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Instructions for Combined Draft Final Research and Supplemental Reports

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Combined Draft Final Research Reports (DFRR) and Supplemental Reports

These instructions apply to supplemental research projects funded in addition to the main funded research project. The information in this document augments and does not replace the main DFRR instructions in the "Draft Final Research Report: Instructions for Awardee."

Requirements

The awardee will submit a single Combined DFRR and Supplemental Report that includes a full account of both studies. It should be noted at the end of the report's Table of Contents that the report is combined and includes a Supplemental Report. The report should be about 1700 lines (or 20,000 words) from the Background to the Conclusions section, not including the Abstract, Tables, Figures, or References.

Aims vs. Standard Structure

The content and format of the Combined Report should follow the "Draft Final Research Report: Instructions for Awardee" for a standard DFRR. Regardless of which structure is chosen for the report, please state that the report includes both studies in the Background section of both the Abstract and the main text. Depending on report type and chosen structure, investigators should refer to the "Standard Template," "Aims Template," and/or "Methods Template" on the Author Resources website to aid the writing process.

STANDARD STRUCTURE

If investigators choose the standard structure to organize the report, detailed information about the main study should be provided first, including Background, Engagement, Methods, and Results. Details about the supplemental study should follow and should include only information that is distinct from what has already been provided in the main study section. Investigators should avoid repeating information in two places. For instance, if the study populations are the same, authors do not need to repeat information and can point readers to the earlier main study population description. However, if the DFRR and the Supplemental Report differ for any report section, investigators should ensure that section descriptions give a complete account of both projects by including additional details. The Combined Report should include a single Discussion section with required subheadings and a single Conclusions section covering both studies and describe any commonalities between the two. Figure 1 outlines the order of sections for a Standard Combined Report.

AIMS STRUCTURE

If the main project and the supplemental project included aims with distinct methods and results, investigators may organize the DFRR by aim. When organizing the Combined DFRR and Supplemental Report by aim, the aims of the main study should appear first, and the supplemental aims should follow.

For the supplemental study, please reference details in prior aims sections to avoid repeating previously provided information. Figure 1 outlines the order of sections for an Aims Combined Report.

Figure 1. Standard vs. Aims Structure Comparison

STANDARD	**AIMS**
ABSTRACT (Structured and up to 1000 words)	ABSTRACT (Structured and up to 1000 words)
MAIN STUDY	OVERALL BACKGROUND
BACKGROUND	ENGAGEMENT OF PATIENTS, CAREGIVERS, AND OTHER HEALTHCARE DECISION MAKERS
ENGAGEMENT OF PATIENTS, CAREGIVERS, AND OTHER HEALTHCARE DECISION MAKERS	AIM 1 (**from Main Study**) • Short Background/Introduction • Methods • Results
METHODS	AIM 2 (**from Main Study**) • Short Background/Introduction • Methods • Results
RESULTS	AIM 3 (**from Supplemental Study**) • Short Background/Introduction • Methods • Results
SUPPLEMENTAL STUDY	OVERALL DISCUSSION
BACKGROUND	OVERALL CONCLUSIONS
ENGAGEMENT OF PATIENTS, CAREGIVERS, AND OTHER HEALTHCARE DECISION MAKERS	REFERENCES
METHODS	
RESULTS	
OVERALL DISCUSSION	
OVERALL CONCLUSIONS	
REFERENCES	

This table provides a side-by-side comparison of **the Standard Template** and **the Aims Template**, highlighting the structural differences and core features of each.

Combined DFRR and Supplemental Report FAQ

Can I see examples of Combined Reports that include the main study and the supplemental study?

Although these examples have 2 abstracts, one for the DFRR and one for the Supplemental Report, please include only one overall abstract in your Combined DFRR and Supplemental Report.

Standard Organization

- *Using Visual Methods to Apply Results from COVID-19 Related Randomized Controlled Trials to Patients Receiving Care at Clinics and Hospitals*.
- *The Impact of Medicaid Health Homes on Patients with Diabetes*.

Aims Organization

- *Comparing the Effectiveness of Breast Cancer Screening and Diagnostic Tests among Women with Different Breast Densities—The BCSC-ADVANCE Study*.
- *Effect of High-Deductible Health Plans and Preventive Drug Lists on Asthma Attacks, Medicine Use, and Out-of-Pocket Costs – The AFFORD Study*.

We invite you to explore PCORI's Portfolio, which encompasses PCORI's wide variety of funding types with over 500 Final Research Reports.

We also welcome you to reach out to Author Services at originreview@kwglobal.com with questions about your specific report.

My supplemental project primarily involved adding a telehealth version of my intervention to the trial to compare against the in-person version and the comparator condition. How should I organize the report?

Investigators can use the combined format and separate the main study and the supplemental study. However, investigators can also consider writing a single Methods section and a single Results section that encompass both projects. For instance, in the Background, include a section about the addition of the telehealth component, how the remainder of the report is organized, and the hypotheses about the additional study arm. In Methods, describe both the in-person and telehealth versions of the intervention. Be sure to accurately describe data collection differences and time period differences and address those differences in the analyses. Describe Results for the intervention vs. comparator analyses as well as for the three-arm analyses if applicable. Address all results and limitations in the Discussion.

My supplemental project has multiple aims and complex methods. How can I fit that and my main project into 1700 lines (or 20,000 words)?

Some supplemental projects are as complex as the original research awards and cannot be completely captured with the main project in 1700 lines (or 20,000 words). If you believe you will need considerably more space, please contact the Author Services team at originreview@kwglobal.com to discuss the appropriate size of the report.