

Principal Investigator: *[Insert Last, First, Middle Name – if applicable: Study ID]*

Acknowledgment Letter from IRB/HRPP Official – Template

INSTRUCTIONS FOR COMPLETING THIS TEMPLATE:

1. Insert study-specific text where included below in *green italics*.
2. Once this template has been completed:
 - a. Delete the orange instructional text
 - a. Change all text to black
 - b. Add Collaborating Institution Letterhead
 - c. Obtain signature of appropriate IRB/HRPP official from collaborating institution
 - d. Save as a PDF

[Insert date]

[Insert name and address of PI of application]

RE: IRB Reliance for *[Insert IMPACT RFA #, followed by project study title.]*

Dear *[Insert name of PI of application]*:

[Insert name of collaborating institution] understands that the code of federal regulations (45 CFR 46.114), with limited exception, establishes the expectation that all institutions participating in federally funded studies involving non-exempt human subjects research will use a single Institutional Review Board (sIRB) to conduct the ethical review required by the Department of Health and Human Services regulations for the Protection of Human Subjects.

[Insert name of collaborating institution] further understands that the funding mechanism for this application, The National Institute on Aging (NIA) Imbedded Pragmatic AD/ADRD Clinical Trials (IMPACT) Collaboratory (U54AG063546), allows projects without a clinical trial component the option of selecting the local IRB of the principal investigator's (or Co-I's) home institution as the sIRB for non-exempt research so long as the following is met:

- the IRB complies with all federal regulations related to the ethical oversight of human subjects research
- the IRB has experience serving as an sIRB

Otherwise, Advarra Inc. will be the sIRB.

[Applicable if the IRB of Record will NOT be Advarra, otherwise delete this paragraph]:

The principal investigator's choice of *[Insert name of chosen IRB of Record]* meets both qualifications above. This letter confirms the willingness of *[Insert name of collaborating institution]* to rely on this IRB as the sIRB for this research should it be funded and not fall under an exemption category.

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[Applicable if the IRB of Record WILL be Advarra, otherwise delete this paragraph]:

This letter confirms the willingness of *[Insert name of collaborating institution]* to rely on Advarra, Inc. for this research should it be funded and not fall under an exemption category. Advarra is an independent IRB and research quality and compliance consulting service that is fully accredited by AAHRPP (<https://www.advarra.com/>).

[Applicable if the collaborating institution is a member of SMART IRB, otherwise delete this paragraph]: *[Insert name of collaborating institution]* has signed onto the SMART IRB Agreement (www.smartirb.org), which is a standard, national, master IRB reliance agreement that is responsive to the NIH sIRB Policy. We can leverage the SMART IRB Agreement as

applicable to this Research Collaboratory to great effect to reduce regulatory oversight burden and facilitate expeditious review.

I look forward to collaborating with you and your team to address the IRB oversight needs for this grant.

Best wishes for a successful application.

Sincerely,

[Insert signature of appropriate IRB/HRPP official from collaborating institution]

[Insert name of appropriate IRB/HRPP official from collaborating institution]