Masters in Clinical Research

Handbook 2025-2026

Full Time and Part Time

September 2025

Ollscoil na Gaillimhe
University of Galway

Contents

Section 1: Welcome Message

Program Director

Welcome to the MSc Clinical Research programme at the School of Medicine, University of Galway. Since its inception, this course has provided essentially training and experience to a large number of graduates, many of whom are working in clinical research including investigators, research assistants, research associates, data managers, study coordinators and pharmacovigilance. I hope that you will enjoy this course and gain skills and experience through your training to become part of the next generation of clinical researchers. I would encourage you all to commit fully to this course, to gain as much practical or hands on experience in clinical research practice. To maximise your learning, I encourage you all to apply the content of your modules to your own area of expertise or clinical research. I trust that you will all enjoy the course and find it interesting and engaging.
E: Sonja.Khan@uiversityofgalway.ie

Lecturers and Members of Faculty

Aideen O Doherty, B.Sc., Ph.D.
B.Sc. (Biotechnology, UoG), Ph.D. (Molecular Genetics, QUB). Aideen's role with the Clinical Research Facility Galway and Institute for Clinical Trials involves supporting local, national and international researchers in the delivery of clinical trials, management of teams providing essential research services, development of policies to safeguard research participants and stakeholders, development of national and international funding applications, education and research dissemination. Aideen's foundation in medical science and genetics drives her passion to collaborate and strategise on optimal ways to resource, conduct and successfully deliver clinical trials.
Email: Aideen.Odoherty@universityofgalway.ie

Finn Krewer PhD BE holds the Greally Lectureship in Applied Clinical Data Analytics and teaches on the Clinical Research Administration module and is a supervisor on the MSc Clinical Research Thesis projects. Finn conducts research in population health data analysis and in the application of Artificial Intelligence (AI) and Deep Learning (DL) in healthcare and healthcare data analysis. Email: finn.krewer@universityofgalway.ie

Dr. Alvarez has a strong academic background in Statistics and Mathematics, with extensive experience in both collaborative and primary research in Biostatistics. His principal research focus is the development of statistical methodologies that facilitate the communication of complex analytical findings to non-technical audiences, such as patients and policy makers. This includes work on alternative pruning methods for tree-based models and the application of the mean residual life function as an intuitive summary of censored survival data. Email: alberto.alvarez-iglesias@universityofgalway.ie

Prof O'Donnell is a Stroke Geriatrician, Established Professor of Neurovascular Medicine and Executive Dean of the College of Medicine, Nursing and Health Sciences. His research focus includes cardiovascular epidemiology and clinical prediction rules. He has published over 250 original peer-review articles, including in high-impact journals (Lancet, NEJM, JAMA, BMJ) and H-index is 82 (Scopus). He is Principal Investigator of the international INTERSTROKE study, which has recruited over 27,000 participants from 32 countries. From 2011-2020, he was Director of the HRB-CRFG and is/was principal investigator on several clinical trials (R-BEAT-1, SLEPT trial, COSIP trial and STICK trial). Email: martin.odonnell@universityofgalway.ie

Prof Andrew Smyth is Professor of Clinical Epidemiology at the University of Galway and Consultant Nephrologist at Galway University Hospitals. He trained in Internal Medicine and Nephrology in Ireland, the Mayo Clinic (USA), and McMaster University (Canada), and holds an MSc and PhD in Clinical Epidemiology from the University of Galway. A former Director of the HRB Clinical Research Facility Galway and the MSc in Clinical Research, he continues to teach and develop modules on observational research, clinical trials, systematic reviews, and research ethics.
Email: andrew.smyth@universityofgalway.ie

Education Administrator

Geraldine Uí Chualáin is the Education Administrator for the Master's programme in Clinical Research and Applied Clinical Data Analytics. Geraldine has a stellar background in management, accounting and administration.
Email: geraldine.uichualain@universityofgalway.ie

Academic Calendar

Further information on term dates can be found here and a list of Irish Bank Holidays is available here

Academic Year 2025 -2026	
Orientation 1st years	Tuesday 2nd September to Friday 5th September*
Start of teaching all years	Monday 8th September
End of teaching all years	Friday 28th November (12 weeks of teaching)
Study week	Monday 1st December to Friday 5th December
Semester 1 exams start	Monday 8th December
Semester 1 exams end	Friday 19th December (10 days of exams)
Christmas Holiday	Saturday 20th December
2025	
Start of Teaching	Monday 12th January 2026
End of Teaching	Thursday 2nd April (12 weeks of teaching)
Easter	Good Friday 3rd April to Easter Monday 6th April
Field Trips	Tuesday 7th to Friday 10th April
Study Week	Monday 13th to Friday 17th April
Semester 2 Exams Start	Tuesday 21st April
Semester 2 Exams End	Friday 8th May (13 days of exams)
Autumn Repeat Exams	Tuesday 4th August to Friday 14th August (9 days of exams)
Holidays	Easter: Good Friday 3rd April to Easter Monday 6th April 2026
	Bank Holidays: Monday 27th October 2025 / Tuesday, 17th March 2026
	Monday 4th May 2026/ Monday 1st June 2026 / Monday 3rd August 2026

You are expected to be in attendance through the academic semester and exam periods. If you have commitment requiring you to miss a class, please let the module leaders know immediately so that arrangements can be made.

Chapter 1: Full Course Structure*

1.1 FULL TIME M.SC. OR PART TIME M.SC. (CLINICAL RESEARCH)

Students are required to complete three compulsory modules (MD510, MD511 and MD1602). Further optional modules are selected from modules available at University of Galway and/or via distance learning, subject to availability and pre-approval. Modules and research selected will total 90ECTS credits.

Thesis (30 ECTS):
The MSc thesis will be completed and submitted by **31st July. TOTAL**: 90 ECTS over 1 year

		ECTS	Semester
	Compulsory Modules:		
MD510	Fundamentals of Health Research & Evaluation Methods	10	1
MD511	Introduction to Biostatistics I	10	1
MD1602	Introduction to the Ethical and Regulatory Frameworks of Clinical Research*	10	1
	Choice of Additional Modules*:		
MD1605	Observational Studies & Biostatistics	10	2
MD514	Research Methods for Randomized Controlled Trials*	10	2
MD515	Systematic Reviews*	10	2
EC572	Economic Evaluation in Healthcare	10	1
EC584	Health Systems and Policy Analysis	10	2
MD517	Clinical Research Administration	10	2
MD1541	Harnessing the Basic Biology of Cancer for Development of Novel Therapeutic	10	1
MD1604	Biobanking for Clinical Research*	10	2
MD1603	Clinical Research Site Level Activities	10	1
	Compulsory Research:		
MD519	Independent Study Module**; paper publication OR	10	Year long
MD520	Original Research and Thesis***	30	Year long
	Total ECTS	**90**	

online modules

****Thesis (Semester 1 and 2) 30 ECTS:***
For PT Students the MSc thesis will be completed over a 2-year period, submitted by **July 2026.**
OR ***Independent Study Module (Semester 1 and/or 2) 10 ECTS:*
The Independent Study Module will be completed and submitted by July 2026.

SEMESTER 1 OVERVIEW

<table>
<tr><th>Time</th><th>Monday</th><th>Tuesday</th><th>Wednesday</th><th>Thursday</th><th>Friday</th></tr>
<tr><td>7.00-8.00</td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>8.00-9.00</td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>9.00-10.00</td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>10.00-11.00</td><td></td><td rowspan="2">MD1541 Harnessing the Basic Biology of Cancer for Development of Novel Therapeutic</td><td></td><td rowspan="2">MD1603 Clinical Research Site Level Activities</td><td></td></tr>
<tr><td>11.00-12.00</td><td></td><td></td><td>MD510 Fundamentals of Health Research</td></tr>
<tr><td>12.00-13.00</td><td></td><td></td><td></td><td></td><td rowspan="2">EC584 Economic Evaluation in Health Care</td></tr>
<tr><td>13.00-14.00</td><td></td><td></td><td></td><td></td></tr>
<tr><td>14.00-15.00</td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>15.00-16.00</td><td></td><td></td><td></td><td></td><td rowspan="2">MD511 Biostatistics I*</td></tr>
<tr><td>16.00-17.00</td><td></td><td></td><td></td><td></td></tr>
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MD510	Fundamentals of Health Research (CORE)	Friday 11-12.30 noon
MD1541	Harnessing the Basic Biology of Cancer for Development of Novel Therapeutic	**Online; Tuesday 10-11.30 am
MD1602	Introduction to the Ethical and Regulatory Frameworks of Clinical Research (CORE)	**Online
MD511	Introduction to Biostatistics I (CORE)	Friday 2-4pm
MD1603	Clinical Research Site Level Activities	Thursday 10-12 noon
EC584	Economic Evaluation in Health Care	CA116a; Cairns Building

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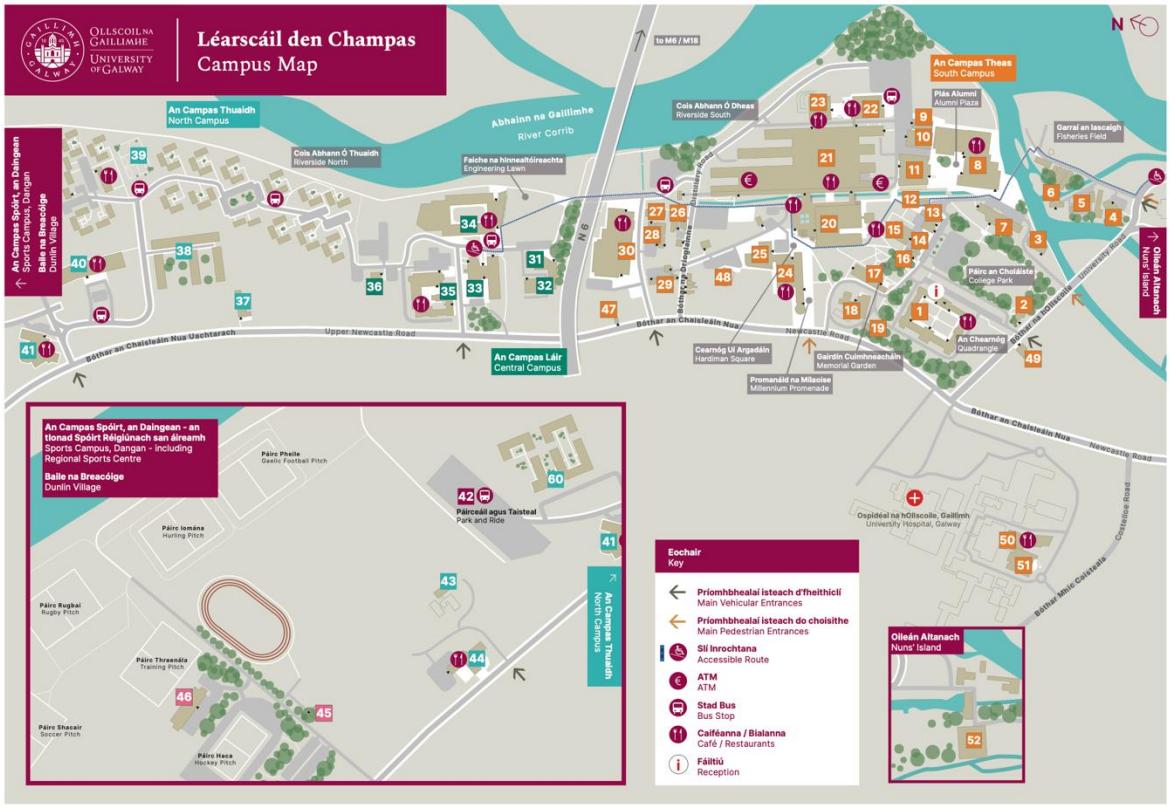
SEMESTER 2 OVERVIEW

Time	Monday	Tuesday	Wednesday	Thursday	Friday
7.00-8.00					
8.00-9.00					
9.00-10.00					MD1605 Observational Studies & Biostatistics
10.00-11.00				MD517 Clinical Research Administration	
11.00-12.00					
12.00-13.00					
13.00-14.00					
14.00-15.00			EC572 Health Systems and Policy Analysis		
15.00-16.00					
16.00-17.00					
17.00-18.00					
19.00-20.00					

MD1605	Observational Studies & Biostatistics	Venue TBD
MD514	Research Methods for Randomised Controlled Trials RCT	Online
MD515	Systematic Reviews	Online
MD517	Clinical Research Administration	TBD
EC572	Health Systems and Policy Analysis	Cairns Building
MD1604	Biobanking for Clinical Research	Online

1.2 Campus Map



Ollscoil na Gaillimhe
University of Galway

An Campas Spóirt, an Daingean - an tIonad Spóirt Réigiúnach san Áireamh
Sports Campus, Dangan - including Regional Sports Centre

An tÁras Spóirt Sports Pavilion	46
Teach Maryville Maryville House	45

An Campas Thuaidh
North Campus

An Daingean A Dangan A	43
Cúrsa Saoil Lifecourse	41
Baile na Breacóige Dunlin Village	60
Baile na Coiribe Corrib Village	39
Baile an Chíorbhuí Goldcrest Village	38
Eolaíochtaí Bithleighis Biomedical Sciences	40
Institiúid na hEolaíochta Sonraí Data Science Institute	44
Naíolann na hOllscoile University Crèche	37
Páirceáil agus Taisteal Park and Ride	42

An Campas Láir
Central Campus

An tIonad Nuálaíochta agus Gnó Business and Innovation Centre	32
An tIonad Taighde agus Nuálaíochta Research and Innovation Centre	31
An tIonad Taighde don Chothú Sláinte Health Promotion Research Centre	36
Áras Cairnes Cairnes Building	35
Áras Innealtóireachta Alice Perry Alice Perry Engineering Building	34
Áras Mhaighe Seola Moyola Building	33
An Clinic Teiripe Urlabhra agus Teanga Speech and Language Therapy Clinic	33

An Campas Theas
South Campus

10 Bóthar an Chaisleáin Nua 10 Newcastle Road	47
14 Bóthar na hOllscoile 14 University Road	49
14 Bóthar na Drioglainne (An Oifig Slándála) 14 Distillery Road (Security)	27
An Chearnóg Quadrangle	1
An Foirgneamh Anatamaíochta Anatomy Building	18
Áras na Ríomheolaíochta Computer Science Building	23
An tIonad Spóirt Sports Centre	30
Áras Dán na Mílaoise Arts Millennium Building	24
Áras de Brún	17
Áras Mhairéad (Ma) Ní Éimhigh	16
Áras Mháirtín Uí Riain Martin Ryan Building	7
Áras na Bitheolaíochta Daonna Human Biology Building	11
Áras na Gaeilge	15
Áras na Mac Léinn	8
Áras Oirbsean Orbsen Building	22
Áras Uí Argadáin Hardiman Building	20
Áras Uí Chathail	10
Aula Maxima	1
Beár na Mac Léinn - Sult College Bar - Sult	8
Bloc E Block E	13
Bloc F Block F	19
Bloc S Block S	12
Bloc T Block T	28
Bóthar na Drioglainne Distillery Road	26
Ceoláras Emily Anderson The Emily Anderson Concert Hall	1
Comhaltas na Mac Léinn Students' Union	8
Deasc Eolais na Mac Léinn (SID) Student Information Desk (SID)	10
Foirgneamh na nDán / na hEolaíochta Arts / Science Building	21
Fortheach Institiúid Uí Riain Ryan Institute Annexe	3
Halla Bailey Allen Bailey Allen Hall	8
Institiúid na hEolaíochta Cliniciúla Clinical Science Institute	51
Ionad na hÉireann do Chearta an Duine Irish Centre for Human Rights	4
Ionad na Seirbhísí Poist Mail Services Centre	9
Ionad Uí Dhonnchadha - An Drámaíocht, an Amharclannaíocht agus an Taibhléiriú O'Donoghue Centre - Drama, Theatre and Performance	8
Institiúid Lambe Lambe Institute	50
Oideachas Education	14
Oideachas Education	52
Réamhdhéantán Cois Abhan Riverside Terrapin	29
Réamhdhéantán Scoil Huston The Huston School Bubble	5
Scoil Scannán agus Meán Digiteach Huston Huston School of Film and Digital Media	6
Séipéal Naomh Columbán The Chapel of St Columbanus	48
Síceolaíocht Psychology	25
Teach an Gheata Gate Lodge	2

Chapter 3: Module Descriptions

FUNDAMENTALS OF HEALTH RESEARCH AND EVALUATION METHODS; MD510

Semester 1
ECTS 10
Module Leader: Prof Andrew Smyth and Prof Martin O'Donnell
Lectures: Friday's 11-12.30 noon in person

Brief Description
Provides a broad overview of clinical research methodology. Module is designed to provide an overview of research methodology, designs and key content areas, including: qualitative methodologies, concept of health, formulation of research questions, literature reviews, study designs, selection of study populations, choice of measuring instruments, and study interpretation issues such as determination of causality and the effectiveness of clinical and community interventions. This course is designed to introduce methodological issues to help students identify further learning objectives related to in-depth study of specific research methods.

Learning Outcomes

- To examine quantitative research approaches, and appreciate their strengths and limitations
- To learn how to apply these research approaches and methods by completing regular assignments and preparing a research protocol/paper in your own area of interest

Unit Topics

1. Posing the Research Question
2. Introduction to Research Designs
3. Disease Frequency
4. Measurement and Sample Size
5. Association & Causation
6. Clinical Trials (RCT) – The Tactics of Performing Therapeutic Trials
7. Evaluating the Accuracy of Screening and Diagnostic Tests
8. Systematic Reviews & Meta-Analyses
9. Introduction to Health Economics

Required Materials
Designing Clinical Research (4th Ed.), Eds. Hulley *et al*., 2013, 3rd Edition, *Users' Guide to the Medical Literature A Manual for evidence-based clinical practice*, JAMA and weekly reading from the literature.

9. Student Evaluation
Students will have to gain a pass rate of 40% overall for a combination of end of module exam (date to be confirmed closer to the time) and contribution to tutorials.

INTRODUCTION TO THE ETHICAL AND REGULATORY FRAMEWORKS OF CLINICAL RESEARCH; MD1602

Semester 1
ECTS 10
Module Leader: Dr Sonja Khan
Lectures: This module is delivered online. Distance learning units using Canvas; each unit consists of required readings, lectures will be posted online

Brief Description
This module is designed to provide an overview of core principles underpinning clinical research practice including the roles and responsibilities of members of the research team. Central to this module are the principles and practical application of Good Clinical Practice (GCP), relevant regulations and legislation, professional guidelines and codes of ethics including ethical dilemmas, vulnerable populations and research integrity.

Learning Outcomes

- Describe, understand and apply the principles of Good Clinical Practice when designing and undertaking clinical research projects.
- Describe and explain the legal and regulatory issues in clinical research
- Overview of research projects with appropriate research governance and operating within applicable ethical and legal frameworks including GDPR.
- Examine ethical issues in clinical research and select appropriate approaches
- Demonstrate an awareness of ethical practices and professional standards applicable to the field of clinical research

Unit Topics

1. Good Clinical Practice including practical examples and applied learning
    a. Introduction to Drug Development and Clinical Research
    b. Clinical Research Governance; Rules and Regulations (Nuremberg Code, Declaration of Helsinki, ICH, GCP, EU CT Directive etc.)
    c. IHC GCP
2. General Data Protection Regulation (GDPR) and Clinical Research General principles of research ethics
3. Submissions to Regulatory Authorities and Ethics Boards
    a. Application to REC and HPRA
4. Regulatory aspects of Clinical Trials & Medical Device Investigations
    a. Safety
    b. Investigational Medicinal Product IMP
    c. Medical Devices

Required Materials: Provided by Module Director

Student Evaluation

- Final Exam 80%
- Discussion board contribution 20%

INTRODUCTION TO BIOSTATISTICS I; MD511

Semester 1
ECTS 10
Module Leader: Dr Alberto Alvarez
Lectures: Friday 3-5 pm

Brief Description
The module is designed to provide an introduction to the basics in Biostatistics, to enable students to understand concepts of population distribution, sampling, probability, data type and presentation, statistical inference and hypothesis testing.

Learning Outcomes

- To introduce students to statistical concepts and thinking;
- To provide a practical introduction to data analysis;
- To demonstrate the importance and practical usefulness of statistics;
- To encourage and equip students to apply simple statistical techniques to design, analyse and interpret studies in a wide range of disciplines;
- To enable students to communicate the results of their analyses in clear non-technical language in writing up laboratory reports and projects;
- To make students aware of the limitations of simple techniques and encourage them to seek expert advice when more complex procedures are required; To provide examples of the uses of statistics in situations of relevance to students' other courses;
- To utilise a statistical package on a computer to illustrate the power of statistical techniques and avoid tedious arithmetic.

Unit Topics

1 Population, sample, parameter, statistic 2 Probability and the Normal distribution
3 Interval Estimation
4 Hypothesis Testing
5 Study Design
6 Sample Size Calculation

Required Materials: Provided by Module Director

Student Evaluation
Students will have to gain a pass rate of 40% overall for a combination of end-of module exam and assignments.

Harnessing the Basic Biology of Cancer for Development of Novel Therapeutic; MD1541

Semester 1
ECTS 10 (Optional Module)
Module Leader: Dr Roisin Dwyer; roisin.dwyer@universityofgalway.ie
Lectures: *We will meet in our virtual classroom* ***every Tuesday from 10 am-11.30am****, a link via e-mail will be circulated, that will take you directly to the relevant session.*

Brief Description
In this module, we will explore how our knowledge of the molecular biology of cancer drives development of novel treatment strategies. Using some of the core pathways involved in cancer progression as examples, you will be introduced to key components of the translational paradigm, from laboratory-based experimentation through to clinical trials and implementation at a population level. The importance of biobanks and clinically relevant models to support translational research will be highlighted. We will also discuss the promise and pitfalls of some current research employing Mesenchymal Stromal Cells (MSCs) and their secreted vesicles for cancer therapy.

Learning outcomes:
By successfully completing this module and all the activities, you should be able to:

- Describe key pathways involved in cancer development and progression, and the treatment strategies that target these specific pathways
- Describe each stage of the Translational Paradigm, from target discovery through to changing standard of care.
- Define the key components of a clinically relevant Biobank, highlighting the ethical and infrastructural requirements
- Describe the potential for clinical application of Mesenchymal Stromal Cells as targeted Cancer therapeutics, and the challenges yet to be overcome
- Demonstrate an understanding of Extracellular Vesicles for Cancer detection and Therapy - characterisation, production, tracking, clinical trials

Student Evaluation

In advance of each session a folder will be made available containing materials relevant to the topic including useful links, reading materials, some pre-recorded segments, and recordings of each session.

Continuous assessment will be employed and so engagement will be required throughout the semester, with details of specific written assignments and oral presentations provided in the relevant sessions. **No final exam!**

There is a **laboratory component** to the module.

Communication is Critical – if issues arise please make contact so appropriate support can be provided as soon as possible.

Clinical Research Site Level Activities MD1603

Semester 1
ECTS 10 (Optional Module)
Module Leader: Dr Sonja Khan
Lectures: Thursday 10-12 noon

Brief Description
This module introduces and examines the methods of clinical research activities involved in operational and clinical trial site-level management.
This module focuses on a variety of components from the administrative viewpoints, document and data management, ethics and collaborations.
This module is delivered using a blend of didactive lectures, problem based learning and project work performed by the student. It is aimed at students who wish to understand the concepts involved in working in clinical research environment.

Learning outcomes:
This module introduces and examines the methods of clinical research activities involved in trial management.
Upon completion of this module, you should be able to:

- Describe the role and responsibilities of research teams and staff involved in clinical trials
- Understand the concepts of clinical trial activities from a site level perspective
- Have a good comprehension of regulations, systems and interactions in a research environment from a site level point of view, from opening to closeout.
- Understand good data preparation, management and control

Unit 1	Module Introduction
	Research Teams and Responsibilities (incl. Sponsor)
Unit 2	Types of Clinical Trials, Achieving Trial Approval, dealing with amendments
Unit 3	Documentation and Site File
Unit 4	Contracts, Budgets, Institutional Approvals
	Study review and opening
Unit 5	Good Clinical Practice – what this actually means in translation
	Safety vigilance and reporting
Unit 6	Consenting, selection, recruitment and retention
Unit 7	Data Management – site perspective. Include Data Protection.
Unit 8	Clinical Activities and Resources
Unit 9	Legislation and Standards (incl. HRR, ISO, MDR, NSAI/CE mark etc.)
	Quality Control and Assurance,
Unit 10	Monitoring – preparing for a monitoring visit
	Auditing – preparing for an Inspection, common findings
Unit 11	Study closeout and reporting

Student Evaluation
Students will have to gain a pass rate if 40%. This will take place in the format of an end of module Exam

SEMESTER 2 MODULES

INTRODUCTION TO RESEARCH METHODS FOR RANDOMIZED CONTROLLED TRIALS; MD514

Semester 2
10 ECTS
Module coordinator: Prof Andrew Smyth
Online Sessions: January; this is an *online* only module. Distance learning units are delivered through Canvas (virtual learning environment) and is self-directed with no scheduled live tutorials. Asynchronous content is available for students to review. This module is composed of units, each of which consists of required readings and contribution to in person tutorials or online discussions.

Brief Description
This course utilizes interactive learning modules, required readings, discussion boards, tutorials and assignments to introduce students to the main elements of clinical trial design, execution and analysis. For aspiring clinical trial researchers, this is an essential introductory course which addresses the formulation of appropriate research questions and clinical trial protocols, essential for aspiring those wishing to work in clinical trials, as investigators, coordinators or project managers. This course explore clinical trial concepts on a deeper level to MD 538 (ECTS 5).

Course Objectives
The objective of this course is to introduce and discuss the core concepts of clinical trial design, execution, and analysis. At the end of the course, students should have a firm grasp of clinical trial methodology at a level that would allow them to prepare detailed clinical trial protocols, suitable for submission to clinical research sponsors, funders, ethics boards and regulators. The 10 ECTS module will provide an in-depth outline of the principles that lead to developments of protocols for clinical trials. It is specifically aimed at individuals with an interest in leading or working on future clinical trials.

Unit Topics
This course will include ethics for clinical trials, research question, study design, clinical trial populations, randomisation, blinding, allocation, design and implementation of clinical trial interventions, measurement issues for clinical trials, biostatistics, data management, safety monitoring and reporting, trial administration and planning and regulatory issues for clinical trials.

Required Materials
List provided by Module Directors

Student Evaluation
Students will have to gain a pass rate of 40% overall for continuous assessment assignments and contribution to tutorials. Assessment for this module will include contribution to tutorials and the completion of assignments.

SYSTEMATIC REVIEW METHODS; MD515

Semester 2
10 ECTS
Module coordinator: Prof Andrew Smyth
Online Sessions: January; this is an *online* only module. Distance learning units are delivered through Canvas and is self-directed with no scheduled live tutorials. Asynchronous content is available for students to review. This module is composed of units, each of which consists of required readings and contribution to in person tutorials or online discussions.

Brief Description
Systematic reviews use rigorous and explicit methods to search for, appraise and bring together existing evidence to provide reliable answers for a specific research question and are a valuable mechanism for informing good health care decisions. This module will enable participants to develop the necessary knowledge and core skills for conducting systematic reviews in healthcare, focussing on the conduct of systematic reviews and meta-analyses of randomised trials of the effects of health care interventions.

Learning Outcomes
On successful completion of this module students will be able to:

- Critically discuss the role of systematic reviews within the context of evidence based health care;
- Identify the key stages of the systematic review process;
- Develop a review question and a review protocol;
- Develop clear study inclusion and exclusion criteria;
- Identify and develop appropriate search methods for identification of studies as part of a comprehensive search strategy;
- Apply inclusion and exclusion criteria to identify relevant studies;
- Critically appraise the quality of included studies ;
- Develop and pilot data extraction
- Understand how to extract relevant outcomes from included studies;
- Critically explore the principles of data synthesis and recognise the relevance of different methods of synthesis to different study designs;
- Explore methods for meta-analysis and non-statistical synthesis
- Be familiar with processes for writing and disseminating a review

Module content

- Establishing need for a review;
- Establishing a review team;
- Question formulation;
- Inclusion & exclusion criteria;
- Data extraction and collection;
- Critical appraisal;
- Methods of data synthesis including meta-analysis
- Reporting and dissemination

Required Materials
Readings and references lists for each unit are given at the end of each unit.

Student Evaluation

a) Four continuous assignments each worth 5% contributing to a total of 20% of overall mark
b) End of module assignment (80% to overall of overall)

Students will have to gain a pass rate of 40% overall.

ECONOMIC EVALUATION IN HEALTHCARE; EC584

Semester 1
ECTS 10
Module Leader: Professor Paddy Gillespie
Lectures: September; Friday 12 – 2 pm in CA116a, Cairnes Building

Brief Description
The purpose of this course is to think about how a society does and should evaluate healthcare.

Learning outcomes:
This module introduces and examines the methods of health economic evaluation which are applied to assess the value of health technologies and/or healthcare interventions. Upon completion of this course, you should be able to:

- Understand the role of health economic evaluation in healthcare decision making
- Outline the different forms of health economic evaluation methods
- Outline value frameworks which underpin health economic evaluation methods
- Identify national and international guidelines for health economic evaluation
- Outline the principles and steps of the method of health economic evaluation
- Discuss the concept of the threshold value in health economic evaluation
- Outline the methods of identifying, valuing and measuring cost data
- Outline the methods of identifying, valuing and measuring health outcome data
- Discuss the roles of trial-based and model-based health economic evaluation
- Discuss the role of discounting in health economic evaluation
- Discuss the role of uncertainty in health economic evaluation
- Conduct a critical appraisal of published health economic evaluation studies

Required Materials:

- Drummond et al (2015). Methods for the Economic Evaluation of Health care Programmes. Oxford University Press.
- Morris/Devlin/Parkin (2007). Economic Analysis in Health Care. John Wiley & Sons.
- Gray et al. Applied Methods of Cost-effectiveness Analysis in Health Care. Handbooks in Health Economic Evaluation Series. Oxford University Press.

Additional notes and resources will be made available on Blackboard.

Student Evaluation
The course is evaluated on the basis of examination (worth 70%) and continuous assessment (worth 30%). The examination will consist of 2 hour paper. The continuous assessment will consist of a presentation (week 10/11) and a report that will focus on the critical appraisal of a published study from the evaluation literature.

HEALTH SYSTEMS AND POLICY ANALYSIS; EC572

Semester 2
ECTS 10
Module Leader: Professor Paddy Gillespie
Lectures: January. Wednesday 2 - 4 pm, Tutorials and Workshops to be decided. This module consists of 8 units. Each unit consists of required readings and an assignment. There will be 1 weekly lecture (2 hours); Tutorials and Workshops to be decided.

Brief Description
This module will provide students with the theoretical foundation and economic skills to:

1. critically examine key national and international healthcare policies
2. compare the structures and mechanisms that governments have put in place to address key health care issues and reforms
3. understand and apply key economics concepts in the financing of health care programmes and policies
4. understand equity issues and their importance in policy analysis and reforms
5. Understand the implications of ageing societies for health systems and policies.

Course Syllabus
University of Galway (School of Economics) prepared and delivered.

Course Objective
The objective of this course is to apply the concepts and principles of economics to the analysis of health systems and policy-making using real world examples, comparative data and case studies.

Prerequisites
Students must have completed the mandatory modules in Fundamentals of Health Research and Evaluation Methods and Biostatistics I.

Learning Outcomes
At the end of this module students will be expected to be able to:

- Understand and define the main attributes of health systems and health policy
- Understand and apply the principles of economics to health policy evaluation
- Appraise the impact of different financing models to efficiency, equity and effectiveness in health care provision
- Understand the key challenges in improving public health
- Determine the pattern of health inequalities in Ireland and Europe
- Understand the implications of ageing for health care systems and policies
- Understand dementia and be able to appraise various strategies for the care of people with dementia across Europe.

Required Readings

There is no single text for this module. Textbooks you may find useful are referenced below.

- J. Bhattacharya et al. (2014) Health Economics, Palgrave 2014
- Stephen Morris et al (2011). Economic Analysis in Health Care, Wiley.
- Mark Pauly et al (2012), Handbook of Health Economics, Volume 2, Elsevier.

- Andrew Jones ed. (2006) The Elgar companion to health economics. Elgar Publishing
- Sherry Glied and Peter Smith, The Oxford Handbook of Health Economics, Oxford: University Press, 2011
- B. Nolan (ed.) (2007) The provision and use of health services, health inequalities and health and social gain. ESRI.
- Tussing A.D and M.A Wren (2006). How Ireland cares: the case for health care reform. New Island books.

The principal sources of data and analysis on health policy for Europe are the *OECD, WHO* and the *European Observatory on Health Systems and Policy* websites. The journals listed at the end of the outline are also very good.

Student Evaluation

There will be an end of semester examination worth 75%. 20% will be allocated to the development of a policy brief in a given area and 5% allocated to participation in the course blog. The policy brief should be 1,500 words long. Rather than formal presentations, we will have a series of themed discussions under the overarching question 'Where would you start?' in an extended class on the last day of the semester (March 29). The policy brief should address a major issue in health policy. A 1 page outline of what you plan to focus on should be submitted by February 25.

BIOBANKING FOR CLINICAL RESEARCH; MD1604

Semester 2
ECTS 10
Module Leader: Dr Sonja Khan and Dr Nicola Miller
Online and two in-person workshops: January

Brief Description
This module is designed to provide an overview of biobank processes, equipment, facilities and methodology for the purposes of clinical research. The module has been designed to provide learner with the capacity to critically evaluate the clinical environment, process and procedures in which specimens are obtained transported, stored, tested and analysed.

Learning outcomes

- Define the role of biobanks in biomedical research and healthcare innovation.
- Assess different models of informed consent in biobanking.
- Explain governance structures and their role in maintaining ethical compliance
- Apply best practices for biobank record management and sample traceability.
- Explain biosafety regulations and risk management strategies in biobank facilities.
- Assess key resource requirements for effective biobank management.

Units:

1. Biobank Overview – Research Quality and Success
2. Ethical and Legal Framework
3. Consent and Governance
4. Workshop I – Consent
    a. Apply ethical and legal principles to consent-taking scenarios.
    b. Develop strategies to address consent-related challenges in biobanking.
    c. Demonstrate effective communication skills in obtaining informed consent.
5. Biobank Quality and Documentation (QMS and record management)
6. Biobank Facility and Safety
7. Management (Resources and Processes)
8. Public Engagement
9. Workshop II – Laboratory Practical
    a. Apply laboratory best practices for sample handling and processing.
    b. Demonstrate proper use of biobank equipment and storage systems.
    c. Interpret and maintain biobank documentation and quality records.

Assessment
Workshop I – Consent (30%)
Workshop II – Laboratory Practical (30%)
2 x Reflection (20% each)

Student Evaluation

Students will have to gain a pass rate of 40%. There will be two half day workshops, students will get hands on training (contributes 80% of final mark). There will be additional 20% from continuous assessment.

CLINICAL RESEARCH ADMINISTRATION; MD517

Semester 2
ECTS 10
Module Leader: Dr Sonja Khan
Lectures: January; Thursday 10-12 noon; weekly lectures and an Workshop.

Brief Description
The successful operation and implementation of clinical research facilities and their services require efficient management, on a number of levels. This module focuses on a variety of critical components from the administrative viewpoint and covers financial considerations, regulatory affairs, study monitoring and implementation, document and data management, ethics and collaborations. The module is delivered using a blend of didactic lectures, problem-based learning and project work performed by the student. This module can be taken by students interested in aspects of the establishment, management and control of CRFs or research units and will contribute to a deeper understanding of the core structure of such facilities. Regular

Course Objectives
- Understanding of the various elements involved in the establishment and operation of clinical research units and associated clinical trials.
- Comprehension of regulations, guidelines, systems and interactions in the clinical research environment.
- Understanding of the role of the Sponsor.
- Competency in establishing and launching a clinical research study.
- Preparation of a clinical trial protocol and other study-associated documentation, from the Coordination or Sponsor perspective.

Unit Topics
1. Good Clinical Practice and Data Protection
2. Introduction to Regulatory Affairs in
3. Clinical Research Clinical Trial Data and Documentation
4. Drug Discovery and Development
5. Resourcing and Setup of Clinical Research Studies
6. Product Manufacture and Introduction to Pharmacovigilance
7. Undertaking Clinical Research WORKSHOP
8. Clinical Trial Monitoring and Auditing
9. Trial Governance and Sponsor Oversight

Student Evaluation
Students will have to gain a pass rate of 40% overall for a combination contribution to CRA group workshop (30%) and Exam (70%)

Observational Studies & Biostatistics; MD1605

Semester 1
ECTS 10
Module Leader: Dr Finn Krewer
Lectures: Friday 9-11 am

Brief Description
This module provides an overview of observational research methods and an introduction to statistical modelling for observational research. Observational research methods include survey research, retrospective study, prospective cohort study, case-control design, diagnostic testing, systematic review and qualitative research methods. Statistical modelling techniques include linear and non-linear regression, Analysis of Variance and Survival Analysis

Learning Outcomes

- Introduce students to the basic concepts and methods used in observational (non-experimental) studies
- To understand the determinants of health (e.g., association between independent/exposure variables and dependent/outcome variables in analytic research)
- To emphasise concepts that are essential to the conduct of epidemiologic studies including internal and external validity, random variability, bias, effect modification, causality, and generalisability.
- To provide a practical introduction to data analysis; and to utilise a statistical package on a computer to illustrate the power of statistical techniques
- To equip students to apply simple statistical techniques to design, analyse and interpret studies in a wide range of disciplines, and to be aware of the limitations of simple statistical techniques

Unit Topics

Measures of Health, Illness and Disease Frequency
Causality (Bradford-Hill, association v causation)
Sampling in research (Quantitative/Qualitative)
Cross-sectional Studies
Cohort Studies (retrospective and prospective)
Case-control Study (incl. nested case-control)
Administrative Data sets (incl. linkage)
Qualitative Research/Mixed Methods
Bias in Observational Studies (Identifying and Addressing)
Measuring Methodological Quality of Observational Studies
Linear and Non-linear Regression
Binary Logistic Regression
Survival Analysis
Confounding: Measured and unmeasured bias
Systematic Review of observational studies

Required Materials: Provided by Module Director

Student Evaluation
Students will have to gain a pass rate of 40% overall for a combination of end-of module exam and assignment

INDEPENDENT STUDY; MD519

Optional (PT only, if not doing Thesis)
ECTS 10

Your Independent study should be structured according to the guidelines of the peer-reviewed journal to which you would like to submit the paper for publication. [Please indicate the journal]. Normally it will include an abstract, introduction, background/rationale, methods, results/findings, conclusion/discussion and references/bibliography.

You must submit only one document, in MS Word format (not PDF), which should contain at least the following parts (you may include additional appendices if needed):

- A cover page with your student number
    - Title
    - Title of degree (Masters in Clinical Research)
- Word count (excluding references and appendices)
- The following declaration: "I ……declare that this Independent Study is entirely my own and I have acknowledged the writings, ideas and work of others. Furthermore, this work has not been submitted by me in the pursuance of another degree. I give permission for this work to be made available to students and staff of the University of Galway College of Medicine, Nursing and Healthcare Sciences for reference purposes".

Word count
The independent study word count is 5,000 words. The abstract, tables, figures, references and appendices are excluded from this word count. Submissions that are more than 10% over the word count will be returned to the student for editing.

Submission
Your independent study should be submitted to Blackboard by the end of July each year under the course MD519: Independent Study.

Supported by University of Galway.

THESIS; MD520

Compulsory (FT) or (PT) Module
ECTS 30

Students will participate in a clinical research project. The aim of this module is to enable students to develop deeper knowledge, understanding, capabilities and attitudes in the context of the programme of study. The thesis should be written at the end of the programme and offers the opportunity to delve more deeply into and synthesise knowledge acquired in previous studies.
Normally it will include an abstract, introduction, background/rationale, methods, results/findings, conclusion/discussion and references/bibliography.

A list of potential supervisors and associated projects will be distributed in October/ November, students can list top 3 supervisors. Every effort will be made to accommodate student choices. Alternatively, students are encouraged to select their own supervisor and project.

Students will be provided feedback on thesis writing throughout semester 1 and 2 as follows:

1. Project and Supervisor — December-January
2. Research proposal submission — January-February
3. Thesis Introduction — March-April
4. Thesis Draft — June
5. Final Submission — July 31st

You must submit only one document, in MS Word format (not PDF), which should contain at least the following parts (you may include additional appendices if needed):

- A cover page with your student number
  - Title
  - Title of degree (Masters in Clinical Research)
- Word count (excluding references and appendices)
- The following declaration: "*I ……declare that this Independent Study is entirely my own and I have acknowledged the writings, ideas and work of others. Furthermore, this work has not been submitted by me in the pursuance of another degree. I give permission for this work to be made available to students and staff of the* University of *Galway College of Medicine, Nursing and Healthcare Sciences for reference purposes*".

Word count
The Thesis study word count is 10,000-15,000 words. The abstract, tables, figures, references and appendices are excluded from this word count. Submissions that are more than 10% over the word count will be returned to the student for editing.

Submission

Your Thesis should be submitted to Blackboard by the31st July each year under the course MD520: Thesis. A dissertation will be judged to have been submitted when all copies (paper and electronic) have been submitted.

Aspect of Thesis	Criteria
Research Aims and Purpose	Clarity of statement of rationale, aims and research questions. ability to position topic with context of relevant literature and/or policy/practice concerns
Relevant and supporting Literature	Thoroughness of the description of the field, drawing on a range of appropriate sources. Capacity to offer critical appraisal of the field including identification of gaps.
Methodology and Data Analysis	Appropriateness of choice of research design. Effectiveness of use of methodological literature to support design. Adequacy of description and justification of research process. Coherence of data analysis and relationship to research question. Clarity regarding ethical approval process.
Results/ Findings	Clarity in in presentation of findings/ results. Relevance to stated research question and specified objectives. Effectiveness of use of supporting data (e.g. tables, figures, quotes). Use of editing to balance need for comprehensiveness and succinctness.
Discussion and Conclusion	Capacity to make sense of findings in light of research questions. Ability to interpret findings in the context of relevant literature. Ability to identify implications. Capacity for reflection and critical exploration of relevant ethical issues. Acknowledgement of methodological scope and limitations.
Overall Style of Writing	Clarity and flow of argument. Fluency and accuracy of writing. Coherence of structure and layout. Accuracy of referencing.

Thesis marking criteria

Failure to submit thesis by the deadline will result in payment of fees of €1,800. Further information is available from UoG Examinations and Fees Office.

Chapter 4: Marks and Standards*

M.Sc. Clinical Research Full Time; 1 Year (12 months)

Level 9
Mode of study: Taught
90 ECTS

Results will be returned at Level 1
Honours awarded at the overall level; Honours awarded in the 1st sitting

- H1 >70%
- Upper H2 60-69%
- Lower H2 50-59%
- 3rd class H 40-49%
- Fail <40%

Students will have to gain a pass rate of 40% overall, for each subject.

M.Sc. Clinical Research Part Time; 2 Years (24 months)

Level 9
Mode of study: Taught
90 ECTS over 2 years

Results will be returned at Level 1
Pass/Fail only at the overall level in Year 1, Honours awarded at the overall level in Year 2; Honours awarded in the 1st sitting

Students must have passed the equivalent of at least 30ECTS before progression to Year 2.

- H1 >70%
- Upper H2 60-69%
- Lower H2 50-59%
- 3rd class H 40-49%
- Fail <40%

Students will have to gain a pass rate of 40% overall, for each subject.

Chapter 5: Useful Information*

General Enquiries and response time

For any enquiries or concerns you may have during your time on the program, please contact the Course Director or Course Coordinator, using the email address clinicalresearch@universityofgalway.ie. All emails will be addressed on Fridays. Repeat emails will not be answered, please be patient, all emails sent during the week will be responded to on Fridays between 10am and 2pm. If there are immediate concerns that require attention, you can email the course coordinator directly. Request for references or similar formal documents need to be made well in advance, least 2 weeks' notice is required and to be made in writing. Provide clear description of the matter in the subject line.

Course netiquette and guidelines:

Ten rules of netiquette

This table describes the code of conduct for our behaviour online, please review this table carefully.

Rule	Explanation
Remember the human	When you communicate electronically, all you see is a computer screen. Remember that you are communicating with other humans. Do unto others as you'd have others do unto you. Imagine how you'd feel if you were in the other person's shoes. Stand up for yourself, but try not to hurt people's feelings.
Adhere to the same standards of behavior online that you follow in real life	Again, sometimes people forget that there's a human being on the other side of the computer and because of this some people think that a lower standard of ethics or personal behaviour is acceptable in online conversations. Remember: the same standards of behaviour you follow in real life also apply online.
Know where you are in cyberspace	Netiquette varies from domain to domain – social conversations in Facebook are very different from academic conversations in an online course. Lurk before you leap – spend some time observing the tone of an academic conversation in your online course before 'jumping in'.
Respect other people's time and bandwidth	We are all busy people and therefore when you send an email or post to a discussion group in your online course, you're taking up other people's time. It's your responsibility to ensure that the time they spend reading your posting isn't wasted.
Make yourself look good online	In an online course, you will be assessed on the quality of your writing. So spelling and grammar do

	count. Also, pay attention to the content of your writing. Be sure you know what you're talking about – when you see yourself writing 'it's my understanding that' or 'I believe it's the case', ask yourself whether you really want to post this message before checking your academic references.
Share expert knowledge	Sharing your own personal knowledge in an online course can be very empowering. Also, when asking questions in an online course, be sure to summarize and share the responses.
Help keep flame wars under control	'Flaming' is the term used when people strongly express themselves and their emotions in an online message. This type of message can dominate the tone and destroy the learning community of an online course. It is important to remind students that they are discussing and debating academic issues, not personality issues and conflicts.
Respect other people's privacy	Most of us now have digital profiles on the internet through our use of social media applications such as *Facebook* and *LinkedIn* where it is sometimes easy to obtain personal information about each other and ourselves. Again, remember that the focus in an online course is on academic discourse rather than on our personal traits and characteristics.
Don't abuse your power	Nobody appreciates a 'know-it-all' in an online course. Remember to 'seek to understand before being understood' in an online discussion forum.
Be forgiving of other people's mistakes	Everyone makes mistakes in life. The difference in an online course is that there is a written record of your content, spelling, and grammar issues. If you decide to inform an online classmate of their mistake, accepted protocol is to inform them by private email rather than in the discussion forum. This is commonly known as 'back-channeling' and is a useful strategy for problematic situations in online courses.

Source: Adapted from Shea (1994).

University of Galway Code of Conduct

Please familiarise yourselves with the University of Galway Code of Conduct, procedures associated with examinations and assessment and other important matters. All students

should read this document https://www.universityofgalway.ie/media/studentservices/files/Student-Code-of-Conduct.pdf

Attendance Guidelines

All students are expected to attend lectures, tutorial and workshops. These classes are critical for supporting progress. In the event of illness causing a student to miss a class, please inform the course coordinator. Students who miss classes are responsible for updating themselves on any information provided during those classes. Dates and deadlines associated with this course are subject to change therefore students must plan on being present and available for the whole semester.

Deadline/Deadline Extensions Guidelines

Each assessed work will have a submission deadline. **If work is handed in after a deadline it will either (a) not be marked or (b) will be subject to a penalty. A deadline extension will only be given in exceptional circumstances and MUST be negotiated ahead of the deadline.**

A deadline extension may be given if a student is affected by illness or other personal difficulties, in the case of a medical condition, the student will normally be required to submit a note from his/her doctor. A deadline must be negotiated with the originator of the assessment and the course coordinator must also be informed of the deadline extension.

Plagiarism Guidelines

Each student is responsible for ensuring that all work is handed in for assessment is his/her own. Plagiarism is the act of copying, including or directly quoting from the work of another without adequate acknowledgement, in order to obtain benefit, credit or gain. Plagiarism can apply to many materials, such as words, ideas, images, information, data, approaches or methods. Sources of University of Galway Plagiarism can include books, journals, reports, websites, essay mills, another student, or another person.

Self-plagiarism, or auto-plagiarism, is where a student re-uses work previously submitted to another course within the University or in another Institution.

All work submitted by students for assessment, for publication or for (public) presentation, is accepted on the understanding that it is their own work and contains their own original contribution, except where explicitly referenced using the accepted norms and formats of the appropriate academic discipline.

Plagiarism can arise through poor academic practice or ignorance of accepted norms of the academic discipline. Schools should ensure that resources and education around good academic practice is available to students at all levels.

How can Plagiarism be avoided?

Most cases of plagiarism can be avoided by citing your sources. Simply acknowledging that certain material has been borrowed, and providing your reader with the information

necessary to find that source, is usually enough to prevent plagiarism. See below on 'Referencing' for information on how to cite properly.

Changing the words of an original source is not sufficient to prevent plagiarism. If you have retained the essential idea of an original source, and have not cited it, then no matter how drastically you have altered its context or presentation, you have still plagiarised.
If you use a direct quotation from another source (using their words exactly), you must enclose it in "quotation marks" and quote the source, giving the page number.

How can plagiarism be detected?

All coursework you submit for assessment will be automatically submitted to "Turnitin", a plagiarism detection software programme which compares submitted work with hundreds of thousands in their database, as well as internet sites. **You are strongly advised to submit a draft of any assignment/thesis to Turnitin to determine its originality and to take corrective action, if necessary, before submitting the final version.**

What are the consequences of plagiarism?

The HRB Clinical Research Facility complies with the procedures outlined in the university policy on plagiarism at http://www.universityofgalway.ie/plagiarism/
Penalties may include automatic failure or disciplinary procedures.

The information above has been adapted from Turnitin

How to access e-journals through the library

http://library.universityofgalway.ie/

Access to current literature will be required during this MSc course, for reports, projects and for the thesis/independent study. The Library at University of Galway can provide access to the full text of many articles, including journals which are not held as paper copies.

1. Go to the University of Galway Library website
2. Click on Resources
3. Go to the Quick access section on right hand side of the screen
4. Click on: I want to…..Search for a journal
5. A basic search page will appear
6. At the top of the page click on Find e journal
7. Type the title of the journal into the box and click go
8. The journal title will appear on the screen along with a red SFX button
9. Click on this and the journal tile will appear with a blue E box beside it.
10. Click on this and you will have access to the full text journal.

If you need any further help please contact the library staff:
Cassidy, Mary
Medical Library / Library & IT Service Desk Assistant
Email: mary.cassidy@universityofgalway.ie
Tel: +353 91493601

Student Services

Using the Library

The library at University of Galway can provide access to the full text of many articles, including journals which are not held as paper copies. You can access this material in the library, on campus and from home if you login to the system appropriately. The library webpage have some excellent 'how to' advice, which are a great place to start orienting yourself.

Career Development Centre

The University of Galway Career Development Centre is a useful resource; I suggest you avail of the many workshops and mentoring opportunities they provide. They can give you help finding and applying for jobs, for PhD positions and for obtaining funding for research positions. They will also give advice about preparing an effective cover letter and *curriculum vitae*.

Academic Writing Centre

Many learners find writing assignments challenging; particularly if they have not written for some time. The Academic Writing Centre can provide support for students who feel that they have a recurrent problem with grammar, punctuation, spelling, or essay structure. They offer free one-on-one teaching sessions on campus tailored to your needs. You can find out more information about the service including contact details via this link. That link also includes some helpful links including video tutorials.

Chapter 6: Contact Details

All course related queries should be directed to our dedicated MSc in Clinical Research email (clinicalresearch@universityofgalway.ie)

Program Director:
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