

	OIA-303 WORKSHEET: Communication of Review Results		
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The purpose of this worksheet is to provide support for Office of IRB Administration (OIA) staff who send communications after an IRB review. This worksheet, or equivalent, lists the letters that need to be prepared and sent after each review. This worksheet, or equivalent, is to be used. It does not need to be completed or retained.

IF THE CONVENED IRB, DESIGNATED REVIEWER, OR OTHER DESIGNEE: COMPLETE THE FOLLOWING TEMPLATE LETTER AND SEND TO ALL INDIVIDUALS LISTED IN CC LIST

Approved protocol	<i>OIA-510 TEMPLATE LETTER: Approval of Protocol, or equivalent</i>
Acknowledged a protocol closure	<i>OIA-511 TEMPLATE LETTER: Acknowledgment of Research Closure, or equivalent</i>
Required modifications to protocol to secure approval	<i>OIA-512 TEMPLATE LETTER: Approved Pending Required Modifications, or equivalent</i>
Determined that the activity is not <u>human research</u>	<i>OIA-513 TEMPLATE LETTER: Non-Human Research Determination, or equivalent</i>
Determined that the activity is <u>human research</u> in which the institution is not engaged	<i>OIA-513 TEMPLATE LETTER: Non-Human Research Determination, or equivalent</i>
With modifications the activity would not be <u>human research</u>	<i>OIA-514 TEMPLATE LETTER: Modifications Required Not Human Research, or equivalent</i>
Approved <u>research</u> conducted or funded by Department of Health and Human Services involving <u>prisoners</u> as subjects	<i>OIA-522 TEMPLATE LETTER: Certification of Approval of Prisoner Research, or equivalent</i>
Reviewed a reportable event	<i>OIA-524 TEMPLATE LETTER: Acknowledgment of Report, or equivalent</i>
Reviewed emergency use notification	<i>OIA-526 TEMPLATE LETTER: Acknowledgment of Emergency Use, or equivalent</i>
Accepted reliance on an external IRB	<i>OIA-527 TEMPLATE LETTER: Acceptance of Reliance on External IRB, or equivalent</i>
Reviewed expired <u>research</u> for continuation of subjects	<i>OIA-532 TEMPLATE LETTER: Continuation of Subjects in Expired Research, or equivalent</i>

THE FOLLOWING DETERMINATIONS CAN ONLY BE MADE BY A CONVENED IRB

Deferred protocol	<i>OIA-516 TEMPLATE LETTER: Deferral of Protocol, or equivalent</i>
Disapproved protocol	<i>OIA-517 TEMPLATE LETTER: Disapproval of Protocol, or equivalent</i>
Tabled the protocol	<i>OIA-518 TEMPLATE LETTER: Tabled Protocol, or equivalent. Place on the agenda for the next IRB meeting</i>
Reviewed an <u>Unanticipated problem involving risks to subjects or others/unanticipated problem report, serious or continuing non-compliance, or a suspension or termination of IRB approval that requires reporting to a federal agency</u>	<i>OIA-520 TEMPLATE LETTER: External Report, or equivalent</i>
Determined that a study submitted under the abbreviated requirements involved a significant risk device (Food and Drug Administration)	<i>OIA-521 TEMPLATE LETTER: Significant Risk Determination, or equivalent</i>
Approved not otherwise approvable <u>research</u> involving <u>children</u> , pregnant subjects, or neonates	<i>OIA-523 TEMPLATE LETTER: Review of Not Otherwise Approvable Research, or equivalent</i>
Approved a waiver of the consent process for planned emergency <u>research</u>	<i>OIA 525: TEMPLATE LETTER: OHRP Notification of Emergency Waiver, or equivalent</i>