joinirb.com Network Onboarding: How Jimmy's Clinics Feed the Registry

Protocol PPRN-001-2025 (IRCM-2025-467). PI: M. Scott Mortensen MD, MPAS, MLT. Prepared 2026-10-30 for Jimmy Piccolo (EdgeMedX, Wesson Technologies, Boomerang Groupe, International Provider Network), Charlie Gamkong (CTO), and partner clinics.

The model in one line

One protocol, one IRB, one database. Jimmy's organization is the Data Coordinating Center for his network: it collects de-identified visit data from every clinic and submits it to us in bulk. Clinics treat patients and sign one form. Nobody at a clinic logs into anything.

This is the Regenative Labs model, approved by the same IRB (IRCM-2022-311): one sponsor repository, hundreds of physicians across 30+ clinics, outcomes submitted centrally, 10,000+ outcome sets, no per-clinic IRB.

Step 1. Jimmy sends the roster (one spreadsheet)

One row per clinic: clinic name, address, treating clinician, credential, state, license number, NPI, EMR, work email. We bulk-create site codes (EDG-01, EDG-02 ...) and send Jimmy the full code list the same day. Site codes stay because the IRB roster and the subject IDs need them; the clinics never have to touch them.

Step 2. Each clinician signs once (2 minutes)

- Jimmy forwards each clinician one link: joinirb.com/apply/?ref=jimmy. Name, NPI, type name to sign. Done.
- Or Jimmy collects signed Investigator Agreements as PDFs and sends them in a batch. Either one satisfies IRCM.
- Clinics keep the patient consent in their chart. Patient signs in the office. Nothing identifiable ever moves.

Step 3. Jimmy's network captures the data at the appointment

Jimmy's IPN survey tool already sits in the appointment slot. Point it at our field list (appendix) and it becomes the case report form. Minimum per visit: - Site code, registry subject ID (PPRN001–0001, assigned by the clinic, key kept at the clinic or in Jimmy's system, never sent to us) - Visit (Baseline, 4–8 wk, 16 wk, 6 mo, 12 mo), study day, year, age band, sex - Molecule, dose, unit, route (one row per molecule) - Pain at rest 0–10, pain with activity 0–10, PGIC 1–7 at follow-ups - Adverse event yes/no; if yes: serious?, severity, relatedness, outcome

Step 4. Bulk submission (Charlie and Jimmy's tech coordinate this)

- Target: Jimmy's system posts a CSV or JSON batch to a coordinating-center endpoint on joinirb.com with one coordinator key. Each row carries its site code; the ledger seals each row under that site exactly as the web form does. Charlie owns the endpoint, the schema, the identifier screen and the Part 11 controls.
- Until the endpoint is live (Charlie to date it today): Jimmy's staff key records into joinirb.com/data using each clinic's site code. Same fields, same ledger.
- Cadence: weekly batch is fine for visits. Serious adverse events go in within 7 calendar days, other adverse events within 5 business days, no waiting for the batch.

Step 5. Paper

- Data Coordinating Agreement between the registry (Mortensen Medical 501(c)(3)) and Jimmy's entity: scope, de-identification at source, no re-identification, data use. Kaveh drafts.
- No BAA needed if identifiers never leave the clinic or Jimmy's system. If Jimmy's tool holds names, that is his HIPAA posture, not ours.
- Clinics appear on the IRCM site roster at the next continuing review (Dec 2, 2026). Pamela maintains the roster.

Rules that cannot bend

- No names, dates of birth, calendar dates, phone, email, MRN. The ledger is append-only; corrections are new rows.
- Say "under an active IRB protocol (PPRN-001-2025)." Never "IRB approved" on any product or ad.
- Registry participation is never a condition of buying anything and never a selling point.

Help

- Registry, roster, adverse events: contact@mortensenmedical.com
- Technical: Charlie Gamkong, CTO
- Participant rights: IRCM Institutional Review Board, (786) 271-2157

Appendix: batch columns (one row per visit per molecule)

site_code · subject_id · record_type (new/correction/withdrawal) · visit (baseline/fu_4_8wk/fu_16wk/fu_6mo/fu_12mo/unscheduled/ae_only) · study_day · year · age_band · sex · molecule · molecule_other · source_class · lot · coa_on_file · mg_per_ml · dose · dose_unit · route ·

cadence · anatomic_site · procedure_code · co_administered · pain_rest · pain_activity · function_instrument · function_score · nsaid_days_wk · opioid_mme_wk · steroid_inj_6mo · pgic · days_to_return · surgery_avoided · ae · ae_serious · ae_severity · ae_relatedness · ae_outcome · notes