

subsequent applications for funding to support dissemination and implementation efforts through separate PFAs and other mechanisms.



Note: PCORI encourages researchers to submit documentation of any implementation agreement with the sponsoring organization, confirming that the organization will implement successful interventions on a large scale. PCORI will view this agreement as a positive factor during merit review. Include this with the [Letters of Support](#) PDF document as the last item.

Return of Aggregate Study Results

In this component (up to one page), applicants should describe how, as awarded, they plan to communicate the aggregate findings from their research to the participants who were enrolled in the study. Note that the proposed activity should return *aggregate* study results (i.e., the overall study findings) to the study participants, and not *individual* results (i.e., participant-specific data, such as genetic or imaging results). Results return may be accomplished by sharing the lay language “Results Summary” that PCORI posts to its website upon completion of the research project, or by distributing a similar summary. Applicants may propose to distribute the study results to study participants by email, mail, newsletter, or other approaches.

In the Detailed Budget tab in PCORI Online and in the [Budget Justification Template](#), specify the costs associated with this return of results to study participants. For studies with fewer than 5,000 participants may budget up to \$2,500. If this amount does not cover studies that need to return results to a larger number of participants, applicants may propose a larger amount with justification. Note that the costs associated with the return of results must be included as part of the Total Budget (in PCORI Online) when determining compliance with the Maximum Project Budget in the [PFA](#).

Applicants should consider whether they will need to obtain IRB approval ahead of the study in order to recontact participants at its conclusion. In addition, awardees should make all efforts to ensure that returning results is in accordance with the jurisdiction and/or state’s guidelines and laws.

Studies may be exempt from this provision if a return of results is not possible. For example, this provision does not apply to studies that use secondary data or those that use anonymous participants. If applicable, applicants’ responses in this section should address why the return of results is not feasible.

Protection of Human Subjects

In this component (up to five pages), describe the protection of human subjects involved in your research. PCORI follows the Federal Policy for the Protection of Human Subjects ([45 CFR part 46](#)), including the Common Rule. For more detailed information, see Section 5, “Human Subjects Research Policy,” from the [Supplemental Grant Application Instructions for All Competing Applications and Progress Reports](#),¹⁵ which was issued by the U.S. Department of Health and Human Services (Department of HHS). Refer to the [Required Education of Key Personnel on the Protection of Human Subject Participants](#) requirement as you complete this section.

¹⁵ See <http://grants.nih.gov/sites/default/files/supplementalinstructions.docx>.

