Expanding the Plan: Integrating Research Compliance Risk Assessments into Existing Monitoring Programs

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Objectives

- Integrating research compliance risk assessments into existing compliance monitoring programs
- Discuss considerations, priorities and options with operationalizing a risk assessment plan
- Communicating results of work, developing targeted training and education

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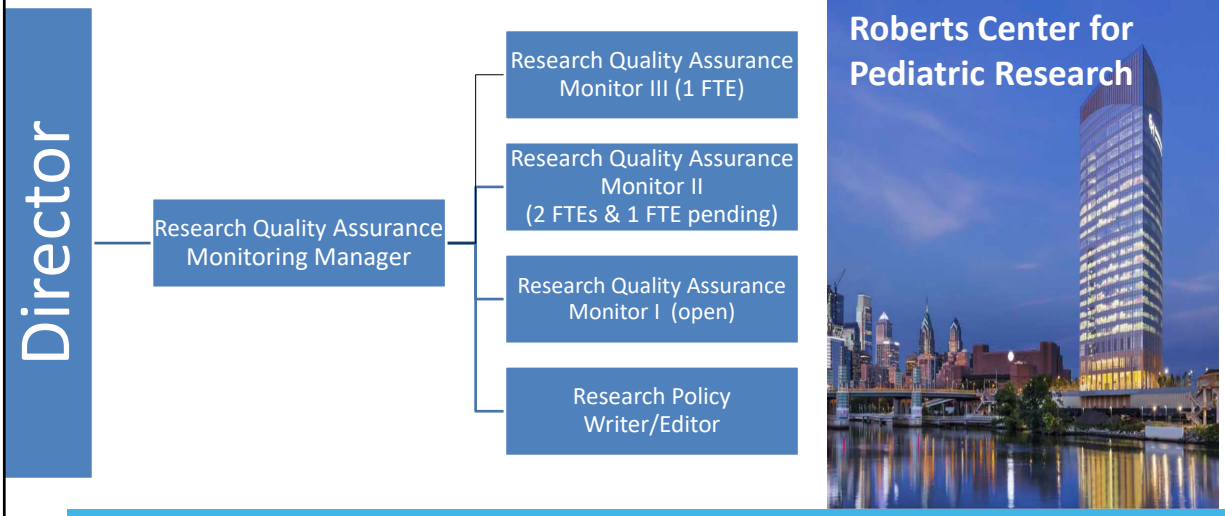
Office of Research Compliance (ORC) Demographics



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ORC Monitoring Activities

- Routine
  - Greater than minimal risk
  - Minimal Risk
- For cause
- Audit preparation
  - FDA, EMA, NIH, Sponsor audits
- Other
  - Research Billing, Cost Transfers, IRB Compliance, Participant Research Card Program, IDS Pharmacy exemption, Controlled Substances

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Expanding the Plan

- Research Compliance Plan
  - Collaborative approach to assess, minimize and manage compliance risks
  - Determine what is the focus of the assessment
    - Who is at risk?
    - What is at stake?
      - Known vs. unknown risks?
      - Action(s) taken, if any?
    - What control measures are needed?
  - Develop a plan and best approach to execute
  - Determine the timeframe to execute and complete
  - Determine the timeframe to assess findings
  - Explore approach(es) to communicating findings

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Goals

1. Identify, minimize and manage compliance risks
2. Process improvement
   - overall compliance and current processes
   - Revise existing policies, procedures
   - Internal controls
3. Assessing improvements
4. Determine need to design or perform further audits

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Scope of Risk Assessments

- Assess current practices and controls
- Ensure practices adhered to institutional policies, sponsor and regulatory requirements
- Ensure policies and procedures support an environment of compliance
- Results used to inform future reviews of research studies
- Educate the research community

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Priorities – Level of Risks

- Institution?
- Specific patient population?
- Division/department risk(s)?
- Specific Principal Investigator (PI)/Lead Investigator?

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Considerations for Planning

- What other departments, teams or stakeholders need to be informed or involved in the process?
- How do we obtain the information for the types of studies to be included?
- What type of existing key controls, processes or resources are available?
- Who will conduct the risk assessments?
  - ORC Team (entire team vs. certain QA Monitors?)
- What tools or forms are needed to conduct the risk assessments?
- What information will be recorded, maintained and shared?

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Considerations – Study type

- Number of studies to be selected for each category?
- Study status
  - Active, open
  - Older studies vs. newer studies
    - Ongoing studies >5 years- review information within last 1-3 years
  - Current enrollment numbers
- Risk determination
  - Minimal risk
  - Greater than minimal risk

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Considerations - Stakeholders

- Research Administration
- Institutional Review Board (IRB)
- Office of General Counsel (OGC)
- Office of Compliance and Privacy (OCP)
- Study Teams
  - Principal Investigators, Study Coordinators and other study personnel

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Options to Operationalize

- Risk-based approached
  - Focused monitoring
  - Impact on safety/well-being of subjects
  - Reliability of data
  - Compliance
    - Federal, state, and institutional requirements, GCP/best practice standards and IRB-approved plan
- Monitoring technique (detectability)
  - In-person vs. remote monitoring vs. hybrid
- Frequent findings from previous monitoring/audits
- Probability of risk (very likely, likely, possibly, unlikely, very unlikely)

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Considerations- Before Implementation

- IRBs involvement
  - Provide lists of applicable studies to be assessed
- Determine areas of perceived risk(s)
- Assess existing requirements for each category
- Define objectives and scope of work
- Form development
  - Monitoring tools and templates
- Evaluate risks (perceived or actual)
- Assess impact of the risks and overall sample size of the (actual or perceived) risk
- Assess impact corrective action(s)

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Other Considerations

- Determine how information gathered will be recorded, summarized, maintained and shared
- Informing study teams of planned risk assessment, expectations
  - Advance email notification
  - Introductory meeting
- Scheduling
  - In-person vs. remote
  - Timeliness of reviews
    - Initial review vs. follow-up review (if needed)
  - Availability of study personnel for introductory and wrap-up meetings

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Other Considerations

- Timelines
  - Communicating findings and addressing deficiencies
  - Report writing
  - Distribution of study-specific report to PI/SC
  - Distribution of overall report to institutional stakeholders
- Results of review
  - Developing educational/training workshops
  - Need for future reviews

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Risk Assessments

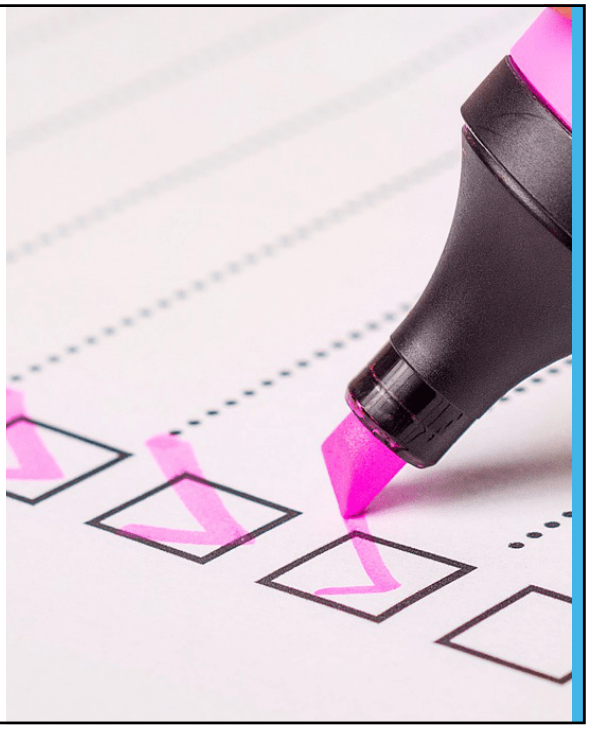
2019
- Data and specimen review
- Informed consent processes

2020
- Eligibility

2021
- Two-parent consent
- Data coordinating centers

2022
- Optional elements of consent- **in progress**
- Pregnancy testing for eligibility – **in progress**

FY-2023 -TBD



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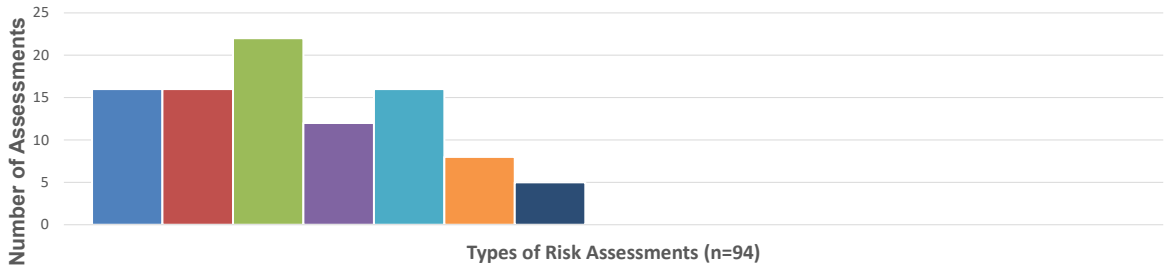
Risk assessments 2019-Present



- ICF (16)
- Data and Specimen (16)
- Eligibility (22)
- Two-Parent Consent (12)
- Data Coordinating Center (16)
- Pregnancy Testing (8)
- Optional Elements of Consent (5)

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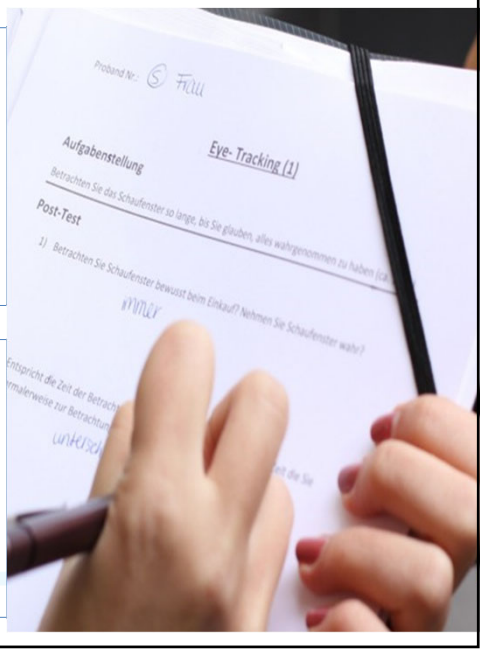
Examples: Risk Assessment Criteria

Data and Specimen Review

- Number of subjects enrolled and biospecimens collected
- Type of biospecimens collected
- Number of biospecimens stored on site
- Accountability, labeling and maintenance of biospecimens

Informed Consent Processes

- Consent documentation
- Consent processes
- Limited English Proficiency (LEP) elements included for applicable LEP participants



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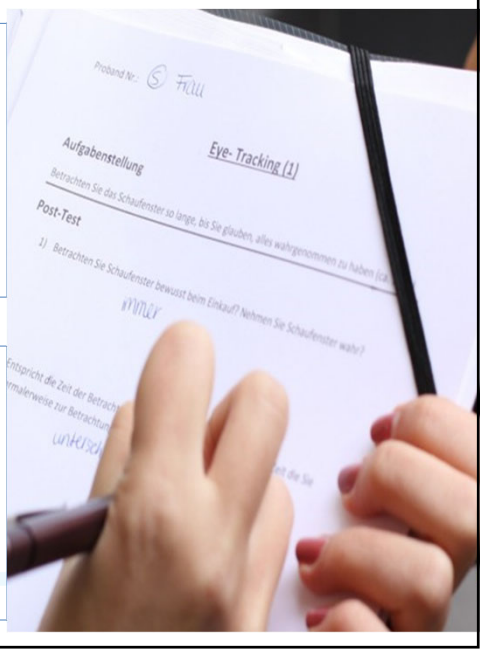
Examples: Risk Assessment Criteria

Data and Specimen Review

- Number of subjects enrolled and biospecimens collected
- Type of biospecimens collected
- Number of biospecimens stored on site
- Accountability, labeling and maintenance of biospecimens

Informed Consent / 2-parent Consent Processes

- Consent documentation
- Consent processes
- Correct IRB approved version used
- Limited English Proficiency (LEP) elements included for applicable LEP participants



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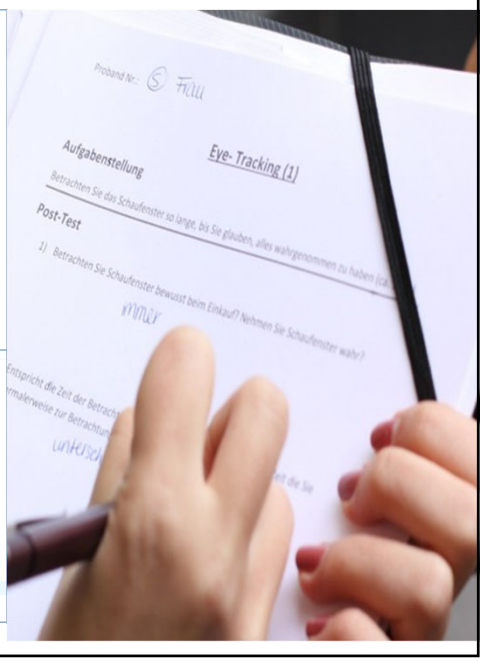
Examples: Risk Assessment Criteria

Eligibility

- inclusion/exclusion criteria met
- Prospective protocol deviation if eligibility criteria was not met
- Eligibility reviewed by qualified study personnel (PI, co-I)
- Supporting documentation of eligibility
- Eligibility criteria consistent between protocol, consent, eIRB application

Data Coordinating Centers

- DCC responsibilities and oversite of subsites (FWAs, IRB approval of all sites)
- Adherence to data safety monitoring plans, data management practices
- Applicable agreements fully executed
- Security measures for data protection



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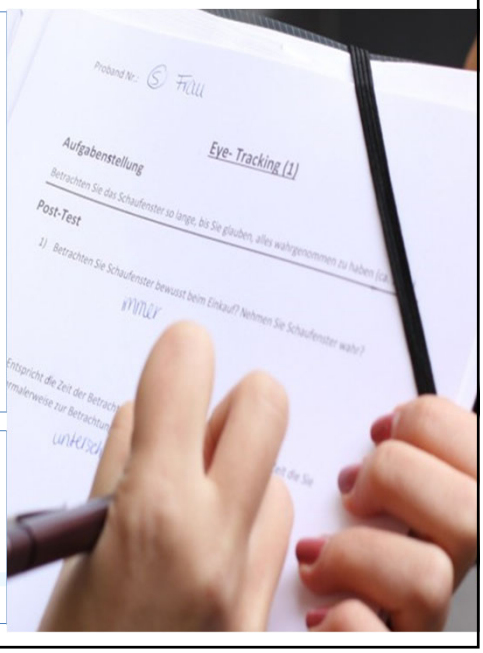
Current Risk Assessments (in-progress)

Optional elements of consent

- IRB approved options (future use of data, specimens, future contact, results reporting to PCP, etc.)
- Processes for tracking optional elements of consent (initial/re-consent)
- Changes in optional consent selections
- Amendments to add, remove, or alter optional consent elements
- Agreements in place for sharing data, biospecimens (internally or externally)

Pregnancy testing

- Testing requirements
- Protocol eligibility criteria
- Testing parameters
- Test results reporting and procedures



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General Observations

- No significant deficiencies or common trends identified
  - Opportunities for improvement identified
    - Documentation and maintenance of essential documents
    - Consent, eligibility verification, data management processes
    - Maintenance of applicable source documentation
    - Consistent approach to incoming agreements (DUA, MTA, CTA)
  - Opportunities for additional controls or standardized practices identified
    - Affirmation of consent (consent process meeting notes/checklist)
    - Eligibility checklist
    - Data entry expectations, escalation plans
  - Improve existing controls to ensure documentation consistency and ongoing adherence
  - Study teams recommended to leverage existing resources, tools when possible

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Response to Risk Assessments

- Training/Education
  - Consent risk assessments
    - Frequently Asked Questions (FAQ) document developed
    - 3-part educational series
  - Two-parent consent assessment
    - updates to existing FAQ
    - *Insights to Two Parent Consent* training session (pending)
- Additional plans
  - Developing/publishing best practice guidance documents for DCCs
  - Additional recommendations for ongoing training/education
  - Additional risk assessments FY23

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Resources

- IRB protocol, consent templates, policies and procedures
- Electronic databases e.g., REDCap, OnCore and Forte electronic data capture system
- Support with SOP, MOP development
- Office of Research Compliance (ORC)
  - QA Monitoring
  - Institutional guidance e.g., Documenting confirmation of Eligibility
- Office of Collaborative and Corporate Research Contracts (OCCRC) provides support for agreement execution between participating subsites
- IND/IDE Support Program/training
- Language Services support (interpreter/translation services)

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Thank You!

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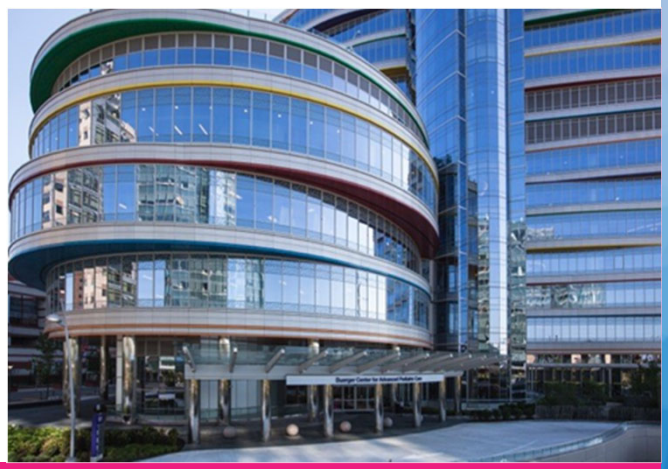

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