

Research 101 – How to Get Started

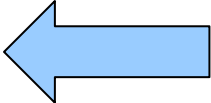


Alison Steiber PhD, RD, LD
Laura Byham-Gray, PhD, RD, CNSD
Debbie Benner, MA, RD, CSR
Jackie Carder, MS, RD, LMNT

Conflicts Of Interest:
Grants & Speaker: Sigma Tau Pharmaceuticals
Grants: Genzyme
Speaker: Abbott & BioGaia

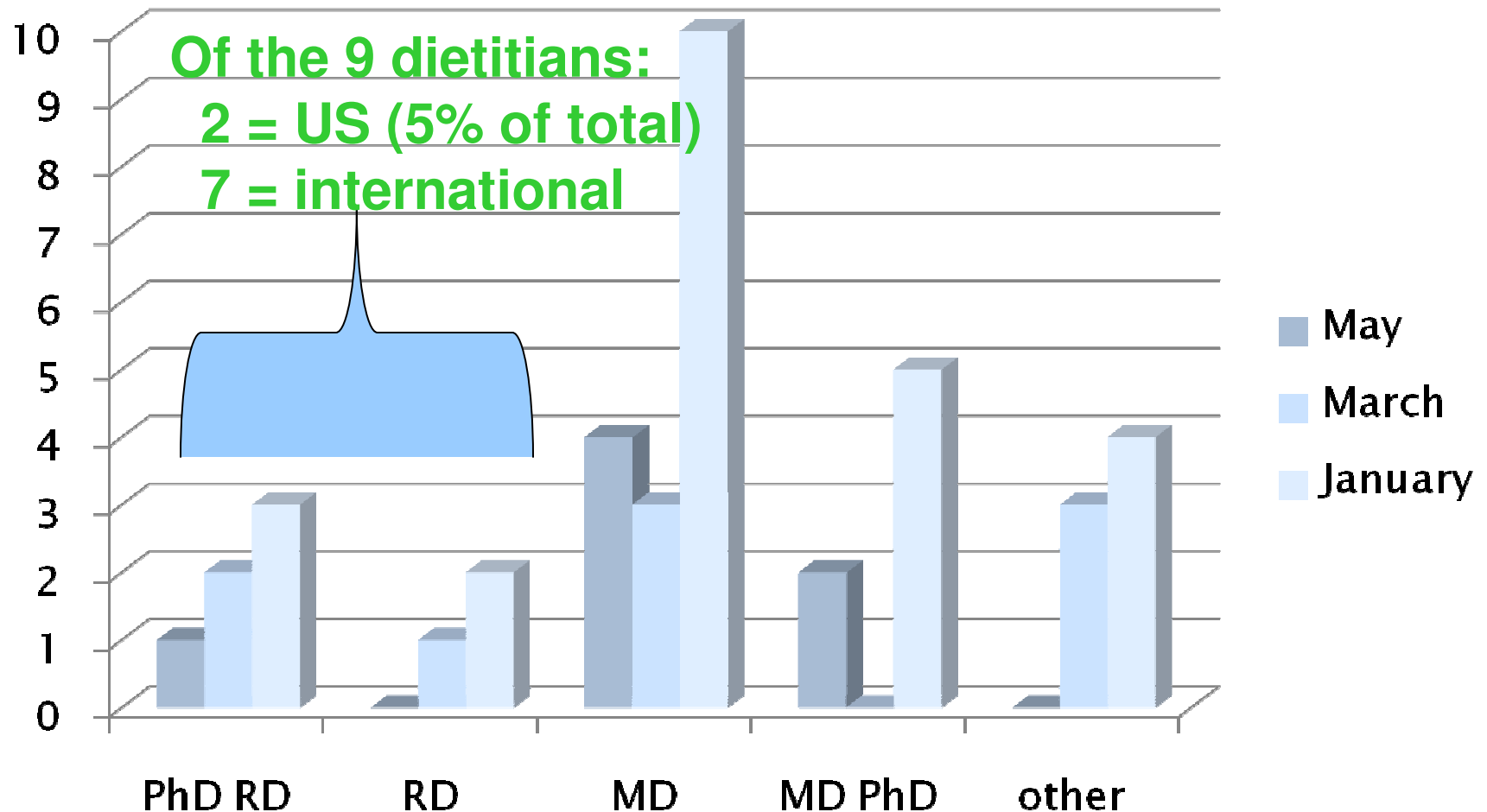


Quiz

- What percent of first authors were dietitians on a original or brief research paper published in JREN in 2009?
 - a. And how many were from the US?
 - a. 52%
 - b. 35%
 - c. 23% 
 - d. 5%



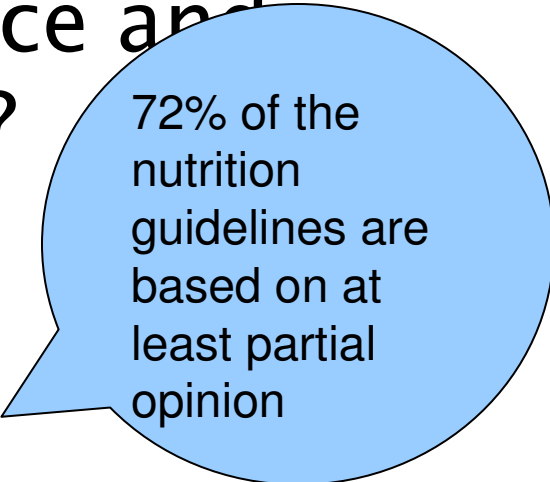
First authors Jan–May for the Journal of Renal Nutrition





Quiz 2

- How many of the KDOQI Nutrition guidelines were based on a. evidence only, b. evidence and opinion, c. opinion only?
 1. a. 45%, b. 50%, 5%
 2. a. 60%, b. 30%, 10%
 3. a. 18%, b. 54%, 18%

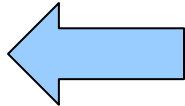


72% of the nutrition guidelines are based on at least partial opinion



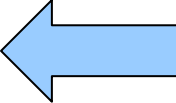
Quiz 3

- Physicians, nurses, social workers, pharmacists and administrators make great collaborators in research projects?
 - a. True
 - b. False





Quiz 4

- Where are good sources of information to assist in developing a research idea or protocol?
 - a. Discussions with colleagues
 - b. [Evidence analysis library](#)
 - c. [Cochrane reviews](#)
 - d. Journal articles ([JREN](#), NDT, AJKD, JASON, etc...)
 - e. All of the above 



Quiz 5

Zane the dietitian and Katerina the nurse would like to submit an abstract to the SCM in 2010.

- Their research question: “Do patients on 3rd shift have better nutritional status than patients on the 1st shift?”
- Their plan is to gather serum alb from the patients chart and compare 1st to 3rd shifts.

Question: Do they need an IRB approval prior to starting this project? Yes or No

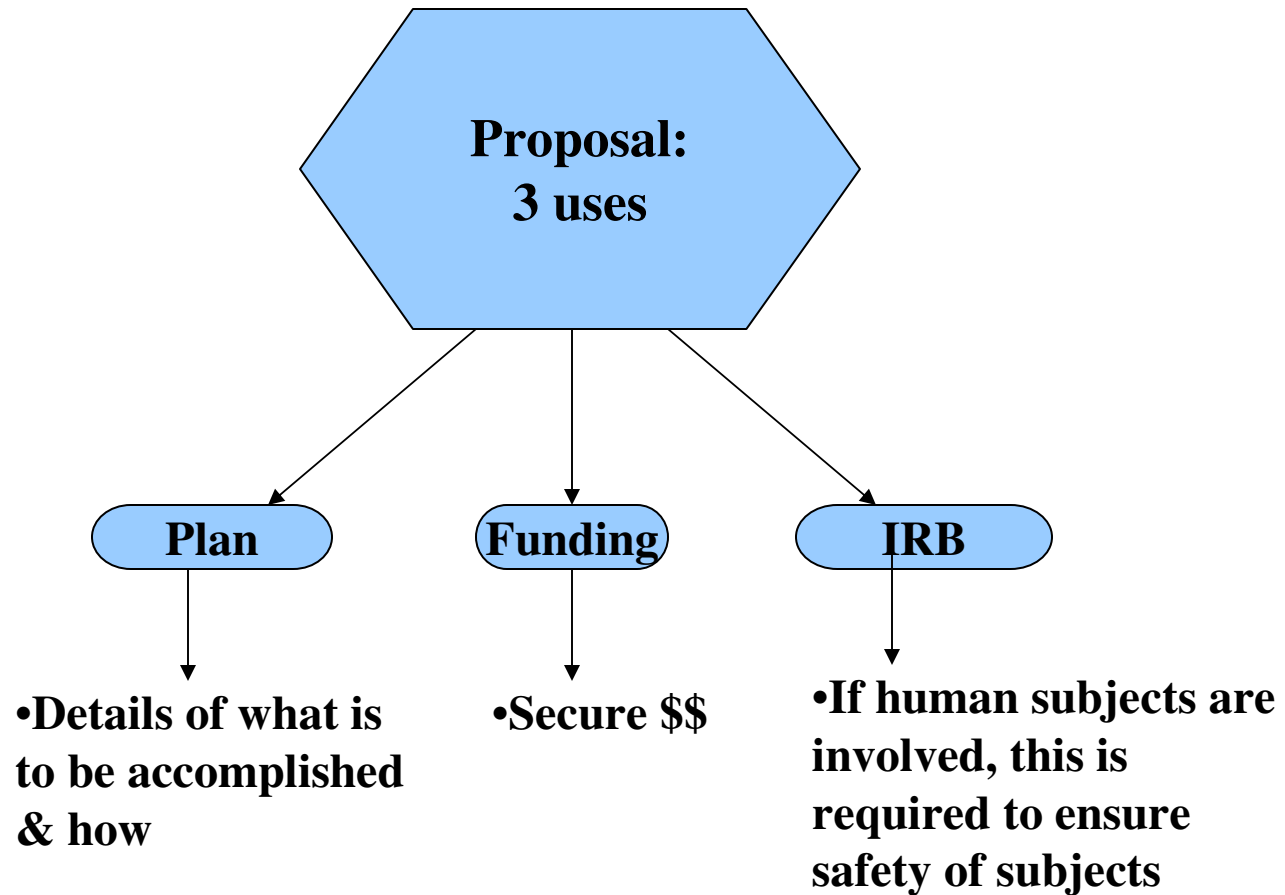
Steps to Initiating

a Research Project





Step 1: Write a proposal



IRB = Institutional Review Board



Outline of a Research Proposal: varies depending on purpose

- Specific Aims Page/Introduction
 - Brief Background leading to Hypotheses
 - End with numbered Specific Aims
- Background & Significance
 - Review the literature concerning the variables and interventions to be used within the study
 - Justifies the study
- Methods
 - What, how, by whom, and when the study will be conducted
 - How the data will be handled
 - Statistics to be done to answer research questions
- Other components:
 - Expected results, limitations & strengths of proposal, budget, timeline

Purpose of Methods Section



REPRODUCIBILITY
Others can follow and
get similar results



Included in Methods

1. Subjects
2. Design and analysis
3. Data collection
4. Intervention
5. Procedures
6. Statistics



Subjects

- Type of subjects
 - Criteria for inclusion & exclusion
- Source of subjects and how selected
- Number of subjects and why number was chosen
 - Power
 - May want to consult a statistician or IRB

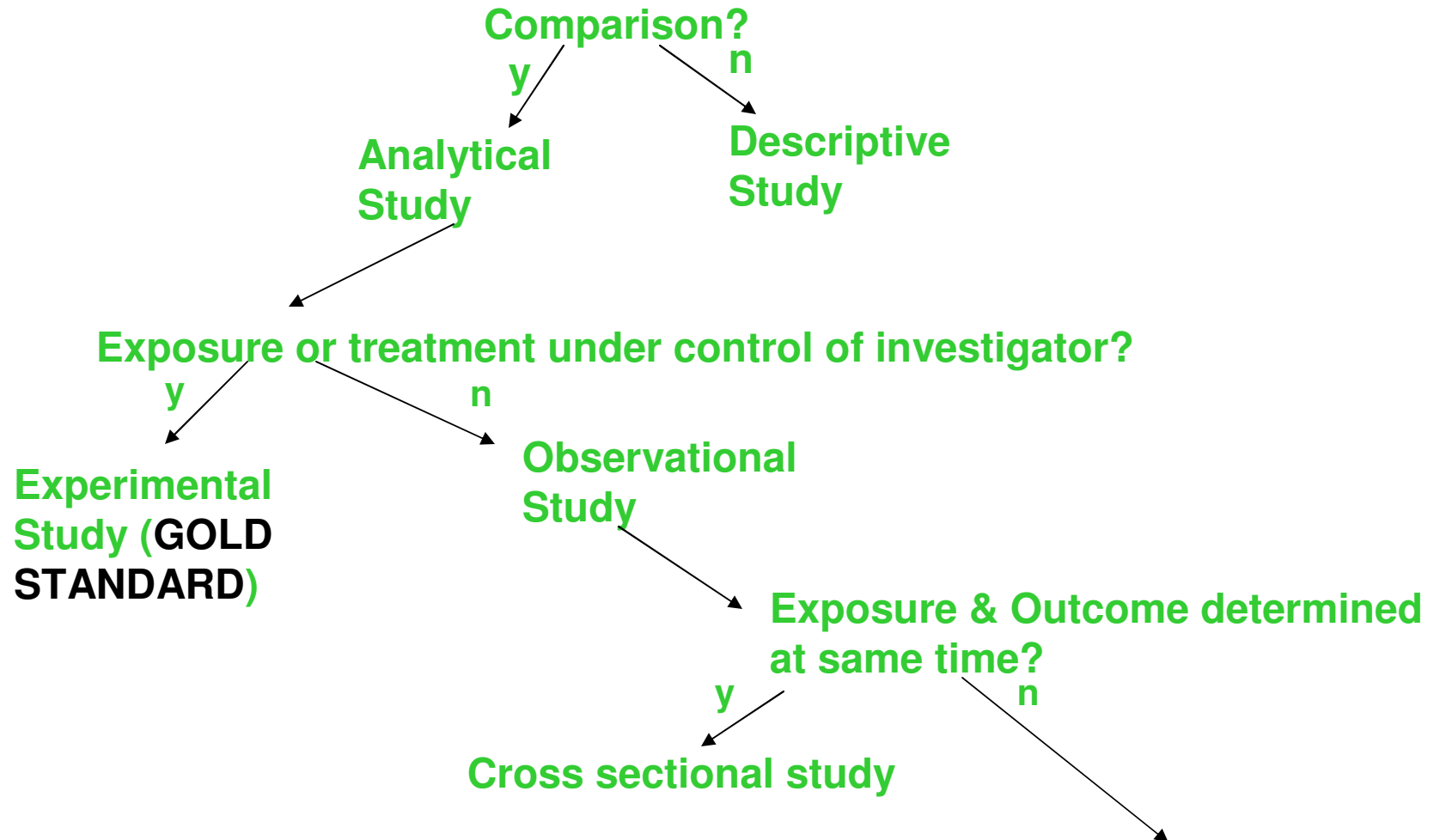


Source of Subjects

- Where will the subjects be recruited from?
 - CKD (pre-ESRD) Clinic
 - Dialysis Center
 - Dialysis Chain (multiple centers within the chain)
 - Physician Group

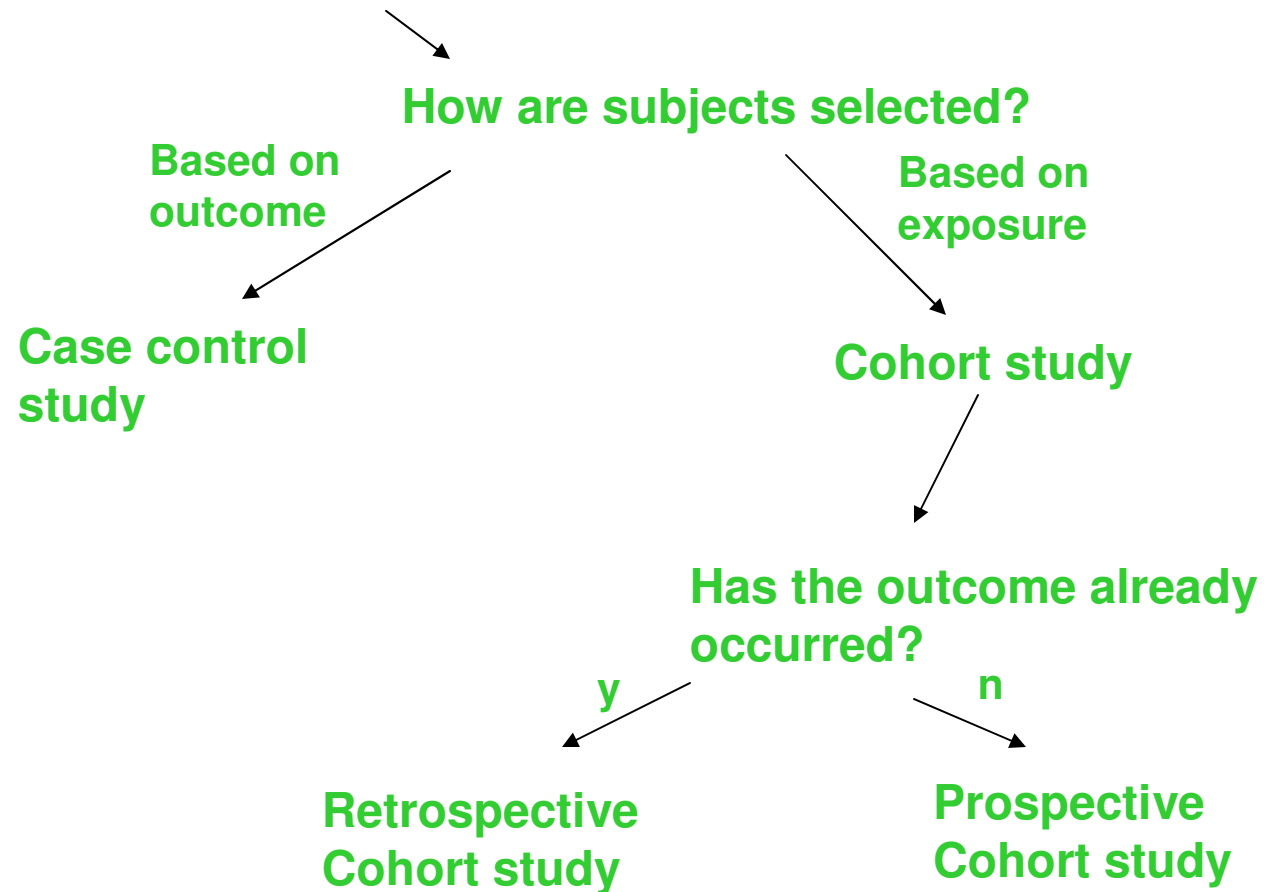


Potential Designs





Design



Data collection Goals:



Collect data accurately
Collect accurate data
Reduce potential
errors



Data Collection

- Types of assessment tools for nutrition-related data collection
 - Interview
 - Questionnaire
 - Participant observation
 - Photography
 - Plate Waste
 - Direct computer entry by subject



Data Collection

- Type of instrument directs outcomes
 - Info from FFQ differs from 24 hr recall
 - TSF differs from DEXA
 - Serum folate differs from RBC folate
 - SF36 differs from KDQOL



Points to consider

- Validity/Reliability of Instrument
- Difficulty to obtain measurements
 - Height in patients with amputations
 - Serum Vitamin A concentrations
- Access to instruments
 - Calipers to measure TSF
- Level of training required
 - Interpreting DEXA
 - Interpreting swallow study
- Subject burden



Procedures

- What is being done?
- How is it being done?
- Who is doing it?
- Where is it being done?
 - EX: RN will infuse 20mg/kg actual or adjusted body weight of L-Carnitine or placebo in a 50 ml infusion bag w/normal saline, immediately after each dialysis treatment. Infusion, into existing access site, will take place over 5 minutes.



Points to consider:

- Pilot procedures & treatments
- Put in place a system for:
 - Acquisition
 - Recording
 - Scoring data
- Length of treatment necessary
- Compliance
- Are measurements/interventions appropriate for population



Step 2: Institutional Review Board aka IRB

- Find out which IRB your facility is covered under
 - Local hospital
 - Chain research department
 - Local university
- Contact the IRB
 - Need most up to date forms
 - New protocol (sometimes call a checklist)
 - Informed consent – if required
 - HIPAA– if required



Institutional Review Board aka IRB

1. Steps for successful IRB submission:

1. Review Policies and Procedures
2. Complete all required forms & secure signatures
3. Complete protocol (note IRB desired length)
4. Write Informed Consent and HIPAA with necessary elements
 - a. Use template if provided!!
 - b. Don't change or delete mandatory wording
5. Consult the IRB frequently,
 - a. have them review a final draft for missing components – they are a resource!!



Step 3: Funding Options

- Government
 - NIH
 - USDA
- Foundations
 - Diabetes Associations
 - National Kidney Foundation
 - Special grants available resulting from KDOQI guidelines
 - Society of Parenteral and Enteral Nutrition
- Local Organizations
 - Kidney Foundation of “Your State”
 - Diabetes Association of “your city or state”
- Industry
 - Pharmaceutical companies
 - Private organizations or foundations

Panel to discuss:



1. Learning points from their own research experience?
2. What were barriers that they experienced and how did they overcome those barriers?
3. If the panel could change something or do something over regarding their research projects what would it be?



Thank You!!