Record of Implementation

Project Name: [Title] | **Project Code:** [XXXX]

How this document is to be used:

Use this document to record notes on the implementation of the project — in particular, anything that did not go according to the plan laid out in the Project Design Document. This template contains prompts for information on specific aspects of implementation that may not go as planned, but these are not meant to be exhaustive. Any details about implementation that may be important for later analysis and interpretation of the results should be recorded—and can be recorded in the final section of the template if they do not fit elsewhere. If external tools are useful—for example, the CONSORT flow diagram or other charts or tables—please feel free to use them and link to them from this document.

Implementation should be documented on an ongoing basis to ensure that all relevant unanticipated events and changing conditions are recorded.

Before OES takes possession of outcome data, the Analysis Plan should be reviewed in light of this Record of Implementation for any required revisions (i.e., while it is possible to revise the Analysis Plan and still report results as coming from planned/confirmatory analyses).

Sample Size:

How many individuals (or other randomized units) were trackable at different points during implementation? Include a funnel chart or flowchart if useful. For example, if the project involves an email intervention, how many emails were sent, how many came back as undeliverable, and so on? Record numbers per treatment condition if available.

[Insert text here, and delete the red prompt above when the document is final.]

Randomization:

[Describe any unanticipated features of the randomization. Describe how randomization was checked - for example, by including team members on mailing lists, looking at return mail, reviewing code, etc.]

[Insert text here, and delete the red prompt above when the document is final.]

Intervention Materials:

[Record any ways in which the intervention materials might have departed from the materials described in the Project Design Document (e.g., printing errors). Include links to intervention materials as implemented, if appropriate.]

[Insert text here, and delete the red prompt above when the document is final.]

Intervention Delivery:

[Record any ways in which the delivery of the intervention might have departed from the plans described in the Project Design Document (e.g., delayed mailing). Include any available data on delivery of intervention at different points during the field period.]

[Insert text here, and delete the red prompt above when the document is final.]

Attrition:

Record anything learned about attrition of individuals (or other randomized units) during the study, whether anticipated or unanticipated. Attrition should be interpreted broadly to mean loss of units, or of observation of units, from randomization to final outcome data.

[Insert text here, and delete the red prompt above when the document is final.]

Changes in Background Conditions:

Were there any changes in environmental or background conditions during the field period that could have affected outcomes? If so, did these changes affect the control and treatment conditions equally, or could there have been differential impact?

[Insert text here, and delete the red prompt above when the document is final.]

Data Collection:

Record any unanticipated limitations on either the completeness or the accuracy of the data collected during implementation.

[Insert text here, and delete the red prompt above when the document is final.]

Any Other Departures From Planned Project Design:

Record any other features of implementation that may be important for later analysis and interpretation of the results.

[Insert text here, and delete the red prompt above when the document is final.]