

PORF SIGNATORY QUICK REFERENCE

- Protocol Oversight Review Form (PORF)
- Human Research Protection Program (HRPP)

WHAT YOU ARE RESPONSIBLE FOR

You attest that appropriate reviews have occurred

- A **scientific review** has been conducted by the appropriate reviewer(s): departmental scientific committee, peer review, industry/federal review, or equivalent process.
- A **quality review** has been completed, ensuring alignment across protocol materials and use of current templates.

You attest that essential requirements are in place

- The protocol and consent **tell the same story**: aligned procedures, risks, benefits, and data plans.
- All study personnel are **qualified, credentialed, and appropriately supervised** for the procedures described.
- Required **HSP and COI trainings** are complete and current for all listed personnel.
- The team has the **resources, staffing, and facilities** to conduct the study as proposed.

You attest the submission is ready for IRB review

- The application has been **proofread**, is **complete**, and contains all required materials.
- The science is **sound, feasible**, and “likely to answer the scientific question”—based on the review completed by the appropriate reviewer(s).

WHAT YOU ARE NOT PERSONALLY VERIFYING

You are NOT personally certifying that you:

- Checked all elements of the scientific review.
- Verified credentials, privileges, or resources.
- Confirmed training or COI completions.
- Validated methodological or statistical detail.
- Reviewed every document line-by-line.

You are attesting that **your unit has a functioning process** in place and that the appropriate reviewer(s) have performed the necessary checks. Your signature verifies that **oversight has occurred**, not that you personally performed all underlying steps.

Core Scientific Elements Confirmed by Your Unit's Reviewers

- Clear purpose and research question
- Appropriate design and methodology
- Adequate sample-size justification
- Feasible recruitment plan
- Appropriate procedures/validated measures
- Awareness of duplicative/competing studies

Core Quality Elements Confirmed by Your Unit's Reviewers

- Protocol ↔ consent alignment
- Accurate and consistent risk/benefit descriptions
- Clear data security/confidentiality practices
- Use of current templates and required institutional language

Common Preventable Errors (to screen before signing)

- Missing or outdated PORF
- Missing training documentation
- Incomplete/inconsistent application content
- Missing attachments or required materials
- Outdated templates
- Misalignment between protocol, consent, and recruitment materials