Internal Data Request Process – 2015

Internal Staff

- Project proposal
- Complete and return forms to Database Owner/Program
- Complete and return forms & documentation to IRB
  - ***Quality Assurance** Review of documentation must occur prior to submission (check for consistency between documents)
  - Initial Review Questionnaire (IRQ)
    > other document's as found necessary from the IRQ
  - Protocol
  - Consent Forms
  - Script
- Request data from Database Owner/Program
- Remain in contact with the IRB for annual reviews and amendments to the study.
  - 12 month review: Continuing Review Questionnaire (CRQ)
  - Amendments: Protocol Revision/Amendment Form
- Complete study/project
  - Final Study Report/Study Closure Form

Database Owner/Responsible Party

- Receive data request
  - Examples:
    - -EPHT
    - -PDMP
    - -Trauma
    - -Vital Records
    - -ALERT
    - -OSCaR
    - -MMIS
    - -Health Analytics
- Send appropriate data release form(s)
  - - Data Use Agreement
    - ✓ Data Security
    - ✓ Confidentiality Assurance
    - ✓ Specific statutes which govern the database
- Review request form(s)
  - Review for scientific Merit, integrity, and researcher capability
- Approve Request moving forward
- Deny Request
- Research?
  - YES – RESEARCH
  - No/Unsure
- Consult with Center PRT Representative/Center Chief Science Officer
  - *If answer is NO, Database Owner/Responsible Party may bypass consultation with Center Chief Science Officer & release the data for Practice
  - YES - PRACTICE
  - UNSURE: Needs PRT Review
- Consult with manager and/or database owner
- Provide requested data
- Complete study/project
- Provide requested data

Project Review Team (PRT)

- Review request
  - Project Review Request Form
- Approve as PH Practice
- Approve as Research

IRB

- IRB Coordinator Review
- Full Board Review [medium to high risk studies]
  - Conditional Approval → IRB Coordinator notify internal staff of conditions that must be met prior to final approval → Conditions are satisfied
  - Approve
- Expedited Review [Completed by the IRB Coordinator - low risk studies]
  - Approve
  - Conditional Approval → IRB Coordinator notify internal staff of conditions that must be met prior to final approval → Conditions are satisfied
- Notify Database Owner/Responsible Party and Internal staff of Research Approval
- Review on an annual basis. Notify Internal Staff/P.I. and Database Owner/Responsible Party of all Continual Approvals.