Did you know? Entering *Real* Data in REDCap: Development vs. Production

Many REDCap users don't realize that *when* you enter data is just as important as *what* you enter. Entering real data in **Development Mode** puts your study at risk. **Production Mode is required** for data integrity, security, and compliance. Here is what you need to know!

Table of Contents:

- Development Mode: Built for Testing – Not Real Data
- Production Mode: Required for Compliance and Data Protection
- Important Reminder: Proceed in Production Mode with Caution!
- *Information for Study Teams*

Development Mode vs. Production Mode

Feature	Development	Production
Intended Use	Build & Test	Real data collection
Data Loss Warnings	None ✗	Yes ✓
Change Review Process	None ✗	Required ✓
Data Integrity Protections	Minimal ✗	Strong ✓
Compliance Readiness	Not Compliant ✗	IRB/HIPAA aligned ✓
Safe for Real Data?	No ✗	Yes ✓

DEVELOPMENT MODE: FOR TESTING ONLY

Development Mode is intended for building instruments, testing logic, and entering mock data only.

1. **Data Fabrication and Falsification Concerns**
   - Data can be edited, overwritten, or deleted without warning.
   - No formal review or audit controls.
   - This creates situations where:
     - Data no longer reflects the original source (**falsification**).
     - Missing or overwritten data may be reconstructed inaccurately later (**fabrication risk**).

2. **HIPAA & Compliance Risk**
   - Lacks required safeguards for protected health information (PHI).
   - Structural changes can expose sensitive fields unintentionally and break data protections or access controls.
   - There is no reliable audit trail of what changed and when.
   - This can lead to **HIPAA non-compliance**, especially if PHI is altered, lost, or improperly accessed.

3. **High Risk of Data Loss**
   - REDCap does NOT warn you about changes that may delete or alter existing data.
   - Simple changes (e.g. renaming a variable or changing answer choices) can **silently overwrite or erase data, causing issues with data fabrication**.

4. **Not Compliant for Real Research Data**
   - Does not meet IRB, HIPAA, or regulatory requirements.
   - **Live data collection is not permitted**.

PRODUCTION MODE: REQUIRED FOR REAL DATA

Production Mode is a controlled, compliant environment designed to protect real data and ensure regulatory readiness.

Key Protections

1. **Controlled Changes**
   - Edits must go through Draft Mode with an impact analysis.
   - High-risk changes require review/approval by a REDCap administrator.
   - Prevents accidental or undocumented data changes.
   - This prevents accidental or undocumented changes that could compromise **data integrity or validity.**

2. **Full Audit Trails and Accountability**
   - Tracks who changed data, what changed, and when. This helps defend against allegations of data **falsification** or **misconduct**, and **ensures transparency** in all data handling.
   - Support IRB audits, sponsor monitoring, and internal quality reviews.
   - Supports Good Clinical Practice (GCP) Standards.

3. **HIPAA-Aligned Data Security**
   Production projects are designed to support secure handling of PHI and have controls that align with **HIPAA's minimum necessary standard**:
   - Role-based user permissions (who can view/edit/export data)
   - Logging of all data access and exports
   - Ability to restrict identifiers during export

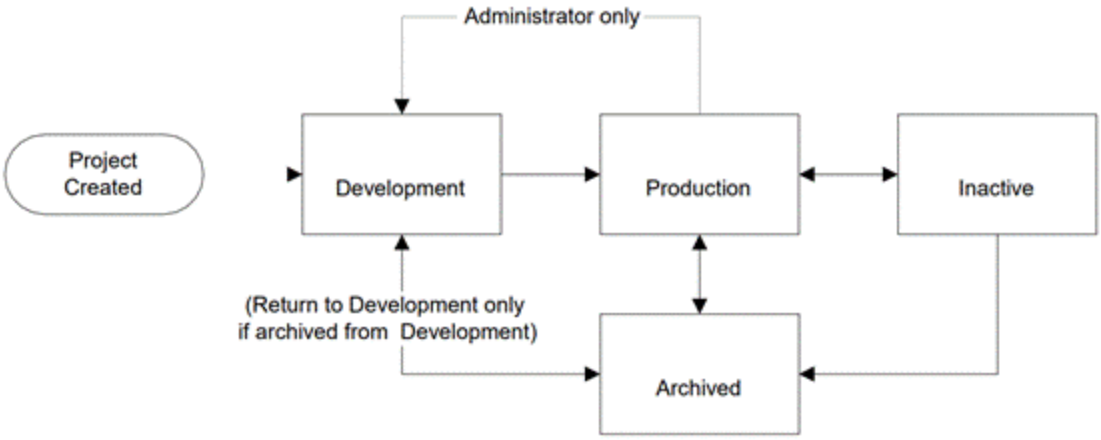
4. **Data Integrity Safeguards**
   1. Preserves the structure and original values that were entered.
   2. Flags changes that may alter or delete existing data.
   3. This ensures that your dataset remains **consistent, analyzable, and reproducible**.

5. **Audit-Ready Data**
   - Clean, traceable data for analysis, reporting, and regulatory submission.
   - Reduces audit risk and supports publication-quality data.

IMPORTANT REMINDER: PROCEED IN PRODUCTION MODE WITH CAUTION!

Production Mode reduces risk but does NOT eliminate responsibility.

- Document all data edits to avoid falsification concerns.
- Assign user permissions carefully to prevent HIPAA violations. Update user permissions when there are study staff changes.
- Review all change warnings before approval. Ignoring these warnings can still compromise data.
- **Best Practice:** Fully test in Development Mode before going live and minimize post-production changes.



https://www.vumc.org/nursingebp/sites/default/files/public_files/Vanderbilt%20Meharry%20REDCap%20User%20Guide%20v4.1.pdf

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INFORMATION FOR STUDY TEAMS

Setting Up e-Consent in REDCap

- Study teams **may not build e-Consents independently**.
- Submit a request through the REDCap eConsent Management Request Form. https://redcap.link/HRPP-Requests
- EQA will:
  - Build the project and provide training (if needed)
  - Allow testing in Development Mode (test data only)
  - Remove test records and move project to Production for go-live.
- Do not collect real data or signatures in Development.
- For any updates to the eConsent (e.g. new consent version you need to upload), please submit a request here: https://redcap.link/HRPP-Requests

If Real Data Was Entered in Development

Act Immediately:

- Export and back up the (raw) dataset, data dictionary, and (for e-Consent) PDF consents and attestation forms.
- Contact the EQA Team by submitting a request here: https://redcap.link/HRPP-Requests. You can submit a request by using the "Other eConsent-related Request" option.
  - They will transition the project to Production.
  - Assist with secure data re-import and validation.