

Committee Member Review - Overview of Changes

Overview of Changes

This document provides a description of the changes to the Reviewer Workspace and Reviewer Checklist form in the upgraded eResearch system. These changes are effective March 23, 2007.

Reviewer Workspace and Reviewer Checklist form changes:

- The Review Workspace and Reviewer Checklist form display **Staff Notes to Reviewers**. This allows the staff to communicate non-issue specific information about the submission to committee members.

Reviewer Checklist form changes:

- The **Reviewer Checklist** section has been reformatted to provide more room for checklist item descriptions and reviewer comments.
- The **Publish to Study Team** and **To be Reviewed by** columns for Reviewer Checklist items have been removed because they are for staff use only.
- The **General Issues for Study Team/Staff** section has been renamed **Additional Issues**. The function of this section has not changed. This section is used to enter additional issues for the study the study team to address.
- The **Reviewer Notes** section has been renamed **Notepad**. The function of this section has not changed. This section is for reviewer use and the information entered is not communicated to staff or study team members.

Details

The following pages display a sample of the current Reviewer Checklist form, a sample of the new Reviewer Checklist form, and a description of the section changes.

Current Reviewer Checklist

Full Committee Review for HUM00005400 - IRB Primary Reviewer
HUM00005400 - Test Study for IRB MED R1.5 Materials

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Identified Issues Assigned to You: *The following identified issues have been assigned to you for review.*

| Section | Identified Issue | Issue Resolved | Publish to Study Team | Created By | Comments |
|---------------------------|---------------------------------|--------------------------|--------------------------|--------------------|----------|
| 10 Adult Informed Consent | Please review to determine..... | <input type="checkbox"/> | <input type="checkbox"/> | IRB Staff Reviewer | |

Reviewer Checklist:

| Section | Reviewer Checklist Item | Condition Met | Publish to Study Team | Comments (* When condition is not met, comment is required and will be converted to identified issue upon submission.) | To be Reviewed by: |
|--------------------|----------------------------------|--|--------------------------|---|-----------------------|
| 05 Research Design | Is the research design adequate? | <input type="radio"/> Yes <input type="radio"/> No | <input type="checkbox"/> | | IRB Primary Reviewer: |

New Reviewer Checklist (Release 1.5.4)

Full Committee Review for HUM00005649 - IRB Primary Reviewer
HUM00005649 - Test Study Release 1.5.4

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A Staff Notes to Reviewers:
Posted by Bill Behave Posted on 3/12/2007
Sample Comment: this is a new study...

B Identified Issues Assigned to You:
The following identified issues have been assigned to you for review.

| Section | Identified Issue | Issue Resolved | Publish to Study Team | Created By | Comments |
|-----------------------|------------------------------|--------------------------|--------------------------|--------------------|----------|
| 06 Benefits and Risks | Is risk reported based on... | <input type="checkbox"/> | <input type="checkbox"/> | IRB Staff Reviewer | |

C Reviewer Checklist:

| Section: | 05 Research Design | * Condition Met: |
|--|----------------------------------|---|
| Checklist Item: | Is the research design adequate? | <input type="radio"/> Yes <input type="radio"/> No |
| * Comments: (When condition is not met, comment is required and will be converted to identified issue upon submission.) | | |

Current Reviewer Checklist

General Issues for Study Team and/or Staff:

Reviewer Notes:

New Reviewer Checklist (Release 1.5.4)

Additional Issues:
Use this box to create additional identified issues for the study team.

D

Notepad:
This information is not communicated to office staff or study team members.

E

| Letter | Checklist Section | Description of Change |
|--------|-----------------------------------|---|
| A | Staff Notes to Reviewers | This new section has been added to the Reviewer Checklist form. This allows staff to communicate non-issue specific information to reviewers. These notes can also be viewed on the Reviewer Workspace. |
| B | Identified Issues Assigned to You | This section will not change with Release 1.5.4. |
| C | Reviewer Checklist | <p>The Checklist Item description has been enlarged.</p> <p>The Publish to Study Team column has been removed.</p> <p>The Comment text box has been enlarged.</p> <p>The To be Reviewed by column has been removed.</p> |
| D | Additional Issues | This section has been renamed. |
| E | Notepad | This section has been renamed. |