DATA CAPTURE BEST PRACTICES

Peptide Pure Research Network | Guide for Participating Sites

OVERVIEW

This guide provides step-by-step instructions for completing each IRB-required data form accurately and consistently across all participating sites. Proper data collection ensures compliance with 21 CFR Part 11, HIPAA, and IRB requirements while producing high-quality research data.

1. PATIENT ENROLLMENT

- Confirm patient eligibility: adult (18+), receiving peptide therapy as part of routine care.
- Obtain signed Informed Consent before collecting any registry data.
- Assign a unique Study ID (format: SITE##-####). Do not use patient names on data forms.
- Record enrollment date and the peptide protocol(s) being initiated.
- File the original signed consent at your site. Provide a copy to the patient.

2. BASELINE DATA COLLECTION

At enrollment, record the following:

- Demographics: age, sex, height, weight, BMI.
- Medical history: active diagnoses, medications, allergies, surgical history.
- Baseline vitals: blood pressure, heart rate, temperature.
- Baseline labs (if available): CBC, CMP, hormones, inflammatory markers, lipids.
- Patient-reported outcomes (PROs): energy (1-10), pain (1-10), sleep quality, appetite, libido, mood, overall well-being. Use the standardized PRO form for consistency.

3. FOLLOW-UP VISITS

Collect data at each scheduled follow-up (target windows below, +/- 2 weeks):

Visit	Timepoint	Key Data
V1	Baseline (Day 0)	Full enrollment data, consent, baseline labs & PROs
V2	4-8 Weeks	Vitals, PROs, adverse events, protocol adherence
V3	16 Weeks	Vitals, PROs, labs (if ordered), adverse events
V4	6 Months	Vitals, PROs, labs, adverse events, protocol adjustments
V5	12 Months	Full repeat: vitals, PROs, labs, adverse events, final assessment

4. ADVERSE EVENT REPORTING

- Record all adverse events (AEs), regardless of severity or suspected relationship to treatment.
- For each AE: description, onset date, severity (mild/moderate/severe), outcome, and action taken.
- Serious Adverse Events (SAEs) must be reported to the IRB within 24 hours.
- SAE criteria: death, hospitalization, life-threatening event, persistent disability.
- Contact IRB: JP Faber, jpfaber@ircm.org, (786) 271-2157.

5. DATA ENTRY & STORAGE

- Enter data into the secure, encrypted, Part-11-compliant electronic system within 5 business days of visit.
- Use Study ID only — never enter patient names, SSNs, or other direct identifiers into the system.
- Double-check all entries for accuracy. Flag any missing or questionable data for query resolution.
- Maintain a site-level enrollment log (linking Study ID to patient identity) in a locked, HIPAA-compliant location.
- Retain all source documents (signed consents, lab reports, visit notes) for a minimum of 6 years.

6. QUALITY CHECKLIST

6. QUALITY CHECKLIST (continued)

- ☐ Signed consent on file before any data collection
- ☐ Study ID assigned and used on all forms (no patient names)
- ☐ Baseline data complete at enrollment
- ☐ PROs collected at every visit using standardized form
- ☐ Adverse events documented within 48 hours
- ☐ SAEs reported to IRB within 24 hours
- ☐ Data entered into electronic system within 5 business days
- ☐ Source documents filed and secured per HIPAA