

As a new reviewer, you will see some additional sections at the bottom of your dashboard. There are 2 new sections called “Reviewer: Action Items” and “Reviewer: In Process”.

The “Reviewer: Action Items” are protocols that require your attention (conduct initial review, review responses, etc.).

The “Reviewer: In Process” are protocols that have already been reviewed and require no further action from you at this time.

REVIEWER: ACTION ITEMS (What is this?)

Hide Section

Show Column Options

| Role | Protocol # | Protocol Director | Form Type | Review Type | Meeting Date | ▲ Status | Action Required | Panel |
|----------|------------|-------------------|-----------|-------------|--------------|----------------------|---------------------------------|-------|
| Reviewer | | | REVISION | EXPEDITED | 10/31/12 | Assigned as Reviewer | Review Protocol | IRB-6 |
| Reviewer | | | NEW | EXPEDITED | 10/31/12 | Assigned as Reviewer | Review Protocol | IRB-6 |
| Reviewer | | | RENEWAL | EXPEDITED | 10/31/12 | Assigned as Reviewer | Review Protocol | IRB-6 |
| Reviewer | | | RENEWAL | EXPEDITED | 10/31/12 | Assigned as Reviewer | Review Protocol | IRB-6 |
| Reviewer | | | RENEWAL | EXPEDITED | 10/31/12 | Assigned as Reviewer | Review Protocol | IRB-6 |
| Reviewer | | | REPORT | REGULAR | 11/20/12 | Assigned as Reviewer | Review Report | IRB-5 |

REVIEWER: IN PROCESS (What is this?)

Hide Section

Show Column Options

| Role | Protocol # | Protocol Director | ▼ Form Type | Review Type | Meeting Date | Status | Current Activity |
|-----------|------------|-------------------|-------------|-------------|--------------|---|---|
| Presenter | | | RENEWAL | REGULAR | 10/16/12 | Recommended for Approval | Review Submitted |
| Presenter | | | NEW | REGULAR | 11/20/12 | Recommended for Approval (MOVED) | Review Submitted |
| Reviewer | | | NEW | REGULAR | 10/16/12 | Contingent (TABLED) | Contingencies are being written |
| Presenter | | | RENEWAL | REGULAR | 09/18/12 | Recommended for Approval (Conditionally Approved) | Review Submitted |
| Reviewer | | | RENEWAL | REGULAR | 10/16/12 | Recommended for Approval | Review Submitted |
| Presenter | | | NEW | REGULAR | 10/16/12 | Recommended for Approval | Review Submitted |
| Reviewer | | | RENEWAL | REGULAR | 09/18/12 | Recommended for Approval | Review Submitted |

In the column on the left hand side, you can see your role in reviewing the protocols. Pink means that you are a presenter on the protocol, yellow indicates you are a reviewer but do not need to present, and blue means that you are not a presenter or reviewer, but that these are protocols that will be voted on at the meeting.

In order to review a protocol, you will want to find the “Action Required” column, and click “Review Protocol”. This will take you to the Reviewer page.

REVIEWER: ACTION ITEMS (What is this?)

Hide Section

Show Column Options

| Role | Protocol # | Protocol Director | Form Type | Review Type | Meeting Date | Status | Action Required | Panel |
|----------|------------|-------------------|-----------|-------------|--------------|----------------------|---------------------------------|-------|
| Reviewer | | | REVISION | EXPEDITED | 10/31/12 | Assigned as Reviewer | Review Protocol | IRB-6 |
| Reviewer | | | NEW | EXPEDITED | 10/31/12 | Assigned as Reviewer | Review Protocol | IRB-6 |
| Reviewer | | | RENEWAL | EXPEDITED | 10/31/12 | Assigned as Reviewer | Review Protocol | IRB-6 |
| Reviewer | | | RENEWAL | EXPEDITED | 10/31/12 | Assigned as Reviewer | Review Protocol | IRB-6 |
| Reviewer | | | RENEWAL | EXPEDITED | 10/31/12 | Assigned as Reviewer | Review Protocol | IRB-6 |
| Reviewer | | | REPORT | REGULAR | 11/20/12 | Assigned as Reviewer | Review Report | IRB-5 |

REVIEWER: IN PROCESS (What is this?)

Hide Section

Show Column Options

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|-----------|------------|-------------------|-----------|-------------|--------------|---|---|
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| Reviewer | | | RENEWAL | REGULAR | 10/16/12 | Recommended for Approval | Review Submitted |
| Presenter | | | NEW | REGULAR | 10/16/12 | Recommended for Approval | Review Submitted |
| Reviewer | | | RENEWAL | REGULAR | 09/18/12 | Recommended for Approval | Review Submitted |

Once you have clicked the “Review Protocol” button, a new page will open. It will have some information about the protocol including what the ‘protocol involves’, and allows you to mark the protocol as “High Risk” or to request an expert consultation, by clicking the checkbox.

To view the protocol, you select ‘Get Protocol,’ to write any comments you may have, you select ‘Write comment(s)’ and if you have no comments you select ‘Recommend for Approval.’

[Home](#) » Review and Comments

Protocol ID: [blurred]

Protocol Title: [blurred]

[Reviewer Checklist](#)

[Reviewers](#)

Protocol involves:

[Laminated Sheets and Guidances](#)

[46.116\(d\) Waiver/Alteration of Informed Consent](#)

Check any that apply:

- High Risk Protocol and Request Additional Primary Reviewers
- Request Expert Consultation

Cycle:

Reviewer Comments

[Get Protocol](#)

[Write Comment\(s\)](#)

[Recommend for Approval](#)

Please click on 'Write Comment(s)' to add Comment(s)

If you would like to see the protocol in its entirety, you can do so by clicking the “Get Protocol” button. The protocol will open in “View mode” in a pop up window.

In order to go back to the “Review Protocol” page, simply close out of the pop up window.

[Home](#) » Review and Comments

Protocol ID: [REDACTED]

Protocol Title: [REDACTED]

[Reviewer Checklist](#)

[Reviewers](#)

Protocol involves:

[Laminated Sheets and Guidances](#)

[46.116\(d\) Waiver/Alteration of Informed Consent](#)

Check any that apply:

- High Risk Protocol and Request Additional Primary Reviewers
- Request Expert Consultation

Cycle:



Reviewer Comments

[Get Protocol](#)

[Write Comment\(s\)](#)

[Recommend for Approval](#)

Please click on 'Write Comment(s)' to add Comment(s)

The “Write comments” button allows you to ask questions or indicate any requests for the protocol.

These comments will be sent to the Panel Manager, then passed on to the Protocol Director anonymously.

[Home](#) » Review and Comments

Protocol ID: [blurred]

Protocol Title: [blurred]

[Reviewer Checklist](#)

[Reviewers](#)

Protocol involves:

[Laminated Sheets and Guidances](#)

[46.116\(d\) Waiver/Alteration of Informed Consent](#)

Check any that apply:

- High Risk Protocol and Request Additional Primary Reviewers
- Request Expert Consultation

Cycle:



Reviewer Comments

[Get Protocol](#)

[Write Comment\(s\)](#)

[Recommend for Approval](#)

Please click on 'Write Comment(s)' to add Comment(s)

Once you click the “Write Comments” button, a comment box will appear for you to add your comment. When you have completed your comment, click the “Save” button. If you would like to add another comment, click the “Save and Add Comment” button. One new comment per box should be written.

You can also set the comment to require a response for approval, or make it a suggestion for the PD, that does not require them to respond, by clicking the “Response Necessary for Approval” or “Suggestion Not Necessary for Approval” buttons

[Home](#) » Review and Comments

Protocol ID: [blurred]

Protocol Title: [blurred]

[Reviewer Checklist](#)

[Reviewers](#)

Protocol involves:

[Laminated Sheets and Guidances](#)

[46.116\(d\) Waiver/Alteration of Informed Consent](#)

Check any that apply:

- High Risk Protocol and Request Additional Primary Reviewers
- Request Expert Consultation

Cycle:

Reviewer Comments [Get Protocol](#) [Write Comment\(s\)](#) [Recommend for Approval](#)

Comment [Save](#) [Cancel](#)

New Comment

Response Necessary for Approval
 Suggestion Not Necessary for Approval

[Save & Add Comment](#)

Once you've added a comment, you will see the "Submit to manager" button. When you are finished entering all of your comments, click this button to submit your comments to the Manager.

[Home](#) » Review and Comments

Protocol ID: [6304](#) (Edgar G Engleman)

Protocol Title: Dendritic and T cell Signaling in Gastrointestinal Cancer

Protocol involves:

[46.116\(d\) Waiver/Alteration of Informed Consent](#)

Cycle: 

[Reviewer Checklist](#)

[Reviewers](#)

[Laminated Sheets and Guidances](#)

Check any that apply:

- High Risk Protocol and Request Additional Primary Reviewers
- Request Expert Consultation



Reviewer Comments

[Get Protocol](#)

[Write Comment\(s\)](#)

[Show All Comments](#)

[Submit To Manager](#)

Comment DW1

[Edit](#)

[Delete](#)

New Comment

- Response Necessary for Approval
- Suggestion Not Necessary for Approval

The recommend for approval button allows you to recommend the protocol for approval, once you have reviewed it.

This button is only visible if you have not entered any comments in the current comment cycle. If you have entered comments, this button is replaced by the “Submit to Manager” button, discussed on the previous page.

[Home](#) » Review and Comments

Protocol ID: [REDACTED]

Protocol Title: [REDACTED]

[Reviewer Checklist](#)

[Reviewers](#)

Protocol involves:

[Laminated Sheets and Guidances](#)

[46.116\(d\) Waiver/Alteration of Informed Consent](#)

Check any that apply:

- High Risk Protocol and Request Additional Primary Reviewers
- Request Expert Consultation

Cycle:



Reviewer Comments

[Get Protocol](#)

[Write Comment\(s\)](#)

[Recommend for Approval](#)

Please click on 'Write Comment(s)' to add Comment(s)

Once you click the “Recommend for approval” button, a pop up window will appear asking that you confirm your recommendation, as well as specify a length of time for the approval, as well as any specifics, such as maximum number of participants.

You can also add notes to the manager, if you would like, but that field is not required.

Once you’ve recommended the protocol for approval, click the “Submit to Manager” button to let the manager know that you have approved.

Approval Notes Cancel Submit To Manager

Recommendation of this protocol for approval means that the member has determined that the following criteria have been met under 45 CFR 46.111(a)(b); 21 CFR 56.111(a),(b),(c):

- Risks to subjects are minimized
- Risks to subjects are reasonable in relation to anticipated benefits
- Selection of subjects is equitable
- Informed consent will be sought from each prospective subject
- Informed consent will be appropriately documented
- When appropriate, data collection is monitored to ensure subject safety
- When appropriate, privacy of subjects and confidentiality of data are protected
- When appropriate, additional safeguards are included for vulnerable populations

The IRB member also confirms that, when appropriate:

- informed consent will be obtained from the participant or the participant’s legally authorized representative 45 CFR 46.111(a)(b); 21 CFR 50.20, and, the consent form includes the required elements of consent 45 CFR 46.116(a),(b); 21 CFR 50.25(a),(b)
- informed consent will be documented using the long form consent document 45 CFR 46.117(a),(b)(1); 21 CFR 50.27 (a)and/or informed consent will be documented using the short form consent document 45 CFR 46.117(a),(b)(2); 21 CFR 50.27 (b)(2).
- if the consent will be waived or altered, the protocol includes and justifies protocol specific findings 45 CFR 46.116(d)
- if the requirement to obtain a signed consent form will be waived, the protocol includes and justifies protocol specific findings 45 CFR 46.117(c)(1) or 45 CFR 46.117(c)(2); 21 CFR 56.109(c)(1).

I recommend approval for 12 months

I recommend approval for (e.g., 6 months, 5 participants, etc.)

Notes To Manager

Cancel Submit To Manager