Title: REDCap Project Build & Management Procedures	Version Number: #1	Effective Date: 12 JAN 2026	Page: I of 7

Revision History		
Version No.	**Effective Date**	**Description**
V1	12Jan2026	Tool to guide building a REDCap database.

Purpose

To standardize how UC San Diego study teams create, build, test, launch, and maintain REDCap projects so data collection is consistent, secure, auditable, and aligned with UCSD and IRB expectations (when applicable). This SOG incorporates core build steps including: creating a new project, designing instruments, enabling surveys, setting up longitudinal events and repeating instruments, configuring user rights, testing prior to production, using alerts/notifications, and exporting data.

Scope and Responsibilities

- **Scope**
  - Applies to all UCSD REDCap projects used for:
    - Research (observational or interventional)
    - Clinical trials
    - Registries
    - Surveys
    - Operational support
    - Quality improvement (as applicable)
    - Practice/training projects (non-study)
- **Responsibilities**
  - **Principal Investigator (PI)**
    a. Accountable for compliant data collection and appropriate access controls
    b. Ensures REDCap use aligns with IRB protocol when human subjects research applies
    c. Approves (or delegates approval for) move to Production for active studies
  - **REDCap Project Owner / Project Lead (CRC, Data Manager, PM)**
    a. Creates and configures the project (purpose, settings, instruments, surveys, longitudinal events)
    b. Maintains project documentation (project notes, build decisions, testing evidence)
    c. Manages user access and roles (least privilege)
    d. Oversees change control after Production

- **Data Entry Staff / Study Team Members**
  a. Enter and verify data according to protocol, source documentation, and data entry standards
  b. Follow required field validation and resolution processes
- **Regulatory Lead (if applicable)**
  a. Confirms IRB documentation aligns with REDCap workflow (especially identifiers, eConsent, survey distribution)

Procedures

1. **Create a New REDCap Project**
   a. Log in to REDCap and select **New Project**.
   b. Enter **Project Title** and select **Project Purpose** (Practice, Operational Support, Research, QI, Other).
   c. If selecting **Research**, complete prompted fields as available.
      i. You may begin building the REDCap project before IRB approval so the build is ready when approval is granted.
   d. Complete **Project Notes** with durable information useful for audits and staff turnover (key decisions, intended workflow, special coding rules).
   e. Select creation method:
      i. **Empty project**, **Upload REDCap Project XML** (useful for transferring between instances), or **Template** (institution-dependent).
   f. Confirm you land on the **Project Setup** page.

2. **Project Setup and Status Standards**
   a. **Development**: build and test only (use test data).
   b. **Production**: live data collection permitted (changes have safeguards).
   c. **Analysis/Cleanup**: after collection when records should not be edited.
   d. **Complete**: archived project.
   e. **Rule:** Do not collect real participant data while in Development.

3. **Configure Main Project Settings (Project Setup)**
   a. On Project Setup, enable as applicable:
      i. **Surveys** (participant-facing data collection)
      ii. **Longitudinal data collection** (multiple events/timepoints)
      iii. **MyCap** (mobile/offline workflows if applicable)
      iv. Document key configuration decisions in Project Notes or a build log.

4. **Design Data Collection Instruments (Online Designer)**
    a. Go to **Online Designer**.
    b. Confirm the default **Record ID field** exists on the first form.
        i. Do not delete or repurpose the Record ID field.
        ii. Auto-numbering is default; custom naming is only used when appropriate and when the first instrument is not a survey.

5. **Field build standards**
    a. Use clear **Field Labels**.
    b. Create short, unique **Variable Names** (these drive exports and analysis).
    c. Use **Required** fields intentionally.
    d. Flag **Identifiers** accurately to support compliant exports.
    e. Use **Validation** whenever possible (email, date, phone, etc.) to reduce entry errors.
    f. **Good build practices from the training workflow**
        i. Remember: multiple choice **codes** are stored as the data, not the text labels.
        ii. Avoid changing labels after collecting real data; retire choices instead when needed.
        iii. Use descriptive fields for instructions and embedded media when helpful.

6. **Branching Logic, Piping, and Field Embedding**
    a. Apply **branching logic** on the field you want to conditionally display.
    b. Use **piping** to display previous responses in headers or instructions.
    c. Use **field embedding** (variable in curly brackets) for "Other, please specify" workflows, and add branching logic so the embedded field appears only when "Other" is selected.

7. **Longitudinal Setup (If Enabled)**
    a. In Project Setup select **Define My Events** and create events/timepoints.
    b. Select **Designate Instruments for My Events** and assign forms per event.
    c. Re-test record workflows after designation changes.
    d. **Note:** Re-designating instruments can make test data appear missing at certain events. This is a key reason to finalize configuration and testing before Production.

8. **Configure Repeating Events/Instruments (If Needed)**
    a. Enable repeating at the project level (optional modules/customizations).
    b. Choose repeating **events** or repeating **instruments independently** (common when only one form needs to repeat).
    c. Re-test survey and data entry workflows once repeating is enabled.

9. **Configure Surveys (If Enabled)**
    a. For each instrument used as a survey:
        i. Select **Enable as Survey** and configure **Survey Settings**.
        ii. Set survey title, instructions, formatting/theme as needed.
        iii. Consider **pagination** for longer surveys so responses are saved as participants move through pages.
    b. Configure survey access controls:
        i. expiration limits
        ii. save/return later and return codes (recommended when identifiers are collected)
        iii. whether respondents can edit completed responses

10. **eConsent (If Applicable)**
    a. Use the **eConsent framework** for consent workflows involving name fields, version control, and signatures.
    b. Test the full eConsent experience and confirm:
        i. participant sees a generated PDF prior to final submission
        ii. consent PDFs are archived in File Repository
    c. Institutional note: eConsent requirements may vary; ensure the workflow is IRB-compliant for the study.

11. **User Rights and Permissions**
    a. Manage users under **User Rights**.
    b. Assign users either:
        i. individually, or
        ii. via **Roles** (recommended for groups doing the same task)
    c. Apply least privilege and consider setting **access expiration** dates.
    d. Reserve high-level rights (Project Design/Setup, User Rights, Data Access Groups) for staff who are trained and require these permissions.

e. **Export rights**
   i. Restrict exports to minimum necessary.
   ii. Use de-identified exports as default when appropriate and consistent with IRB/data plan.

12. Testing Prior to Production

a. Before moving to Production, test:
   i. required fields and validations
   ii. branching logic and embedded fields
   iii. survey flow end-to-end
   iv. longitudinal event designation behavior
   v. repeating instrument behavior (if enabled)
   vi. export output format and de-identification settings
   vii. alerts and ASIs (if used)
b. **Rule:** Testing must be completed in Development with test data.

13. Survey Distribution and Automation

a. **Distribution options**
b. **Public Survey Link**: creates new records per response; can be taken multiple times; use anti-spam controls as appropriate.
c. **Participant List**: requires known emails; uses unique survey links.
d. **Email field for communications**
e. Designate a validated email field for communications so collected emails populate participant list when appropriate.
f. **Automation**
g. Use **Survey Queue** to control access to sequential surveys based on completion and logic (e.g., consent = yes).
h. Use **Automated Survey Invitations (ASI)** to schedule surveys based on logic and timing rules; enable reminders as appropriate.

14. Alerts and Notifications

a. Configure Alerts to trigger when logic is met (e.g., allergy = yes).
b. Decide whether the alert triggers once per record or once per event.
c. Include Record ID (and event context if relevant) in the alert message.
d. Test alerts using test records.

15. Data Quality and Calculated Fields

a. Use Data Quality rules to identify discrepancies.
b. If calculated fields are added after test data exists, run the appropriate Data Quality rule to recalculate and update values.

16. Snapshots and Change Control

a. In Development, take **instrument snapshots** regularly (Project Revision History) to allow rollback.
b. After Production, maintain change control documentation for updates (what changed, why, when, who approved).

17. Data Exports and Reporting

a. Use **Data Exports, Reports, & Stats** for exports and custom reports.
b. Prefer raw exports for analysis; labeled exports for human review.
c. Use de-identification options consistent with IRB/data plan (remove identifiers, handle dates appropriately, remove unvalidated free text when needed).

Applicability Across All Study Types

This SOP applies across project types with the following expectations:

A. **Practice/Training Projects**
   a. May be built and tested without IRB.
   b. Must not contain real participant PHI or study data.
   c. Can be used for staff training and workflow prototyping.
B. **Operational Support / Non-Research Tracking**
   a. Use least privilege access and validation features.
   b. Avoid collecting identifiers unless required and permitted by institutional policy.
C. **Quality Improvement (QI)**
   a. Use the same build/testing and access control standards.
   b. Ensure QI classification is appropriate per UCSD oversight processes and documentation requirements.
D. **Research Studies (Including Human Subjects)**
   a. REDCap build may start before IRB approval, but **Production data collection must not begin until approvals are in place**.
   b. Identifier flags, export permissions, survey settings, and data sharing must align with the IRB protocol and data management plan.

E. **Clinical Trials / Regulated Research (If Applicable)**
   a. Strongly emphasize audit trail preservation, change control, role-based access, and rigorous testing evidence prior to Production.
   b. Consider additional requirements for eConsent, monitoring access, and documentation retention based on sponsor/regulatory expectations. REDCAP is not 21 CFR Part 11 compliance.

Document Approval

- Name and Title of Approver
- Date in the format (MM/DD/YYYY)
- Insert Name and Title below Signature

Approved By: Date:

Name: Title:
