Objectives of Workshop
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- Define the purpose of quality assurance/quality improvement (QA/QI) in the research environment.
- Define the role of the QA/QI in clinical trials at Drexel University.
- Identify services provided by the QA/QI.
- Identify how QA/QI supports PI to achieve research excellence.
Quality Assurance (QA)
- Evaluation of processes
- Examination of processes

Quality Improvement (QI)
- Performance enhancement of processes in response to observed trends or findings.
Concept Chart - QA/QI

- Identify Findings/Determine Root Cause
- Evaluate CAPA Plan (QA/QIP)
- Create CAPA Plan (QA)
- Conduct Follow-Up Review
- Implement CAPA Plan (QI)
QA/QI support to Drexel University Shared Values

- Supports **quality** by providing support to researchers to achieve excellence in research compliance and reliability of data.
- Supports **integrity** though adherence to institutional and regulatory research laws and guidelines.
- Supports **access** through research related education.
- Supports **stewardship** by enhancing the strive for excellence in research.
Purpose of QA/QI

- Prevent regulatory and institutional non-compliance
  - Identify processes within research which increase risk of non-compliance
  - Revise processes/policies to promote compliance
- Liaison between research team and IRB
- Enhance the human research protection plan
- Promote excellence in research
The Trouble with Research Regulations:
(too many, too confusing!)
QA/QI Program

- NOT policing
- NOT research
- Tool to maintain, correct and/or properly guide researchers to maintain compliance.
- Promotes proper research conduct
- Promotes research excellence
QA/QI Focus for Regulatory Compliance:

(it is not just a walk in the park!)
Consequences of Improper Conduct

Improper conduct leads to non-compliance:

The term [PI] turns from [Principal Investigator] to [Prison Inmate]!
QA/QI role
...Help decipher and adhere to regulations/policies
Preparing a research study
Protocol Design

- The design determines which regulations need to be followed—reference HRP 103, Investigator manual located on human subject protection website.

- The funding source also will mandate certain regulations or requirements be followed.

http://www.drexel.edu/research/compliance/humanSubjects/irb/applications/
Preparing a research study
Protocol Process Design

- Design forms (crf, data collection tools, regulatory file forms) to support regulatory compliance: samples located on QA/QI website.

  http://www.drexel.edu/research/compliance/qa/tools/
Preparing a research study
Protocol Process Design

- Incorporate a data management plan within your research team in line with the University policy

- [https://www.library.drexel.edu/data-management](https://www.library.drexel.edu/data-management)
Preparing a research study
Protocol Process Design

- Create a Data Safety Monitoring plan (DSMB)-detail on HRP website under “SOPs and Guidance”
Preparing a research study
Protocol Process Design

- Design case report forms
  - Collect data required by protocol
- Create visit intervention grid
  - With each visit, identify process, interventions data required for collection
  - Serves as a guide for team
  - Promotes protocol adherence, prevents protocol deviations
QA/QI provides a safety net........
Resources

- HRP 103: Investigator Manual
- CITI training

When Protocol Design Involves:
Evaluation of drugs, devices, biologics or interventional/behavioral treatments
National Science Foundation (NSF) funding
Access and review of Protected Health Information (PHI)
Access and review of Protected Health Information (PHI)
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Shipping biologic samples off DU campus
Enrollment of subjects unable to provide consent
Use of recombinant materials, manipulation/alteration/modification
Use or processing of high risk controlled chemical/biologic agents
Collection and analysis of biologic specimens in a “non” CAP/CLIA certified laboratory

Prisoners are engaged in the research protocol

Additional Training Required:
Good Clinical Practice (GCP)
Responsible Conduct of Research (RCR)
Health Information Privacy & Security (HIPS)
Drexel Core Module HIPAA I
Drexel Core Module HIPAA II
Infectious Substances Packaging
Substituted (Surrogate) Consent
Recombinant DNA Molecules Training
Select Agent Policies and Procedures
Laboratory Safety and Bloodborne Pathogen Training

CITI course: ID 506 Research with Prisoners in Social/Behavioral protocols
OR
CITI course: ID 8 Research with Prisoners in Medical/biomedical protocols
Resources

QUALITY ASSURANCE/QUALITY IMPROVEMENT

The Quality Assurance/Quality Improvement Program (QA/QI) is a unit within the Office of Research Independent of the IRB and all human research related departments.

QA/QI’s objective is twofold:
1. To support institutional regulatory compliance
2. To assist investigators in the human clinical research process

QA/QI is independent of the IRB. QA/QI supports the Human Research Protection Program. The objectives of this group is no way conflict with those of IRB and/or other regulatory agencies. The QA/QI functions independently.

The QA/QI aims to promote a culture of compliance with the highest legal and ethical standards for the conduct of human research. It is also committed to education of the Drexel and affiliates research community and outreach to collaborating institutions striving for research excellence.

QA/QI has free, unlimited and unrestricted access to all books, records, files, property, systems and personnel of Drexel University and its subsidiaries during review of research-related activities. To the degree that audit rights have been established, affiliates, partnerships, joint ventures, licensees, contractors, vendors, distributors, third parties or other operations are also subject to quality assurance/quality improvement review. The QA/QI team has the authority to recommend improvements and to monitor the implementation of approved recommendations and has the duty to report findings to the appropriate compliance committees when deemed applicable.

REQUEST SERVICES

To request service from QA/QI please fill out our service request form.
QA/QI role

- Conducts reviews of processes and documents of every human research related component
- Identifies practice or areas of non-compliance.
- Identifies practice which may promote non-compliance
- Educates research teams and staff involved in supporting human support research
Staff

- Team-Identify who is needed to execute the protocol
- Researcher qualifications
- Delegation log
  - Signed/initialed by PI and team members
- Protocol specific training of research team
QA/QI Focus for Regulatory Compliance:

- GCP 4.1.1: As the investigator, you are qualified by education, training, and experience to assume responsibility for the proper conduct of the trial. You meet all the qualifications specified by the applicable regulatory requirement(s), and can provide evidence of such qualifications.

- GCP 8.2.10, GCP 8.3.5: Documents qualification and eligibility to conduct trial.
QA/QI Focus for Regulatory Compliance: Investigator's Brochure/Device Manual/Package Insert

- GCP: 8.2.1: To document the research team is in possession of relevant and current scientific information about the investigational product or device
- GCP: 8.3.1: To document the investigator is informed of relevant information related to device/drug used in study
QA/QI Focus for Regulatory Compliance: Logs

Examples:

- IRB Submission Log
- Enrollment Log
- Staff Signature Log and Delegation of Responsibility Log
- Protocol specific training
- Participant ID Log
- Study Monitoring/Visit Log
- Adverse Event Tracking Log
- Participant Payment Form
- Human Research Training Log
- Other

• Refer to QA/QI website for samples under Study Management tools

http://www.drexel.edu/research/compliance/qa/
IRB Process and Review
Approval documents/regulatory file

- Regulatory files
  - Dates of approval compared with dates of protocol implementation/recruitment
  - Executed ICFs, dated
  - Documents with identifiers housed separate from “coded” data
- Approval Dates
- Additional approvals: i.e. radiation safety, biosafety, IACUC, site approval.
- QA/QI:
  - Study start up support
  - Monitors post approval compliance
QA/QI Focus for Regulatory Compliance:

- ...ensuring that progress reports and requests for continuing review and approval are submitted to the IRB in accordance with the policies, procedures, and actions of the IRB
- 45 CFR 46.103(b)(4), 45 CFR 46.109(e), 45 CFR 46.115(a)(1)
- ...providing to the IRB prompt reports of any unanticipated problems involving risks to subjects or others
- 45 CFR 46.103(b)(5);
- ...providing to the IRB prompt reports of serious or continuing noncompliance with the regulations or the requirements or determinations of the IRB
- 45 CFR 46.103(b)(5)
- ...keeping certain records as required by the federal regulations for at least three years after completion of the study
- 45 CFR 46.115(b)
QA/QI Focus for Regulatory Compliance: Laboratory Documents

Tips:
(These documents assure quality control: assuring data is valid and standards maintained)

- Keep updated documents to exhibit the competency of all lab facilities being utilized, and to support the reliability of test results.

- If lab documentation is filed separately, write a signed and dated note to file indicating the location.

- If documents are maintained electronically, write a note-to-file indicating the location.

- Research labs typically do not have lab certifications, e.g., CLIA, CAP, and may not have “normal” lab values. If research labs are used, ensure that the lab director’s CV and research lab references values are on file.
What happens After Approval
Recruitment

- Screen logs/screen fail logs/enrollment logs
- Eligibility checklist
- Source documents-to validate data, confirm eligibility
- Flyers/advertisements
- Reference HRP 103
QA/QI Focus for Regulatory Compliance:

- …ensuring that selection of study participants is equitable in relation to anticipated risks and benefits and that recruitment methods are appropriate
- …obtaining and documenting informed consent of subjects or subjects’ legally authorized representatives prior to the subjects’ participation in the research, unless these requirements have been waived by the IRB
  45 CFR 46.116; 45 CFR 46.117
- …obtaining prior approval from the IRB for any modifications of the previously approved research, including modifications to the informed consent process and document, except those necessary to eliminate apparent immediate hazards to subjects
  45 CFR 46.103(b)(4)
What happens After Approval Consent Process

- Review for compliance of consenting
- IRB approved stamped consent
- Uses the most current IRB approved stamped consent
- Document consenting process
QA/QI Focus for Regulatory Compliance: Consent/recruitment

- GCP: 8.2.3: Document informed consent, subjects are provided with written information to support ability to give full informed consent, document recruitment measures are appropriate and not coercive
- GCP: 8.3.12: signed and dated prior to subject participation in protocol
What happens After Approval
Data Collection

- Source documents-validates and supports data/information collected
- Accuracy of data collection
  - Validated by source documents
  - Data entry confirmed
    - Data management plan to prevent data entry errors and assure accuracy
QA/QI Focus for Data Integrity

- Does case report form match protocol questions?
- Does source data match data in collection tool?
- Does a data management plan exist?
- Is data secure?
- Does data reflect protocol compliance?
Amendments and Continuing Review
When and How to Submit Amendments

- Protocol amendments not implemented until after IRB approval
- Re-consent process if necessary-inform subjects of changes in protocol and processes directly affecting the subjects
- Evidence of research team education related to amendment and changes
QA/QI Focus for Regulatory Compliance:

- **GCP8.2.2**: Signed protocol, amendments, sample case report form documents process to be adhered during research study.

- **GCP 8.3.2**: Maintain all revised protocol/amendments, CRF, informed consent, written information provided to subject and advertisement for subject recruitment documents the revisions of these trial documents that take effect during the trial.
Closing a study

When and How to Close a Study

- DO NOT let protocol expire – send closure notice.
  - PI may ultimately end on “restricted list”
- Notification of affiliated departments/etc.
- Notify subjects of outcomes if the consent indicated they would be informed.
Achieving Compliance-Research Excellence

- Coordination of study information
- Communication of study information
- Collaboration and clarity of study documents
Achieving Compliance-Research Excellence
Questions
Thank You
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References

