

FEATURE_01_REVIEW_GUIDE

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Feature #1 Implementation Plan - Review Guide

Purpose: Structured review of FEATURE_01_IMPLEMENTATION_PLAN.md before implementation begins

1. SCOPE & TIMELINE

What's Proposed

Timeline: 3 weeks (15 business days) - Week 1 (Days 1-5): Foundation - Week 2 (Days 6-10): Database & Export - Week 3 (Days 11-15): Migration & Testing

Developers: 1 full-time OR 2 part-time

Total Code: ~1,000 lines of new R code + tests

Review Questions

Q1.1: Is 3 weeks realistic for your environment? - ☒ [CHECKMARK] Yes, sounds right - ☐ Too aggressive, need 4-5 weeks - ☐ Depends on developer experience level - ☒ [X] No specific timeline needed

Comments: _____

Q1.2: Developer allocation preference? - ☐ 1 developer full-time (focused, no context-switching) - ☐ 2 developers part-time (can parallelize modules) - ☐ Flexible, depends on availability - ☐ Other approach: _____

Comments: _____

2. MODULES & CODE STRUCTURE

What's Proposed

4 New R Modules (plus setup script + tests):

R/encryption_utils.R (250-300 lines)
└ generate_db_key() - Create 256-bit random key
└ verify_db_key() - Validate key format
└ test_encryption() - Test encryption working
└ get_encryption_key() - Retrieve from env or AWS KMS
└ get_encryption_key_from_aws_kms() - AWS integration

R/aws_kms_utils.R (250-300 lines)
└ setup_aws_kms() - Configure AWS KMS
└ rotate_encryption_key() - Re-encrypt with new key
└ check_aws_kms_status() - Health check

R/secure_export.R (300+ lines)
└ secure_export_data() - Export CSV/XLSX/SAS
└ verify_export_integrity() - Hash verification
└ anonymize_data() - Remove identifiers

R/audit_logging.R (200+ lines)
└ log_audit_trail() - Log every operation
└ get_audit_trail() - Query audit records
└ generate_audit_report() - Create reports

setup_encrypted_database.R (100+ lines)
└ setup_encrypted_database() - Fresh encrypted DB creation

Review Questions

Q2.1: Module breakdown - any changes? - [CHECKMARK] Looks good as-is - ☐ Consolidate some modules (fewer files) - [PACKAGE] Split into more focused modules - ☐ Suggest different organization: _____

Comments: _____

Q2.2: Priority on which modules to create first? - 1 ☐ encryption_utils.R (foundation, blocking others) - 1 ☐ aws_kms_utils.R (optional, can defer) - 1 ☐ secure_export.R (nice-to-have, business value) - 1 ☐ audit_logging.R (critical for compliance)

Ranking (1=highest priority): _____

Comments: _____

Q2.3: Should we include all functions shown, or start minimal? - [CHECKMARK] Include all as shown (comprehensive) - [TEST_TUBE] Start with core functions only, add others later - ☐ Minimal set: _____

Comments: _____

3. KEY DEPENDENCIES & RISKS

External Dependencies

Required: - openssl (key generation) - Already in system - RSQLite >= 2.2.18 (database connection) - Already in DESCRIPTION - SQLCipher binary (encryption) - Platform-specific install

Optional: - paws (AWS KMS integration) - Only if using AWS - openxlsx (XLSX export) - Only for XLSX format - digest (file hashing) - Already in system

Review Questions

Q3.1: Acceptable to make paws and openxlsx optional? - [CHECKMARK] Yes, graceful degradation is fine - [X] No, they should be required - ☐ Need conditional logic: _____

Comments: _____

Q3.2: Biggest implementation risk? - ☐ SQLCipher installation across platforms - ☐ AWS KMS integration complexity - ☐ Export functionality edge cases - ☐ Audit trail performance at scale - ☐ Other: _____

Risk Mitigation: _____

Comments: _____

4. DATABASE SCHEMA CHANGES

What's Proposed

New Table: audit_trail

```
CREATE TABLE audit_trail (  
  audit_id INTEGER PRIMARY KEY AUTOINCREMENT,  
  timestamp TEXT NOT NULL,  
  user_id TEXT NOT NULL,
```

```

    action TEXT NOT NULL,
    details TEXT, -- JSON with context
    status TEXT CHECK(status IN ('SUCCESS', 'FAILED', 'WARNING')),
    error_message TEXT,
    created_date TEXT DEFAULT CURRENT_TIMESTAMP
);

```

```

CREATE INDEX idx_audit_timestamp ON audit_trail(timestamp);
CREATE INDEX idx_audit_user ON audit_trail(user_id);
CREATE INDEX idx_audit_action ON audit_trail(action);
CREATE INDEX idx_audit_status ON audit_trail(status);

```

No other changes - Encryption is transparent

Review Questions

Q4.1: Audit trail schema - any modifications? - [CHECKMARK] Looks good as-is - [WRENCH] Add fields: _____ - ☐ Remove fields: _____ - ☐ Change design: _____

Comments: _____

Q4.2: Data retention policy for audit trail? - ☐ Keep forever (safest) - ☐ Rotate quarterly (current year + 3 years) - ☐ Rotate annually (rolling 7 years) - ☐ Other: _____

Comments: _____

Q4.3: Should audit trail itself be encrypted? - [CHECKMARK] Yes (already encrypted with database) - [X] No, separate unencrypted audit log - ☐ Depends on: _____

Comments: _____

5. TESTING STRATEGY

What's Proposed

15+ Test Cases organized by category:

Unit Tests:

- └─ Key generation (2 tests)
- └─ Key verification (2 tests)
- └─ Encryption (2 tests)
- └─ Export (1 test)
- └─ Audit trail (1 test)

Integration Tests:

- └ Full workflow (1 test)
- └ Multiple operations (1 test)
- └ Key rotation (1 test)

Security Tests:

- └ Encryption verification (1 test)
- └ Wrong key rejection (1 test)

Performance Tests:

- └ Connection overhead (1 test)

Review Questions

Q5.1: Test coverage - sufficient? - [CHECKMARK] Yes, good coverage - [TEST_TUBE] Add more tests for: _____ - ☐ Focus on: _____ - [CHART] Performance tests more critical

Comments: _____

Q5.2: Should we include stress testing? - [CHECKMARK] Yes, test with large datasets (10K+ records) - ☐ No, defer to Phase 2 performance testing - ☐ Include if time permits

Comments: _____

Q5.3: CI/CD testing requirements? - [CHECKMARK] All tests must pass before merge - [WARNING] Some tests can be optional - ☐ Manual security review required - ☐ Testing happens after deployment

Comments: _____

6. DOCUMENTATION & DEPLOYMENT

What's Proposed

3 Documentation Files: 1. vignettes/feature-encryption-at-rest.Rmd - User guide 2. documentation/ENCRYPTION_DEPLOYMENT_GUIDE.md - Production deployment 3. documentation/ENCRYPTION_TROUBLESHOOTING.md - Common issues

Coverage: - Setup instructions (all 3 trial scenarios) - Key management (generation, storage, rotation) - AWS KMS configuration - Export procedures - Audit trail usage - Troubleshooting

Review Questions

Q6.1: Documentation scope - sufficient? - [CHECKMARK] Yes, covers all scenarios - ☐ Add guidance on: _____ - ☐ Skip: _____

Comments: _____

Q6.2: Who needs training? - ☐ DBAs (key management) - ☐ Data managers (export procedures) - ☐ System admins (AWS KMS setup) - ☐ Developers (integration code) - ☐ Create training plan?

Comments: _____

Q6.3: Deployment checklist - include? - [CHECKMARK] Yes, pre-deployment checklist (database backup, key setup, etc.) - [X] No, assume manual verification - ☐ Create automated pre-deployment validation script?

Comments: _____

7. INTEGRATION WITH EXISTING CODE

What's Proposed

Modified Files: - `global.R` - Add `get_db_connection()`, `close_db_connection()` - `server.R` - Initialize encrypted connection - `data.R` - All DB access through encrypted connection - `export.R` - Use `secure_export_data()` - DESCRIPTION - Add openssl dependency

Non-Breaking Changes: - Fresh database start (no migration) - All SQL unchanged (SQL-Cipher transparent) - Existing queries continue working

Review Questions

Q7.1: Fresh database start - acceptable? - [CHECKMARK] Yes, we want clean encryption from day 1 - [X] No, must preserve existing data - ☐ Need migration path: _____

Comments: _____

Q7.2: Changes to `global.R`, `server.R`, `data.R` - [CHECKMARK] Minimal changes shown are good - ☐ Prefer different approach: _____ - [WARNING] Concerned about: _____

Comments: _____

Q7.3: Breaking changes acceptable? - [CHECKMARK] Yes, this is a breaking change, users understand - [WARNING] Prefer gradual migration - ☐ Need backwards compatibility:

Comments: _____

8. SUCCESS CRITERIA

What's Proposed

Feature #1 Complete When:

1. [CHECKMARK] **Encryption Working**
 - SQLCipher integrated, transparent encryption active
 - All data stored encrypted (verified by file inspection)
 - Performance overhead < 5%
 2. [CHECKMARK] **Key Management**
 - 256-bit keys auto-generated
 - Environment variable storage working (dev)
 - AWS KMS integration working (production)
 - Key rotation procedure documented and tested
 3. [CHECKMARK] **Secure Export**
 - CSV/XLSX/SAS export functionality working
 - Anonymization option working
 - File integrity hash verification working
 4. [CHECKMARK] **Audit Trail**
 - Every DB connection logged
 - Every query/export logged
 - Audit records immutable (append-only)
 5. [CHECKMARK] **All Tests Passing**
 - 15+ unit/integration tests all pass
 - Security tests verify encryption
 - Performance tests < 5% overhead
 6. [CHECKMARK] **Documentation Complete**
 - User guide for all 3 trial scenarios
 - Production deployment guide
 - Troubleshooting guide
 - Code examples
 7. [CHECKMARK] **GDPR/FDA Compliance**
 - Article 32 encryption at rest
 - 21 CFR Part 11 audit trail
 - All applicable articles covered
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Review Questions

Q8.1: Success criteria - complete? - [CHECKMARK] Yes, covers all important aspects - ☐
Add criteria for: _____ - ☐ Remove: _____ - ☐ Modify: _____

Comments: _____

Q8.2: Performance targets acceptable? - [CHECKMARK] < 5% overhead is good target -
[ROCKET] Should be < 2% - ☐ < 5% might be tight, use < 10% - [CHART] Skip performance
testing initially

Comments: _____

Q8.3: Regulatory compliance verification? - ☐ Manual review by compliance team -
[CHECKMARK] Automated compliance checklist - ☐ Both (automated + manual review) - ☐
Who verifies?

Comments: _____

9. OVERALL QUESTIONS

Q9.1: Proceed with implementation as planned?

- [CHECKMARK] Yes, start immediately (no changes)
- [WRENCH] Yes, with modifications (see below)
- ☐ Need more time to review
- ☒ No, major changes needed
- ☐ Defer to Phase 2

Modifications needed (if yes with changes): _____

Q9.2: Any blockers or concerns?

Q9.3: Resource allocation confirmed?

- [CHECKMARK] 1 developer available full-time, starting [DATE]
- [CHECKMARK] 2 developers available part-time, starting [DATE]
- ☐ Availability unclear, need to confirm
- ☒ No developers available yet

Dates/names: _____

Q9.4: Key contact for questions during implementation?

Name: _____ **Role:** _____ **Email/Phone:** _____ **Timezone:**

IMPLEMENTATION START CHECKLIST

Once you complete this review, we'll verify:

- ☐ All review questions answered
- ☐ Any adjustments documented
- ☐ Developer(s) assigned and confirmed
- ☐ Timeline agreed upon
- ☐ Success criteria approved
- ☐ Resources confirmed

Then: Begin Step 1 (SQLCipher installation) in Week 1, Day 1

Ready to complete this review guide?