CE Course Handout

The Transition from Clinical Dental Hygiene to Clinical Research

Thursday, June 18, 2015
2:30pm-5:30pm

2015 Center for Lifelong Learning at the 92ⁿᵈ Annual Session

The Transition from Clinical Dental Hygiene to Clinical Research
Presenters: Sharon Varlotta, RDH, MS
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June 18, 2015

I.   **Objective #1: Describe the scope of clinical research**
   A. Types of research – clinical studies, clinical trials
      1. Single-blind vs. double blind
      2. Randomization of interventions
      3. Placebo controlled
      4. Multi-centered
      5. Parallel groups
      6. Phase I, II, and III trials
   B. Research process
      1. Identification of a problem
      2. Design and methodology
      3. Inter-rater/intra-rater reliability and validity
      4. Data collection
      5. Analysis and interpretation of findings
   C. Where is research being performed
      1. Educational institutions
      2. Public health
         a. Disease prevention and health promotion
         b. Preventive modalities
         c. Innovative solutions to health problems
      3. Federal Government – from HHS to NIDCR
         a. Largest source of grant monies
         b. Renewable funding
         c. Opportunities to revise and resubmit
      4. Industry
         a. Free products with good funding
         b. Conflict of interest disadvantages
      5. Private practice
         a. NIH/NIDCR objective
         b. Practice-based research networks (PBRNs)
      6. Nonprofits – charitable foundations
         a. Less funding opportunity
         b. Narrow scope
         c. Lack of peer-review
   D. Funding
      1. Government

a. Research grants (R series – RO1, RO3, R15, R21)
b. Career Development Awards (K series)
c. Research Training & Fellowships (T & F series)
d. Program Project/Center grants (P series)
e. Trans-NIH-Programs
2. Grant life cycle and information
3. Funding databases

II. **Objective #2: Identify areas of personal interest and application of skills and knowledge**
  A. Personal qualities
    1. Organized
    2. Self-motivated, self-promoting
    3. Willingness to engage in new tasks
      a. Higher education advanced degrees
      b. Pursuit of certifications ex. Clinical Research Professionals, phlebotomy
    4. Critically analyze
    5. Ability to interact inter-professionally
    6. Process and summarize data
    7. Interest in spreadsheet and statistical software, SPSS
    8. Professional ability to interact with human subjects
    9. Objectivity
  B. Create professional profiles
    1. Creative CV's
    2. Linkedin
  C. Application of dental hygiene skills and education
    1. Screening – oral cancer, blood pressure, saliva samples, cheek swabs
    2. Laboratory procedures - blood processing, microbial assays, cultures
    3. Interviews – health assessments, oral health literacy, oral care
    4. Periodontal and radiologic assessments
    5. New product analysis
    6. Drug/medication application
  D. Grant writing

III. **Objective #3: Understand the role of a research assistant and study coordinator**
  A. Regulatory compliance
    1. Office of Human Research Protection (OHRP)
    2. Human Research Protections Program (HRPP)
    3. Institutional Review Board (IRB)
  B. Education and training
    1. Good Clinical Practice standards
    2. The Common Rule
    3. Belmont Report
      a. Respect for persons

        b. Beneficence

        c. Justice

C. Human Research Protections

1. Informed consent and its basic elements
2. HIPAA training
3. Investigator manual
4. Study conduct
5. CITI training
6. Good Clinical Practice (GCP)
7. Good Documentation Practice (GDP)

D. Principal Investigator obligations

1. In academics, an assoc or assist professor
2. Assures compliance for study procedures, FDA, DHHS compliance
3. Protocol compliance
4. Ultimate responsibility for all policies and procedures in protecting rights and safety of human subjects
5. Sufficient time to oversee and complete research
6. Adequate qualified staff
7. Access to population to allow necessary participants to recruit

E. Point of Contact

F. Study Coordinator

1. Regulatory compliance
2. Recordkeeping
3. Training logs
4. Recruitment
5. Financial management
   a. Participant payments
   b. Study materials budget

G. Research Assistant

1. Study team cross training
2. Study team calibration
3. Recruitment

H. Biostatistician

1. Assist with study design from initial concept to analysis and interpretation of study outcomes
2. May be contractually separate

IV.   Conclusion

A. Question and answer

B. Sharing of ideas

<u>Recommended reading historical account of the conduct of clinical research:</u>
<u>The Immortal Life of Henrietta Lacks</u> by author Rebecca Skloot

<u>Employment</u>

Linked-in

The Clinical Center is a team of medical professionals and support staff working together and who are looking for qualified staff to join them. Access current job links and other links for training, knowledge, and volunteer opportunities
www.cc.nih.gov/about/jobs.shtml

<u>Education and Training</u>

Facts about Clinical Studies with sections for researchers and potential subjects
www.cc.nih.gov/participate/faqaboutcs.shtml

Office of Clinical Research Training and Medical Education
  Courses of note:
    Introduction to the Principles and Practice of Clinical Research
    Bioethics
www.cc.nih.gov/training/training.html

National Institute of Dental and Craniofacial Research – supports career development programs
Links to home page and others from the NIDCR
www.nidcr.nih.gov/CareersAndTraining/

U.S. Department of Health & Human Services – for educational resources, policies, guidelines, compliance
http://www.hhs.gov/ohrp/humansubjects/index/.html

<u>Career Development</u>
<u>Academic</u>
Find a Research Career Development Program which offers:
  Workshops, classes, and seminars in subjects that are critical to an academic research career

Find a Research Information Specialist in your area
  Assist with identifying sources of funding
  Assist with planning, organizing, writing and revising a research grant application

Educational Opportunities

As example: Clinical Research Program at UMB School of Medicine
   Certificate in Clinical Research – 12 credit hours
   Masters in Clinical Research – 36 credit hours
Programs may include essential training in study design, biostatistics, epidemiology, ethical and regulatory issues as well as grant proposal writing and research team management

Certifications
Clinical Research Professionals
https://www.socra.org/certification/certification-program-overview/introduction/

Association of Clinical Research Professionals
http://www.acrpnet.org/MainMenuCategory/Certification.aspx

Research Skills Workshops

Coursework on the Introduction of Clinical and Translational Research

Private industry/or general……search for??
Forte Research Systems – www.forteresearch.com developer of specialized clinical and translational research management software solutions
   Have resources in the form of articles, job openings, ebooks, webinars
   A blog is available

Dental Practice-based Research
http://www.nidcr.nih.gov/grantsandfunding/See_Funding_Opportunities_Sorted_By/ConceptClearance/CurrentCC/PracticeBasedResearch.htm

Funding Databases and Grant Information

National Institutes of Health – nation's medical research agency
http://nih.gov/

Grants.gov – ability to search for federal grants by keywords, apply and track and search for policies
http://www.grants.gov/web/grants/search-grants.html

Fordfoundation – Economic, education, Human Rights, Sustainable Development
http://www.fordfoundation.org/grants

RePORT Expenditures and Results
http://projectreporter.nih.gov/reporter.cfm

NIH Electronic Submission of Grant Applications
http://grants.nih.gov/grants/electronicreceipt/

Grant Writing Tips Sheet
http://grants.nih.gov/grants/new_investigators/index.htm

NIH National Center for Complementary and Integrative Health
Tips for New NIH Grant Applications
http://nccam.nih.gov/grants/resources/tips.htm