AL NEELAIN UNIVERSITY
GRADUATE COLLEGE
FACULTY OF MEDICINE AND HEALTH SCIENCES
DEPARTMENT OF COMMUNITY MEDICINE

DIPLOMA IN
RESEARCH METHODOLOGY AND ETHICS CURRICULUM
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Updated curriculum
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لائحة القبول برنامج دبلوم منهجية وأخلاقيات البحث

اسم الدرجة العلمية
الدبلوم العالي في منهجية و أخلاقيات البحث

شروط الترشيح للقبول

1. حصول الطالب على:
   - درجة البكالوريوس في الطب والجراحة من جامعة النيلين أو أي جامعة أخرى معترف بها.
   - درجة البكالوريوس في طب الأسنان أو الصيدلة أو المختبرات الطبية أو علوم التمريض أو الصحة العامة أو الطب البيطرى أو العلوم البيئية أو العلوم الأسرية أو العلوم الطبيعية أو علم النفس.

2. دفع الرسوم الدراسية المقررة

3. إستيفاء شروط القبول العامة بكلية الدراسات العليا بجامعة النيلين.

نظام الدراسة

- الدراسة بالمناقرات والبحث العلمي
- فترة الدراسة فصلان دراسيان وتشمل على:
  - الدراسة النظرية
  - الدراسة العملية
  - البحث العلمي
- مدة الدراسة لكل فصل دراسي 12 أسبوعًا
- كل المواد إجبارية
- لغة التدريس الأساسية هي اللغة الإنجليزية.
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1. **Introduction:**
The conduct of research nowadays has become an integral part of medical and public health practice. In addition, submission of a dissertation is a mandatory requirement of post-graduate degrees in medical and health sciences. However, conduct of quality research requires adequate competency of research methodology and ethics with emphasis on skills and practical applications. The program is intended for all candidates require grounding of basic competencies in research methodology and ethics in order to be able to conduct quality research. The course targets all the post-graduate candidates from various disciplines including medicine, public health, laboratory, nursing, social, veterinary sciences as well as researchers and academicians.

The length of the course is expected to be 9 months. In order to be awarded a diploma in research methodology and ethics, the candidates must take a total of 22 credit hours. In addition, the candidates are required to prepare, submit a review article for publication in one of the national, regional and international peer-reviewed journals before their final examinations.

The course is expected to be competency based rather than theoretical based with active participation of the candidates in the learning process. The course is expected to be composed of 8 modules. The modules are designed to encourage and facilitate participation and discussion, and open-minded reflection on the research process and central issues of research methodology and research ethics. In addition the candidates are encouraged to be self-learners during the modules sessions and to allow for extra time equal to the formal contact hours.
2. **Educational objectives**
By the end of the course, the candidates are expected to be able to:

- Formulate competently a research proposal
- Review and analyze critically the literature relevant to the research topic.
- Conduct and implement efficiently a research project
- Describe and apply ethical principles in research involving human subjects
- Apply the principles of scientific writing with preparation and submission of review article for publication.
- Prepare and finalize research reports and dissertations.

3. **Credit hours**
The Diploma of Research Methodology and Ethics program includes a minimum of 22 credit hours of study.

- 19 credit hours in studying research methodology and ethics
- 3 credit hours for the scientific article
4. The modules mapping

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Core Courses:
Module 2: Study designs
Module 3: Biostatistics in research
Module 6: Introduction to research ethics
Module 7: Responsible conduct of research
Module 8: Ethical review committees, processes and procedures

It is mandatory to achieve a pass level of 60% in all the core courses, failing to pass one of the core courses will mean that you failed the diploma program. It is also mandatory that students participate and engage in all courses. Failing to participate in any course will also fail students.
5. Details of the modules description (including learning objectives, learning methods, resources and contents)

DRME1: Introduction to research methodology

1.1. Learning objectives

By the end of the module, the candidates are expected to be able to:

- Define research and its significance in solving health problems.
- Describe the classification of research
- Discuss health research classification
- Define operational research, aims, applications and its significance
- Explain the term "research for health" and clarify the impact on health from policies, programs and events originating from other sectors.
- Conceptualize and raise research questions
- Select, define and state a research problem
- Describe the criteria to be fulfilled for research problem selection.
- Discuss and apply criteria for prioritizing the research problems.
- Write rationale for the research problem
- Formulate general and specific research objectives.
- Identify, develop and enlist the study variables
- Describe measurement scales
- Use measurement scales for classification of variables
- Identify relations between variables, importance and features.
- Explain the statistical significance of the relationship between variables i.e. P value

1.2. Learning methods:

- Small group work.
- Case study
- Assignments
- Exercises
- Lectures.
1.3. **Learning resources:**
- Two facilitators
- Online training materials

1.4. **Contents**
- Introduction to research definition and its significance
- Classification of research
- Classification of health research
- Operational research: definition and applications.
- Research for health and its scope
- Conceptualization of research questions.
- Selection, definition and statement of a research problem
- The criteria for selection research problem
- The criteria for prioritizing research problems.
- Writing justification/rationale for research
- Formulation of general and specific research objectives.
- The criteria of a good research objective
- Research objectives versus project objectives
- Qualitative versus quantitative variables
- Dependent versus independent variables
- Confounding variables (intervening) and their influence in case control designs
- Background variables
- Measurement scales
- Classification of variables using the measurement scales.
- The statistical significance of the relation between variables.
**DRME 2: Study designs and systematic review:**

**2.1 Learning objectives**

By the end of the module, the candidates are expected to be able to:

- Identify the various categories of research designs
- Discuss the main features of the epidemiological study designs
- Recognize the criteria for selection of the right design
- Explain the main features of the descriptive study designs.
- Outline the procedures of the descriptive study designs.
- Outline the characteristics of survey
- Describe the features and benefits of cross sectional studies.
- Illustrate and explain the cross sectional design
- Describe the steps of conduct of hospital-based longitudinal studies
- Formulate an epidemiological hypothesis
- Enlist uses of descriptive study designs
- Define analytical study designs
- Explain the common features and basic steps of case control study
- Illustrate and explain the case control design
- Identify the practical steps and sources for selection of the cases and controls
- Define matching indicting its importance in case control study
- Describe and compare group matching with individual matching
- Calculate and interpret exposure rates among cases and controls using models of 2X2 tables.
- Calculate and interpret Odds ratio using models of 2X2 tables.
- Clarify the advantages and disadvantages of case control study designs.
- Describe the features and basic steps of cohort study designs
- Define the concept of a cohort giving examples.
- Illustrate and explain the cohort study design
- Enlist indications of a cohort study designs
- Describe and illustrate different types of cohort studies
• Describe the selection process of the study subjects for a cohort study with explanation of the sources of information about exposure
• Enlist the follow up procedures of the exposed and the non-exposed groups in a cohort study.
• Calculate and interpret the incidence rate of a disease among exposed and non-exposed groups using 2X2 table
• Calculate and interpret relative risk based on cohort study results.
• Calculate and interpret attributable risk based on cohort study results.
• Calculate and interpret Odds ratio based on cohort study results.
• Compare the relative risk and the Odds ratio as calculated based on cohort study results.
• Recognize the advantages and disadvantages of a cohort study design.
• Identify the features, advantages and disadvantages of nested case control design
• Illustrate models of nested case control study design
• Identify the features, aims, advantages and disadvantages of experimental study designs
• Compare experimental and analytical study designs
• Describe the types of experimental study designs
• Explain the quasi-experimental design
• Discuss the basic steps undertaken for conduct of randomized clinical control trials
• Describe the cross over randomized clinical control trials
• Illustrate and explain the randomized clinical control trial design
• Describe the specifications of protocols of randomized clinical control trials
• State the principles of random allocation
• Define bias and its main sources in randomized clinical control trials
• Describe the process of blinding in planning and conduct of randomized clinical control trials
• Overview the preventive trials and their applications
• Illustrate and explain the preventive trial design
• Differentiate the phases of clinical trials
• Discuss the factors that influence the design and analysis of clinical trials

Systematic review component:
• Develop a plan for the literature review process indicating all the required steps.
• Discuss the importance of the literature review in conduct of research
• Select, appraise, summarize and present the literature review using standard frame
• Differentiate between literature, systematic review and meta-analysis showing the strengths and weaknesses of each.
• Identify core principles and methods for conducting systematic reviews.
• Describe components of the protocols of systematic review of clinical trials and public health interventions
• Describe the practical steps for undertaking the systematic review
• Discuss other review approaches and their significance and applications
• Plan for dissemination of the systematic review findings and research results
• Define meta-analysis explaining its aim and validity
• Discuss the benefits and limitations of meta-analysis
• Recognize the practical steps for conduct of meta-analysis through using the PRISMA checklist

2.2 Learning methods:
• Small group work.
• Case study
• Assignments
• Exercises
• Lectures.
2.3 Learning resources:

- Two facilitators
- Online training materials

2.4 Contents:

- Categories of study designs
- Main features of the epidemiological study designs.
- The selection criteria of the right design.
- The features, uses, procedures and illustration of descriptive study designs.
- The features and benefits and illustration of cross sectional study designs.
- Hospital-based longitudinal study designs.
- Analytical study designs: types and aims
- Features, steps and illustration of case-control study designs
- Selection of cases and controls in a case-control study
- Matching: definition, importance and types.
- Calculation and interpretation of exposure rates and Odds ratio for case and controls using 2X2 table.
- Advantages and disadvantages of case control study designs
- Features, indications, basic steps and illustration of a cohort study design
- The selection of the study subjects for a cohort study
- The follow up procedures of the exposed and the non-exposed groups in a cohort study
- Calculation of interpretation of incidence rates, relative risk and Odds ratio in a cohort study using 2X2 tables.
- Relative risk versus Odds ratio based on cohort study results.
- Advantages and disadvantages of cohort study designs.
- Features of nested case control study designs
- Nested case control versus case control designs
- Features, aims, advantages and disadvantages of experimental study designs.
- Experimental versus analytical study designs
Types of experimental study designs
• Quasi-experimental study designs
• Basic steps for conduct of randomized clinical trials
• Illustration of randomized clinical control trials
• Protocols of randomized clinical control trials
• Cross over randomized clinical control trials
• Principles of random allocation
• Bias and its main sources in clinical trials
• Process of blinding in clinical trials.
• Preventive trials and their applications
• Illustration of preventive trials
• Phases of clinical trials
• Factors influence the design and analysis of clinical trials.

Systematic review component:
• Literature review process, types and steps
• Importance of literature review in conduct of research
• Selection, appraisal, summarization and layout of literature review
• Comparison of literature, systematic reviews and meta-analysis
• Core principles and methods for conduct of systematic review
• Protocols for systematic review of clinical trials and public health interventions.
• Practical steps for undertaking systematic review.
• Overview of other review approaches
• Dissemination plan for systematic review findings and research results.
• Meta-analysis aim and validity.
• Benefits and limitations of meta-analysis
• Conduct of meta-analysis through usage of PRISMA checklist.
DRME 3: Biostatistics in Research:

3.1. Learning objectives

By the end of this course, students should be able to:

- Describe statistics & its role in modern health science
- Define variables & describe different types
- Construct and use a frequency table
- Construct and use specific graphic representation of data including pie charts, histograms, frequency polygons and box plots.
- Calculate and interpret summary measures; range, interquartile range, mean, variance, standard deviation, and coefficient of variation.
- Calculate the confidence interval for a single or for a difference between two summary measures.
- Perform a significance test to compare various summary measures.
- Apply a chi-squared test.
- Explain the distinction between linear correlation and regression.
- Explain the principles of sample size estimation
- Estimate the sample size through the usage of formulae
- Estimate the sample size through usage of appropriate computerized statistical packages
- Describe and apply the sampling techniques and their practical steps.

3.2. Learning methods

- Small group work.
- Case study
- Assignments
- Exercises
- Lectures

3.3 Learning resources

- Two facilitators
- Online training materials
3.4 Contents:

- Introduction to Biostatistics
- Defining & Displaying Data I & II
- Measures of Central Tendency
- Measures of Dispersion
- The normal distribution
- Confidence interval for a mean/proportion & its interpretation
- Comparison of mean- confidence intervals, hypothesis test, and \( P \)-values (paired data)
- Comparison of mean- confidence intervals, hypothesis test, and \( P \)-values (unpaired data)
- Analysis of proportions
- Understanding Probability, risk & Odds.
- Chi-squared Analysis.
- Linear regression & Correlation
- Sample size calculation.
- Principles of sample size estimation
- Strategies for estimation of sample size
- Computerized packages for estimation of sample size
- Sampling techniques and their applications
DRME 4: Data Collection, management, analysis and presentation:

4.1. Learning objectives

By the end of the module, the candidates are expected to be able to:

- Recognize the data collection techniques
- Describe and construct the data collection instruments using the appropriate layout format.
- Utilize the study variables for construction of data collection instruments.
- Apply questioning techniques in formulation of both close and open-ended questions
- Pre-test the data collection instruments.
- Organize appropriate training for the data collectors.
- Discuss the uses, advantages, disadvantages, weaknesses and strengths of each data collection instruments.
- Explain the data management procedures, rules including safety, legal and ethical aspects
- Plan and conduct data analysis using manual and computerized statistical packages.
- Summarize data using the appropriate layout format

4.2. Learning methods

- Small group work.
- Case study
- Assignments
- Exercises
- Lectures.

4.3. Learning resources

- Two facilitators
- Online training materials

4.4. Contents

- Data collection techniques
- Data collection instruments: Construction and layout
• Data collection instruments: advantages, disadvantages, weaknesses and strengths.
• Utilization of study variables for construction of data collection instruments
• Questioning technique: formulation of question.
• Pre-test of the data collection instruments
• Training of the data collectors: organization, duration and contents.
• Principles and rules of data management.
• Manual data analysis
• Data analysis through usage of appropriate computerized statistical packages.
• Summarization of data: tables, cross tables, figures, diagrams etc
• Data layout format
DRME 5: Scientific writing

5.1. Learning objectives

By the end of the module, the candidates are expected to be able to:

- Discuss the principles of scientific writing
- Describe the components of the research proposal.
- Develop and finalize a research proposal.
- Discuss the components of the final dissertation
- Describe the frame of scientific journal article
- Describe the principles of the commonly used reference citation style
- Discuss the principles of the commonly used reference citation style for electronic documents i.e. web citation
- Cite correctly the references in the text and the list.
- Describe the steps in the process of writing a scientific paper
- Write case report
- Write a secondary scientific paper
- Apply the IMRAD structure for scientific writing of a journal article.
- Explain the term plagiarism and how to avoid it
- Describe the steps toward publication of a scientific article

5.2. Learning methods

- Small group work.
- Case study
- Assignments
- Exercises
- Lectures
- Access to Internet

5.3. Learning resources

- Two facilitators
- Online training materials
5.4. Contents

- Principles of scientific writing
- The steps in the process of scientific writing
- Components of research proposal
- Preparation and finalization of the research proposal
- Components of the final dissertation
- Proposal versus final dissertation
- The frame of a scientific journal article.
- The Vancouver and Harvard Styles for reference citation
- The web-based reference citation styles
- Case report
- Secondary scientific paper
- IMRAD structure for scientific writing of a journal article
- Plagiarism
- Publication of a scientific article
DRME 6: Introduction to research ethics

6.1. Learning objectives

- Outline the history of research ethics.
- Explain the importance of research ethics.
- Identify types of research involving human subjects.
- Recognize the ethical principles that guide research involving human subjects.
- Discuss competently the contents of both the national international ethics guidelines, codes and declarations.
- Define and prepare an informed consent.
- Identify elements of informed consent.
- Describe the process of obtaining the informed consent.
- Describe the meaning and use of “minimal risk” concept in research involving human subjects.
- Explain the meaning of coercion concept in research involving human subjects.
- Explain the meaning of an acceptable inducement and undue inducement in research involving human subjects.

6.2. Learning methods

- Small group work.
- Case study.
- Assignments.
- Lectures.

6.3. Learning resources

- Two facilitators.
- Online training materials.
6.4. Contents

- History of research ethics
- Importance of research ethics
- Research involving human subjects
- Ethical principles in research involving human subjects
- National, international ethics guidelines, codes and declarations
- Informed consent: definition and preparation
- Informed consent: elements and obtaining process
- Minimal risk concepts and meaning
- Coercion: meaning and definition
- Acceptable versus undue inducement
DRME 7: Responsible conduct of research

7.1. Learning objectives

1. Consider their role as scientists in society and the kinds of ethical considerations that are implicated in scientific activity.
2. Demonstrate understanding of the changing nature of science and the ways in which science is shaped by social values.
3. Demonstrate understanding of the federal definition of “scientific misconduct,” factors driving the prevalence of misconduct, the processes for investigating misconduct, and the penalties for committing misconduct.
4. Demonstrate understanding of the relevant governmental and non-governmental policies regarding authorship, data retention and sharing, financial conflicts of interest, and the use of human participants and animal subjects in research.
5. Consider broader ethical issues, beyond policies per se, regarding each of the aforementioned areas.

7.2. Learning methods

- Small group work.
- Case study
- Assignments
- Lectures

7.3. Learning resources

- Two facilitators
- Online training materials

7.4. Contents

- Introduction to the Responsible Conduct of Research (RCR)
- Research Misconduct
- Conflicts of Interest in Research
- Authorship & Publication
- Ethical Issues in Data Management
- Mentoring in Research
- Research with Human and Animal Subjects
DRME 8: Ethical review committees, processes and standard operational procedures

8.1. Learning objectives

By the end of the module, the candidates are expected to be able to:

- Discuss the importance of research ethics committee
- Identify the purposes, functions and responsibilities of the research ethics committee
- Describe the composition, membership, resources and chairing of the research ethics committee
- Analyze the ethical basis for decision making in research ethics committee
- Identify barriers for performance of research ethics committee
- Explain the contents of various national forms used by research ethics committee
- Explain the contents of the various national forms used for ethical review
- Enlist and discuss the standard criteria for ethical review

8.2. Learning resources

- Small group work.
- Case study
- Assignments
- Lectures

8.3. Learning resources

- Two facilitators
- Online training materials
- Copies of the standard forms of application for ethical review
8.4. Contents

- Importance of research ethics committee.
- Purposes, functions and responsibilities of the research ethics committee
- Composition, membership, resources and chairing of the research ethics committee
- Ethical basis for decision making in research ethics committee
- Barriers for performance of research ethics committee
- National forms of ethical review
- The standard criteria for ethical review
**Assessment**

4.5. **The assessment of the DRME will be held as follows:**
- Exercises
- Assignments
- Discussion Forums
- Scientific article assessment

4.6. **The assessment will be held as follows:**
- Exercises: 20%
- Assignments: 35%
- Discussion forums: 30%
- Scientific article: 15%

It is mandatory that students score a 60% pass mark in all the above four domains (exercises, assignments, discussion forums and scientific article). It is also mandatory that students achieve a 60% pass mark in the core courses.

It is also mandatory that students participate in all modules; failing to participate in one module with no explanation will discontinue students from the program.

4.7. **Module Evaluation:** (a narrative and statistical report on module implementation)
1. Continuous assessment & final exam marks results
2. External examiners report
3. Student’s feedback
4. Facilities & resources
References


6. World Medical Association, General Assembly: DECLARATION OF HELSINKI Ethical Principles for Medical Research Involving Human Subjects Adopted by the 18th, Helsinki, Finland, June 1964


9. The council for international Organizations of Medical Sciences (CIOMS) with WHO and the Islamic Organization for Medical Sciences (IOMS): International Ethical Guidelines for Biomedical Research Involving Human Subjects: An Islamic Perspectives; Geneva 2004


12. Oxford Handbook of Medical Statistics