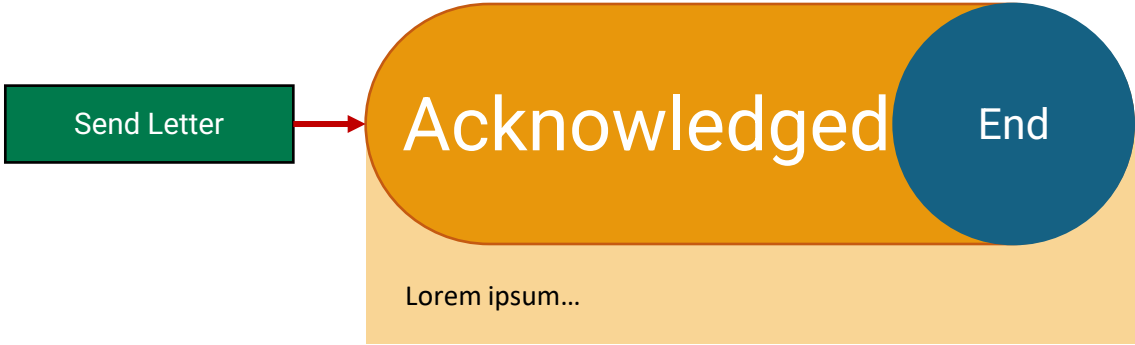





Roles & Project Assignments			
Principal Investigator	✓		✓
PI Proxy	✓		✓
Primary Contact	✓		✓
Study Team Member	✓		
Assigned IRB Coordinator	✓		
IRB Director	✓		
Designated Reviewer	✓		
Staff Reviewer	✓		
Ancillary Reviewer	✓		✓

Available Non-Workflow Actions

- Assign Coordinator
- Correspond with External IRB
- Create Task

Note: Some actions are dependent upon a related pending task or require specific user credentials.



Roles & Project Assignments			
Principal Investigator	✓		✓
PI Proxy	✓		✓
Primary Contact	✓		✓
Study Team Member	✓		
Assigned IRB Coordinator	✓		
IRB Director	✓		
Designated Reviewer	✓		
Staff Reviewer	✓		
Ancillary Reviewer	✓		✓




Available Non-Workflow Actions

- Assign Coordinator
- Create Ancillary Review
- Create Related Project
- Copy Submission
- Create Related Project
- Create Task
- Manage Ancillary Reviews
- Manage Relationship
- Prepare Letter
- Report New Information

Note: Some actions are dependent upon a related pending task or require specific user credentials.



Roles & Project Assignments

			
Principal Investigator	✓		✓
PI Proxy	✓		✓
Primary Contact	✓		✓
Study Team Member	✓		
Assigned IRB Coordinator	✓		
IRB Director	✓		
Designated Reviewer	✓		
Staff Reviewer	✓		
Ancillary Reviewer	✓		✓

Available Non-Workflow Actions

- Submit Ancillary Review

Note: Some actions are dependent upon a related pending task or require specific user credentials.



Send Letter

Approved

This is the final state in the Initial Study happy path.

If the determination in the review is “Approved”, the submission is updated to this state when the *Send Letter* action is executed.

Note: This state can automatically transition to [Lapsed](#) due to a lapsed deadline.

Actions Available at This State

- [Close Study \(Admin\)](#)
- [Create CR/Mod \(CR/Mod workflow\)](#)
- [Create Study Closure](#)
- [Create Reportable New Information \(RNI workflow\)](#)
- [Discard](#)
- [Report New Information \(RNI workflow\)](#)
- [Send Letter](#) (after Prepare Letter)
- [Submit Committee Review](#)
- [Submit Designated Review](#)
- [Suspend](#)
- [Terminate](#)

Available Non-Workflow Actions

- Assign Coordinator
- Copy Submission
- Create Ancillary Review
- Create Related Project
- Create Task
- Prepare Letter
- Submit Ancillary Review

Note: Some actions are dependent upon a related pending task or require specific user credentials.

Roles & Project Assignments



Principal Investigator

✓

✓

PI Proxy

✓

✓

Primary Contact

✓

✓

Study Team Member

✓

Assigned IRB Coordinator

✓

IRB Director

✓

Designated Reviewer

✓

Staff Reviewer

✓

Ancillary Reviewer

✓

✓

States where this action is found

- [Approved](#)
- [Lapsed](#)
- [Suspended](#)
- [External IRB Approved](#)

Close Study (Admin)

This action administratively closes a study. All open follow-on submissions (except RNIs) moves to the state of Discarded.

Closed

End

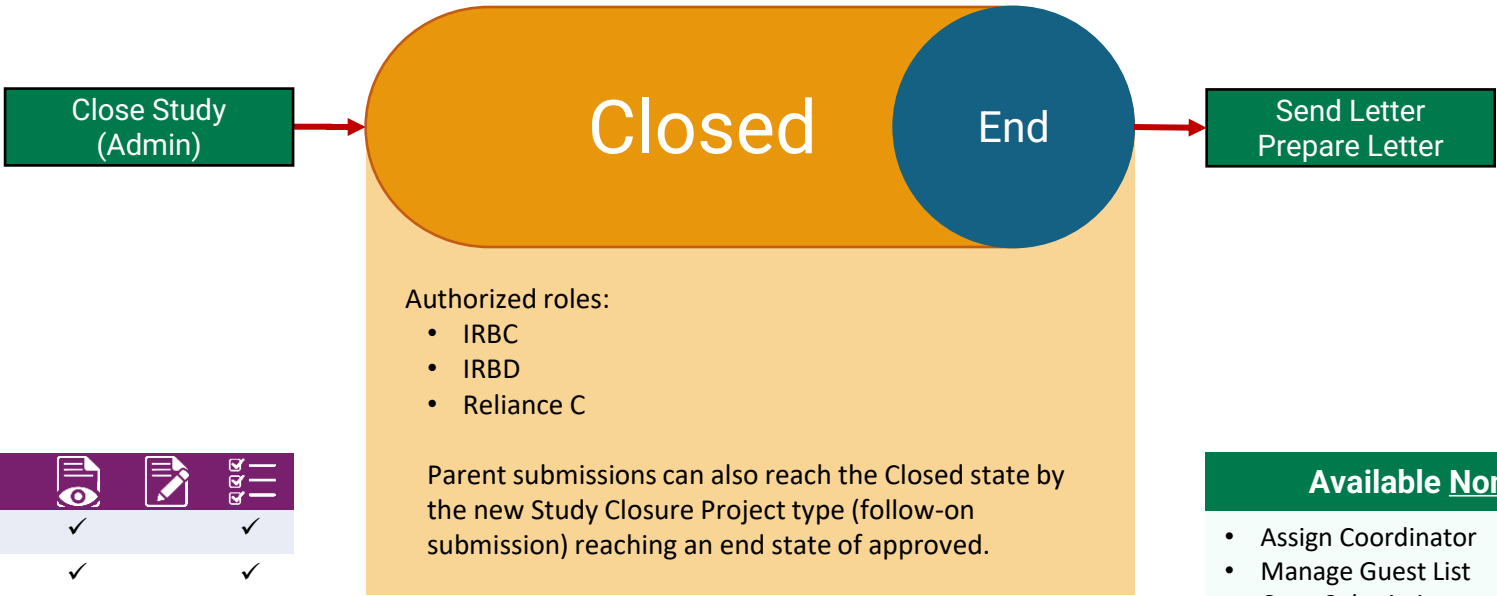
Who can execute this action

- IRB Director
- Assigned IRB Coordinator

Notifications Generated



PI
PI Proxy
Primary Contact






Roles & Project Assignments			
Principal Investigator	✓		✓
PI Proxy	✓		✓
Primary Contact	✓		✓
Study Team Member	✓		
Assigned IRB Coordinator	✓		
IRB Director	✓		
Designated Reviewer	✓		
Staff Reviewer	✓		
Ancillary Reviewer	✓		✓

- Available Non-Workflow Actions**
- Assign Coordinator
 - Manage Guest List
 - Copy Submission
 - Create Ancillary Review
 - Create Related Project
 - Manage Relationships
 - Create Task



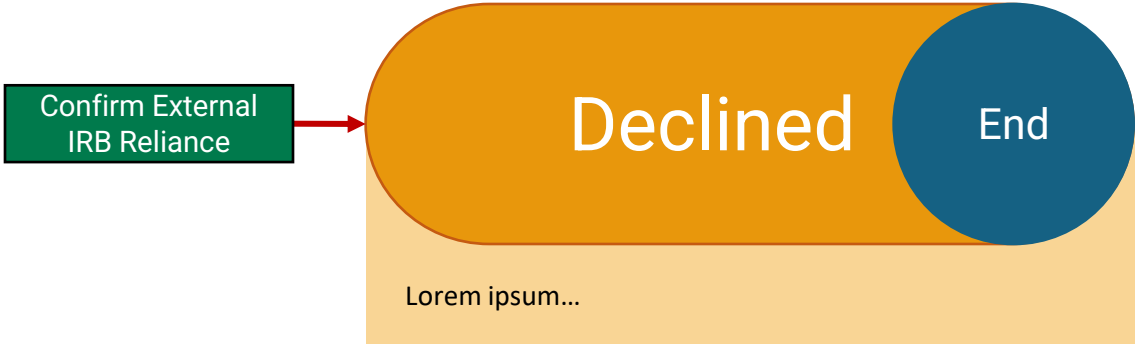
Roles & Project Assignments

			
Principal Investigator	✓		✓
PI Proxy	✓		✓
Primary Contact	✓		✓
Study Team Member	✓		
Assigned IRB Coordinator	✓		
IRB Director	✓		
Designated Reviewer	✓		
Staff Reviewer	✓		
Ancillary Reviewer	✓		✓




Available Non-Workflow Actions

- TBD

Note: Some actions are dependent upon a related pending task or require specific user credentials.



Roles & Project Assignments

			
Principal Investigator	✓		✓
PI Proxy	✓		✓
Primary Contact	✓		✓
Study Team Member	✓		
Assigned IRB Coordinator	✓		
IRB Director	✓		
Designated Reviewer	✓		
Staff Reviewer	✓		
Ancillary Reviewer	✓		✓

Available Non-Workflow Actions

- Assign Coordinator
- Manage Guest List
- Copy Submission
- Create Task

[illegible]

¹ Lorem ipsum

² Lorem ipsum

³ Lorem ipsum

Available Non-Workflow Actions

- Submit Ancillary Review

Note: Some actions are dependent upon a related pending task or require specific user credentials.



Send Letter




Disapproved

Actions Available at This State

Send Letter

Disapproved

- [Submit Response \(Pre-Review\)](#)
- [Submit Committee Review](#)
- [Submit Designated Review](#)
- [Submit for Review](#)
- [Discard](#)

Roles & Project Assignments			
Principal Investigator	✓	✓	✓
PI Proxy	✓	✓	✓
Primary Contact	✓	✓	✓
Study Team Member	✓	✓	
Assigned IRB Coordinator	✓	✓	
IRB Director	✓	✓	
Designated Reviewer	✓		
Staff Reviewer	✓		
Ancillary Reviewer	✓		✓

Available Non-Workflow Actions

- Copy Submission
- Create Ancillary Review
- Create Related Task
- Create Task
- Manage Access
- Manage Relationships
- Submit Ancillary Review

Note: Some actions are dependent upon a related pending task or require specific user credentials.

States where this action is found

- [Awaiting Site Materials](#)
- [Clarification Requested \(Non-Committee Review\)](#)
- [Clarification Requested \(Pre-Review\)](#)
- [Committee Review](#)
- [Deferred](#)
- [Disapproved](#)
- [Invitation Pending](#)
- [Modifications Required](#)
- [Non-Committee Review](#)
- [Pending sIRB Review](#)
- [Pre-Review](#)
- [Pre-Review Completed](#)
- [Pre-Submission](#)
- [Updating Study](#)

Discard

Permanently remove the submission.

Discarded

End

Who can execute this action

- Study Team Member
- IRB Coordinator
- IRB Director


Notifications Generated



Assigned IRBC
Principal Investigator
PI Proxy
Primary Contact



Roles & Project Assignments

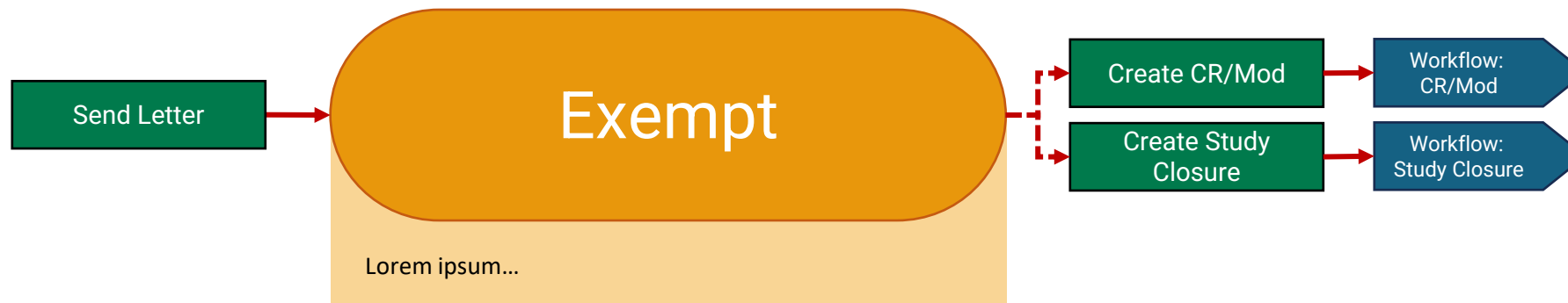
		
✓	✓	✓
T	B	D

¹ Lorem ipsum
² Lorem ipsum
³ Lorem ipsum

Available Non-Workflow Actions

- Copy Submission
- Create Related Project
- Manage Access
- Manage Participating Sites
- Manage Relationships

Note: Some actions are dependent upon a related pending task or require specific user credentials.

[illegible]

Available Non-Workflow Actions

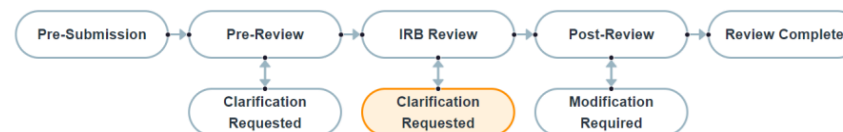
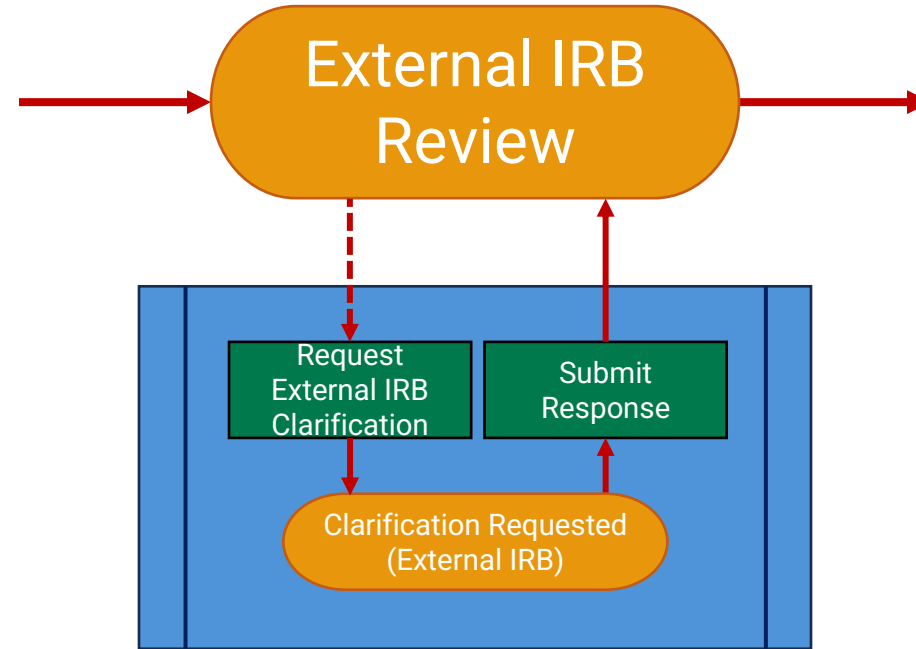
- Create Ancillary Review
- Create Related Project
- Create Task
- Manage Relationships

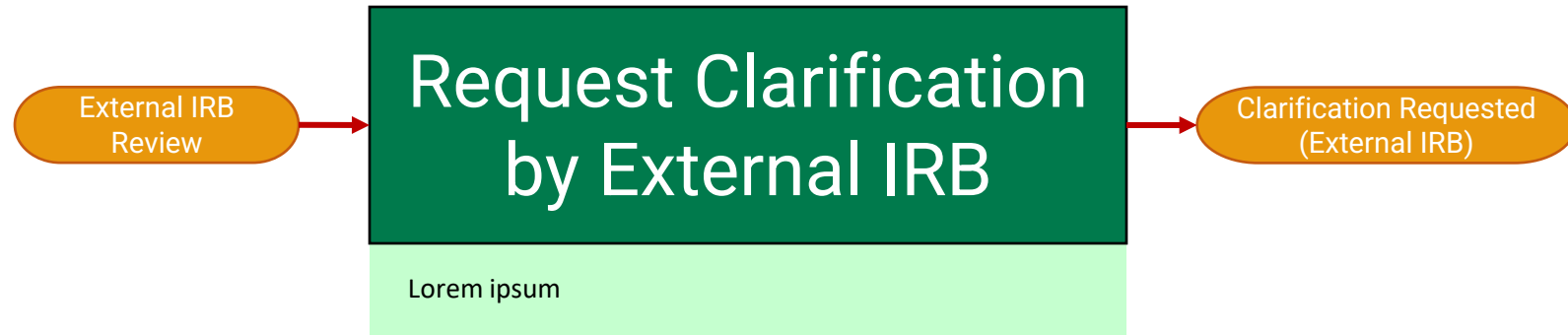
Note: Some actions are dependent upon a related pending task or require specific user credentials.

¹ Lorem ipsum

² Lorem ipsum

³ Lorem ipsum

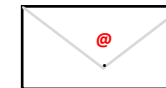




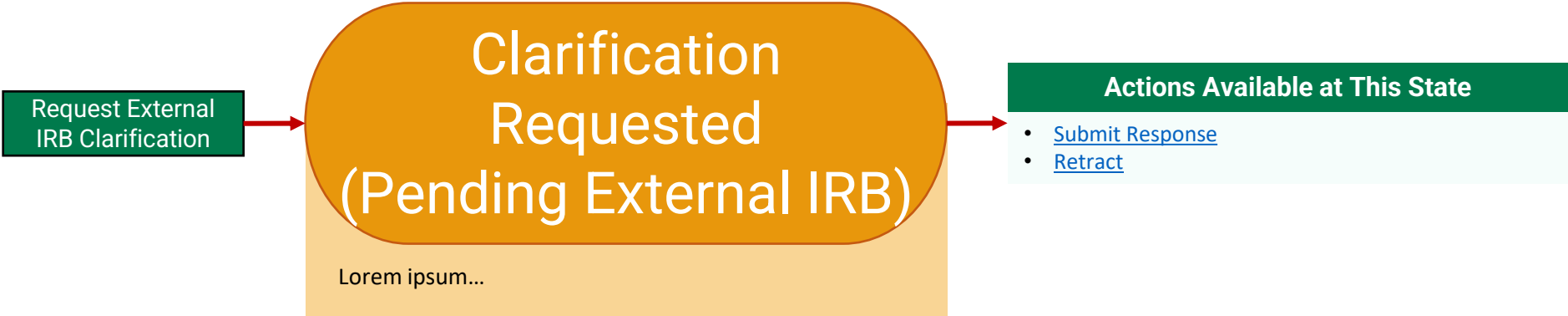
Who can execute this action




- IRB Director
- Assigned IRB Coordinator

Notifications Generated



Principal Investigator
PI Proxy



Roles & Project Assignments			
TBD	✓	✓	✓

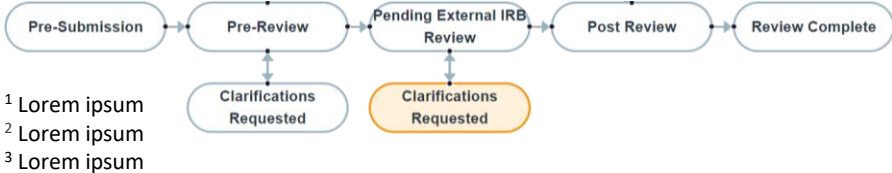
Available Non-Workflow Actions

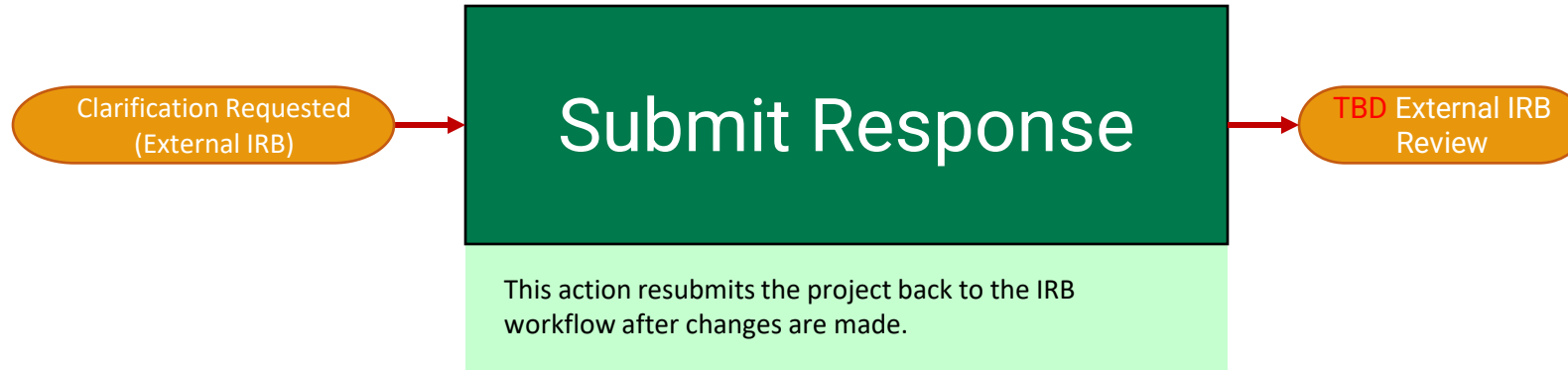
• Assign Coordinator

• Correspond with External IRB

• Create Task

Note: Some actions are dependent upon a related pending task or require specific user credentials.



**Who can execute this action**

- Principal Investigator
- PI Proxy

Notifications Generated

Assigned IRB Coordinator



Roles & Project Assignments



Principal Investigator

✓

✓

PI Proxy

✓

✓

Primary Contact

✓

✓

Study Team Member

✓

Assigned IRB Coordinator

✓

IRB Director

✓

Designated Reviewer

✓

Staff Reviewer

✓

Ancillary Reviewer

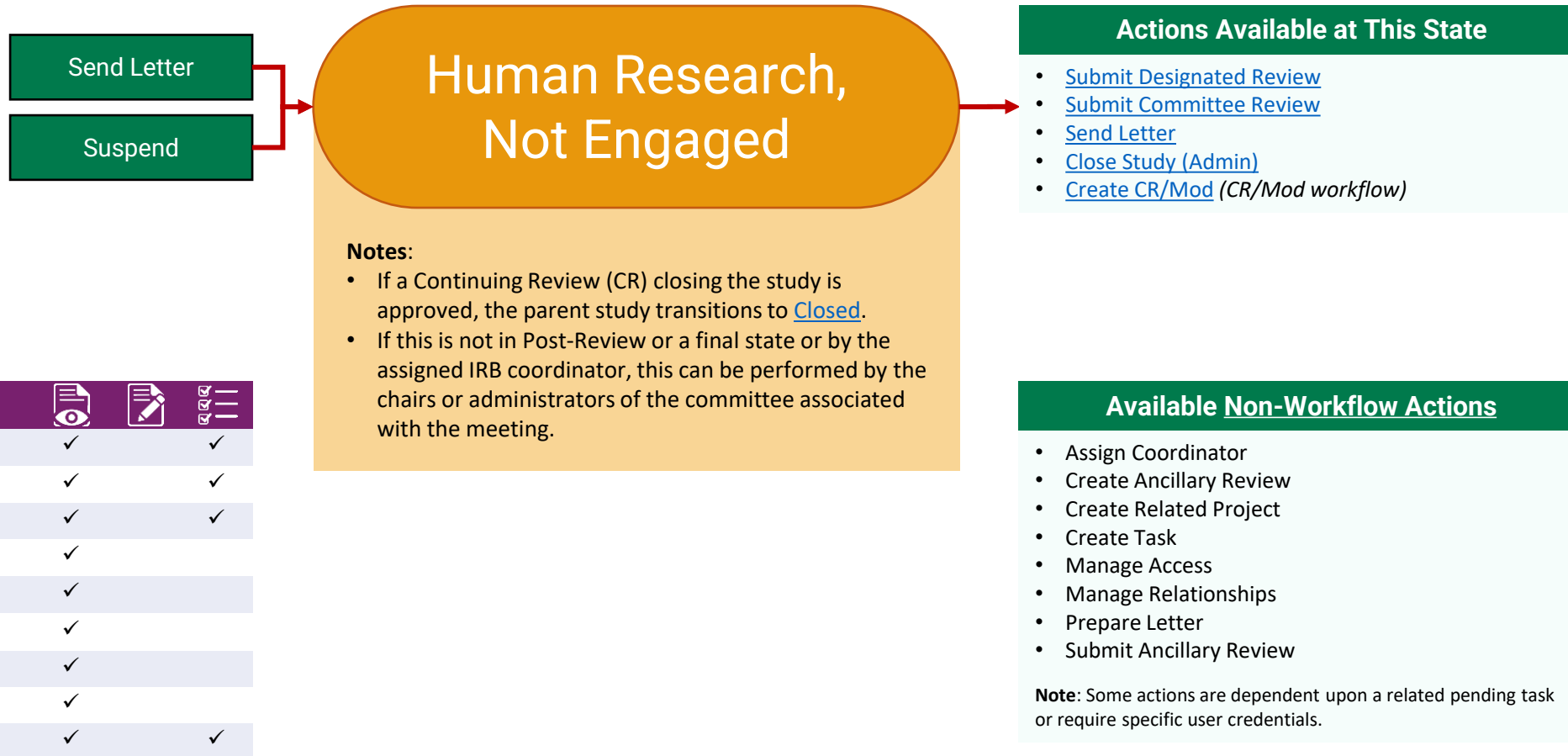
✓

✓

Available Non-Workflow Actions

- Create Related Project
- Create Task
- Manage Relationships
- Submit Ancillary Review

Note: Some actions are dependent upon a related pending task or require specific user credentials.

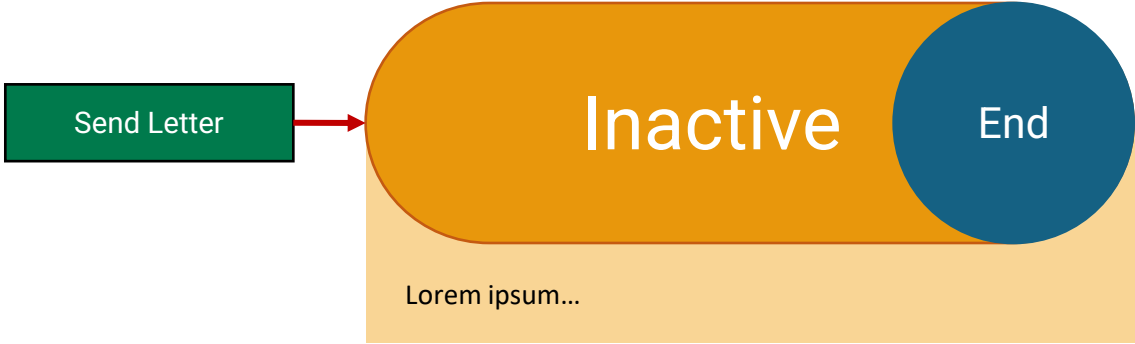





Roles & Project Assignments			
Principal Investigator	✓		✓
PI Proxy	✓		✓
Primary Contact	✓		✓
Study Team Member	✓		
Assigned IRB Coordinator	✓		
IRB Director	✓		
Designated Reviewer	✓		
Staff Reviewer	✓		
Ancillary Reviewer	✓		✓



Roles & Project Assignments			
Principal Investigator	✓		✓
PI Proxy	✓		✓
Primary Contact	✓		✓
Study Team Member	✓		
Assigned IRB Coordinator	✓		
IRB Director	✓		
Designated Reviewer	✓		
Staff Reviewer	✓		
Ancillary Reviewer	✓		✓

Available <u>Non-Workflow</u> Actions
<ul style="list-style-type: none">• Assign Coordinator• Copy Submission• Create Ancillary Review• Create Related Project• Create Task• Manage Access• Manage Relationships• Prepare Letter• Submit Ancillary Review
Note: Some actions are dependent upon a related pending task or require specific user credentials.



Roles & Project Assignments			
Principal Investigator	✓		✓
PI Proxy	✓		✓
Primary Contact	✓		✓
Study Team Member	✓		
Assigned IRB Coordinator	✓		
IRB Director	✓		
Designated Reviewer	✓		
Staff Reviewer	✓		
Ancillary Reviewer	✓		✓

Available Non-Workflow Actions

- Manage Ancillary Reviews
- Submit Ancillary Review

Note: Some actions are dependent upon a related pending task or require specific user credentials.



States that can advance to Lapsed

- [Approved](#)
- [Suspended](#)
- [Human Research, Not Engaged](#)

A state can also transition to Lapsed due to the automated process: *Continuing Review Deadline Passed*.

Lapsed

Lorem ipsum...

Actions Available at This State

- [Submit Designated Review](#)
- [Submit Committee Review](#)
- [Send Letter](#)
- [Close Study \(Admin\)](#)
- [Report New Information](#) (RNI Workflow)
- [Suspend](#)
- [Terminate](#)

Roles & Project Assignments



Principal Investigator

✓

✓

PI Proxy

✓

✓

Primary Contact

✓

✓

Study Team Member

✓

Assigned IRB Coordinator

✓

IRB Director

✓

Designated Reviewer

✓

Staff Reviewer

✓

Ancillary Reviewer

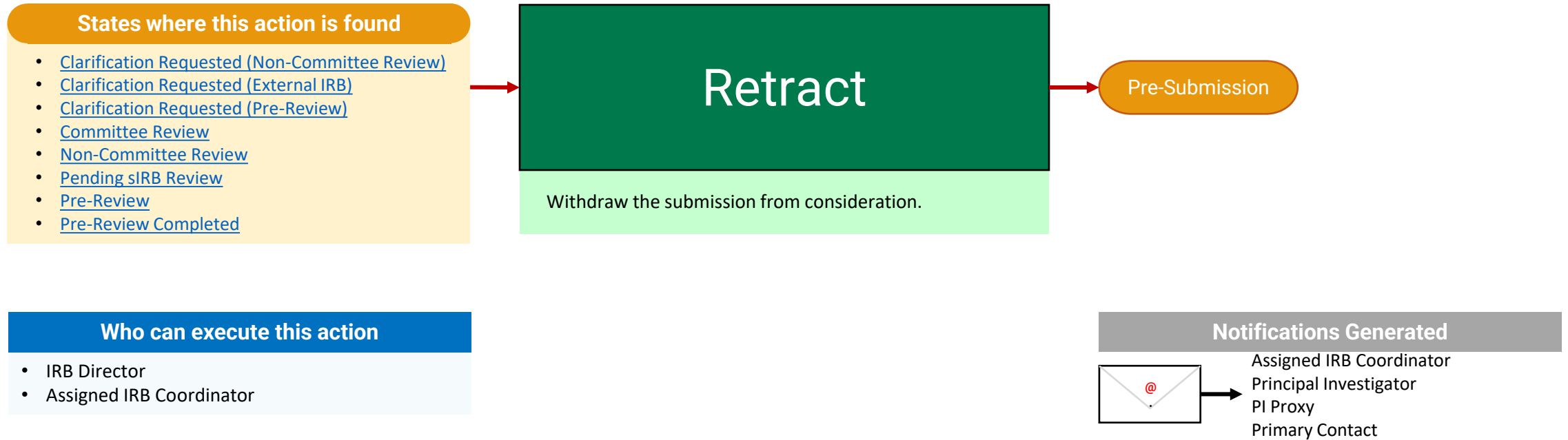
✓

✓




Available Non-Workflow Actions

- Assign Coordinator
- Bypass Ancillary Block
- Copy Submission
- Create Ancillary Review
- Create Related Project
- Create Task
- Manage Access
- Manage Participating Sites
- Manage Relationships
- Prepare Letter
- Submit Ancillary Review

Note: Some actions are dependent upon a related pending task or require specific user credentials.



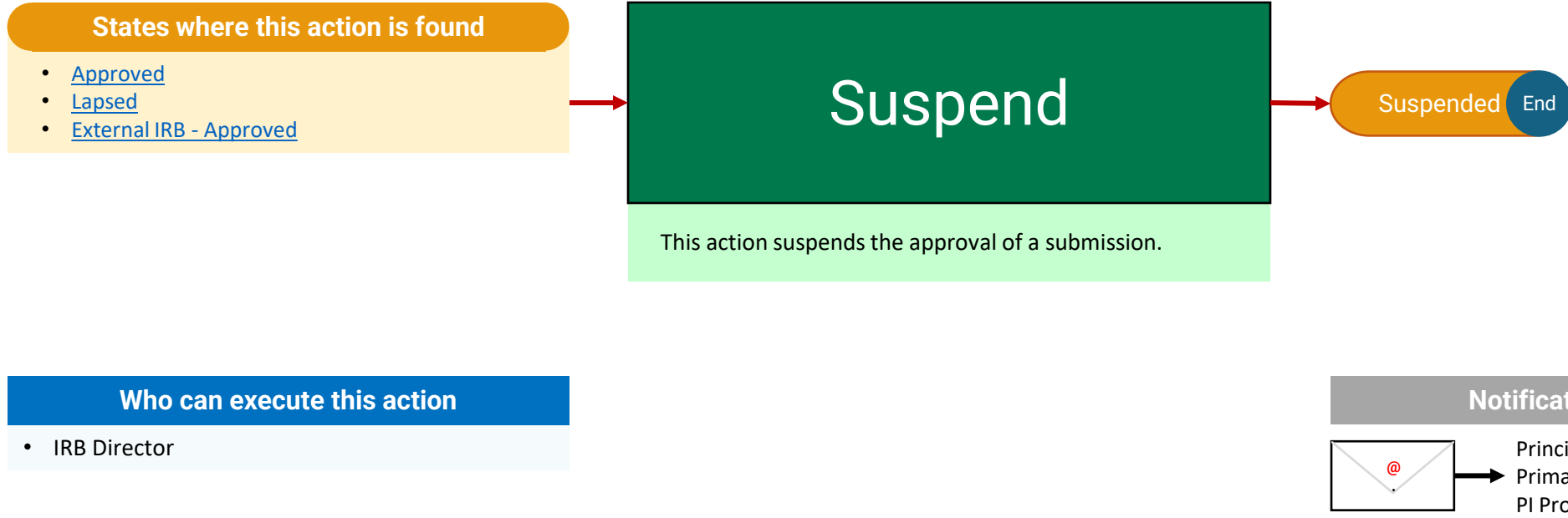


Roles & Project Assignments			
Principal Investigator	✓		✓
PI Proxy	✓		✓
Primary Contact	✓		✓
Study Team Member	✓		
Assigned IRB Coordinator	✓		
IRB Director	✓		
Designated Reviewer	✓		
Staff Reviewer	✓		
Ancillary Reviewer	✓		✓

Available Non-Workflow Actions

- TBD

Note: Some actions are dependent upon a related pending task or require specific user credentials.





Suspend

Suspended

Note: If the study state is Suspended but a Modification (MOD), Continuing Review (CR), or MOD/CR is approved, then the study transitions to Approved that the follow-on action ended on.

Note: A suspended submission can automatically transition to Lapsed due to a lapsed deadline.

Actions Available at This State




The following actions available from this state:

- [Close Study \(Admin\)](#)
- Human Research, Not Engaged**
- Not Human Research**
- [Create CR/Mod](#) (Create CR/Mod workflow)
- [Report New Information](#)
- [Submit Committee Review](#)
- [Submit Designated Review](#)
- [Send Letter](#)
- [Terminate](#)

Available Non-Workflow Actions

- Create Related Project
- Manage Access
- Manage Participating Sites
- Manage Relationships
- Submit Ancillary Review

Note: Some actions are dependent upon a related pending task or require specific user credentials.




Roles & Project Assignments			
			
	✓	✓	✓
	T	B	D

¹ Lorem ipsum

² Lorem ipsum

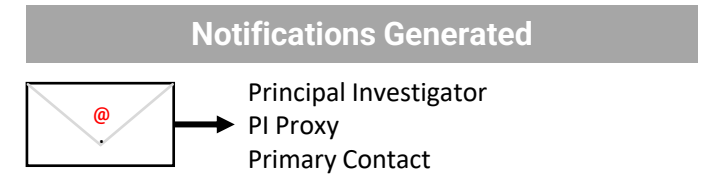
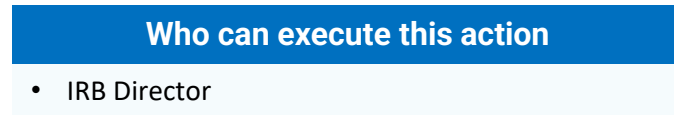
³ Lorem ipsum



Roles & Project Assignments			
Principal Investigator	✓		✓
PI Proxy	✓		✓
Primary Contact	✓		✓
Study Team Member	✓		
Assigned IRB Coordinator	✓		
IRB Director	✓		
Designated Reviewer	✓		
Staff Reviewer	✓		
Ancillary Reviewer	✓		✓

Available Non-Workflow Actions

Note: Some actions are dependent upon a related pending task or require specific user credentials.





States that can advance to Terminated

- [Approved](#)
- [External IRB Approved](#)
- [Suspended](#)
- [Lapsed](#)
- [Terminate](#)

Terminated

End

Lorem ipsum...

Actions Available at This State

- [Submit Designated Review](#)
- [Submit Committee Review](#)

Roles & Project Assignments



Principal Investigator

✓

✓

PI Proxy

✓

✓

Primary Contact

✓

✓

Study Team Member

✓

Assigned IRB Coordinator

✓

IRB Director

✓

Designated Reviewer

✓

Staff Reviewer

✓

Ancillary Reviewer

✓

✓

Available Non-Workflow Actions

- Submit Ancillary Review

Note: Some actions are dependent upon a related pending task or require specific user credentials.

States where this action is found

- [Clarification Requested \(Non-Committee Review\)](#)
- [Clarification Requested \(Pre-Review\)](#)
- [Committee Review](#)
- [Non-Committee Review](#)
- [Pending sIRB Review](#)
- [Pre-Review](#)
- [Pre-Review Completed](#)

Retract

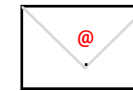
Lorem ipsum

Pre-Submission

Who can execute this action

- IRB Director

Notifications Generated



Principal Investigator
PI Proxy
Assigned IRB Coordinator



Roles & Project Assignments



Principal Investigator

✓

✓

PI Proxy

✓

✓

Primary Contact

✓

✓

Study Team Member

✓

Assigned IRB Coordinator

✓

IRB Director

✓

Designated Reviewer

✓

Staff Reviewer

✓

Ancillary Reviewer

✓




✓

Available Non-Workflow Actions

- Next

Note: Some actions are conditionally available based on user credentials or are dependent upon a related pending task.



Roles & Project Assignments			
Principal Investigator	✓		✓
PI Proxy	✓		✓
Primary Contact	✓		✓
Study Team Member	✓		
Assigned IRB Coordinator	✓		
IRB Director	✓		
Designated Reviewer	✓		
Staff Reviewer	✓		
Ancillary Reviewer	✓		✓

Available Non-Workflow Actions

- Submit Ancillary Review

Note: Some actions are dependent upon a related pending task or require specific user credentials.

Workflow: Continuing Review & Modification

This workflow creates an IRB Continuing Review or Modification study.

In a **Continuing Review (CR)**, the submission is created to extend the approval period while offering an opportunity for general oversight. The IRB is required to review certain studies at least annually.

In a **Modification (MOD)**, the original study is duplicated in a draft state and will contain the requested modifications. Once the draft study is approved, the modifications are applied to the original study.

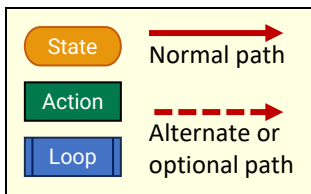
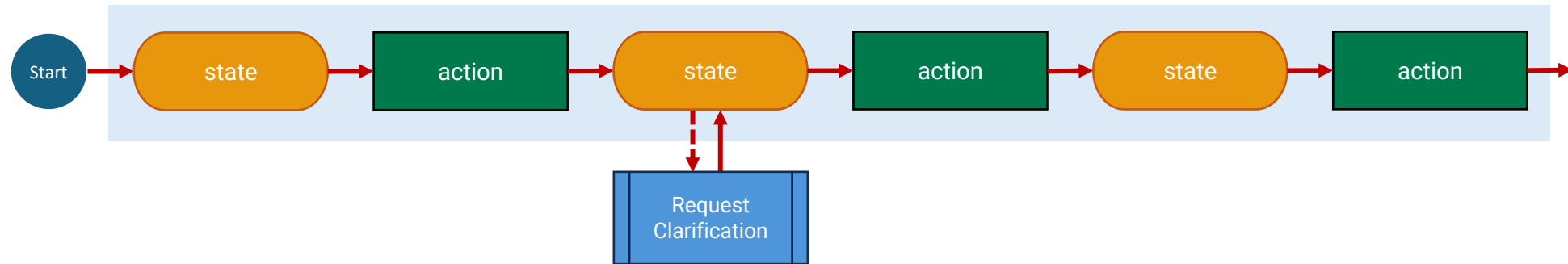


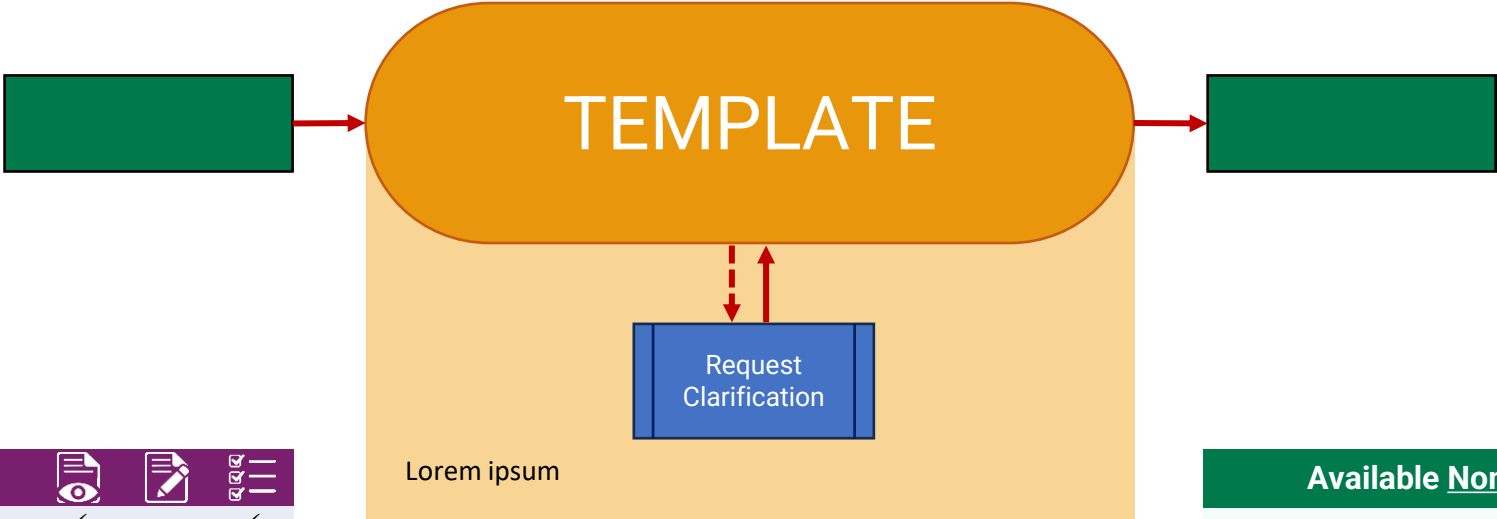
Workflow: Continuing Review (CR), Modification (MOD)



Initial Study:
Post-Review

Reportable New
Information





Roles & Project Assignments



Principal Investigator

✓

✓

PI Proxy

✓

✓

Primary Contact

✓

✓

Study Team Member

✓

Assigned IRB Coordinator

✓

IRB Director

✓

Designated Reviewer

✓

Staff Reviewer

✓

Ancillary Reviewer

✓

✓

Available Non-Workflow Actions

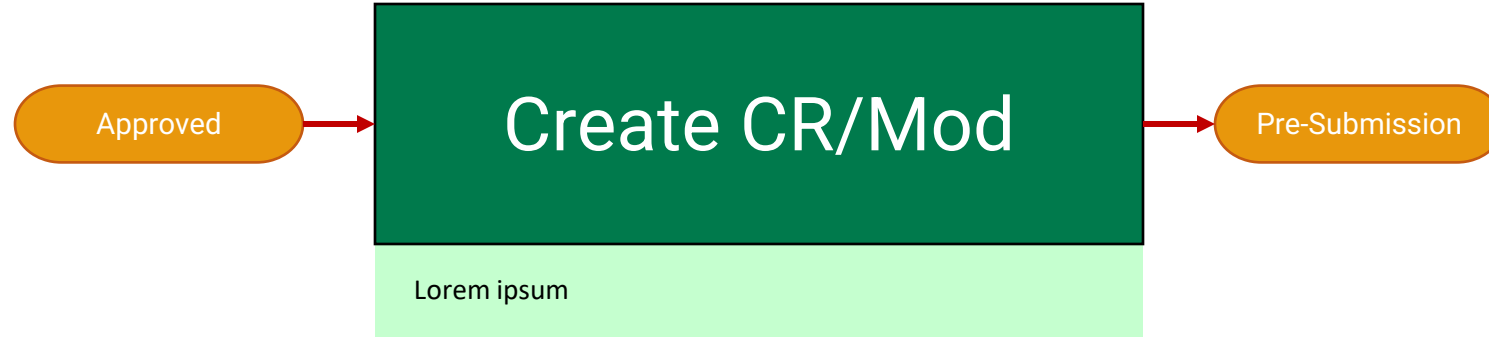
- Add Comment
- Add Participating Sites³
- Add Discussion
- Add Related Grant
- Assign Coordinator²
- Copy Submission
- Manage Tags
- Submit Ancillary Review¹

¹ Except Closed and Discarded

² Except Pre-Submission

³ Only for MSS studies - available after Pre-Review has been submitted

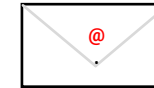
Note: Some actions are dependent upon a related pending task or require specific user credentials.



Who can execute this action

- IRB Director

Notifications Generated



None

Workflow: Reportable New Information

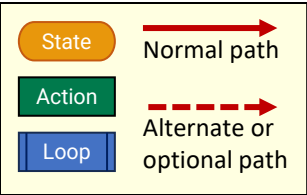
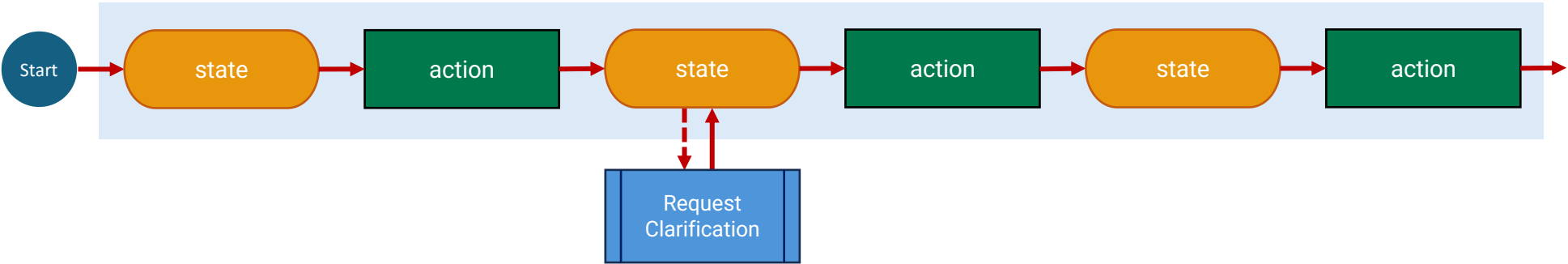
The **Reportable New Information (RNI)** workflow is used to report any significant updates or changes related to their submission. These reportable instances include a range of events that influence the research study's execution, participants' well-being, and the ethical dimensions associated with the research. An example of a reportable instance is an adverse event.

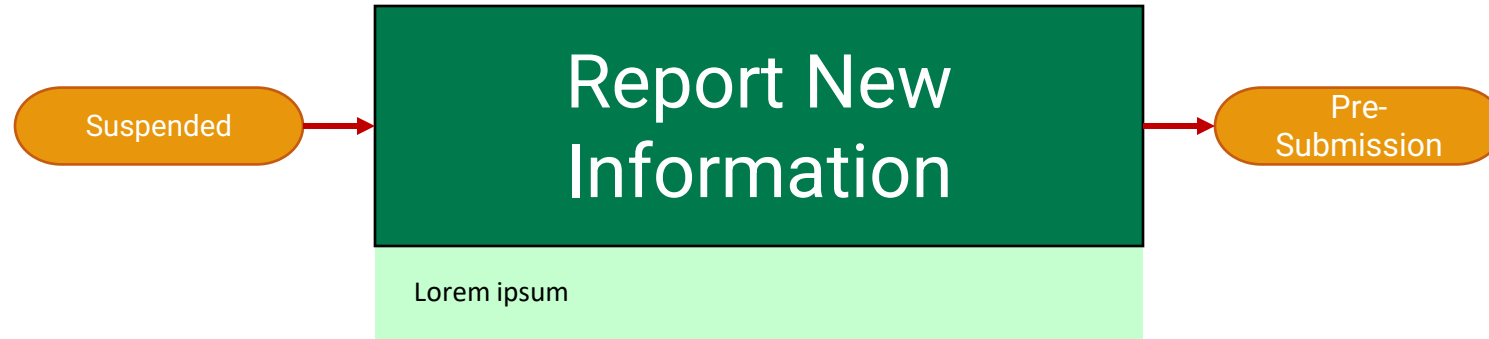




Continuing Review
& Modification

External
Single-Site

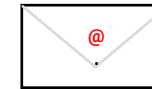




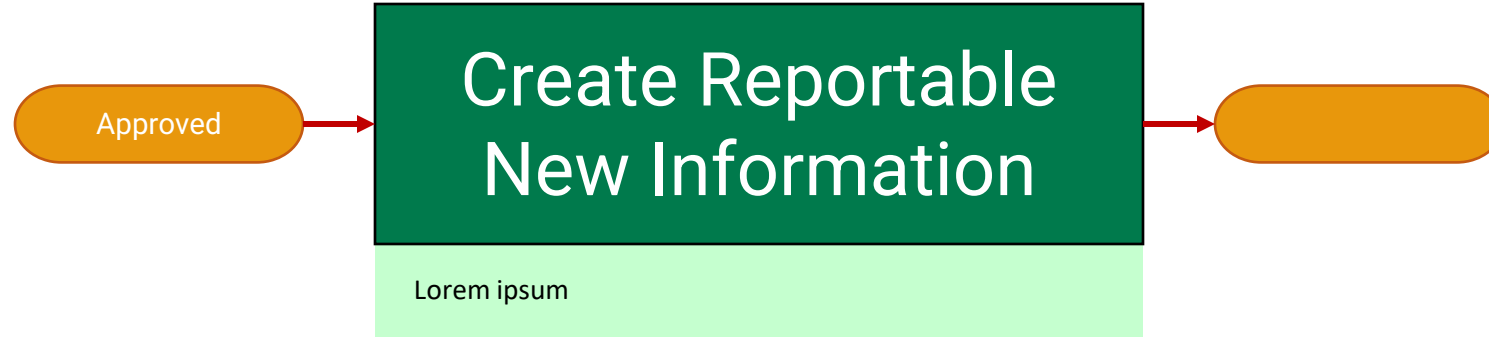
Who can execute this action

- Principal Investigator
- PI Proxy
- Assigned IRB Coordinator
- IRB Director

Notifications Generated



None



Who can execute this action

- TBD

Notifications Generated



TBD



States where this action is found

- [Action Submitted](#)
- [Post-Review](#)

Review Required Actions

This action validates the RNI actions that were completed as required.

Action Can Lead to These States

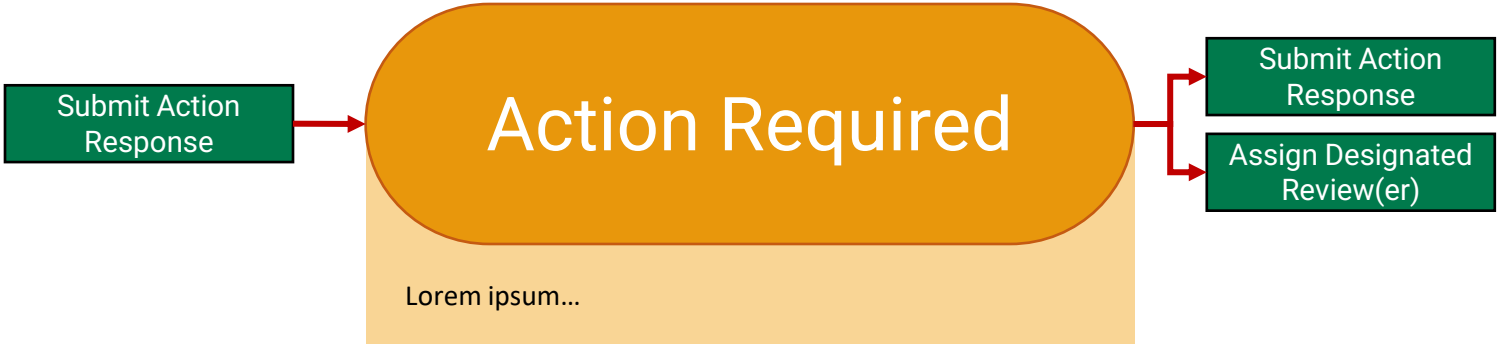
- [Post-Review](#)
- Action Required

Who can execute this action

- IRB Director
- Assigned IRB Coordinator
- Assigned Designated Reviewer

Notifications Generated



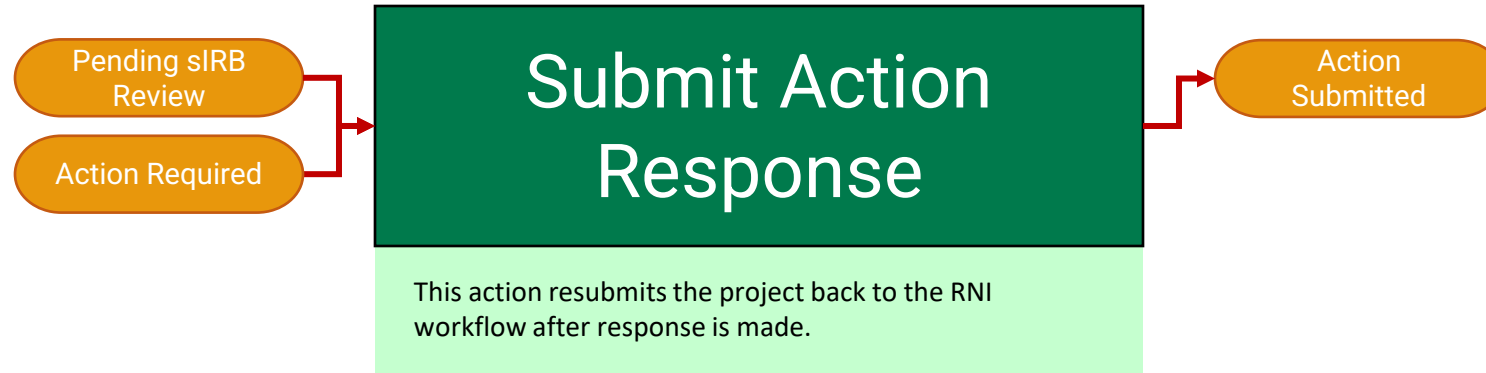


Roles & Project Assignments			
Principal Investigator	✓		✓
PI Proxy	✓		✓
Primary Contact	✓		✓
Study Team Member	✓		
Assigned IRB Coordinator	✓		
IRB Director	✓		
Designated Reviewer	✓		
Staff Reviewer	✓		
Ancillary Reviewer	✓		✓

Available Non-Workflow Actions

- Submit Ancillary Review

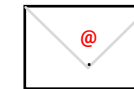
Note: Some actions are dependent upon a related pending task or require specific user credentials.



Who can execute this action

- Assigned IRB Coordinator
- Assigned Responsible Party
- Additional Editor
- Principal Investigator (of related studies)
- PI Proxy (of related studies)

Notifications Generated



Assigned IRB Coordinator
Assigned Responsible Party
Assigned Editor






Action Submitted

Lorem ipsum...

Actions Available at This State

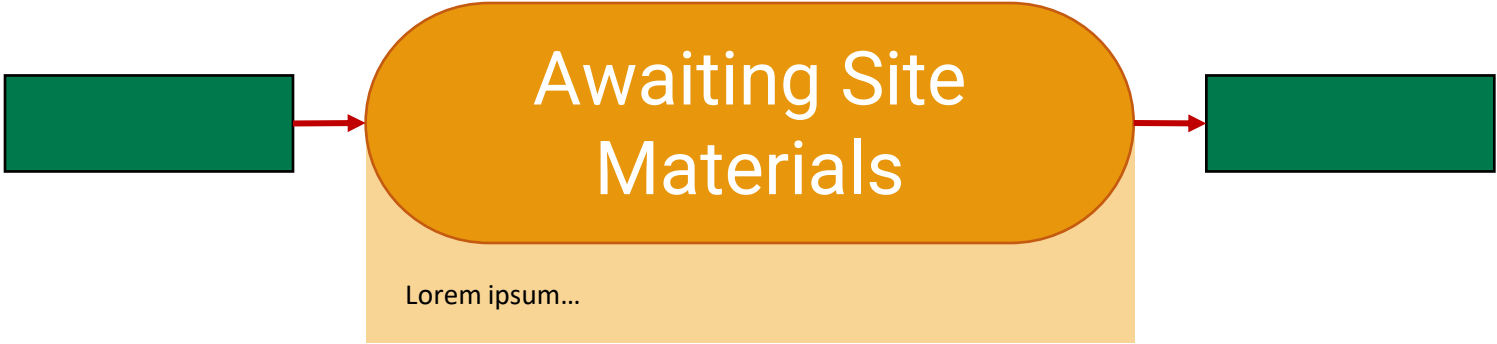
- [Review Required Actions](#)
- [Assign Designated Reviewer](#)
- [Assign to Committee Review](#)




Roles & Project Assignments			
Principal Investigator	✓		✓
PI Proxy	✓		✓
Primary Contact	✓		✓
Study Team Member	✓		
Assigned IRB Coordinator	✓		
IRB Director	✓		
Designated Reviewer	✓		
Staff Reviewer	✓		
Ancillary Reviewer	✓		✓

Available Non-Workflow Actions

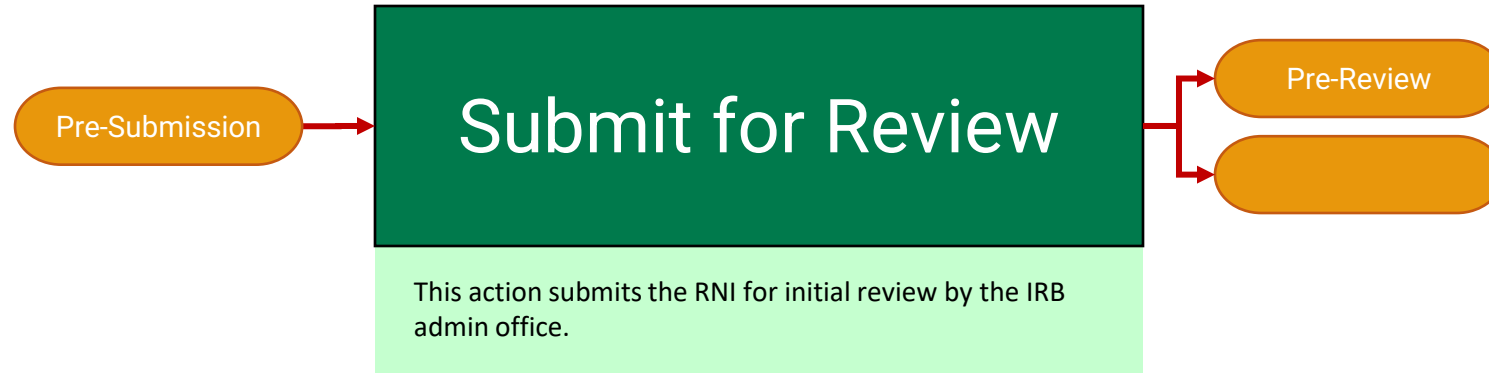
- Create Task
- Manage Ancillary Reviews
- Manage Tags
- Review Required Actions
- Submit Ancillary Review

Note: Some actions are dependent upon a related pending task or require specific user credentials.



Roles & Project Assignments			
Principal Investigator	✓		✓
PI Proxy	✓		✓
Primary Contact	✓		✓
Study Team Member	✓		
Assigned IRB Coordinator	✓		
IRB Director	✓		
Designated Reviewer	✓		
Staff Reviewer	✓		
Ancillary Reviewer	✓		✓

Available <u>Non-Workflow</u> Actions
<ul style="list-style-type: none">None



Who can execute this action

- Primary Contact
- Related submissions PI and PI Proxy
- Additional Editor
- IRB Coordinator (any user with the IRBC role)

Notifications Generated



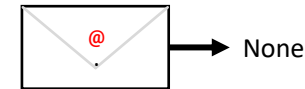
Related submissions PI and PI Proxy

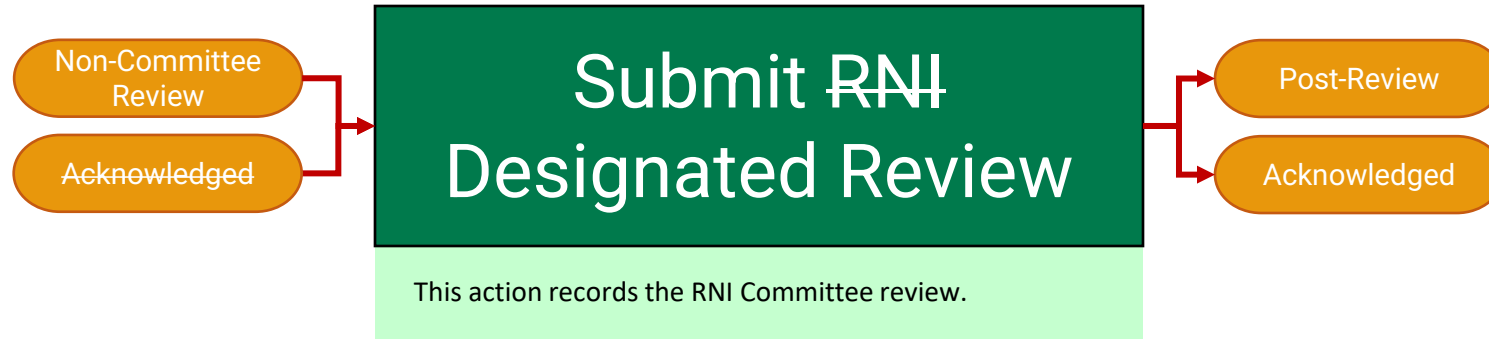


Who can execute this action

- ~~Global IRB Viewer~~
- ~~IRB Staff~~
- ~~Committee Member~~
- Assigned IRB Coordinator
- IRB Director

Notifications Generated

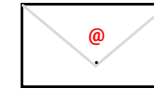




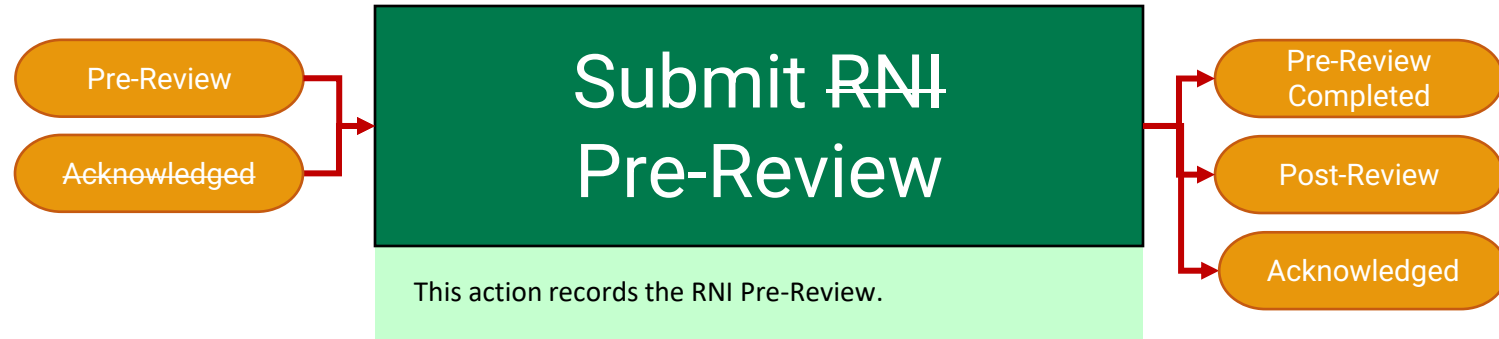
Who can execute this action

- Assigned IRB Coordinator
- IRB Director
- Assigned Designated Reviewer

Notifications Generated



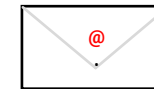
None



Who can execute this action

- IRB Director
- Assigned IRB Coordinator

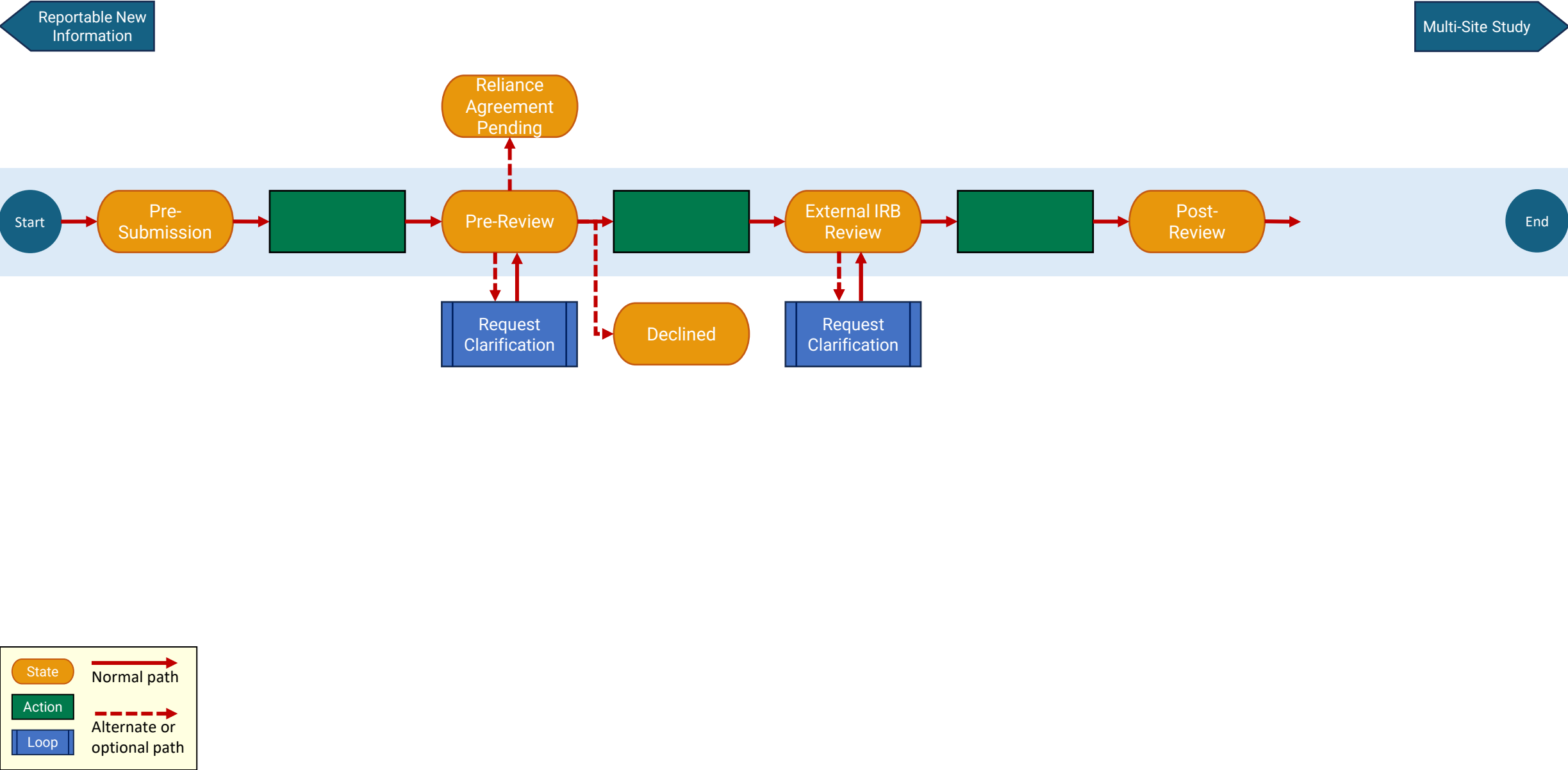
Notifications Generated

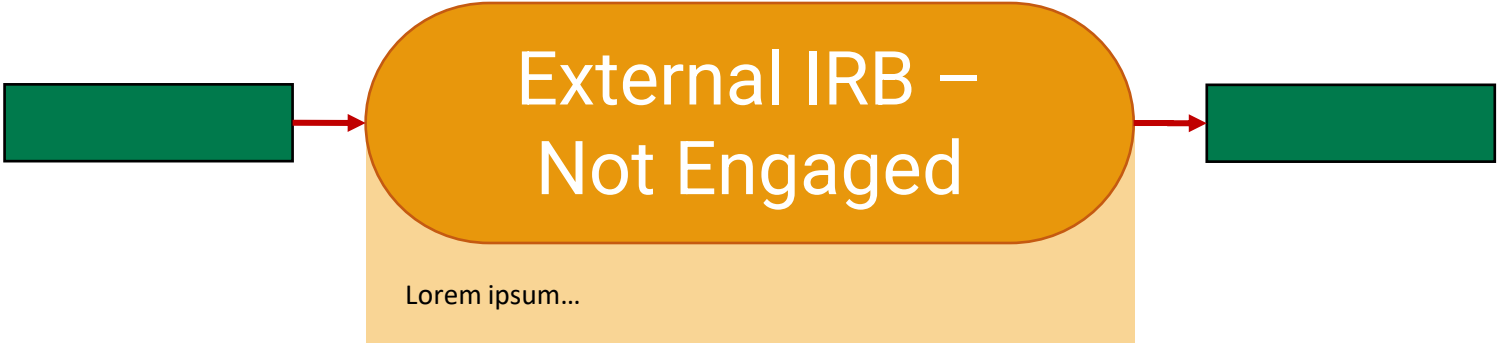


None

Workflow: External Single-Site Study







Roles & Project Assignments



Principal Investigator

✓

✓

PI Proxy

✓

✓

Primary Contact

✓

✓

Study Team Member

✓

Assigned IRB Coordinator

✓

IRB Director

✓

Designated Reviewer

✓

Staff Reviewer

✓

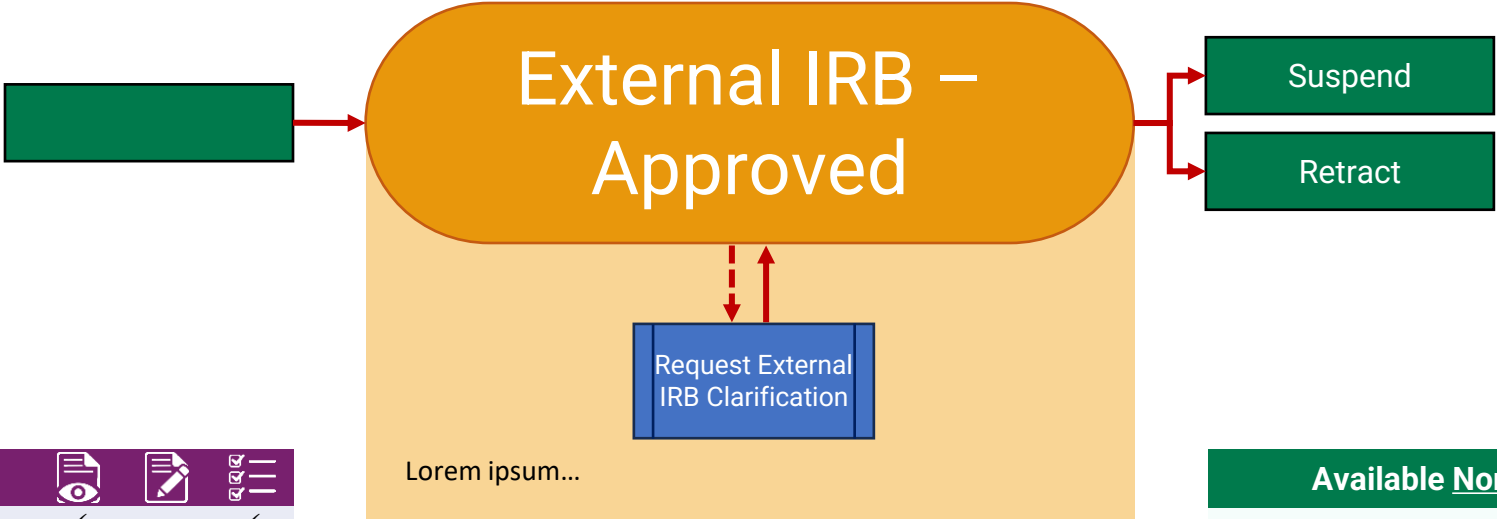
Ancillary Reviewer

✓

✓

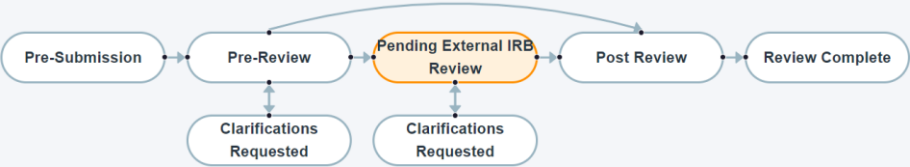
Available Non-Workflow Actions

- TBD



Roles & Project Assignments

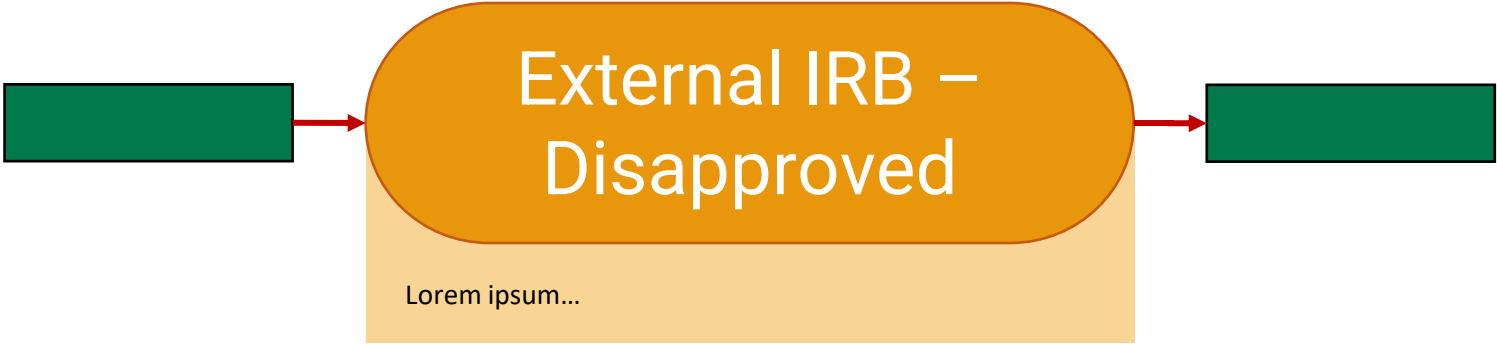
Principal Investigator	✓		✓
PI Proxy	✓		✓
Primary Contact	✓		✓
Study Team Member	✓		
Assigned IRB Coordinator	✓		
IRB Director	✓		
Designated Reviewer	✓		
Staff Reviewer	✓		
Ancillary Reviewer	✓		✓



Available Non-Workflow Actions

- Assign Coordinator
- Correspond with External IRB
- Create Task
- Edit Update Review
- Update External IRB Decision

Note: Some actions are dependent upon a related pending task or require specific user credentials.



Roles & Project Assignments



Principal Investigator

✓

✓

PI Proxy

✓

✓

Primary Contact

✓

✓

Study Team Member

✓

Assigned IRB Coordinator

✓

IRB Director

✓

Designated Reviewer

✓

Staff Reviewer

✓

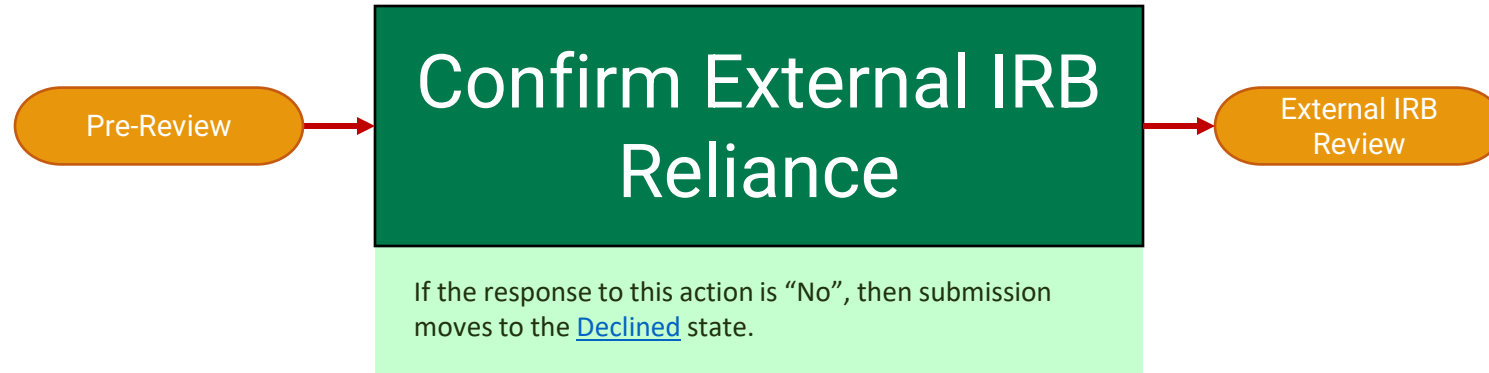
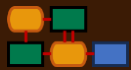
Ancillary Reviewer

✓

✓

Available Non-Workflow Actions

- TBD



Who can execute this action

- Principal Investigator
- PI Proxy

Notifications Generated



Assigned IRB Coordinator

Workflow: External Multi-Site Study

This workflow creates and submits IRB studies that are conducted at multiple locations or institutions. In this configuration, one institution acts as the single Institutional Review Board (sIRB), while the other functions as a participating site.

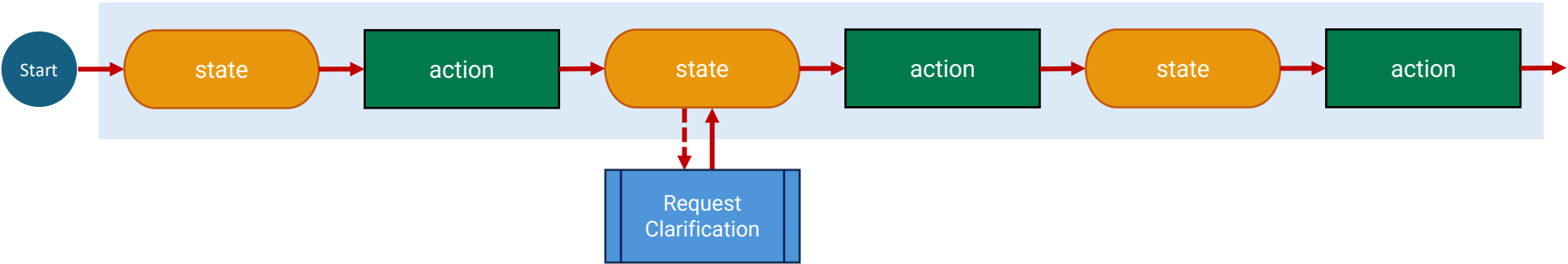
The sIRB reviews the study across all sites, including its own institution and any other participating institutions.

Any registered IRB user can create a MSS, but only the Principal Investigator (PI) or PI proxy can submit a multi-site study.



External
Single-Site

Study Update



State

Action

Loop

Normal path

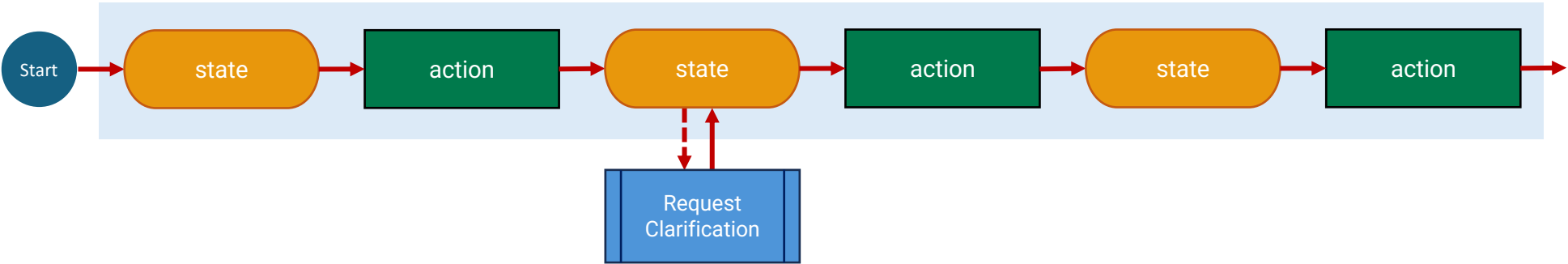
Alternate or optional path

Workflow: Study Update



Multi-Site Study

Study Closure



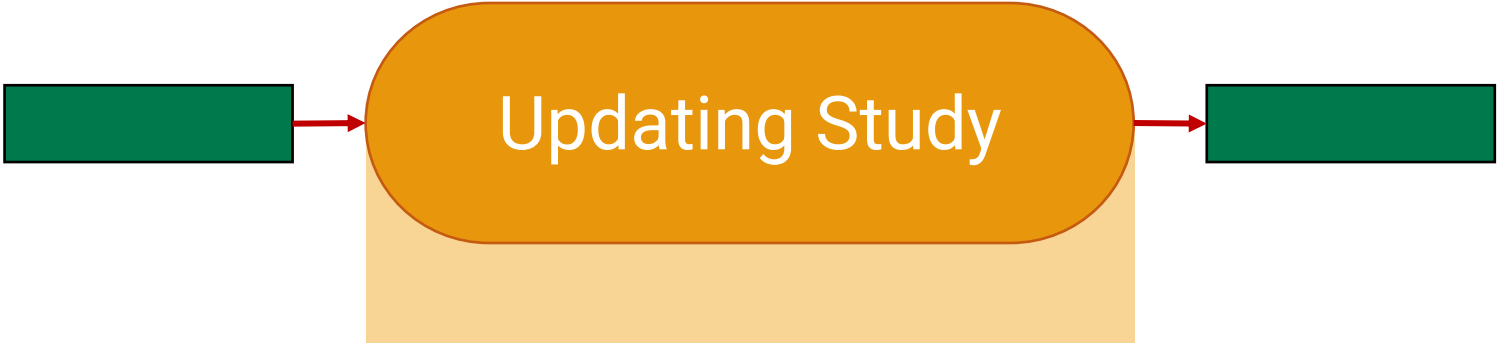
State




Action

Loop

Normal path

Alternate or optional path

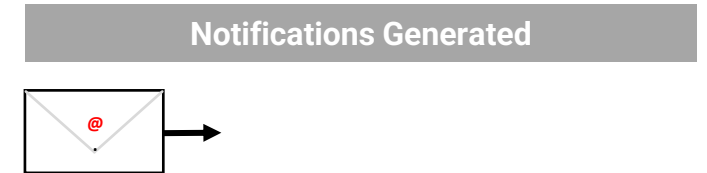
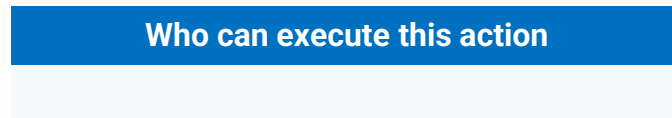
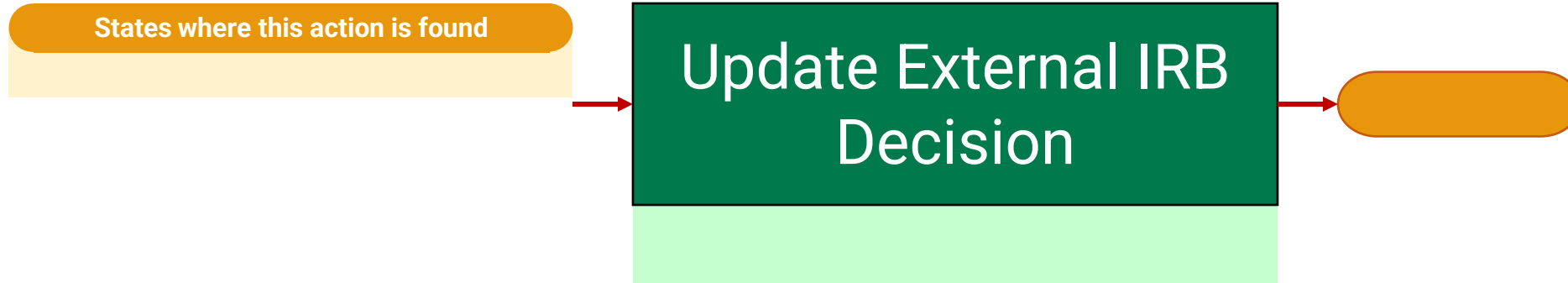


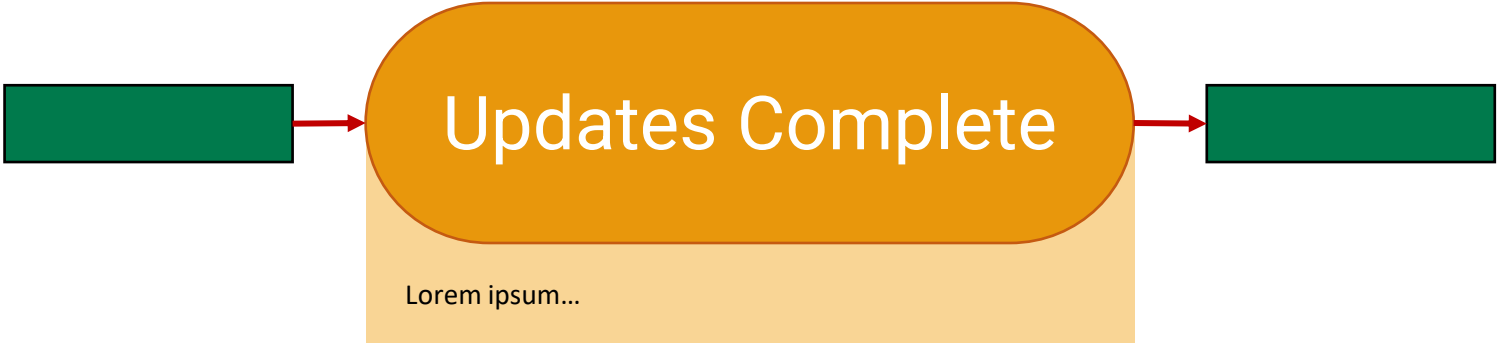
Roles & Project Assignments			
Principal Investigator	✓		✓
PI Proxy	✓		✓
Primary Contact	✓		✓
Study Team Member	✓		
Assigned IRB Coordinator	✓		
IRB Director	✓		
Designated Reviewer	✓		
Staff Reviewer	✓		
Ancillary Reviewer	✓		✓




Available Non-Workflow Actions

- Submit Ancillary Review

Note: Some actions are conditionally available based on user credentials or are dependent upon a related pending task.



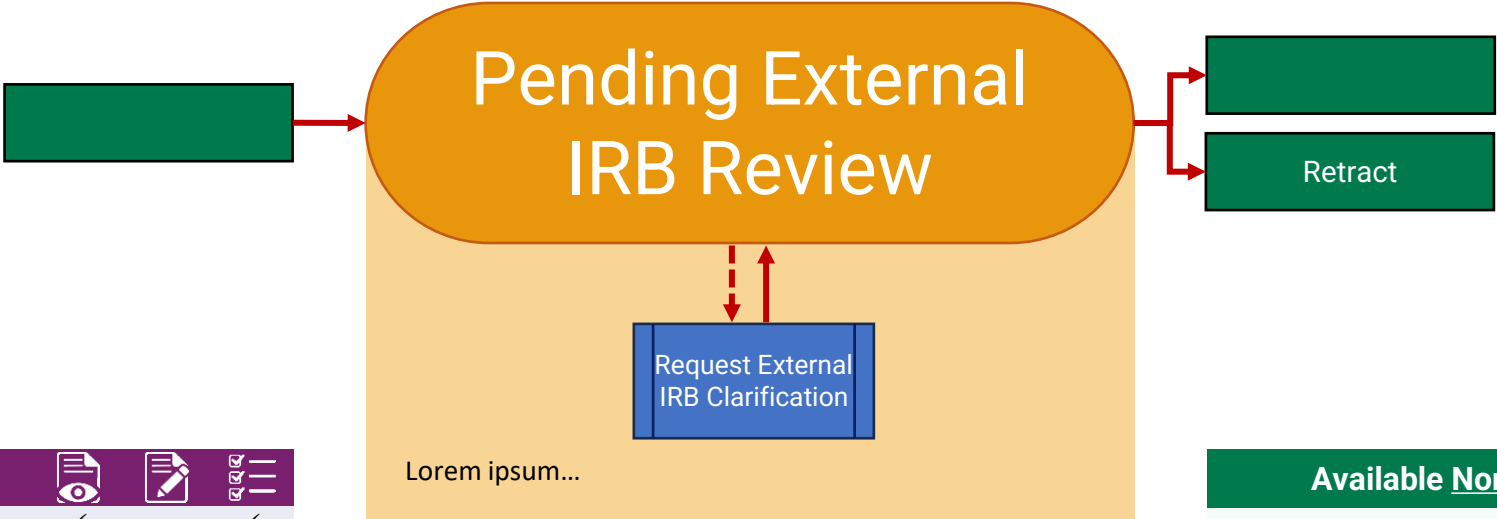


Roles & Project Assignments			
Principal Investigator	✓		✓
PI Proxy	✓		✓
Primary Contact	✓		✓
Study Team Member	✓		
Assigned IRB Coordinator	✓		
IRB Director	✓		
Designated Reviewer	✓		
Staff Reviewer	✓		
Ancillary Reviewer	✓		✓


Available Non-Workflow Actions

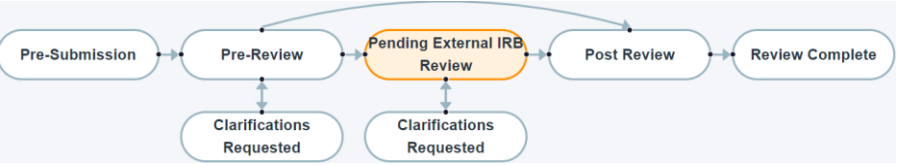
- Submit Ancillary Review

Note: Some actions are conditionally available based on user credentials or are dependent upon a related pending task.



Roles & Project Assignments

			
Principal Investigator	✓		✓
PI Proxy	✓		✓
Primary Contact	✓		✓
Study Team Member	✓		
Assigned IRB Coordinator	✓		
IRB Director	✓		
Designated Reviewer	✓		
Staff Reviewer	✓		
Ancillary Reviewer	✓		✓



Available Non-Workflow Actions

- Assign Coordinator
- Correspond with External IRB
- Edit Update Review
- Update External IRB Decision
- Submit Ancillary Review

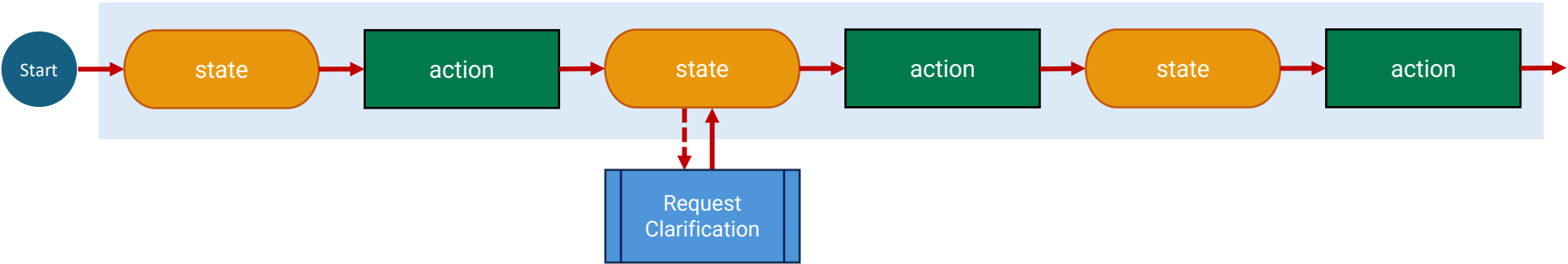
Note: Some actions are dependent upon a related pending task or require specific user credentials.

Workflow: Study Closure



Study Update

pSite Study



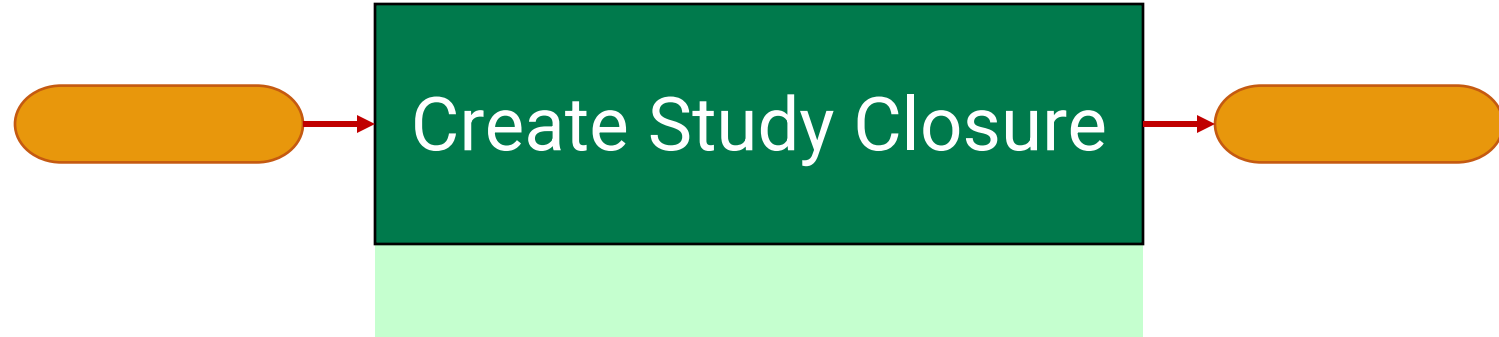
State

Action

Loop

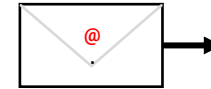
Normal path

Alternate or optional path



Who can execute this action

Notifications Generated



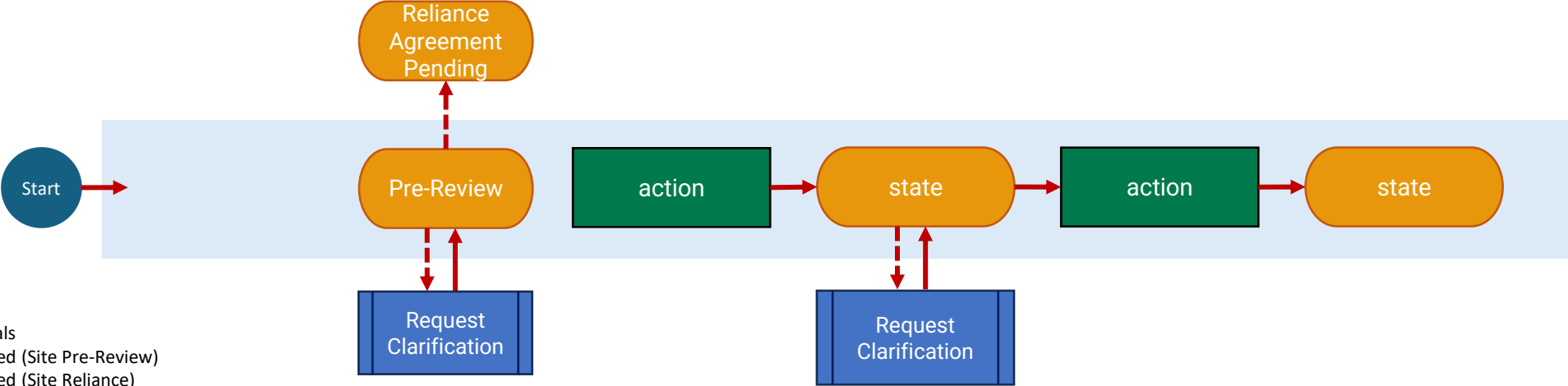
Workflow: Participating Site (pSite) Study





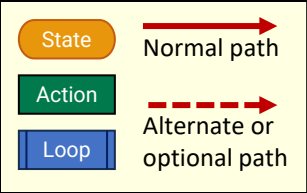
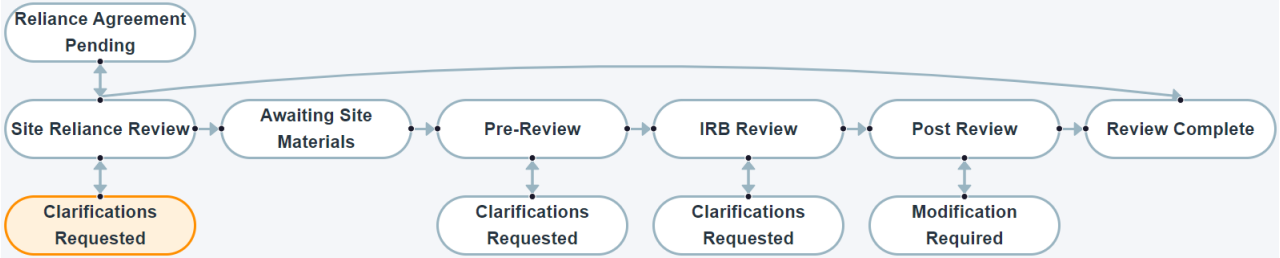
Study Closure

Central Actions



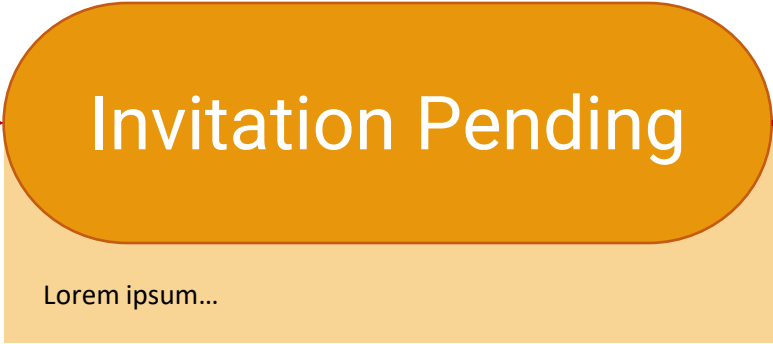
- Workflow States:**
- Active
 - Awaiting Site Materials
 - Clarification Requested (Site Pre-Review)
 - Clarification Requested (Site Reliance)
 - Committee Review
 - Inactive
 - Non-Committee Review
 - Post-Review
 - Pre-Review
 - Reliance Agreement Pending
 - Site Reliance Review

- Workflow Actions:**
- TBD





When a pSite is created via the Manage Participation Sites action, the pSite starts in this state



Submit Reliance Decision
Reliance Agreement Pending
Request Site Reliance Clarification

Roles & Project Assignments



Principal Investigator	✓	✓
PI Proxy	✓	✓
Primary Contact	✓	✓
Study Team Member	✓	
Assigned IRB Coordinator	✓	
IRB Director	✓	
Designated Reviewer	✓	
Staff Reviewer	✓	
Ancillary Reviewer	✓	✓

Available Non-Workflow Actions

- Create Ancillary Review
- Copy Submission
- Submit Ancillary Review
- Assign Coordinator
- Create Task
- Manage Access
- Bypass Ancillary Review
- Discard

Note: Some actions are dependent upon a related pending task or require specific user credentials.



Roles & Project Assignments



Principal Investigator

✓

✓

PI Proxy

✓

✓

Primary Contact

✓

✓

Study Team Member

✓

Assigned IRB Coordinator

✓

IRB Director

✓

Designated Reviewer

✓

Staff Reviewer

✓

Ancillary Reviewer

✓






✓

Available Non-Workflow Actions

- Submit Ancillary Review

Note: Some actions are dependent upon a related pending task or require specific user credentials.

IRB Central Actions

Central Actions	
	Admin Offices
	Assign Coordinator
	Assign Primary Contact
	Manage Guest List
	Create Institutional Profiles

Central Actions typically make changes to multiple projects of the same type at once.

Central Actions are typically performed by a Business Analyst, or other designated persons in the central staff. They are found on a tab on the Home page.

Many of these actions are used to create or perform mass updates to multiple projects. Some are used for site-wide settings.



Admin Offices

Who can execute this action

- IRB Administrator
- IRB Business Analyst

Notifications Generated



→ None

Assign Coordinator

This action assigns an IRB Coordinator for one or more submissions.

Who can execute this action

- IRB Administrator
- IRB Business Analyst

Notifications Generated



→ None

Assign Primary Contact

Who can execute this action

- IRB Administrator
- IRB Business Analyst

Notifications Generated



→ None

Manage Guest List

This action manages a list of users who have read access to the submission.

Who can execute this action

- IRB Administrator
- IRB Business Analyst

Notifications Generated



→ None

Create Institutional Profiles

Who can execute this action

- IRB Administrator
- IRB Business Analyst

Notifications Generated



→ None

Reference

[Non-Workflow Actions \(NWAs\)](#)

Executing these actions does not affect the workflow. Hence, they are called Non-Workflow Actions. They are available in various states in IRB.

[NWAs per Workflow State](#)

This is a cross-reference showing which Non-Workflow Actions (NWAs) are available in each workflow state.

[Committee Actions by Role](#)



Non-Workflow Actions by State (1 of 2)

Non-Workflow Actions List

This is a cross-reference showing which [non-workflow actions](#) are available in each state. **Note:** Some SmartForm options determine the availability of some actions.

Assignment Needed: This column indicates who is allowed to execute the action.

Notifications: This column indicates who will receive a notification when the action is executed.

Non-Workflow Actions (2 of 2)

[illegible]

Non-Workflow Actions by State (2 of 2)

Non-Workflow Actions (1 of 2)

This is a cross-reference showing which [non-workflow actions](#) are available in each state. **Note:** Some SmartForm options determine the availability of some actions.

Assignment Needed: This column indicates who is allowed to execute the action.

Notifications: This column indicates who will receive a notification when the action is executed.

Committee Actions by Role

[illegible]

Committee Actions by Role

Actions	Committee Administrator	Committee Chair	Committee Member	IRB Coordinator	IRB Director	Notes
Add Documents				✓	✓	Update Documents activity
Add Other Items to the Agenda	✓	✓			✓	Update Other Agenda Items activity
Approve Previous Meeting Minutes	✓	✓				
Assign Reviewers	✓	✓		✓	✓	
Close Meeting	✓					
Confirm Attendance	✓	✓	✓	✓	✓	
Create a Meeting	✓	✓	✓	✓	✓	
Decline Attendance	✓	✓	✓	✓	✓	
Display the Expedited Submissions Approved Report	✓	✓	✓	✓	✓	IRB-only task
Edit Meeting Attendance	✓					
Edit Meeting Details	✓					
Notify Reviewers	✓	✓		✓	✓	
Open an Existing Meeting	✓	✓	✓	✓	✓	
Prepare Minutes	✓	✓				
Prepare the Agenda	✓					
Remove an Agenda Item	✓	✓			✓	These permissions are for Update Other Agenda Items
Rename Meeting		✓				
Send the Agenda	✓					
Start the Meeting	✓					Convene Meeting activity

//End of document

