

IRB Post-Approval Review Checklist

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Data Entry

-- Overview and Review of Study Location --

Study Title

⇒ Displays the protocol title.

IRB

⇒ Displays the protocol code.

PI

⇒ The name and contact information of the Investigator for this protocol will be displayed.

Department

⇒ Displays the department on the protocol.

Expiration Date

⇒ Expiration Date for the latest Protocol Site Approval.

Study personnel

⇒ Show a list of contacts for the project.

Date of Review (Required)

⇒ Enter a valid date.

Discuss the following:

1. Introduction
2. Study progress
3. Any problems or concerns?
4. Any upcoming amendments planned?

Comments

⇒ Enter an unlimited amount of text.

Enrollment data

How many total screened, enrolled, and withdrawn?**(Required)**

⇒ Enter an unlimited amount of text.

**Has the study been audited by a funding agency or another IRB?
(Required)**

⇒ Select either 'Yes' or 'No'

Is there documentation related to the external audit? (Required)

Depending what you find, you may ask the researchers to send you a copy of this documentation to add to the files in I-Manager.

⇒ Select either 'Yes' or 'No'

Have any corrective actions been completed? (Required)

⇒ Select either 'Yes' or 'No'

Comments

⇒ Enter an unlimited amount of text.

View space and/or equipment, if applicable**Comments**

⇒ Enter an unlimited amount of text.

-- Data and document review --**Is there documentation that all research personnel have completed the appropriate training? (Required)**

Training records should document who was trained, when, by whom, and what training was done.

While CITI training is important, this should be focused more on lab- or protocol-specific training. We want to verify that research personnel learn how to conduct the study appropriately and in accordance with the approved protocol.

⇒ Select either 'Yes' or 'No'

Comments

⇒ Enter an unlimited amount of text.

Are all IRB-related records (approval letters, protocol form, consent forms, recruitment material, correspondence, etc.) stored in an accessible location for study personnel? (Required)

⇒ Select either 'Yes' or 'No'

Comments

⇒ Enter an unlimited amount of text.

Is there a clear method for ensuring that only the current, approved documents are used? (Required)

This applies to recruitment materials, consent forms, data collection instruments, etc.

⇒ Select either 'Yes' or 'No'

Comments

⇒ Enter an unlimited amount of text.

Data and confidentiality

- 1. View data storage location(s).**
- 2. Briefly review the data.**
- 3. If there are transcripts or a survey, pick 1-2 at random to verify they match the approved questions/instruments.**

Brief review of data should be restricted to viewing the spreadsheet, transcripts, etc. Does what you are seeing generally seem consistent with the protocol, enrollment numbers, etc.?

Are hard copy / paper data and consent forms stored in a secure location, with access limited to approved personnel? (Required)

⇒ Select either 'Yes' or 'No'

Are electronic data (and consent forms, if applicable) stored on a secure and protected computer or server, with access limited to approved personnel? (Required)

⇒ Select either 'Yes' or 'No'

Are coding and/or deidentifying procedures being followed as described in the approved protocol? (Required)

⇒ Select either 'Yes' or 'No'

Comments

⇒ Enter an unlimited amount of text.

Consent forms

- 1. Choose 1-3 consent forms at random.**
- 2. Verify the form matches the approved version in effect on that date.**
- 3. Verify the form is signed and dated appropriately.**

Comments

⇒ Enter an unlimited amount of text.

-- Wrap-up --

Positive observations (Required)

⇒ Enter an unlimited amount of text.

Summary table (Required)

⇒ Displays a table containing existing Question Types in a repeat group.

List any questions / items needing follow-up by IRB office staff.

⇒ Enter an unlimited amount of text.

Summary report

This Group of pages will repeat.

-- Summary table --

Classification (Required)

⇒ Select *one* of the following options from the drop down list presented:
‡Finding ‡Suggestion

Observation (Required)

⇒ Enter an unlimited amount of text.

Corrective action (Required)

⇒ Enter an unlimited amount of text.

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