



PSI Research Ethics Program
PREPARING A COMPLETE PACKET FOR THE PSI/REB:
SUBMISSION FORM, STUDY DESIGN, SIGNATURE PAGE

Version: February 2012

A description of a complete packet:

Instructions for completing the Submission Form

The Submission Form is required for each new submission to the PSI/REB. Detailed instructions for completing the Submission Form are found in the document “Instructions for Completing the REB Submission Form.”

General Guidance for Completing a TRaC or FoQus or MAP Study Design

The Study Design explains the proposed study in detail and is the basis for completing the Submission Form. Detailed instructions for completing the Study Design templates are included within the template itself. Forms are located on the PSI/R&M Kix page. In order to increase the likelihood that a study will be reviewed as quickly as possible and to minimize the number of issues raised by the REB, it is important that the document address all the topics raised in the Study Design template.

Complete the Signature Page

The Signature Page documents the technical review of a research protocol prior to submission to the PSI/REB or to an alternate committee. The Signature Page template provides the names, titles and signatures of all those who have reviewed the submission package. The signatures represent each reviewer’s assurance that the submission is acceptable according to each person’s area of expertise (Regional Researcher, Expert Reviewer(s) and Country Representative).

Ensure that the submission package is complete.

Researchers should submit a complete package to the REB. If components are missing, the REB will not initiate the review. A complete submission package includes the following (Section 2 of the Submission Form):

- ✓ The Submission Form
 - Human Subject Training Certificates and CVs for all investigators, if not previously submitted
- ✓ Signature Page
- ✓ Study Design
 - Recruitment Script
 - Consent Forms (including parental consent if applicable)
 - Assent Forms (for minors if applicable)
 - Timeline/Gnatt Chart
 - Budget
 - Tract Indicators
 - Dummy Tables
 - Screening Questionnaire
 - Questionnaire
 - Interview Guide
- ✓ Other annexes specific to the study:
 - Recruitment materials (brochures, printed advertisements, coupons, etc.)
 - Data use agreements (for the use of data from another source)
 - Photo-narrative instructions
 - Any other document researchers deem useful for a better understanding of the study.