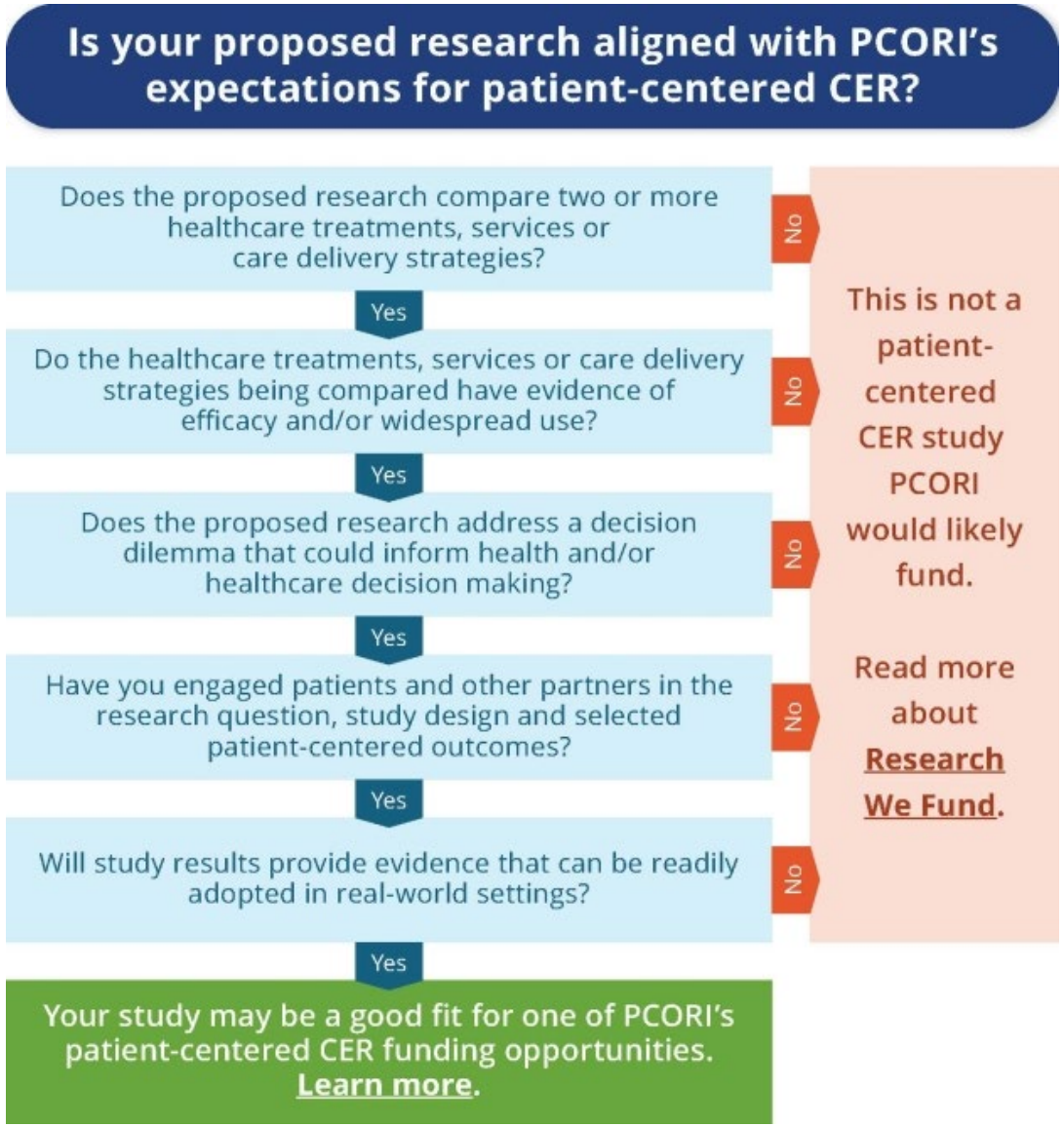

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The Letter of Intent Hurdle

Framing Your Research for PCORI/PCORnet Proposals

What is a PCORI Letter of Intent (LOI)?

- PCORI Letters of Intent (LOIs) are required, 3-page (typically) preliminary submissions that must align strictly with specific PCORI Funding Announcements (PFAs).
- MUST be submitted before an organization is invited to submit a full application

- Sample PFA

LOI Basic Tips

- Follow the PFA very carefully
- Use the PFA-specific LOI template
  - Replace the gray italics and any instructional text with your responses, but retain the bold headings and question numbers.
- Prioritize Patient-Centeredness
  - If you have done this well, your question will be better, it will be focused on a decisional dilemma and appropriate patient-centered outcomes
- Focus on PCORI-allowed comparators
- Include Stakeholder Engagement
- Be Concise and Focused
- Check Eligibility
  - In 2026, PI or dual-PI can only submit one LOI per cycle across select funding opportunities

LOI Common Pitfalls

- Ignoring the specific requirements in the PFA
  - Read the fine print
- Proposing research that does not include a comparative element
  - Or comparators that are too “niche”, costly, or not available for real-world use
- Focusing solely on scientific rigor without sufficient attention to patient engagement
  - How have patients been involved it determining the CER question?
  - How will patients co-develop measures, tools, procedures, etc, etc, etc
- Using a PFA from a previous funding cycle
  - Use the old one as a guide for early drafts, but carefully review the actual PFA when released
  - Very tricky – usually only 4 weeks from release to LOI submission deadline

A few examples

	NET-PRO	MOMS-KT	Obstetric Patient Safety Bundles
Funding Mechanism	Limited Competition: Rare Disease Using PCORnet	Retrospective Observational Studies Leveraging Existing Data Sources	Maternal Morbidity and Mortality Topical PCORI Funding Announcement
Allowable duration	3 years	18 months (!)	Up to 5 years
Funding amount	$3.5 million	Up to $2 million	Up to $12 million
Study design proposed	Prospective observational	Retrospective	Mostly retrospective with patient surveys
Approved for proposal submission?	Yes	No	Yes
Awarded?	Yes	No	No

Questions and Comparators

	NET-PRO	MOMS-KT	Obstetric Patient Safety Bundles
Overarching research question	No clear consensus guidelines as to the ideal sequencing of therapeutic options. This has led patients to ponder not only 'what therapy would be best to try next?', but 'if I were to take this option now, what treatment options will be closed off to me in the future?'	Women with KT face an extraordinarily difficult decisional dilemma: forego pregnancy to protect their health and life-saving KT, or accept significant risks of rejection, graft loss requiring return to dialysis, and shortened lifespan in pursuit of motherhood	Which bundle elements and strategies ensure the best maternal clinical outcomes and patient-reported outcomes if only a portion of the bundle is implemented
Comparators	Co-production partners framing a suite of CER questions under the broad frame of interest to NET patients i.e.: "what limits my treatment path?"	**Immunosuppression transition strategies**, including timing of mycophenolate discontinuation and approaches to azathioprine conversion. **Timing of pregnancy after transplantation** (<1 year, 1–3 years, >3 years post-transplant).	type classification based on process and structure measures data from ACOG and implementation strategies based on interview data from perinatal quality collaboratives

Nature of the research question and “fit” to the PFA

- NET-PRO – strong, direct fit with the Rare Disease PCORnet PFA
  - Addresses a clear, patient-expressed decisional dilemma, outcomes map well onto PCORI’s patient-centered outcomes mission
- MOMS-KT – Excellent science, weaker structural alignment
  - Highly responsive to patient engagement with stakeholders involved for 12 months, real and urgent decisional dilemma
  - The PFA prioritizes broad applicability and MOMS-KT may have been perceived as affecting a small clinically complex population and/or pregnancy timing not viewed as a “comparator” in the same sense as health interventions.
- Obstetric Bundles – conceptually strong but stretched
  - Aligned with MMM priorities and equity
  - LOI tried to do 4 demanding things simultaneously may have increased perceived risk

Organization and aesthetic appeal

- Organization matches LOI required elements (subheadings), uses enumeration
- White space
- Invites reviewers

	NET-PRO	MOMS-KT	Obstetric Patient Safety Bundles
Organization	paragraphs	Enumerated headings corresponding to LOI template headings	Paragraphs, bolded LOI template headings sometimes embedded in paragraph
Visual appeal	Text dense	White space, mirrors the LOI template	Text dense

Population size and reviewer comfort

	NET-PRO	MOMS-KT	Obstetric Patient Safety Bundles
Population	Rare but thousands nationally	Very small (800–1,200 pregnancies)	Very large (state/national)
Reviewer familiarity	Oncology, registry science	Transplant + pregnancy (niche)	Maternal health, QI
Outcome types	Symptoms, toxicity, progression	Graft function, rejection	SMMM, respectful care, mortality

- PCORI panels lean toward breadth and translational immediacy
- MOMS-KT requires specialized clinical literacy to appreciate its importance (as currently written)

Engagement

- All three strong, but differently leveraged

	NET-PRO	MOMS-KT	Obstetric Patient Safety Bundles
Engagement	Patients as co-creators of question and infrastructure (portal+survey)	Deep, authentic engagement but not structurally integrated into the study outputs	Stakeholders engaged deeply as informants and dissemination partners
Sample language	• "Our founding patient partner organization is the Northern California CacriNET Communities (represented by its President Josh Mailman, Co-I)…. engage other national orgs during proposal writing" • "….patients may run out of resilience to withstand toxicity before they run out of treatment options (personal communication, Josh Mailman, patient Co-I)…. "Using participatory design tools and human-centered design principles, we will involve patients in creating the NET Patient Health	• "Through 12 months of engagement including meetings and surveys with three patient stakeholder organizations (EndPreeclampsia, Transplant Pregnancy Registry International, and Improving Renal Outcomes Collaborative), we identified…" • "Patient advocacy partners serve as study co-Investigators" • Will meet quarterly	• "Aim 2: Measure the receipt of respectful, equitable, and supportive care among patients from 10 PCORnet sites with either a severe hypertension or substance use disorder diagnosis using a survey co-developed with patient stakeholders." • "Aim 4: Disseminate study findings broadly to stakeholders through partnership with ACOG, patient stakeholders, and perinatal quality collaboratives."

Discussion

- Your experience
- Your questions
- Your suggestions

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