

Streamlined PRO SmartForm for Clinical Trials!

The IRB Office has implemented a simplified SmartForm for clinical trials that leverages the information provided in the protocol. Seventeen questions/sections of the PRO SmartForm have been removed. The most significant revision is the addition of a table in Section 30 where research activities are entered. The format allows the research team to reference the protocol directly rather than duplicating information; indicate when, where, and who will perform procedures; note local variations; or indicate when specific procedures will not occur locally.

The table consolidates information previously scattered across multiple sections, and the duplicate questions have been removed. By leveraging the protocol as the primary reference document, the process eliminates unnecessary documentation burden while ensuring IRB reviewers have clear visibility into how trials are conducted locally, including any site-specific adaptations or exclusions.

30. Procedures and Analysis

30.0 * Explain all project procedures and how they will be conducted locally. Either refer to a schedule of events in the table below, in the "When will the activity occur?" section and upload the document in Section 52, or list out the specific timepoints when the activity will occur in the table below. ⓘ

	Research Activity	Description	Location	Performed By	Timepoint	Order
	Health history including height, physical examination, and weight	As described in Protocol	Adult TRU	Cancer Center TRU Nurse	Screening	1
	International Prognostic Index	As described in Protocol	Cancer Center	Physician	Screening	2
	Blood draw	As described in Protocol	Wisconsin Diagnostics Laboratory (WDL) or FH Outpatient setting	WDL staff or Froedtert Hospital staff	Screening within 4 weeks of treatment initiation and 4-6 weeks after completing treatment	3
	Bone Marrow biopsy/aspirate	As described in Protocol	Cancer Center	Physician	See Schedule of Events pages 12-15 in the protocol	4
	Drug administration	As described in Protocol	Froedtert Hospital IDS	Pharmacist	See Schedule of Events, [ages 12-15 in the protocol	5
	Quality of Life questionnaires	As described in Protocol	Neurosciences Research Clinic	Clinical Research Coordinator	See Schedule of Events pages 12-15 in the protocol	6
	MRI	As described in Protocol	Daniel Soref Research Imaging Facility	MRI technologist	See Schedule of Events pages 12-15 in the protocol	7

eBridge

Validating... Comparing... Editing: PRO00057686

30. Procedures and Analysis

30.0 * Explain all project procedures and how they will be conducted locally. Either refer to a schedule of events in the table below, in the "When will the activity occur?" section and upload the document in Section 52, or list out the specific timepoints when the activity will occur in the table below. ⓘ

Add APP 30 Project Procedures

* **Research Activity** (examples: ECG, Quality of Life Questionnaires, Drug administration, Post-infusion CRS observation period, Alfapump implant procedure):

* **Description:**

As described in Protocol

Adhering to differing local policy

Not participating in this portion of the Protocol

* **Location of the activity** (examples: Adult TRU, Froedtert Hospital Pavilion, Wisconsin Diagnostics Laboratory (WDL)):

* **Who will perform the activity?** (examples: TRU Nurse, Cardiologist, Clinical Research Coordinator, PI)

* **When will the activity occur?** (examples: Screening, Baseline, See Schedule of Events uploaded in Section 52)

* **Enter a number to sort the display of activities in the table.** (example: "1" will display the research activity first in the table)

* Required

OK OK and Add Another Cancel

Section 30 Tips & Tricks

You are able to control the order that the research activities appear on the table. It is preferred that activities be listed sequentially and/or by specific cohort when possible.

Location of the Activity – Avoid room numbers or specific clinic names, and instead use larger areas or building names, (e.g., Neurosciences Research Clinic, Froedtert Cancer Center Clinics, Adult TRU, Department Research Space, inpatient TRU, Wisconsin Diagnostic Laboratory, Radiology, Daniel Soref Imaging Research building).

Who will perform the activity? - Avoid specific names of people performing research procedures, and instead use titles, roles, or profession, (e.g., Radiologist, Principal Investigator, treating physician, Clinical Research Coordinator, Adult TRU nurse).

When will the activity occur? - Reference a Schedule of Events or similar if available in the protocol.

If an activity is listed within the Protocol but is not occurring locally, the activity should be represented within the table in Section 30. You are able to indicate the activity will not be conducted locally.

If you have questions, need assistance or would like help completing the PRO SmartForm, please email irboffice@mcw.edu and we will set up a time to meet with you.