Clinical Research Career Development for Nurses

Ralueke Ekezie (my brief)

- **SANOFI**: Connecting-Nurses Care-Challenge Innovation Award Winner 2012
- **HIFA** Country Representative of Year 2013
- Maternal Health Ambassador **(MAMA)**
- **INSEAD:** Strategic Innovation for Community Health(STICH) Nairobi 2017
- Fellow Circle of Health International **(COHI)** -Austin Texas

Chief Executive Officer: Blue Torch Home Care Limited

Flow of Presentation

- Skills required: Clinical Research Nurse (CRN)

- Career Growth: CRN

- Responsibilities / job description: CRN

- Scopes and standard of practice: CRN

- Education and Training: CRN

- Employers: CRN

- Salary: CRN

- Summary

Basic Definitions

- Clinical research nurse : **nurse researcher(s) conducting research that informs evidence-based practices to improve patient care and work independently and with other research team members in conducting clinical based research**

- Clinical nursing research: **Research carried out by nurses in the clinical setting and designed to provide information that will help improve patient care:**

- **Specialized practice of nursing profession which focuses on equilibrium between care of research participants and fidelity to research protocol-IACRN 2012**

Preparing for a career in Clinical Research Nursing

Need:

- Knowledge-Education

- Current / relevant: Courses, Trainings, workshops

- Professional association/organization membership

- Clinical research environment

- **Start!**

Skill Required by a Clinical Research Nurse

- A solid foundation in General Nursing practice
- Understanding of the research process and terminology
- An in-depth knowledge of a variety of specialties working in investigation
- Further development of management, leadership, organizational, communication, teaching and mentoring skills
- IT and data recording skills

Clinical Research Nursing:
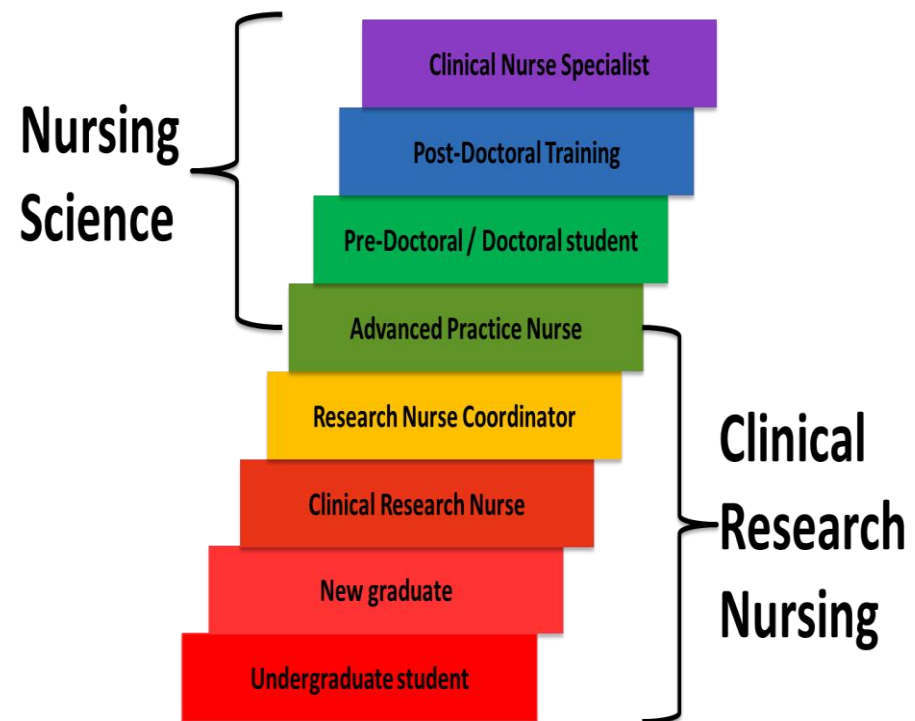# a bespoke career succession

@GRNurses
https://globalresearchnurses.tghn.org/

Typical CRN career titles: LMIC

- **Research nurse**
- **Clinical research nurse**
- **Research nurse coordinator**
- **Clinical research worker**
- **Research assistant**
- **Study coordinator or Project coordinator**
- **Data Manager**
- **Field worker**

- **Clinical Research Associate (CRA)**
- **Clinical Research Coordinator (CRC)**
- **Clinical Research Scientist (CRS)**
- **Clinical Quality Assurance Auditor (CQA)**
- **Principal Investigator (PI)**

NIH Clinical Center

Nursing Science {
- Clinical Nurse Specialist
- Post-Doctoral Training
- Pre-Doctoral / Doctoral student
- Advanced Practice Nurse
}

Clinical Research Nursing {
- Advanced Practice Nurse
- Research Nurse Coordinator
- Clinical Research Nurse
- New graduate
- Undergraduate student
}

Roles of Clinical Research Nurse

- **Clinician (Direct care provider, study coordinator, Advanced clinician)**
- **Manager**
- **Clinical research associate (CRA)** Jr. research associate, clinical trial administrator
- **Clinical Research Coordinator (CRC)**
- **Educator**
- **Advocate**

LMIC: development required for CRNs to fulfill

- **Regulatory specialist**
- **Nurse scientist**

Roles include

- Doing the job on pre-trial procedures
- Participating investigator meetings (IM)
- Coordinating with ethics committee (EC)
- Coordinating with regulatory authority
- Monitoring and training Jr. staff
- Project management

Clinical Research Nursing:
Scope & Standards of Practice

Practice domains:

Clinical Research Nursing practice
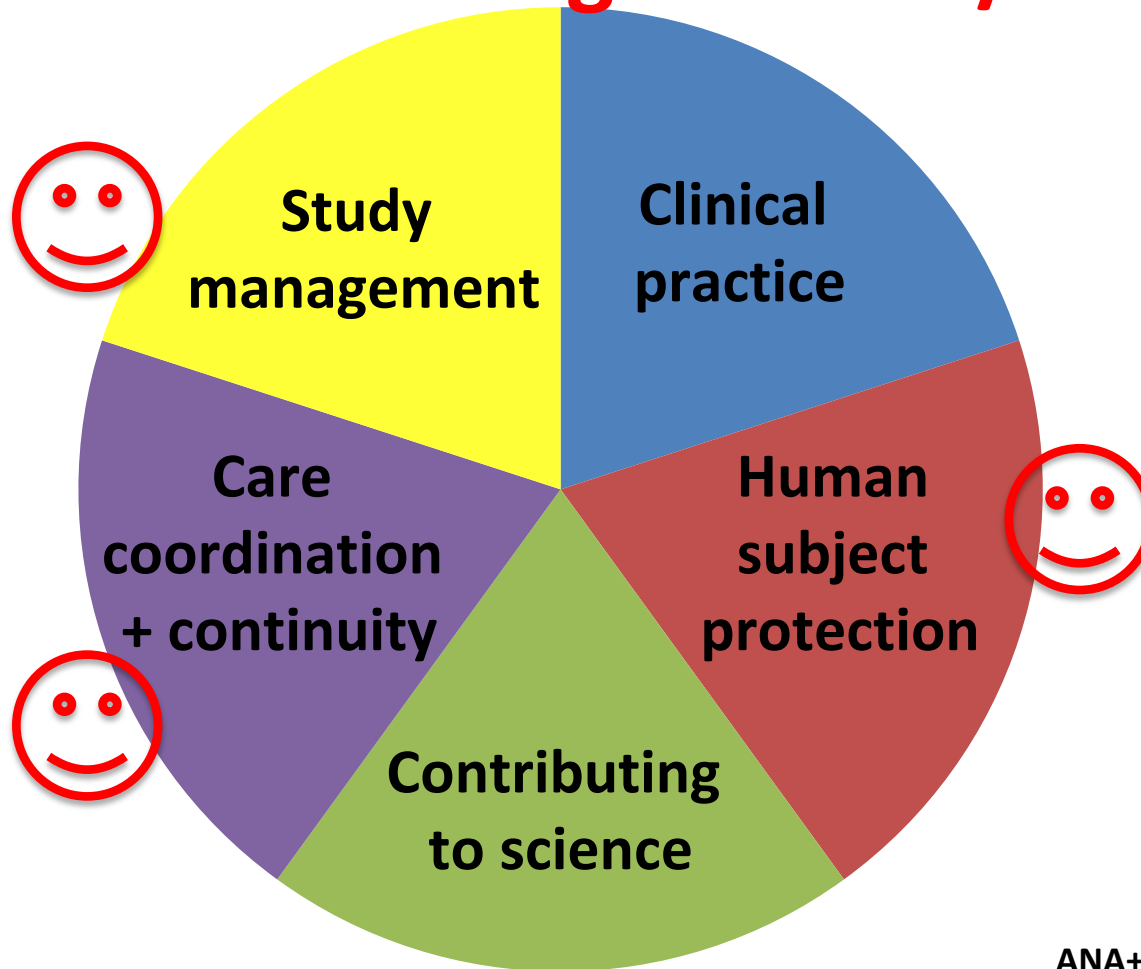
TGHN/ GRN e-Learning courses / workshops

Study Management:
Domain of Practice

CLINICAL RESEARCH NURSE

GRN support / e-learning courses

Research Participant needs

Non-CRN nurses

Standard of care needs

Protocol needs

Principles guiding Clinical Research Nursing practice

- Synthesis of **nursing practice** integrated with **Good Clinical Practice** (GCP)

- **Direct** nurses practicing in CRN specialty

- **Combined** with patient care: **safe** research environments, produce **reliable**, **valid** data

  - Safety and determination
  - Research informed consent
  - Fidelity to the research protocol
  - Regulatory compliance(LAWS)

Professional nursing ethics in Clinical Research Nursing practice

- **Respect** for the individual

- **Commitment** to the patient

- **Advocacy** for + **protection** of the patient

- Authority, accountability + **responsible** practice

- Duties to **self** + **others**

- Ethical **work** settings + **care** environments

- Nursing **profession advancement**

- **Collaboration** with the public + health professionals

- Nursing profession **integrity**, values + **social justice**

Standards of Practice

Clinical Research Nursing practice

Nursing process:

1. Assessment, 2. Diagnosis 3. Outcomes identification

4. Planning 5. Implementation 6. Evaluation

Professional performance

7. Ethics

8. Cultural congruent practice

9. Communication

10. Leadership

11. Education

12. Evidence based practice and research

13. Quality of practice

14. Professional practice evaluation
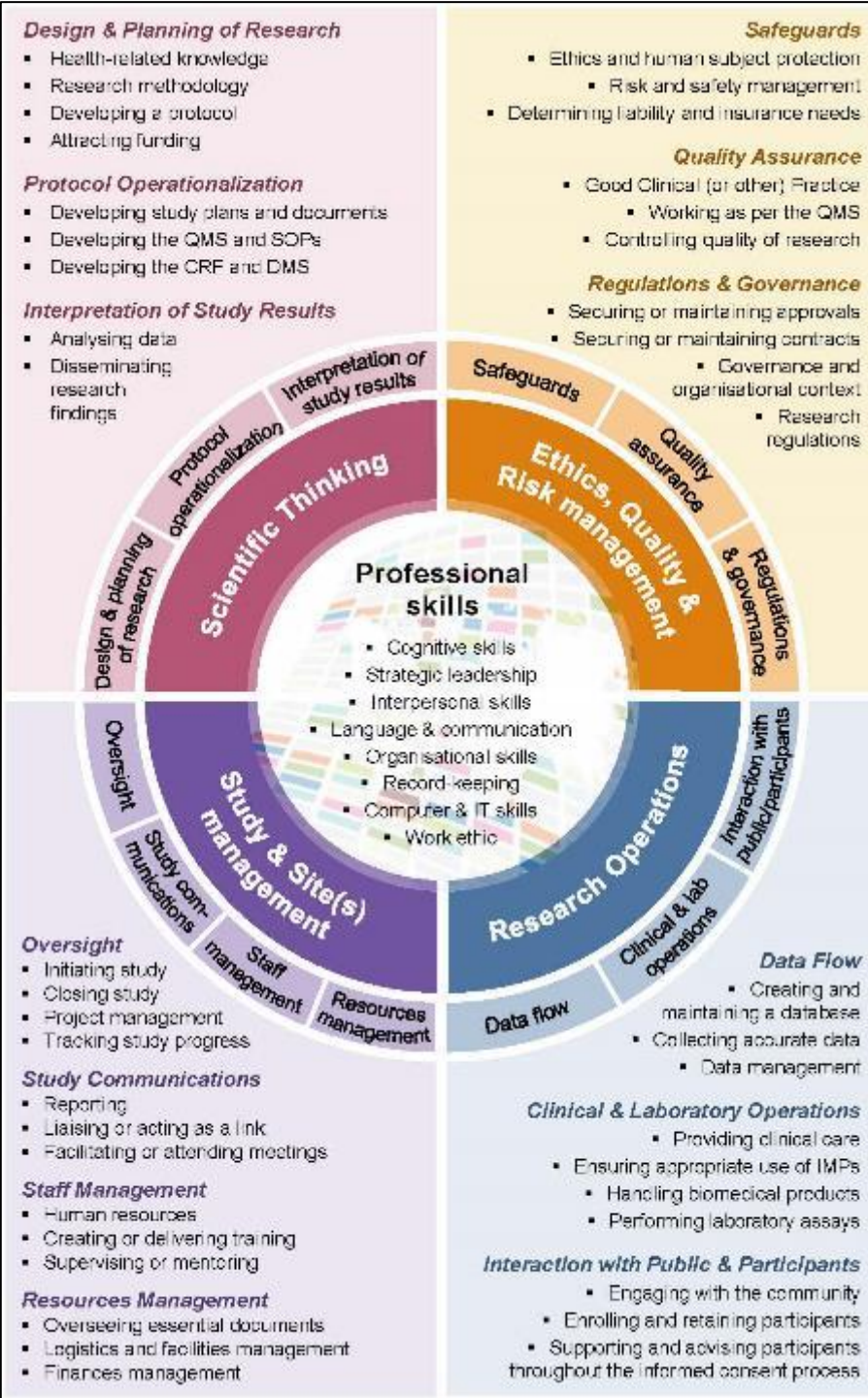
15. Environmental health

Core Competency Framework

Map the different roles within the clinical research teams.

Create a set of **global competencies** needed for the conduct of **clinical research.**

TDR

Area of competency	Data management
Type	Task-based
Definition	The individual manages the data process in the trial; they oversee the ... and the specifications for its safe storage. They operate the data mana... system (DMS), and execute quality management strategies for the dat... check the timely resolution of database queries, and review reports ge... from the databases as required. Data management requires excellent ... of the data flow plan, processes and guidelines, and good project man... skills. **Expert:** Experts may work with other sites to implement data manage... solutions during multicentre trials, and support the improvement of th... management process when necessary.
Related competencies	**Similar tasks:** Developing CRF & data management system; Analysing ... Collecting accurate data; Creating and maintaining database; Project management; Safety & AEs management **Knowledge base:** Research regulations; Ethics & human subject prote... (confidentiality); Good Clinical (or other) Practice **Required skills:** Computer and IT skills; Record-keeping
Keywords	Data management; Data flow; Data transfer.
Abilities	• Manage the flow of data in the trial: how it is acquired, cleaned and... • Oversee quality of data management and data systems • Operate data management system • Assist in defining data specifications and summaries, and data listing... • Reconcile data transfers

Design & Planning of Research
- Health-related knowledge
- Research methodology
- Developing a protocol
- Attracting funding

Protocol Operationalization
- Developing study plans and documents
- Developing the QMS and SOPs
- Developing the CRF and DMS

Interpretation of Study Results
- Analysing data
- Disseminating research findings

Safeguards
- Ethics and human subject protection
- Risk and safety management
- Determining liability and insurance needs

Quality Assurance
- Good Clinical (or other) Practice
- Working as per the QMS
- Controlling quality of research

Regulations & Governance
- Securing or maintaining approvals
- Securing or maintaining contracts
- Governance and organisational context
- Research regulations

Professional skills
- Cognitive skills
- Strategic leadership
- Interpersonal skills
- Language & communication
- Organisational skills
- Record-keeping
- Computer & IT skills
- Work ethic

Oversight
- Initiating study
- Closing study
- Project management
- Tracking study progress

Study Communications
- Reporting
- Liaising or acting as a link
- Facilitating or attending meetings

Staff Management
- Human resources
- Creating or delivering training
- Supervising or mentoring

Resources Management
- Overseeing essential documents
- Logistics and facilities management
- Finances management

Data Flow
- Creating and maintaining a database
- Collecting accurate data
- Data management

Clinical & Laboratory Operations
- Providing clinical care
- Ensuring appropriate use of IMPs
- Handling biomedical products
- Performing laboratory assays

Interaction with Public & Participants
- Engaging with the community
- Enrolling and retaining participants
- Supporting and advising participants throughout the informed consent process

Scientific Thinking · Ethics, Quality & Risk management · Study & Site(s) management · Research Operations

Framework parts
How does it work?

Competency Wheel

The Competency Wheel shows on a single page all the 50 competencies that make the Framework, applying to the entire research team.

Competency Dictionary

The Competency Dictionary gives a full description of each competency, and its associated tasks and keywords. This should clarify what is meant by the competencies listed on the Wheel.

The Competency Wheel and Dictionary are very flexible, and can be used to determine how a team will break down responsibilities involved in a new study, or to perform analyses of gaps in resources at a site.

Grading System

The grading system includes a template for grading an individual's level of expertise for each area of competency; as well as a scale (0-5) to help grading consistently. Grades can be represented pictorially through the use of a radar diagram.

Role-Specific Frameworks

The role-specific frameworks are adapted from the generic framework for specific roles (research nurse, investigator, etc.). They contain examples of what a competency means for that particular role, and suggest a desired grade for junior/senior staff.

TDR

Team roles

Role	Junior	Senior	Expert or Specialist setting
Data staff	Data clerk; Data assistant; Data entry and administration personnel	Data manager; Senior or Lead data manager	Biostatistician
Laboratory scientist	Laboratory (lab) technician; Scientific lab technician; Lab technologist; Lab research assistant	Assistant lab manager; Lab manager; Lab scientist; Head of laboratory (at site)	Head of laboratory(ies); Chief specialist scientist; Research scientist (medical); Senior lab analyst; Science lead; Clinical pharmacologist
Trial pharmacist	Pharmacy administrator/coordinator; Trial pharmacist; Pharmaceutical technologist; Pharmacy technician	Lead pharmacist	
Community engagement staff	Fieldworker; Research assistant	Senior fieldworker; Field research officer; Community engagement or liaison officer; Community engagement and ethics coordinator	Counsellor
Research nurse	Nurse; Nurse assistant; (Clinical) research nurse; Study nurse; Vaccination nurse	Clinical research coordinator; Study coordinator	
Study physician	(Clinical) research physician; Clinical development physician; Study physician; Medical officer; Research clinician; Clinical investigator	Sub-investigator; Lead clinical research physician	(Clinical) safety physician; Pharmacovigilance physician; Public health officer
(Principal) investigator	Investigator (at site); Co-investigator; Medical science physician	Principal Investigator; Head of clinical trials; Global clinical Leader; Senior director of clinical R&D; Senior global clinical pharmacologist	
Trial manager or Project coordinator	(Clinical) research/trial coordinator; Project/study coordinator; (Clinical) research/trial manager; Clinical research operations manager; Clinical research administrator; Trial clinical officer; Support officer; Clinical trials facility manager	Senior research coordinator; Chief trial manager	
Quality Control monitor	Clinical trial monitor; Quality assurance manager; Quality control specialist; (Clinical) Research associate (industry)	Lead monitor; Monitoring senior associate; Monitoring team leader; Quality assurance officer	Data quality controller; Safety specialist; Regulatory affairs specialist; Regulatory coordinator; Senior ethic clinical trials specialist
ECs and IRBs	Ethics Committee (EC) or Institutional Review Board (IRB) member (permanent or lay)	EC/IRB coordinator; EC/IRB vice-chair or chair	
Sponsor	Not applicable		

Competency grading

Grade	Corresponding behaviour
5	**Task**: Highly experienced; able to train and guide others. **Knowledge**: Expert knowledge; able to teach and assess others. **Skill**: Use skill appropriately, consistently and confidently.
4	**Task**: Experienced; regularly perform the task in their job. **Knowledge**: Highly knowledgeable; use, reflect, critically evaluate information related to the topic. **Skill**: Use skill appropriately, in all relevant situations.
3	**Task**: Capable to perform the task. **Knowledge**: Knowledgeable; frequently apply knowledge of topic. **Skill**: Use skill appropriately, but only occasionally.
2	**Task**: Some experience; already performed the task at least once. **Knowledge**: Some exposure; already applied knowledge of topic in their job at least once. **Skill**: Use skill inconsistently and occasionally.
1	**Task**: Little experience, but received training. **Knowledge**: Little exposure, but followed courses or read about the topic. **Skill**: Use skill with difficulty and/or very rarely.
0	**Task**: No experience; never performed the task before. **Knowledge**: No exposure; never heard of the topic before. **Skill**: Unable to use skill.
NA	Not applicable (e.g. if the competency is not useful for the role of the individual assessed)

Clinical Research Nursing:
education towards bespoke career?

?

- **Employer specific only**

- **Employer specific + informal career focused**

  (short courses / modules / certificates)

- **Employer specific + formal career focused**

  (degree / post graduate diploma / CRN certification)

- **Formal career focused**

- **Informal career focused**

| PhD | Masters degree | Clinical specialisation | Short courses | ? |

Typical CRN education requirement + Importance + Need

Required minimum education and training

Diploma in General Nursing (3 years)

Required minimum work experience

Minimum 1 year research experience

Desirable additional education, work experience

Diploma in **Primary Health Care** or similar will be an advantage

Certification in **good clinical practice**

Experience in a research environment

Good **administrative skills** together with working knowledge of **Microsoft Office**

Self-motivated, able to work independently and as part of a **multidisciplinary team**

Working knowledge of **Microsoft Office packages**

Examples: Clinical Research programmes offered

- Sollers College, New Jersey
  - Clinical Research Nursing Program (also online)
  - MSC. In Clinical trials management, short term courses and graduate certificate programmes
- James Lind Institute, Singapore
  - PG Diploma in Clinical research
  - Clinical programmes (also online programmes)
- University of San Diego, USA
  - Masters of Science in Clinical research

Examples: Organizations involved Clinical Research Nursing in Africa

- The Global Health Network (TGHN) – Global Research Nurses (GRN)

- International Association of Clinical Research Nurses (IACRN) - African chapter pending

- American Society of Clinical Oncology (ASCO): International Society of Clinical Trials Workshops (ICTW)

Typical employers: CRNs

- Universities
- Private research organisations
- Contract Research Organization (CRO)
- Biotech companies
- Pharmaceutical companies
- Self-employment (Freelance basis)

Country Annual Average clinical research nurses

USA and Canada	**$60,000-74,000**
Singapore	**S$ 37,000**
United Kingdom	**£ 35,000**
South Africa	**R 297,599**
AustraliaAU	**$ 79,200**

SUMMARY

- No limitation to roles nurses can play in clinical research

- Education, trainings and resources available to explore as career pathways for CRN

- Need for formalized career pathway for CRN

- Existing clinical research nursing organization supporting clinical research nurses / nursing in Africa

- Clinical research is vital for discovering innovative ways to improve our patients care

Acknowledgements

TGHN: Prof Trudie Lang and team in Oxford

GRN:Organisers of this workshop

Dr. Elize Pietersen

Blue Torch Home Care Limited

Regulatory specialist role of the Clinical Research Nurse

1.   Monitor, oversee progress of clinical trial (conducted, recorded + reported) in accordance with protocol standards SOP, GCP + applicable regulatory requirements
2.   Must conduct work in settings of research practice, center, or hospital or within industry or governmental agencies
3.   Have advanced knowledge of regulatory science (train through research-specific continuing education or Master's education with focus on regulatory science

Examples of job title:
Clinical research associate, Monitor, Industry Review Board (IRB) Director, Quality Assurance manager

Nurse scientist role of the Clinical Research Nurse

- Prepared at the doctoral level

    [Doctor of philosophy (PhD) or Doctorate of nursing science (DNSc)]

- Work in inter-professional teams with myriad of collaborators

- Engage in scientific pursuit of new knowledge to ultimately improve patient outcomes + health care delivery

- Activities include conducting + disseminating original research, participating on advisory boards/appointed committees + educating/mentoring others

Examples of jobs: senior leadership positions in clinical research enterprises as **Directors, Senior scientists, Consultants**

Master's degree in clinical research – UC San Diego

Program overview

- principles of epidemiology
- bio-statistics
- patient-oriented research
- health services/outcomes research
- applied quantitative analysis
- professional development for clinical researchers
- integrative, high-level clinical research project in the student's final term

https://clre.ucsd.edu/program-overview/

Master's degree in clinical research – UC San Diego

Objectives and Competencies

- **Analyse a clinical problem including its relevant epidemiology, pathophysiology, and current therapy**
- **Design potential observational and interventional studies or health services research including:**
  - **Grants to support the study**
  - **Protocol with hypothesis, background, methods, and analytic plans**
  - **Human subjects application**
  - **Budgeting**

https://clre.ucsd.edu/program-overview/

Master's degree in clinical research – UC San Diego

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Competencies gained

- **Epidemiological concepts**
- **Bio statistical concepts, skills including use of SPSS and R software**
- **Scientific writing for grant requests and research papers**
- **Ability to design and implement a clinical (patient-oriented) research study including:**
  - **Selection of study methods**
  - **measures of the intervention and outcomes**
  - **data collection, management**
  - **Data analysis**
  - **Ethical and regulatory knowledge and practical skills** (write IRB applications and utilise Data Safety Monitoring Boards)

https://clre.ucsd.edu/program-overview/

Research Process

- Selection of Research Problem
- Extensive Literature Survey/review
- Making Hypothesis
- Preparing the Research Design
- Sampling
- Data collection
- Data Analysis
- Hypothesis Testing
- Generalization and Interpretation
- Preparation of Report