

# Masters in Clinical Research

**Handbook 2020-2021**

**Full Time and Part Time**

**September 2020**



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Note: \* denotes *Subject to Change*

## Message from the Director



Welcome to the MSc Clinical Research programme at the School of Medicine, NUI 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.

## Message from the Coordinator



Welcome! The aim of this Program is to provide you with up-to date clinical research content and training to become the next generation of healthcare workers in the clinical research arena, by providing you with a platform for more enhanced efficiencies in the translation of medical discoveries into clinical practice.

Please don't hesitate to get in touch with me if you have any queries or concerns. I also welcome any suggestions for improving the course. Don't forget to find us on Twitter and LinkedIn for updates.

Enjoy the year,  
Sonja Khan, PhD

[Sonja.khan@nuigalway.ie](mailto:Sonja.khan@nuigalway.ie)

091-493533

## Section 1: Full Course Structure\*

### 1. FULL TIME M.SC. OR PART TIME M.SC. (CLINICAL RESEARCH)

Students are required to complete three compulsory modules. Further optional modules are selected from additional modules available at NUI 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 over a 1-year period, and submitted by August 2020.

**TOTAL: 90 ECTS over 1 year**

		ECTS	Semester
<b>Compulsory Modules:</b>			
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
<b>Choice of Additional Modules*:</b>			
MD513	Introduction to Biostatistics II	10	2
MD518	Observational and Analytical Research Methods	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
MD516	Translational Medicine	10	2
MD517	Clinical Research Administration	10	2
MD1600	Bio-Ethics	10	1
MD1602	Biobanking – Advanced Clinical Application and Testing	10	2
MD1528	First in Human, Early Phase Clinical Trials	10	1
<b>Compulsory Research:</b>			
MD519	Independent Study Module**; paper publication OR	10	Year long
MD520	Original Research and Thesis*	30	Year long
	<b>Total ECTS</b>	<b>90</b>	

#### **\*Thesis (Semester 1 and 2) 30 ECTS:**

For PT Students the MSc thesis will be completed over a 2-year period, submitted by August 2021.

#### **OR \*\*Independent Study Module (Semester 1 and/or 2) 10 ECTS:**

The Independent Study Module will be completed and submitted by July 2022.

**TOTAL: 90 ECTS over 2 years**

## **Section 2: Timetable**

### 2019-2020 SEMESTER 1 OVERVIEW

Time	Monday	Tuesday	Wednesday	Thursday	Friday
7.00-8.00					Fundamentals of Health Research & Evaluation Methods
8.00-9.00					
9.00-10.00					
10.00-11.00					
11.00-12.00					
12.00-13.00					Economic Evaluation in Health Care <sup>3</sup>
13.00-14.00					
14.00-15.00		<i>First in Man Human Clinical Trials</i>			Biostatistics I
15.00-16.00					
16.00-17.00	Project Management <sup>2</sup>				
17.00-18.00					
18.00-19.00				<i>Bio-Ethics*</i>	
19.00-20.00					

MD510 Fundamentals of Health Research and Evaluation Methods

MD1602 Introduction to the Ethical and Regulatory Frameworks of Clinical Research

MD511 Introduction to Biostatistics I

MD512 Ethics of Health Research

MD1600 *Bio-Ethics*

MD1528 *First in Man Human Clinical Trials*

EC584 Economic Evaluation in Health Care

Room 2012 CSI

\*Online Via Blackboard- Times TBD

IT106 IT Building

Online via Blackboard

\*Online Via Blackboard- Times TBD

Aras Cairns building; Room CA 001 Lecture room

CA116a; Cairns Building

<sup>1</sup> Ethics of Health Research starts mid-November. Ethics Workshop dates TBC. Position on timetable indicates material will be released online.

<sup>2</sup> Additional MS Office laboratory sessions will be provided from end October, with a variety of times available to facilitate individual timetables.

<sup>3</sup> Economic Evaluation in Healthcare presentations will occur in addition to this lecture. Days and times will be determined following consultation with students.

## 2019-2020 SEMESTER 2 OVERVIEW; TBC

Time	Monday	Tuesday	Wednesday	Thursday	Friday
7.00-8.00					Observational & Analytical Research Methods
8.00-9.00					
9.00-10.00					
10.00-11.00					
11.00-12.00		Translational Medicine	Translational Medicine		Biostatistics II
12.00-13.00					
13.00-14.00					
14.00-15.00			Health Systems and Policy Analysis		Biostatistics II (Lab tutorials)
15.00-16.00					
16.00-17.00				Biobank –Clinical Testing and Application Online*	
17.00-18.00			Clinical Research Administration		
7.00-8.00					

MD513 Introduction to Biostatistics II

Mid-January

MD518 Observational and Analytical Research Methods

Mid- January Room 305 CSI

MD514 Research Methods for Randomised Controlled Trials RCT

Early January - Online Delivery

MD515 Systematic Reviews

Early January - Online Delivery

MD516 Translational Medicine

Early January

MD517 Clinical Research Administration

Early January

EC572 Health Systems and Policy Analysis

Early January

MD1601 Biobank –Clinical Testing and Application

Early January – Online Delivery\*

# Campus Map

[http://www.nuigalway.ie/media/buildingsoffice/files/maps/M12122\\_General\\_CampusMapWEBpdf220217.pdf](http://www.nuigalway.ie/media/buildingsoffice/files/maps/M12122_General_CampusMapWEBpdf220217.pdf)





## Section 3: Module Descriptions

### FUNDAMENTALS OF HEALTH RESEARCH AND EVALUATION METHODS; MD510

**Semester 1**

**ECTS 10**

**Module Leader:** Prof Martin O'Donnell and Prof Andrew Smyth

**Lectures:** Friday 7 – 9 am; Room 2012 Clinical Science Institute, (#1 on map)

#### 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. Measures of Health, Illness and Disease Frequency
3. Measurement and Sample Size
4. Determining Causation
5. Randomised Controlled Trials (RCT) – The Tactics of Performing Therapeutic Trials
6. Evaluating the Accuracy of Screening and Diagnostic Tests
7. Systematic Reviews
8. Economics: Introduction to Health Technology Assessment (HTA)
9. First in Man, Biomarkers and early phase clinical trials
10. Knowledge Translation

#### Required Materials

*Designing Clinical Research* (4<sup>th</sup> Ed.), Eds. Hulley *et al.*, 2013, 3<sup>rd</sup> 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, continuous assessment assignments and contribution to tutorials.

**MD1602****Introduction to the Ethical and Regulatory Frameworks of Clinical Research****Semester 1****ECTS 10****Module Leader: Dr Sonja Khan & Prof Andrew Smyth**

**Lectures:** This module is delivered online. Distance learning units through Blackboard; 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
- Design, plan and execute 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 strategies to navigate
- 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 **(3 Units)**

- 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 **(2 Units)**
  - a. What are the Health Research Regulations?
  - b. Consent
  - c. Privacy, Legal and Ethical Considerations
3. General principles of research ethics **(2 Units)**
  - a. Research Ethics
  - b. Ethics of RCT's
4. Submissions to Regulatory Authorities and Ethics Boards **(1 Unit)**
  - a. Application to REC and HPRA
5. Regulatory aspects of Clinical Trials & Medical Device Investigations **(2 Units)**
  - a. Safety
  - b. IMP
  - c. Medical Devices

**Required Materials:** Provided by Module Director

**Student Evaluation**

- Continuous Assessment (100%)
  - GCP test
  - Weekly assignments

## INTRODUCTION TO BIOSTATISTICS I; MD511

### Semester 1

### ECTS 10

**Module Leader:** Dr Alberto Alvarez and Dr John Ferguson

**Lectures:** Friday 2-4 pm, IT106 IT Building (#16 on map); Practical's will be student-directed. 13<sup>th</sup> September 2019.

### 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 and probability
- 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.

## BIO-ETHICS (MD1600)

### Semester 1

#### ECTS 10 (Optional Module)

**Module Leader:** Dr Sonja Khan

**Lectures:** This module is delivered online. Distance learning units through Blackboard; each unit consists of required readings, lectures will be posted online prior to tutorials (1 hour each). There will be weekly tutorials (1 hour each) delivered via the Virtual Learning Environment (VEL), and laboratory sessions as directed by module leader. Time to be decided.

#### Brief Description

This module will provide a comprehensive introduction to bio-ethics in the context of clinical research sciences. The module will instil the importance of balancing the need to advance our knowledge of medicine against the legal and ethical mandate to protect society.

#### Learning Outcomes

- Evaluate ethical issues from given scenarios and thus demonstrate a capacity to apply across a broad spectrum.
- Evaluate the ethics relating to biobanking and current legislation around informed consent and ethical approval.
- Consider the ethics of previous practice and hence demonstrate a capacity to review processes for the advancement of future endeavour.
- Evaluate legislation practices and protocols, given consideration to all participants and, create a framework for disseminating learning to both peers and non-peers.

#### 5. Unit Topics

- Ethics: Discusses the importance of ensuring that biospecimens and

personal health-related information are used ethically and optimally for research purposes.

- Informed consent: Identifies and describes processes related to informed consent in the biobank setting.
- Safety: It covers the importance of biobank facility design and security in maintaining a safe environment.
- Legislation, policy, procedure practice: Introduces aspects of Legislation, policy and practice related to biobanking
- Public engagement: Facilitate students in developing a clear and engaging style of written and/or oral communication
- Governance: The concept of biobank governance and its importance to the everyday operations of a biobank.

**Required Materials:** Provided by Module Director

#### Student Evaluation

Students will have to gain a pass rate of 40% overall for a combination 2 project essays worth 50% each.

## FIRST IN HUMAN, EARLY PHASE CLINICAL TRIALS (MD1528)

### Semester 1

#### ECTS 10 (Optional Module)

**Module Leader:** Dr Veronica McInerney

**Lectures:** 10<sup>th</sup> September 2019; 2-3 pm; Aras Cairnes building: CA001 Lecture room (#22 on campus map)

#### Brief Description

This module will introduce learners to the fundamental elements necessary to conduct First in Man, Early Phase Research in adherence to Good Clinical Practice guidelines, using didactic and practical teaching. Learners will be guided through the meaning of early phase research, study design, safety and clinical oversight, statistical considerations, emergency training, biological specimen management and clinical site preparation with the objective to enable learners conduct early phase research to standards that surpass audit and inspection requirement.

#### Learning outcomes:

1. Understand and describe the processes for translating novel drug/ device from the bench to bedside
2. Draft essential documents necessary for the conduct of phase 1 FIM Clinical Trials
3. Describe dose escalation and dose expansion
4. Define and differentiate pharmacokinetics and pharmacodynamics and the implications of biological specimen management
5. Identify challenges of conducting phase 1 trials and methods to overcome these

6. Demonstrate an in-depth knowledge of measure to ensure patient safety which includes safety event clinical management, data capture and reporting, Data Safety Monitoring Board Coordination, Investigator Brochure and Data Safety Update Reporting

#### Student Evaluation

Students will have to gain a pass rate of 40% overall for a combination projects, continuous assessment and practical's.

## BIOSTATISTICS II; MD513

**Semester 2**

**ECTS 10**

**Module Leader:** Dr Alberto Alvarez and Dr John Ferguson

**Lectures:** January 2020; Friday 11-1 pm, Tutorials and Workshops to be decided. Venue TBD

### Brief Description

The module is designed to provide an introduction to statistical modelling techniques such as linear and non-linear regression, Analysis of Variance and Survival Analysis.

### Learning Outcomes

- To provide a practical introduction to data analysis;
- To encourage and equip students to apply simple statistical techniques to design, analyse and interpret studies in a wide range of disciplines;
- To make students aware of the limitations of simple techniques and encourage them to seek expert advice when more complex procedures are required;
- To utilise a statistical package on a computer to illustrate the power of statistical techniques and avoid tedious arithmetic.

### Unit Topics

1. Linear Regression
2. Logistic Regression
3. Non-linear Regression
4. Analysis of Variance
5. Survival Analysis
6. Confounding: Measured and unmeasured bias

**Required Materials:** Provided by Module Director

### 7. Course Format

This module consists of 6 units. Each unit consists of required readings and an assignment. There will be 2 weekly lectures (1 hour each), and laboratory sessions as directed by module leader. Optional tutorials will be run for one hour each week for additional support.

### Student Evaluation

Students will have to gain a pass rate of 40% overall for a combination continuous assignments (40%) and final end of module assignment (60%).

## OBSERVATIONAL AND ANALYTICAL RESEARCH METHODS; MD518

**Semester 2**

**ECTS 10**

**Module Leader:** Prof. Martin O'Donnell

**Lectures:** January 2020; Lectures and Tutorials Friday 7.30 -9am; Venue TBD

### Brief Description

Review of observational research methods, including survey research, retrospective study, prospective cohort study, case-control design, scale development, diagnostic testing and qualitative research methods.

### Learning outcomes

An in-depth understanding of;

- Sampling (Unit and Frame)
- Causation
- Survey research
- Cohort study (retrospective and prospective)
- Case-control
- Confounding + Bias in Observational research
- Multivariable analysis
- Propensity analysis

### Unit Topics

1. Measures of Health, Illness and Disease Frequency
2. Causality (Bradford-Hill, association v causation)
3. Sampling in research (Quantitative/Qualitative)
4. Survey Research
5. Cross-sectional Studies

6. Cohort Studies (retrospective and prospective)
7. Case-control Study (incl. nested case-control)
8. Administrative Datasets (incl. linkage)
9. Qualitative Research/Mixed Methods
10. Bias in Observational Studies (Identifying and Addressing)
11. Measuring Methodological Quality of Observational Studies

**Required Materials:** List provided by Module Director

### Course Format

This module consists of 11 units. Each unit consists of required readings and an assignment. There will be a weekly lecture/tutorial (2 hours) in addition to problem-based workshops (2 hours).

### Student Evaluation

Students will have to gain a pass rate of 40% overall for a combination of end of module exam (20%), 2 x assignments (20%), end-of-term assignment (40%) and contribution to tutorials (20%).

## **INTRODUCTION TO RESEARCH METHODS FOR RANDOMIZED CONTROLLED TRIALS; MD514**

**Semester 2**

**10 ECTS**

**Module coordinator:** Prof Andrew Smyth

**Online Sessions:** January 2020; this module consists of 10 units, each unit 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 & Dr Sonja Khan

**Online Sessions:** January 2020; module consists of 11 units, delivered and facilitated online. Each unit consists of required readings and contribution to 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 generation and evidence based health care;
- Identify the key stages of the systematic review process;
- Develop a review question and understand how to develop a review protocol;
- Develop clear study inclusion and exclusion criteria;
- Identify and develop appropriate search methods for identification of studies including the development of a comprehensive search strategy;
- Apply inclusion and exclusion criteria to identify relevant studies;
- Critically appraise the quality of included studies using methods

appropriate to included study design types;

- Develop and pilot a data extraction form
- 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 statistical (meta-analysis) and non-statistical synthesis of data/findings;
- Be familiar with processes for writing and disseminating a review

#### Module content

- Establishing need for a review;
- Establishing a review team;
- Question formulation;
- Study inclusion and 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. In addition, the following two online manuals are required:

- Higgins JPT, Green S. Cochrane Handbook for Systematic Reviews of Interventions. Cochrane Collaboration. Version 5.1.0 [updated 2011 March] <http://www.cochrane->

handbook.org/ (available also, and preferably, through REVMAN (see below).

- Centre for Reviews and Dissemination. Systematic Reviews. CRD's guidance for undertaking reviews in health care. York, UK: NHS Centre for Reviews and Dissemination; 2009.  
[http://www.york.ac.uk/inst/crd/index\\_guidance.htm](http://www.york.ac.uk/inst/crd/index_guidance.htm)

Students are encouraged strongly to obtain both texts and refer to them throughout the course. The following textbook is recommended as an additional resource:

Review manager (RevMan) software will be used in the course (available free of charge): Download at:  
<http://ims.cochrane.org/revman/download>

### **Student Evaluation**

For students undertaking MD515, the module is assessed by means of:

- a) Continuous assignments each worth 10% contributing to a total of 20% of overall mark
- b) Two end of module assignments (contributing 80% to overall module assessment)

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

## Economic Evaluation in Healthcare; EC584

### Semester 1

### ECTS 10

**Module Leader:** Dr Brendan Kennelly

**Lectures:** 14<sup>th</sup> September 2019. Friday 12 – 2 pm in CA116a, Cairnes Building (#22 on campus map)

### 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:** Dr Brendan Kennelly

**Lectures:** January 2020. 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

NUI 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.

## MD1601-BIOBANK – ADVANCED CLINICAL TESTING AND CLINICAL APPLICATION

### Semester 2

### ECTS 10

**Module Leader:** Dr Sonja Khan

**Online:** January 2020. This module consists of 7 units. Each unit consists of required readings and an assignment, lectures will be pre-recorded and available online. Lectures will be made available online; tutorials will be delivered at via Virtual Learning Environment (VEL). January 2020

### 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. Indicatively the module included: collection process, control protocol, storage and distribution, facilities and safety, quality management systems and data systems. This module introduces the students to a range of standardised Biobank clinical testing and outcome measures used in Clinical Research, the downstream analysis of biospecimen and how these influence correct administration, scoring and interpretation.

### Learning outcomes

- Evaluate of the requirements of a given test protocol and thus create a robust yet user-friendly SOP for clinical sampling, identification, transportation, storage and handling.
- Provide a comprehensive review of process regarding specimen control and thus critically appraise relative to that that of emerging technologies and cutting edge

national and international practice and report on findings.

- Appraise current research in the area of biobank management, and report on the importance of functional operations such as specimen collection and handling.
- Employ advanced clinical techniques and thus test, record, quantify and disseminate data for future analytical evaluation
- Apply learning relating to clinical testing to advance new areas of clinical research in a particular field

### Unit Topics

- Collection process
- Control protocol, storage and distribution
- Facilities and safety
- Quality management systems and process improvement
- Data systems and record management
- Downstream analysis of bio-specimen in relation to Protein, DNA, RNA
- Processes and critically evaluate protocol prior to application and

### Student Evaluation

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

## TRANSLATIONAL MEDICINE; MD516 (10 ECTS)

### Semester 2

**MD516 - ECTS 10** [Register for either the 10 or 5 credit module]

**Module Leaders:** Dr Mary Murphy & Dr Linda Howard

**Lectures:** January 2020. Tuesdays and Wednesdays 11 – 12 noon,

This module consists of 12 units. Each unit consists of required readings and an assignment. There will be 2 weekly lecture (1 hour); Tutorials (for major Project) to be decided.

### Brief Description

Processes to translate novel therapies to clinical practice must be developed to ensure that patients and society benefit from basic research and observations. This course describes the pathway taken as a potential new therapy moves from a research observation to an approved and regulated patient treatment. The overall scope of this module is broad as it moves from 'Bench to Bedside' and 'Molecules to Population' with emphasis in complexities of Regenerative Medicine.

### Course Syllabus

NUI Galway (HRB Clinical Research Facility, REMEDI and College of Medicine, Nursing and Health Sciences) prepared and delivered.

### Learning outcomes

On successful completion of this module the learner will be able to:

- Describe the key stages and regulatory requirements of the translational process as a biomedical research development moves to the clinic.
- Discuss the ethical principles associated with the translational process.
- Describe the pre-clinical process and underpinning Good Laboratory Practice (GLP) for efficacy, safety and toxicology studies.

- Explain the principles of Good Clinical Practice (GCP), and the design and implementation of a clinical trial.

### Unit Topics

1. Translation of cellular/ gene therapeutics
2. Pre-clinical Translation of Basic Research Findings
3. Clinical Translation of Advanced therapies
4. Advanced Therapy Medicinal Product manufacture
5. Medical Device manufacture
6. Ethical issues associated with ATMP translation

### Required Materials

- Emanuel EJ, Wendler D, Grady C. "What Makes Clinical Research Ethical?" JAMA.2000; 283(20):2701-2711.  
<http://jama.jamanetwork.com/article.aspx?articleid=192740>
- Website: US Food and Drug Administration (FDA)Biologics Guidance Documents for Cellular/Gene Products  
<http://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/default.htm>
- Website: European Medicine Agency Advanced-therapy medicinal products  
<http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/gener>

*al/general\_content\_000294.jsp&mid=WC0b01ac05800241e0 )*

- Irish Medicine Board Guidelines Website: Health Products Regulatory Authority Regulation of Medicines in Ireland  
*<https://www.hpra.ie/homepage/medicines/regulatory-information>*

### **Student Evaluation**

Students will have to gain a pass rate of 40% overall for a combination of assignments, group presentation and, end of module project. The *10 ECTS MD516* will be run in conjunction with the REM502 module but will also include an additional project assignment (contributing to 50% over overall mark).



## CLINICAL RESEARCH ADMINISTRATION; MD517

### Semester 2

### ECTS 10

**Module Leader:** Dr Aideen O'Doherty

**Lectures:** January 2020. Wednesday 4-6 pm. This module consists of 9 units. There will be 1 weekly lecture (2 hour) and a 3-hour Workshop in addition to an optional ICH-GCP Training workshop, date to be confirmed.

### 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 GCP Training will be a prerequisite for all working in Clinical Research and students will be provided with a current GCP certificate during this module.

### Course Objectives

- An understanding of the various elements involved in the establishment and operation of clinical research facilities and associated clinical trials.
- An appreciation of procedures involved in the successful completion and reporting of clinical trials.

- Comprehension of systems and interactions in the CRF environment.
- An understanding of the ethics involved in running clinical trials.
- An understanding of financial management issues.
- Preparation of a clinical trial protocol and other study-associated documentation, from the managerial perspective.

### Unit Topics

1. Introduction to regulatory affairs in clinical research
2. Good Clinical Practice (GCP) and Quality Control
3. Ethics of Clinical Research
4. Product Manufacture
5. Pharmaco-/Medical Device-vigilance
6. Drug Discovery and Development
7. Clinical Trial Set-up and Management
8. Budget Development and Management
9. Clinical Trial Monitoring and Auditing
10. Indemnification and Liability
11. Organisation of Trial Governance

### Student Evaluation

Students will have to gain a pass rate of 40% overall for a combination of end of module exam, contribution to CRA group workshop and individual project assignment.

## INDEPENDENT STUDY; MD519

Compulsory (**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 NUIG 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 NUI Galway.*

## THESIS; MD520

### Compulsory (FT) or Optional (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 can also 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 |
| 2. Research proposal submission | January  |
| 3. Thesis Introduction          | March    |
| 4. Thesis Draft                 | June     |

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 NUIG College of Medicine, Nursing and Healthcare Sciences for reference purposes”*.

#### Word count

The independent study word count is 10-15,000 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 the 31<sup>st</sup> August, 5 pm 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.

<b>Aspect</b>	<b>Criteria</b>
<b>Research Aims and Purpose</b>	Clarity of statement of rationale, aims and research questions. ability to position topic with context of relevant literature and/or policy/practice concerns
<b>Relevant and supporting Literature</b>	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.
<b>Methodology and Data Analysis</b>	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.
<b>Results/ Findings</b>	Clarity 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.
<b>Discussion and Conclusion</b>	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.
<b>Overall Style of Writing</b>	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 NUIG Examinations and Fees Office.*

## Section 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 1<sup>st</sup> sitting

- H1 >70%
- Upper H2 60-69%
- Lower H2 50-59%
- 3<sup>rd</sup> 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 1<sup>st</sup> sitting

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

- H1 70%
- H2 60%
- Pass 40%

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

## Section 5: Useful Information\*

### NUI Galway Code of Conduct

[http://www.nuigalway.ie/student\\_life/university\\_code\\_conduct/code.shtml](http://www.nuigalway.ie/student_life/university_code_conduct/code.shtml)

The above webpage contains useful information about life at the NUI Galway, procedures associated with examinations and assessment and other important matters. All students should read this document.

### 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

<http://www.nuigalway.ie/plagiarism/>

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 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.nuigalway.ie/plagiarism/>. Penalties may include automatic failure or disciplinary procedures.

*The information above has been adapted from [www.turnitin.com](http://www.turnitin.com)*

## How to access e-journals through the library

<http://library.nuigalway.ie/>

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

1. Go to the NUIG Library website <http://library.nuigalway.ie/>
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@nuigalway.ie](mailto:mary.cassidy@nuigalway.ie)

Tel: +353 91493601

## Instructions for Blackboard

Modules listed in the MSc for Clinical Research may use the Blackboard system to distribute lecture notes, reading lists, assessment information and other course related material. Certain modules may also require you to submit assignments to tutors or to participate in discussions via Blackboard.

Students can access Blackboard by going to <https://nuigalway.blackboard.com/> and logging in by using their student ID number (e.g. 0000123) and password.

Further information on Blackboard <http://www.nuigalway.ie/information-solutions-services/services-for-students/blackboard/>

Students who would like more information about this service should visit the following website <http://www.nuigalway.ie/information-solutions-services/services-for-students/>

Finally for all your general computer needs you can contact the Service Desk at NUI Galway's Information Solution and Services, Tel: 091-495777 or Email: [servicedesk@nuigalway.ie](mailto:servicedesk@nuigalway.ie)

## Getting Started

1. Open your internet browser and go to <https://nuigalway.blackboard.com/>
2. Enter your username (Student ID) and password (unless you have changed it, this is "galwayddmm" where "dd" is your birth date and "mm" is your birth month).

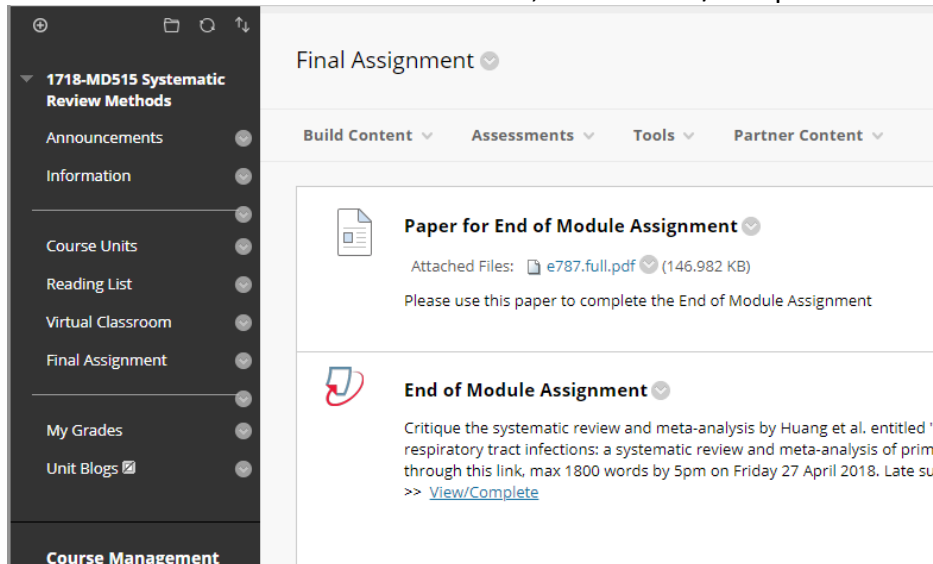
The image shows the Blackboard login interface. At the top, the 'Blackboard learn+' logo is displayed. Below the logo, there are two input fields. The first is labeled 'USERNAME:' and has a red box pointing to it with the text 'Enter your 8-digit Student ID here (e.g. 13456789)'. The second is labeled 'PASSWORD:' and has a red box pointing to it with the text 'Enter your CASS password'. Below the password field is a 'Login' button.

3. You will see a list of modules you are enrolled in, on the right hand side of the screen. Click on the name of the module you wish to enter.



## Submitting your work for Assessments

1. When preparing your assignments to submit for an assessment, please follow guidelines provided by module leader.
2. When you are ready to submit, follow the steps 1-3 in the 'Getting Started' section.
3. On the left hand side of the screen, select 'Assignment'
4. Under the title of the submission, select 'View/Complete'.



5. When you entered the requested information and uploaded your document, select 'Submit'. Don't worry if the format appears to have been changed – it will revert back to the correct format when downloaded from Blackboard. Note: please don't paste your submission in the textbox provided, always upload as attachment.
6. Following submission you should receive a confirmation when your assignment has been uploaded. Contact module leader if you haven't received this.
7. You can view the 'similarity' score, showing the percentage of text in your assignment that matches other sources. Some matching is inevitable – what is crucial is that you have correctly referenced all your sources. If you submit assignments before the due date, you can take corrective actions (if necessary) after viewing the 'similarity report', and resubmit.

## Checking your Grades

You will be notified by email, or via announcement on Blackboard when your submissions have been marked. You can check your grades via Blackboard. Depending on how the module leader has approached the assessment, there are two possible ways to view your mark and feedback as follows:

*Method 1: Via My Grades:*

1. Select 'My Grade' on the left hand side of the screen.
2. Scroll down to the heading "GRADED". Here you'll find the mark you've been awarded.

3. To view your feedback (if provided), click on the title of the submission.
4. Scroll down to Section “Feedback from Instructor”.
5. Next to “Files from Instructor”, select attachment to open your feedback.

#### *Method 2: Via Turnitin*

1. Select “Assessment”
2. Under the title of the assignment you want feedback for, select “View/Complete”
3. Near the bottom right of the screen, select “View”.
4. Your assignment will appear in a new window
  - a. Your grade appears in the top right hand corner
  - b. To see any general comments the module leader has made about your assignment, click on the grey callout box near bottom of screen. General comments (if any) will appear in a panel on the right half of the screen.
  - c. Your module leader may also (or instead) have inserted specific comments at particular points in your essay. To see these, scroll through your assignment and look for any **blue** text.

### **Collaborate Ultra**

Blackboard collaborate is an online collaboration platform which provides a web conferencing interface. This online meeting room allows for sharing of information, understandings and building collaboration with your peer learners on the course. Course students will have access to a dedicated teaching and online learning meeting room. Sessions using the room will be facilitated by the module leaders during each module. The times and dates for the sessions will be negotiated with the group at the beginning of the semester. They tend to take place a weekday evening and last 1-2 hours. The highly responsive audio and video features, along with the instant chat and interactive white board features, create a real time environment for all users. Within Blackboard

#### *Collaborate session user can:*

- Communicate with each other using several choices of media such as video, audio and the chat window.
- Interact with the whiteboard
- Follow the web browsing session
- Share files with each other
- Share applications with each other (e.g. the module leader can demonstrate tasks on an application e.g. Excel, then pass control of the mouse to a student, while the rest of class can observe the actions)

After a Blackboard Collaborate session users can review the session by replaying the recording of the entire session (if recorded).

More information, along with a short video demonstration is available:

<https://www.nuigalway.ie/teaching-with-technology/technologies/webconferencing/#tab1>

Students are advised to check their home or work computer and make sure it is equipped with a microphone and speakers.

## Section 6: Contact Details

Prof. Andrew Smyth  
HRB Clinical Research Facility,  
NUI Galway and UHG,  
Galway,  
H91 YR71  
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Email: [andrew.smyth@nuigalway.ie](mailto:andrew.smyth@nuigalway.ie)

Dr. Sonja Khan  
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H91 YR71  
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Email: [sonja.khan@nuigalway.ie](mailto:sonja.khan@nuigalway.ie)  
Tel: +353 91 493533

Alternate email: [clinicalresearch@nuigalway.ie](mailto:clinicalresearch@nuigalway.ie)

Follow us on:

**Twitter:** @CRFGHRB

**LinkedIn:** [linkedin.com/in/nuig-clinical-research-masters](https://www.linkedin.com/in/nuig-clinical-research-masters)

MODULES:		MODULE LEADER	Contact
1	Fundamentals of HRM	Prof Andrew Smyth and Prof Martin O'Donnell	<a href="mailto:Martin.odonnell@nuigalway.ie">Martin.odonnell@nuigalway.ie</a> <a href="mailto:Andrew.smyth@nuigalway.ie">Andrew.smyth@nuigalway.ie</a>
2	Introduction to Biostatistics I	Dr Alberto Alvarez and Dr John Ferguson	<a href="mailto:Alberto.alvarez@nuigalway.ie">Alberto.alvarez@nuigalway.ie</a> <a href="mailto:John.ferguson@nuigalway.ie">John.ferguson@nuigalway.ie</a>
3	Introduction to the Ethical and Regulatory Frameworks of Clinical Research	Prof Andrew Smyth, Dr Sonja Khan	<a href="mailto:Andrew.smyth@nuigalway.ie">Andrew.smyth@nuigalway.ie</a> <a href="mailto:Sonja.khan@nuigalway.ie">Sonja.khan@nuigalway.ie</a>
3	Introduction to Biostatistics II	Dr Alberto Alvarez, Dr John Ferguson	<a href="mailto:Alberto.alvarez@nuigalway.ie">Alberto.alvarez@nuigalway.ie</a> <a href="mailto:John.ferguson@nuigalway.ie">John.ferguson@nuigalway.ie</a>
4	Observational and Analytical RM	Prof Martin O'Donnell	<a href="mailto:Martin.odonnell@nuigalway.ie">Martin.odonnell@nuigalway.ie</a>
5	Research Methods for RCTs	Prof Andrew Smyth	<a href="mailto:Andrew.smyth@nuigalway.ie">Andrew.smyth@nuigalway.ie</a>
6	Systematic Review Methods	Prof Andrew Smyth & Dr Sonja Khan	<a href="mailto:Andrew.smyth@nuigalway.ie">Andrew.smyth@nuigalway.ie</a> <a href="mailto:sonja.khan@nuigalway.ie">sonja.khan@nuigalway.ie</a>
7	Economic Evaluation in Healthcare	Dr Paddy Gillespie	<a href="mailto:Paddy.gillespie@nuigalway.ie">Paddy.gillespie@nuigalway.ie</a>
8	Health Systems and Policy Analysis	Dr Paddy Gillespie	<a href="mailto:Paddy.gillespie@nuigalway.ie">Paddy.gillespie@nuigalway.ie</a>
9	Translational Medicine	Dr Linda Howard & Dr Mary Murphy	<a href="mailto:Linda.howard@nuigalway.ie">Linda.howard@nuigalway.ie</a> <a href="mailto:Mary.murphy@nuigalway.ie">Mary.murphy@nuigalway.ie</a>
10	Clinical Research Administration	Dr Aideen O' Doherty	<a href="mailto:Aideen.odoherty@nuigalway.ie">Aideen.odoherty@nuigalway.ie</a>
11	Bio-Ethics	Dr Sonja Khan	<a href="mailto:Sonja.khan@nuigalway.ie">Sonja.khan@nuigalway.ie</a>
12	First in Man Clinical Trials	Dr Veronica McInerney	<a href="mailto:Veronica.mcinerney@nuigalway.ie">Veronica.mcinerney@nuigalway.ie</a>
13	Advanced Biobanking Application and Testing	Dr Sonja Khan	<a href="mailto:Sonja.khan@nuigalway.ie">Sonja.khan@nuigalway.ie</a>

