Incorporating Research Quality Assurance into MD/PhD and PhD Research Training

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training new generations of scientists is a key issue
Research Training: two aspects of quality in research

What We Do

How We Do It

Sound Scientific Principles
Good Quality Practices
How sound scientific principles and good quality practices contribute to the credibility of results


<table>
<thead>
<tr>
<th></th>
<th>Sound Scientific Principles</th>
<th>Good Quality Practices</th>
<th>Credibility of Results</th>
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</thead>
<tbody>
<tr>
<td>Study 1</td>
<td>No</td>
<td>No</td>
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<tr>
<td>Study 2</td>
<td>No</td>
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<td>Study 3</td>
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<td>No</td>
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<tr>
<td>Study 4</td>
<td>Yes</td>
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<tr>
<td>Sound Scientific Principles</td>
<td>Good Quality Practices</td>
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<tr>
<td>Premise, Hypothesis, Literature Review</td>
<td>Project Management</td>
<td></td>
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<tr>
<td>Study Design, Bias</td>
<td>Data Management</td>
<td></td>
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<tr>
<td>Statistics, Inference</td>
<td>Personnel</td>
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<tr>
<td>Variables (Example: Sex)</td>
<td>Facilities</td>
<td></td>
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<tr>
<td>Authentication of Critical Reagents</td>
<td>Equipment</td>
<td></td>
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<tr>
<td>Quality Control</td>
<td>Materials and Reagents</td>
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<tr>
<td>Method Selection</td>
<td>Method Validation</td>
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<tr>
<td>Research Review</td>
<td>Procedures</td>
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<td>Research Quality Systems</td>
<td>Research Records</td>
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**Who, What, Where, When, How, Why**

Research Records throughout the research and data life cycle.

**Data Integrity**
Research Stakeholder Strategies are driving Academic Responses

Established Programs

Focus on Fraud, Fabrication, Plagiarism

Sound Scientific Principles

Research Integrity

Good Quality Practices

A Critical Gap

Focus on Study Design, Statistics, Bias, Reagent Verification

Meet new requirements for funding and publishing
Strategies are needed to fill the gaps

Research Records throughout the research and data life cycle: Data Quality and Integrity

Research Quality Assurance best practices could be one systematic strategy to improve research conduct
# Problems Reported with Research Records

<table>
<thead>
<tr>
<th>Publication</th>
<th>Results</th>
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<tbody>
<tr>
<td>On the reproducibility of science: unique identification of research resources in the biomedical literature. Vasilevsky et al, PeerJ1:el 48, 2013;</td>
<td>54% of resources are not uniquely identifiable in publications</td>
</tr>
<tr>
<td>Who’s sample is it anyway? Widespread misannotation of samples in transcriptomics studies; L Toker et al, F1000Research, 2016</td>
<td>Apparent mislabeled samples in 46% of the datasets studied</td>
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<tr>
<td>Gene names are widespread in the scientific literature; Ziemann et al, Genome Biology 2016</td>
<td>Approximately one fifth of papers with supplementary Excel gene lists contain erroneous gene name conversion</td>
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<td>Scientists behaving badly, Martinson et al, Nature 435, June 2005</td>
<td>27.5% of scientists self report inadequate record keeping</td>
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</table>
Quality Assurance Approaches Safeguard Records

- Error Analysis
- Continuous Improvement
- Monitoring
- Facilities
- Environment
- Materials
- Document
- SOPs, Forms, Records
- Equipment
- Calibration
- Preventive Maintenance
- Repair
- Research Methods
- Validation
- Quality control
- Reagent
- RQA
- Records
- Data
- Quality
- Integrity
- Traceability
- Personnel

Credible Evidence leading to Data Traceability, Trust in Data and Confidence in Research Outcomes

Rare in Basic Research Settings
Quality Central

Sharpening the focus on sound science and quality practices
QuARRC
Quality Assurance Research Reproducibility Collaborative

Who

- **Trainees:** 12 MD/PhD and PhD predoctoral trainees [Lab Med & Path, Biochemistry, Neuroscience, Genetics, Microbiology, Immunology, and Cancer Biology]

- **Instructors:** Scientists with expertise in Quality Assurance (Quality Central Program), Educational Paradigms (Center for Education Innovation) and Data Management (Library)

What

- **Pilot program** to facilitate the adoption of Research Quality Assurance (RQA) best practices within basic research settings to enhance research rigor and reproducibility.

How

- **Trainee project based** – ‘Research in context’
Learning Objectives

• Establish a Research Quality Assurance (RQA) process to maintain research rigor, data quality and data integrity throughout the research life cycle.

• Implement RQA procedures to allow the full reconstruction and traceability of research activity.

• Provide evidence that data are fit for their intended purpose.
Training Resources

- Quality in Research: Guidelines for working in non-regulated research. Research Quality Association

- Quality Systems Workbook. Research Quality Association

- World Health Organization Quality Practices in Basic Biomedical Research (QPBR)

- Research Quality Assurance Toolkit Michelson Prize and Grant Program.
<table>
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<tr>
<th>Kick Off Event</th>
<th>Introduction, Research Scientist Panel Discussion</th>
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<tbody>
<tr>
<td>Workshop 1</td>
<td>Targeting Research Quality Assurance (RQA) to your research project</td>
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<tr>
<td>Workshop 2</td>
<td>Identifying risk to research data</td>
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<td>Workshop 3</td>
<td>Mitigating risk to research data</td>
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<td>Workshop 4</td>
<td>Managing research data to improve reproducibility</td>
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<td>Workshop 5: Individual consultations</td>
<td>Using RQA to demonstrate the quality of your research</td>
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<tr>
<td>Workshop 6</td>
<td>Securing data and records now and in the future</td>
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<tr>
<td>Workshop 7</td>
<td>Monitoring and maintaining the quality and integrity of your research data with RQA audits.</td>
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<tr>
<td>Individual consultations</td>
<td>RQA Coaching and audit/assessment</td>
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Voluntary Participation Outcomes

Initial enrollment: 12

Dropped out:
- Two trainees did not see value from onset
- One trainee cited time constraints after attending 4 workshops

Full Participation: 9
Lessons learning

Mentor commitment is critical
- Time, resources, communication, trust

Lack of Mentor experience with QA
- Distrust, Anxiety

Voluntary or mandatory approach

Sustainable monitoring model

Consider additional targets (lab managers, technician)

Time constraints (blended curriculum)
Why integrate RQA?

Promote Best Practices and Sound Science

Demonstrate Research Quality

Improve Research Rigor

Establish and Drive Research Standards

Support and Train our Scientists

Scientist Driven Response to Research Reproducibility Concerns
Conclusions

Integrating RQA into basic research settings addresses a critical gap and may be a reasonable strategy for addressing research reproducibility concerns.

training new generations of scientists is a key issue and new models of research training are needed.
## Acknowledgements

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<th>University of Minnesota</th>
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<tr>
<td>Christina Petersen</td>
<td>Center for Educational Innovation</td>
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<td>Katrina Laube</td>
<td>Quality Central, College of Veterinary Medicine</td>
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<td>Caitlin Bakker</td>
<td>University of Minnesota Libraries</td>
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<tr>
<td>Franklin Sayre</td>
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<td>Yoji Shimizu</td>
<td>Director, Medical Scientist Training Program</td>
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Thank you!
QUALITY TIME

IT MAY NOT BE SEXY, BUT QUALITY ASSURANCE IS BECOMING A CRUCIAL PART OF LAB LIFE.