joinirb.com FAQ: What Data We Need, and Why

Protocol PPRN-001-2025 · IRCM-2025-467 · PI: M. Scott Mortensen MD, MPAS, MLT

The mission in two lines

More patients in the dataset means more statistical power. Statistical power is what turns "my patients do well on this" into evidence that regulators, payers and courts have to reckon with. That is how proactive care gets legalized: efficacy and safety, counted.

1. What data do you need?

Four things per visit. Everything else is optional.

1. The protocol. What was given. - Molecule (BPC-157, TB-500, semaglutide, tirzepatide, CJC-1295, ipamorelin, NAD+, MOTS-c, and so on). Molecule, not brand. - Dose and unit (500 mcg, 2.5 mg, 100 IU). - Route (subcutaneous, IM, intra-articular, oral, nasal, topical). - One line per molecule. A stack is three lines.

2. The visit. When. - Baseline, 4–8 weeks, 16 weeks, 6 months, 12 months. - Study day (days since baseline; baseline is 0). Never a calendar date.

3. The outcome. Did it work. - Pain at rest and pain with activity, 0–10. - At follow-ups: global change, 1–7 (1 = no change or worse, 7 = a great deal better).

4. Safety. Did anything go wrong. - Adverse event since last visit: No or Yes. - If Yes: serious?, severity, related to the protocol?, outcome.

Plus a registry ID (PPRN001–0001), age band (50-59) and sex. That is the whole form.

2. What else can we send if we have it?

Send it; every extra field sharpens the signal. None of it is required. - Source class (503A, 503B, FDA-approved, research-use-only), lot number, COA on file. - Concentration after reconstitution, cadence (daily, 2x/week), anatomic site, procedure code. - Co-administered agents in the same injectate (steroids, anesthetics). Flag these; they confound results. - A validated function score: KOOS-JR, HOOS-JR, QuickDASH, VISA-A, ODI, NDI, PROMIS. - NSAID days per week, opioid MME per week, steroid injections in the prior 6 months. - Days to return to work or sport. Surgery avoided or deferred.

3. What must we never send?

Names, dates of birth, calendar dates, phone, email, address, MRN or chart numbers, photos. The form blocks them. The key linking a registry ID to a

patient stays at the clinic. We never see it and never want it.

4. Why no dates?

A visit date plus a ZIP code plus an age re-identifies people. Study day (0, 42, 112, 180, 365) and year carry all the science with none of the exposure.

5. What does the patient sign?

The participant informed consent at joinirb.com/forms/, in your office, kept in your chart. One signature covers every visit. Patients can withdraw any time; you send one "withdrew" record.

6. What does the clinician sign?

Once: the investigator agreement (PDF) or the online application at joinirb.com/apply/, which signs the site consent electronically. Two minutes. License and NPI are verified.

7. Do I need my own IRB?

No. One protocol, one IRB (IRCM), one registry. Your clinic is listed as a site under it. This is how Regenative Labs runs 30+ clinics under the same IRB.

8. Do I need a BAA or a data use agreement?

Not for de-identified data, which is the only kind we take. Networks that submit on behalf of many clinics sign a data coordinating agreement with the registry.

9. How does the data get to you?

- One clinic: the web form at joinirb.com/data, about 90 seconds per visit.
- A network: the batch CSV at joinirb.com/forms/, one row per visit per molecule, submitted by the network coordinator. API endpoint for direct feeds is being built by our CTO.

10. When is it due?

Visit data within 14 days. Serious adverse events within 7 calendar days. Other adverse events within 5 business days.

11. Can I fix a mistake?

Yes. Submit a correction record that references the original record number. Originals are never edited or deleted; the ledger is append-only and hash-chained. That is what makes it evidence.

12. Who owns the data?

The registry, sponsored by Mortensen Medical, a 501(c)(3). Participating sites can request aggregate reports and are named as contributors on publications drawn from their data.

13. What do I get out of it?

Your outcomes, measured against everyone else's. Published evidence with your name on it. A regulatory posture: you treat under an active IRB protocol with prospective safety reporting, which is the strongest position a peptide clinic can hold today.

14. What can I say publicly?

"We participate in the PPRN-001-2025 registry under an active IRB protocol." Never "IRB approved" about any product, and never use the registry to sell anything.

15. What does it cost?

Nothing. No fee, no purchase, no account with any company.

16. Who do I call?

Registry, roster, adverse events: contact@mortensenmedical.com. Participant rights: IRCM IRB, (786) 271-2157.