

**OIA-430 CHECKLIST: Staff Quality Improvement Assessment**

NUMBER	DATE	PAGE
OIA-430	12/21/2023	1 of 1

The purpose of this checklist is to allow Office of IRB Administration (OIA) to conduct a quality improvement assessment of OIA staff who serve as designated reviewers; make exempt, not human subjects research (NHSR), or not engaged determinations; or support IRB review. This checklist, or equivalent, is to be used. It does not have to be completed or retained.

<b>OIA Staff Designated Reviewer</b>	
<b>Submissions Selected for Assessment</b>	
<b>Name of Person Completing Checklist</b>	
<b>Date Assessment Completed</b>	

**1 Review Requirements**

<input type="checkbox"/> Yes <input type="checkbox"/> No	Does the "review type" in the review assignment match the final determination (i.e. NHSR, exempt, expedited)?
<input type="checkbox"/> Yes <input type="checkbox"/> No	Was the appropriate committee selected in the review assignment?
<input type="checkbox"/> Yes <input type="checkbox"/> No	Is the OIA staff member appropriately listed as admin reviewer and/or primary reviewer in the review assignment?
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	For <u>non-committee reviews</u> , was the submission assigned to a meeting date after the date of approval/determination?
<input type="checkbox"/> Yes <input type="checkbox"/> No	Was the correct review type identified?
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Were the correct agencies identified as having regulatory oversight based on the electronic submission system application?
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Based on information in the electronic submission system application, have the appropriate exempt or expedited categories been selected?
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Have any required special determinations been identified (e.g. <u>children</u> , <u>HIPAA</u> waiver, etc.) based on the electronic submission system application?
<input type="checkbox"/> Yes <input type="checkbox"/> No	Are the appropriate determinations in the determination letter, or equivalent?
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Were all action items/review comments resolved?
<input type="checkbox"/> Yes <input type="checkbox"/> No	Does the determination letter, or equivalent, use the appropriate OIA template language?
<input type="checkbox"/> Yes <input type="checkbox"/> No	Has the determination letter, or equivalent, appropriately modified the OIA template language to reflect the relevant determinations?
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Have notes to file, or equivalent, been added/updated to include any relevant information for future reviewers? (e.g. expedited category 9 determination, IRB assignment, relevant determinations, etc.)

**2 Review Efficiency**

Indicate the number of days between assignment to designated reviewer and first review:

Indicate the number of days between resubmission after first analyst review and action (i.e. request revisions, assign to IRB, approve, accept):

*Add additional lines as necessary for multiple rounds of review and revision.*

Indicate number of days between meeting date and determination communication:  N/A, studies not reviewed by convened IRB

*Add additional lines as necessary for multiple rounds of review and revision.*