

**Default Question Block****HRP-432 - CHECKLIST - Expedited Review Quality Assurance Assessment - Qualtrics Survey**

Welcome to the Expedited Review Audit Checklist toolkit. If you have any questions about how to utilize the online toolkit or if you find an error, please contact Kathleen Murphy. If you have general questions about the Expedited Review Audit Checklist, please discuss with your manager or contact the compliance team.

Choose the quarter in which the submission was reviewed and approved:

- Q1 (September - November)
- Q2 (December - February)
- Q3 (March - May)
- Q4 (June - August)

Input the IRB study number (STU) associated with this review:

Input the name of the analyst that reviewed the submission:

Input the date the submission was approved:

Input the name of the person that conducted the audit:

Input the date the audit was conducted (mm/dd/yyyy):

Choose the type of submission being reviewed:

- Initial Study
- Continuing Review
- Modification

The following questions pertain to Initial New Study reviews:

Did the review include a summary of the study?

- Yes
- No

Did the review include a statement about sound research design?

- Yes
- No

Did the review include a statement that risks are reasonable in relation to anticipated benefits?

- Yes
- No

Did the review include a statement that criteria for IRB approval of research has been met and the correct citation is included?

- Yes

No

Did the review include a statement on outcome of COI review?

Yes

No

Did the review include a statement that consent form meets the criteria for approval?  
(45CFR46.111 or other citation if applicable)

Yes

No

N/A

Did the review include any applicable Checklists uploaded for waivers?

Yes

No

N/A

Did the review include any applicable checklists for subpart populations?

Yes

No

N/A

Comments: (include any noted trends, areas of concern, etc.)



The following questions pertain to Modifications:

Did the review include a summary of the modifications being requested?

- Yes
- No

Did the review include a statement about change in risks if applicable?

- Yes
- No
- N/A

Did the review include a statement about change in study design if applicable?

- Yes
- No
- N/A

If applicable, did the review include the selection of a new expedited category (1-7)?

- Yes
- No
- N/A

For change in PI or Co-I, did the review include a statement on the outcome of COI review?

- Yes
- No
- N/A

Comments: (include any noted trends, areas of concern, etc.)

The following questions pertain to Continuing Reviews:

Did the review include a summary of current status of the study?

- Yes
- No

Did the review include a summary of modifications over the past year?

- Yes
- No

Did the review include a summary of RNIs over the past year?

- Yes
- No

Did the review include a statement about any change in risks?

- Yes
- No

Did the review include a statement of any changes to COI review over the past year?

- Yes
- No

Did the review include a statement that the criteria for IRB approval of research continues to be met with the relevant citation(s) that apply?

- Yes
- No

Did the review include a statement that consent form(s) continue to meet the criteria for IRB approval of research?

- Yes
- No
- N/A

Did the review include a statement that there has been no changes over the past year that would impact previously made waiver or subpart determinations?

- Yes
- No
- N/A

Comments: (include any noted trends, areas of concern, etc.)

Powered by Qualtrics