Good research citizenship, collaboration, authorship, and available resources

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Agenda

1. Research Citizenship: Collaboration and Research Team Roles

2. Research vs. Standard of Care and associated Costs and Budgets

3. Authorship

4. Available Resources

Responsible Research

- **Immense benefits** to quality of care

- **Serious consequences** if done poorly or in violation of standards
    - Example: Research can be shut down at a Hospital (many examples)
    - Example: Lawsuits

Pathways to responsible research

- **Engaged Principal Investigator** (research mentor)
- **Start early**
- **Research Institute**
- **Data management &** best practices
- Conduct a **feasibility assessment**:
  - Sample Size
  - GANTT Chart

Gantt Chart

Task Name	Q1 2019			Q2 2019		Q3 2019
	Jan 19	Feb 19	Mar 19	Apr 19	Jun 19	Jul 19
Planning						
Research						
Design						
Implementation						
Follow up						

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Research Citizenship: Staffing appropriately, Collaboration and Research Team Roles

Who to Involve in your Research

- Principal Investigator: ALWAYS NEEDED

- NCHS Regulatory Affairs: ALWAYS NEEDED

- Sub-investigators (e.g., fellows, residents, other faculty physicians): SOMETIMES NEEDED

- Administrative staff: SOMETIMES NEEDED

- Clinical Research Coordinators: SOMETIMES NEEDED

- Research Pharmacists: OCCASIONALLY NEEDED

- Research Data Manager: OCCASIONALLY NEEDED (unless that is you as the fellow)

- Biostatistician: SOMETIMES NEEDED

- Contract specialist: OCCASIONALLY NEEDED

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Roles of the Research Team: Principal Investigator/Mentor

- *Engaged in the research*
- Identifies unmet needs/gaps in the literature
- Reviews and provides feedback to fellow/resident
- Aids in identification of relevant data
- Considers different study designs
- Assures following of research protocol
- Monitors timely progress on project
- Reviews data analysis and results interpretation
- Provides feedback on abstracts, posters, presentations, and manuscripts
- Reviews relevant documents and maintains involvement in the study
- Much more….

Fellow/Resident

- Seeks out relevant team members for study (collaborators)

- Conducts <u>thorough</u> literature reviews

- Writes protocol

- Executes research protocol

- Ensures accurate data collection

- Prepares abstracts, presentations, and manuscripts

Biostatistician Role

- If your planned study requires more than basic descriptive statistics, please consult RAD:
  - RAD@Nicklaushealth.org
  - https://redcap.mch.com/surveys/?s=7C3HDDM7JK
- RAD can provide guidance on data management practices
- This person is responsible for
  - Aiding in planning analyses
  - Writing up methods and results
  - Building surveys in REDCap
  - Data extraction from EMR data (when available)
  - Reviewing results with study team
  - ***Reviewing abstracts, presentations, and manuscripts before submission***

Clinical Research Coordinator Role (CRC)

- If your study interacts directly with patients, families or other "human subjects", you likely will need to at least discuss the need for a CRC (ClinicalResearch@Nicklaushealth.org)

- Note: Residents and fellows generally do not participate in prospective clinical trials

- Role of a CRC
    - Obtain informed consent/assent
    - Help execute prospective studies

Clinical Research Pharmacist

- If your study at all involves off-label use of a drug, investigational drug products, or other non-standard use of medications, you will need to consult a Clinical Research Pharmacist within NCRI (ClinicalResearch@Nicklaushealth.org)

- Role of a Clinical Research Pharmacist
  - Plans use of investigational drugs
  - Oversees use/administration of investigational drugs
  - Consults on considerations of off-label use of medications (this protects you, the fellow or resident)

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Research Costs and Budgets

Research is not free

- Someone is paying for research to happen
  - Example: CRCs and Clinical Research Pharmacists currently have a direct cost

- Who is paying for the time of each individual on your team?
  - My service line's budget
  - Industry sponsor (e.g., Pharmaceutical Company)
  - Grants

- If planning a prospective study, consult NCRI about planning a budget for your research

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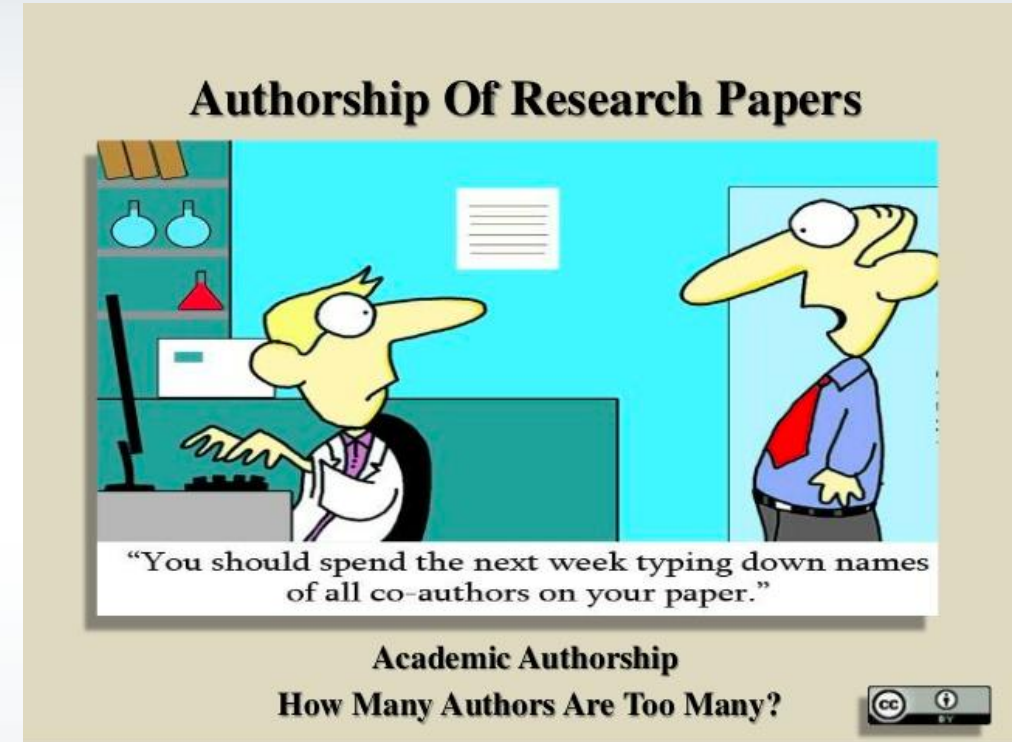
Intervention Research is not Standard of Care

- Non-Standard of Care *cannot* be charged to insurance.

- Don't put your career or the hospital at risk by trying to charge insurance companies or Medicaid for your research

- Interventions or medications for research purposes require funding

- When in doubt consult both your PI and the Research Institute

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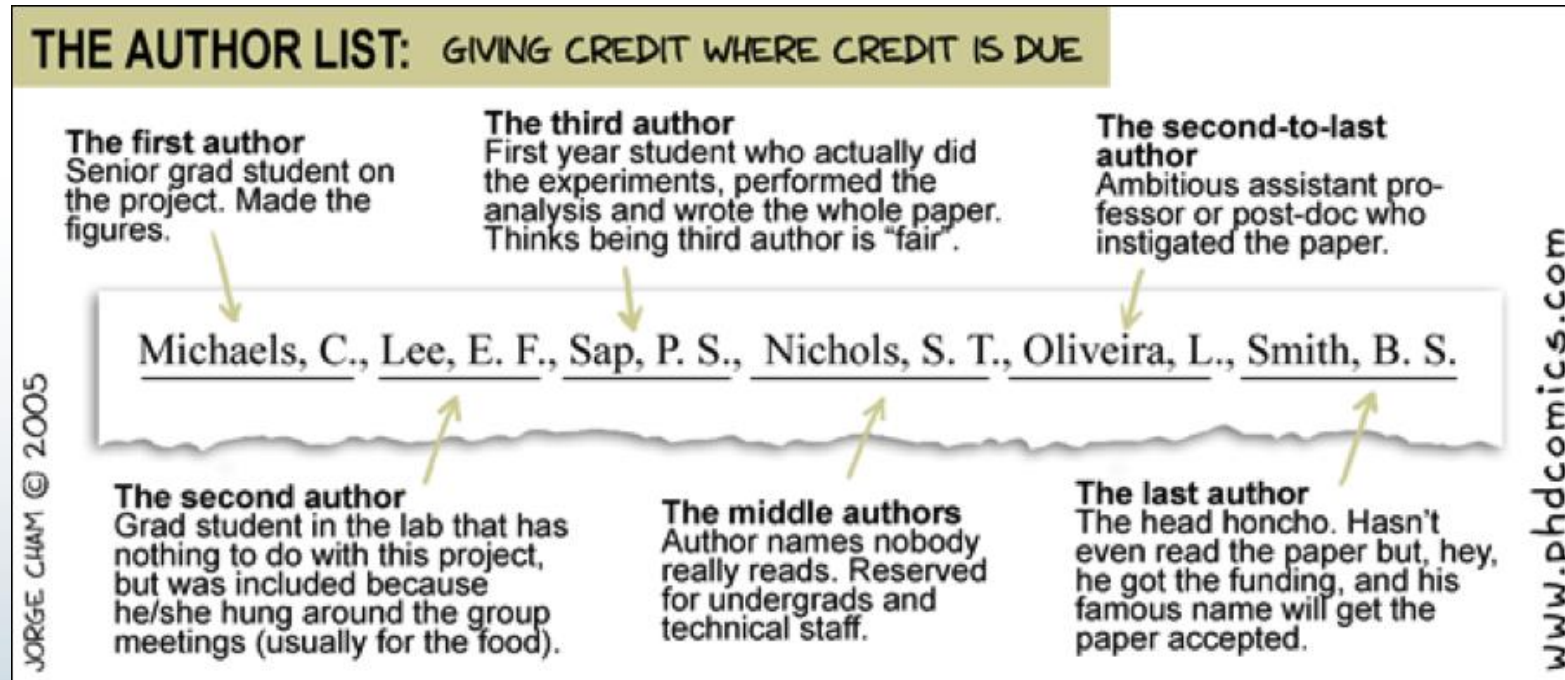Hospital
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Authorship

Study Authorship Guidance

- NCHS has an authorship policy: if someone contributes to a study, they should be recognized.

- Activities that warrant authorship in most circumstances:
    1. Write portions of manuscripts
    2. Conduct portions of the study protocol
    3. Work with the data at all
    4. Conduct statistical analyses

- When in doubt, initiate discussion with research team--early.

Authorship Of Research Papers

"You should spend the next week typing down names of all co-authors on your paper."

Academic Authorship
How Many Authors Are Too Many?

Authorship Order

- First Author
- Senior Author
- Corresponding Author

Available Resources

Available NCRI Resources

- NCHS and NCRI want to support you and collaborate with you

Clinical Research Operations Team
- Aiding on conducting Prospective Studies
- Clinical Research Coordinators
- Clinical Research Pharmacists
- Aiding in budget planning
- ClinicalResearch@Nicklaushealth.org

Research Analytics and Data Team
- Statistical analytical support for studies
- EMR data extraction (when accessible)
- Analytic methods planning of protocols
- Methods and Results section writing
- REDCap Secure survey construction
- RAD@Nicklaushealth.org
- https://redcap.mch.com/surveys/?s=7C3HDDM7JK

Regulatory Affairs Team
- Questions on IRB protocols
- IRB Protocol Review
- Questions on research regulations
- RegulatoryAffairs@Nicklaushealth.org

Nicklaus Children's Research Institute website
- https://intranet.mch.com/EN/Departments/cr/default.aspx
- A good resource to consult before planning your study
- Relevant forms and other documents required for conducting research at MCHS

Office of Sponsored Projects
- Pre award support
- Post award support
- Contract Negotiation
- Budget Development & Negotiation
- Financial Management & Invoicing for Services Rendered
- Coverage Analysis & Research Billing Support
- Pre and post award for extramural grants
- sponsored.programs@Nicklaushealth.org

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Thank you!
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