MASTER OF HEALTH RESEARCH ETHICS | By Coursework

POSTGRADUATE'S PROGRAMME

Name of Programme : Master of Health Research Ethics
Mode : By Coursework
Faculty : Faculty of Medicine

1. Classification of Programme

The Master of Health Research Ethics is a programme by coursework in which the credits for the research component comprises less than thirty (30) percent of the total credits for the whole programme of study. After completion of the relevant programme of study specified in this Schedule, a candidate shall be eligible for the award of the Master of Health Research Ethics degree.

2. Entry Requirements

(1) A Bachelor's degree related to health research ethics with CGPA of at least 3.0 and above or equivalent; **or**

(2) A Bachelor's degree with at least 1 year of working experience in related field; **or**

(3) An equivalent qualification approved by the Senate from time to time.

AND

Pass the entrance assessment set by the faculty

Language Requirement

The Non-Malaysian applicant whose degree is from university or institution of higher learning that did not use English as the medium of instruction for that degree shall be required:

Type of English Qualifications		Minimum Score
International English Language Testing (IELTS)		6
Test of English as a Foreign Language (TOEFL)	IBT (Centre based)	60
	IBT Essentials	8.5
Pearson Test of Academic English (PTE)		59
Cambridge English Qualifications and Tests	B1 Preliminary, B2 First, C1 Advanced, C2 Proficiency	169
	Lingua skill Online	169
	Occupational English Test (OET) (Conventional/Online)	250

3. Duration of Study

(1) The minimum duration of study shall be two (2) semesters and one (1) special semester
(2) The maximum duration of study shall be eight (8) semesters

4. Structure of Programme

(1) The Master of Health Research Ethics programme by coursework comprises of forty-two (42) credits namely.

(a) six (6) core courses, each of three (3) credits, totalling eighteen (18) credits

(b) Practicum in Health Research Ethics of nine (9) credits;

(c) A Research Project of nine (9) credits;

(d) Two (2) elective courses, each of three (3) credits, totaling six (6) credits.

(2) Details of the courses offered are as approved by Senate from time to time on the recommendation of the Faculty and candidates shall be informed of such details at the beginning of each session.

(3) The lists of courses for the programme of Master of Health Research Ethics are provided in List 1.

Programme Aim

To produce graduates equipped with the knowledge, skills and attitudes to lead in the field of research ethics through responsible conduct and governance of health research.

Programme Educational Objectives (PEO)	
PEO 1	are knowledgeable in the concept of research ethics and able to apply them to ensure responsible conduct of health research.
PEO 2	have the skills and attitudes to solve research ethical issues when conducting or governing health research.
PEO 3	are able to work with stakeholders in advancing ethical conduct of health research in an institution.

Programme Learning Outcomes (PLO)	
PLO1	Master the concepts and theories in the field of research ethics.
PLO2	Apply the principles of research ethics in the conduct of health research and its governance.
PLO3	Safeguard societal values through enhancing the implementation of health research ethics
PLO4	Conduct health research by adhering to legal, ethical and professional codes of practice.
PLO5	Demonstrate leadership qualities through communicating and working effectively with peers and stakeholders in the field of health research ethics.
PLO6	Solve problems related to health research ethics by using scientific and critical thinking skills.
PLO7	Engage in lifelong learning by continuously updating the knowledge and skills in health research ethics.

List 1

Code	Title	Credits
Core Courses		
MQF7001	Health Research Methods	3
MQF7002	Research Project	9
MQF7003	Foundations of Research Ethics	3
MQF7004	Research Ethics in Special Populations	3
MQF7005	Responsible Conduct of Research	3
MQF7006	Ethical Issues in Global Health Research and Clinical Trials	3
MQF7007	Ethical Issues of Emerging Sciences	3
MQF7008	Practicum in Health Research Ethics	9
Elective Courses (choose two)		
MQF7009	Good Clinical Practice	3
MQF7010	Ethics in Animal Research	3
MQF7011	Healthcare Law and Ethics	3
SQE7006	Ethics of Sustainability	3
	Total	**42**

- **MQF7001: Health Research Methods (3 credits)**

Learning Outcomes

At the end of the course, students are able to:

1. Describe a range of quantitative and qualitative research designs used in health research
2. Formulate appropriate research objectives & questions.
3. Conceptualize the step process in planning a health research
4. Design a research project on health research ethics

Synopsis

The course is intended to expose students to the various approaches of heath research methods. Selected quantitative and qualitative studies will be introduced to enable the students to have a deeper understanding of research paradigms, designs and methodologies as well ethical issues across various study designs. In addition, this course is designed to provide knowledge and skills to students regarding the scientific process of health research including identifying a problem, articulating research questions, selecting appropriate research methods, and writing a health research ethics proposal.

Main Reference

1. Creswell, J. W., & Creswell, J. D. (2018). Research design: qualitative, quantitative, and mixed methods approaches. Thousand Oaks, CA: SAGE Publications, Inc.

2. Koporc, Z (2018). Ethics and Integrity in Health and Life Sciences Research Vol: 4. Emerald Publishing Limited: Yorkshire
3. Jacobsen, K. H. (2016). Introduction to health research methods. Burlington, MA: Jones & Bartlett Learning.
4. Sugarman J & Sulmasy DP (2010). Methods in Medical Ethics (2nd ed). Georgetown University Press.
5. Gall, M. D., Gall, J. P., & Borg, W. R. (2007). Educational research: An introduction (8th ed.). Boston: Pearson Allyn & Bacon.

Assessment Weightage

Continuous Assessment: 100%
Final Examination: -

- **MQF7002: Research Project (9 credits)**

Learning Outcomes

At the end of the course, students will be able to:

1. Propose a research project that examines the ethical issues.
2. Conduct appropriate research to address the ethical challenges.
3. Present the research plan and results professionally.

Synopsis

The course requires candidates to formulate a research question, design and conduct a research project that aims to address the ethical challenges in research, clinical practice, and program implementation. During the project, students will collect data and apply suitable analytic methods in order to evaluate specific ethical principles such as informed consent, individual and community rights, confidentiality, and other ethical standards.

Main Reference

1. Silvia PJ (2018). How to Write a Lot. A Practical Guide to Productive Academic Writing (2 nd ed). APA LifeTools.
2. Sieber JE & Tolich MB (2013). Planning Ethically Responsible Research (2nd ed). Sage Publications Inc.
3. Sugarman J & Sulmasy DP (2010). Methods in Medical Ethics (2 nd ed). Georgetown University Press.
4. Hoffman AH. (2020). Scientific Writing and Communication. Papers, Proposals, and Presentations (4 th ed). Oxford University Press
5. Lecture notes

Assessment Weightage
Continuous Assessment: 100%
Final Examination: -

- **MQF7003: Foundations of Research Ethics (3 credits)**

Learning Outcomes

At the end of this course, students are able to:

1. Demonstrate an awareness of key ethical theories and principles guiding research.
2. Differentiate relevant ethical theories and principles in various research contexts.
3. Assess the impact of ethical decisions and choices in a research setting

Synopsis

This course provides the candidate an overview of research ethics including the history, theories and principles of research ethics. Key topics such as consent, risks and benefits, confidentiality and justice will be taught. The student will have an opportunity to discuss and debate basic issues surrounding research ethics through small group discussions and individual presentations.

Main Reference

1. Rothman, David J. Strangers at the bedside: A history of how law and bioethics transformed medical decision-making. Basic Books 1991
2. General Assembly of the World Medical Association, 2014. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects at https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/
3. Department of Health, E., 2014. The Belmont Report. Ethical principles and guidelines for the protection of human subjects of research at https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html
4. International Ethical Guidelines for Health-related Research Involving Humans, Fourth Edition. Geneva. Council for International Organizations of Medical Sciences (CIOMS); 2016. At https://cioms.ch/wpcontent/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf
5. Emanuel, E.J., Wendler, D. and Grady, C., 2000. What makes clinical research ethical? Jama, 283(20), pp.2701-2711.
6. Herring, Jonathan., 2018 Medical Law and Ethics. Oxford University Press

Assessment Weightage

Continuous Assessment: 70%
Final Examination:30%

- **MQF7004: Research Ethics in Special Populations (3 credits)**

Learning Outcomes

At the end of this course, students are able to:
(1) apply the principles of research ethics and protecting values and rights of special populations
(2) examine research ethical issues unique to the population
(3) solve research ethical problems in special populations relevant to the local cultural context

Synopsis

This course focuses on research ethical issues in special populations including children and pregnant women, key populations, and people with physical and mental illnesses and disabilities. It teaches candidates how to apply research ethical concepts in the real world and equips them with the skills to appraise and solve research ethical problems when conducting research in these populations through case studies. This course also allows the candidates to reflect on their own values when examining research ethical issues in these vulnerable populations through case presentations and case reports.

Main Reference

1. International ethical guidelines for health-related research involving humans https://cioms.ch/publications/product/international-ethical-guidelines-for-health-related-research-involving-humans/
2. The Oxford Textbook of Clinical Resaerch ethcis
3. Website: Office for Human Research Protection. Available at:https://www.hhs.gov/ohrp/
4. The Belmont Report. Available at: https://www.hhs.gov/ohrp/regulations-and- policy/belmont-report/read-the-belmont-report/index.html

Assessment Weightage

Continuous Assessment: 70%
Final Examination: 30%

- **MQF7005: Responsible Conduct of Research (3 credits)**

Learning Outcomes

At the end of the course, students are able to:
1. Relate the multiple roles, responsibilities and values of an investigator with ethical conduct of research
2. Appraise the impact of responsible conduct of research on ethical dissemination of research findings
3. Propose strategies to manage and prevent publication misconduct

Synopsis

This course teaches the candidates the elements of responsible conduct of research. It stimulates the student to reflect on the importance of publication ethics as a culmination of research conducted in a responsible manner and its implications in the context of research dissemination by case reports and presentation. The course will also use case studies to demonstrate how publication misconducts can be prevented and addressed.

Main Reference

1. Committee on Publication Ethics. (2019). Core practices, in A4 poster format. Retrieved from https://publicationethics.org/core- practices [accessed Feb 2019]
2. American Society for Biochemistry and Molecular Biology. (2017). Code of ethics. Retrieved from http://www.asbmb.org/Advocacy/CodeOfEthics/?terms=ethics [accessed Feb 2019]
3. 1. Macrina, F.L. (2014). Scientific integrity: text and cases in responsible conduct of research. Washington, DC: American Society for Microbiology Press. Chapter 3: Mentoring. pp53-82.
4. Macrina, F.L. (2014). Scientific integrity: text and cases in responsible conduct of research. Washington, DC: American Society for Microbiology Press. Chapter 8: Collaborative research. pp243-286.
5. How to Work with Your Institutional Animal Care and Use Committee (IACUC) https://ori.hhs.gov/education/products/ncstate/index.htm
6. Macrina, F.L. (2014). Scientific integrity: text and cases in responsible conduct of research. Washington, DC: American Society for Microbiology Press. Chapter 10: Scientific record keeping. pp329-360.
7. Himanen, L., Auranen, O., Puuska, H.M., and Nieminen, M. (2009). Influence of research funding and science policy on university research performance: A comparison of five countries, Science and Public Policy, Volume 36, Issue 6, 1 July 2009, Pages 419–430,https://doi.org/10.3152/030234209X461006.
8. Handling Misconduct. ORI Policy on Plagiarism. Guidelines for avoiding plagiarism (pdf – 71 pages). Retrieved from https://ori.hhs.gov/ori-policy-plagiarism.

Assessment Weightage

Continuous Assessment: 100%
Final Examination: -

- **MQF7006: Ethical issues in global health research and clinical trials (3 credits)**

Learning Outcomes

At the end of this course, students are able to:

1. Demonstrate an awareness of key aspects of global health and public health research ethics.
2. Analyse the ethical and legal issues involved in global health and public health situations.
3. Assess the impact of ethical choices and actions in a global health setting.

Synopsis

This course is designed for the candidate to understand the key aspects of global health research and public health situation through case studies. This course also introduce the candidates on certain topics for example ancilary care, vaccine research, HIV research and so on.

Main Reference

1. Millum, J. and Emanuel, E.J. eds., 2012. Global justice and bioethics. Oxford University Press.
2. Lavery, J.V., Grady, C. and Wahl, E.R. eds., 2007. Ethical issues in international biomedical research: a casebook. Oxford University Press, USA.
3. Emanuel, E.J., Wendler, D., Killen, J. and Grady, C., 2004. What makes clinical research in developing countries ethical? The benchmarks of ethical research. The Journal of infectious diseases, 189(5), pp.930-937.
4. 4. Cash, R., Wikler, D., Saxena, A., Capron, A. M., & World Health Organization. (2009). Casebook on ethical issues in international health research [electronic resource]/edited by Richard Cash [... et al]. In Casebook on ethical issues in international health research [electronic resource]/edited by Richard Cash [... et al]. at http://apps.who.int/iris/bitstream/handle/10665/44118/9789241547727_eng.pdf?sequence=4

Assessment Weightage

Continuous Assessment: 100%
Final Examination: -

- **MQF7007: Ethical Issues of Emerging Sciences (3 credits)**

Learning Outcomes

At the end of this course, students are able to:

1. Illustrate the ethical and legal issues surrounding the area of emerging sciences
2. Examine the conflicting moral values and ethical principles involved in various areas of emerging sciences
3. Evaluate possible course of actions to address the ethical issues at stake

Synopsis

This courses introduces the ethical and legal issues arising from the emerging sciences, such as research in genetics and genomics, neuroethics, stem cell and biobanking. It teaches the candidate how to examine and deconstruct ethical problems arising from these emerging sciences, and determine and justify ethical principles that are relevant to the ethical problem. It also guides the candidate to find possible solutions to the ethical problem and make ethical decisions, including using regulatory measures. The candidates will be trained to make decisions when faced with situations where ethics, legal, and the values of the technologies interplay through case studies..

Main Reference

1. Universal Declaration on Bioethics and Human Rights
2. Universal Declaration on the Human Genome and Human Rights
3. UNESCO's Core Curriculum on Bioethics
4. World Commission on the Ethics of Scientific Knowledge and Technology (COMEST) Reports
5. Declaration of Helsinki
6. Belmont Report
7. Nuremberg Code
8. Emanuel et. al. Framework
9. Beauchamp, T. L., & Childress, J. F. (2013). Principles of biomedical ethics. Oxford University Press, USA.
10. Resnik, D. B. (2005). The ethics of science: An introduction. Routledge.

Assessment Weightage

Continuous Assessment: 70%
Final Examination: 30%

- **MQF7008: Practicum in Health Research Ethics (9 credits)**

Learning Outcomes

At the end of this course, students are able to:

1. Interpret the principles of research ethics in practical setting.
2. Demonstrate leadership and teamwork while working with key population
3. Solve real world ethical issue in research through various attachments and field work.

Synopsis

This course focuses on the practical aspects of research ethical issues in special populations including prisoners, those who are culturally vulnerable and with physical and mental illnesses and disabilities. It intends to provide a broad but reasonably detailed examination of central ethical issues in these populations. This course follows a format, which after an introductory session, time is devoted to gain hands-on experience through working with special populations, attending research ethics meetings, presentations, group discussions and development of the research report. The candidate will have the opportunity to be attached to two different research ethics committees, so that they can learn and compare different systems of reviewing research ethics. It teaches the candidates how to apply research ethical concepts as well as to equip them with the skills to appraise and solve research ethical problems when conducting research with these populations through field visits and feedback.

Main Reference

1. UMMC MREC. Research Ethic . Available from: http://www.ummc.edu.my/research/research_ethics.asp
2. MOH. Medical Research and Ethics Committee. Availabler from http://nih.gov.my/web/mrec/

Assessment Weightage

Continuous Assessment: 100%
Final Examination: -

- **MQF7009: Good Clinical Practice (3 credits)**

Learning Outcomes

At the end of this course, students are able to:

1. Apply the principles of Good Clinical Practice in Clinical Trial
2. Examine clinical trials that involve the participation of human subjects.
3. Solve ethical problems in Clinical Trials to ensure study subjects' wellbeing are safeguarded

Synopsis

This course teaches international and local ethical and scientific quality standards for designing, conducting, recording and reporting clinical trials that involve the participation of human subjects. It will include ethical and regulatory issues related to the conduct of clinical trials such as responsibilities of investigators, safety monitoring and reporting, legal issues in clinical trials, audit and inspections. Besides, Good Clinical Practice, other relevant practice guidelines such as Good Laboratory Practice, Good Manufacturing Practice, Good Statistical Practice will be covered.

Main Reference

1. Malaysian Guideline for Good Clinical Practice Fourth Edition, 2018
2. Wandile P, Ghooi. R (2017), A Role of ICH:GCP in Clinical Trial Conduct. Journal Clinical Research Bioethics 8:1000297
3. Malaysian Guideline for Independent Ethics Committee Registration and Inspection, First Edition, 2016, NPRA, MOH.
4. Malaysian Guideline for Application of Clinical Trial Import Licence and Clinical Trial Exemption. 6.3 edition, July 2016, NPRA, MOH.
5. Malaysian Guidelines for Independent Ethics Committee Registration and Inspection, 1 st edition, May 2016, NPRA, MOH
6. Malaysian Guideline For Safety Reporting of Investigational Products, First Edition, 2014, NPRA, MOH
7. g) Malaysian Guideline for Bioequivalence Inspection, First Edition, 1st October
8. 2014.
9. Guidelines For Good Clinical Practice (Gcp) Inspection, August 2010, NPRA, MOH.
10. Noor Zurani MHR, Aziz N, Abd Aziz, Abd Hamid, Mohamed M, Othman S, Hussein N (2008). The need for 'Good Clinical Practice' in Health care research. Journal of the South Africa Academy of Family Practice/Primary Care 51:3 (202–205)
11. The conduct of Bioavailability and Bioequivalence Studies, First edition, 14th September 2000.
12. International Council Harmonisation (ICH) Guidelines.

Assessment Weightage

Continuous Assessment: 100%%
Final Examination: -

- **MQF7010: Ethics in Animal Research (3 credits)**

Learning Outcomes

At the end of this course, students are able to:

1. Describe different methods and techniques used in experiments involving animals
2. Explain ethical and welfare issues with regards to animal experimentation
3. Analyze the applications of laboratory animals in research

Synopsis

This course is designed to provide facts and instil principles essential to the humane use and care of animals that will in turn ensure the quality of biomedical research. Students will be taught basic animal biology and husbandry, as well as animal handling techniques during experimental procedures. The students' responsibilities towards the welfare of the animals used and the ethical concerns of biomedical research will be emphasised.

Main Reference

1. Hau, J. & Schapiro, S. J. (2010). Handbook of Laboratory Animal Science, Volume I Essential Principles and Practices (3rd Edition). CRC Press.
2. NRC (2011). Guide for the Care and Use of Laboratory Animals (8th Edition). The National Academies Press.
3. Laboratory Animal Science Professional, AALAS
4. University of Malaya Faculty of Medicine IACUC Policy (2018); http://resfom.um.edu.my/ethics/ethics-institutional-animal-care-and-use-committee-iacuc/
5. Danio Rerio (2011) Guidance on the housing and care of Zebrafish
6. OECD (2000) Guidance for Use of Clinical Signs as Humane Endpoints

Assessment Weightage

Continuous Assessment: 70%
Final Examination: 30%

- **MQF7011: Healthcare Law and Ethics (3 credits)**

Learning Outcomes

At the end of this course, students are able to:

1. Evaluate the ethical and medico-legal issues that might arise in health research;
2. Analyse the adequacy or inadequacy of existing law in conducting and managing health research;
3. Examine a specific health research ethics issue, present a critique of the issue and offer possible solutions.

Synopsis

The study of healthcare matters may be considered from four aspects. First the relationship between the healthcare provider and the patient; Second, the relationship between the state and the individual in relation to public health; Third, the relationship between the state and the healthcare provider and lastly, selected bioethics issues that require a consideration of the relationship between law and ethics in dealing with advances in science and technology.

The emphasis of this course is on the first aspect mentioned above, namely, the patient-doctor/hospital relationship. Selected bio-ethics issues will also be examined.

Main Reference

1. M Brazier & E Cave, (2016) Medicine Patients and the Law, 5th ed, Manchester University Press
2. G Laurie, S Harmon, and G Porter. (2016). Mason and McCall Smith's Law and Medical Ethics (10th ed.). OUP
3. Herring J, Medical Law and Ethics [2018] Oxford University Press; 7th edition
4. Puteri Nemie Jahn Kassim.(2010) Law and Ethics Relating to the Medical Profession, International Law Books Series
5. Jonathan Herring (2018), Medical Law and Ethics (7 th edition) OUP Oxford

Assessment Weightage
Continuous Assessment: 70%
Final Examination: 30%

- **SQE7006: Ethics of Sustainability (3 credits)**

Learning Outcomes

At the end of this course, students are able to:

1. analyse ethical issues in sustainability based on basic ethical principles.
2. suggest solution to contemporary ethical problems related sustainable development.
3. exhibit skills associated with decision-making process.

Synopsis

Introduction to the worldview of modern science and emphasis on its relation with ethical issues of sustainable development. Ethical implications of new technologies and moral choices. Professional ethics in science, technology, experimentation and research related to sustainable development.

Main Reference

1. Lemons, J., & Brown, D. A. (Eds.). (2013). Sustainable development: Science, ethics, and public policy (Vol. 3). Springer Science & Business Media.
2. Maxwell, B. (2008). Professional Ethics Education: Studies in Compassionate Empathy [electronic resource] / by Bruce Maxwell. Dordrecht: Springer Netherlands.
3. Briggle, A., & Mitcham, C. (2012). Ethics and science: An introduction. Cambridge University Press.

4. MacKinnon, B., & Fiala, A. (2014). Ethics: Theory and contemporaryissues. Nelson Education.

Assessment Weightage
Continuous Assessment: 60%
Final Examination: 40%

Master of Health Research Ethics
Programme Schedule

Special Semester	▪ A practicum of nine (9) credits	Examination (i) End of Semester I (ii) End of Semester II
Semester II	▪ A research project of nine (9) credits ▪ Two (2) elective courses, each of three (3) credits, totalling six (6) credits; and ▪ Two (2) core courses, each of three (3) credits, totalling six (6) credits;	
Semester I	▪ Two (2) elective courses, each of three (3) credits, totalling six (6) credits ▪ Four (4) core courses, each of three (3) credits, totalling twelve (12) credits	Registration (Admission Evaluation)