

جامـعــة مـحــمــد بـن راشــد لـلـطـب والـعـلـوم الـصــحــية Mohammed Bin Rashid University of Medicine and Health Sciences

# **Guide for Research During Residency Training**

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#### Section 1: Introduction

#### Why conduct clinical research during residency?

Research plays a pivotal role in your medical residency, and its significance cannot be overstated. Here's why research should be an integral part of your training:

Advancing Medical Knowledge

Research allows you to contribute to the ever-evolving field of medicine. Your findings can lead to new treatments, protocols, and guidelines that benefit patients worldwide.

By engaging in research, you become part of a larger community dedicated to improving healthcare through evidencebased practice.

Strengthening Critical Thinking and Problem-Solving

Research challenges you to think critically, analyze data, and develop hypotheses. These skills are invaluable in diagnosing and treating patients effectively. The ability to approach clinical problems with a scientific mindset enhances your decision-making abilities.

Developing a Lifelong Learning Mindset

In medicine, staying current with the latest research is essential. Engaging in research during residency fosters a habit of continuous learning. You'll be better equipped to adapt to new medical technologies, treatments, and guidelines throughout your career.

• Enhancing Patient Care

Research-driven practices often lead to improved patient outcomes. As a resident, your research can directly impact the care your patients receive. Implementing evidence-based approaches in your clinical work ensures that your patients benefit from the latest advancements.

Building a Stronger Resume and Future Opportunities

Research experience enhances your curriculum vitae (CV) and opens doors to fellowship programs, academic positions, and leadership roles in healthcare. It distinguishes you as a physician who actively contributes to the field, making you an attractive candidate for various career paths.

In summary, embrace the opportunities to engage in research, and you'll not only become a better clinician but also make a lasting impact on the world of medicine.

#### Section 2: Expected Research Tasks for Residents

During your residency training, you are required to complete a research project individually or with a group. This process will involve selecting a research topic, collecting and analyzing data and write a manuscript for publication. You will have protected time to complete these tasks and the Research Division in GME will provide you with all the support that is needed. You will also have the opportunity to present your work to the wider Dubai Health community and in regional or international conferences.

Timeline to complete your research during residency:



#### Research Milestones for PGY 2

#### Residency Research Orientation

During your second year of training, you are required to attend the orientation organized by the Research Division during your second year of residency training. This orientation aims to introduce you to the basic principles of scientific

research and give you an overview of the research project and timeline. Attendance is mandatory and any absences should be justified by the resident and acknowledged by the Program Director.

#### Complete the Online research training -Phase 1

You will receive access to the British Medical Journal (BMJ) Research to Publication Online (RtoP) Training during the Residency Research Orientation. Research to Publication is an online research methodology and publishing program specifically designed for doctors and healthcare researchers. It develops research skills and helps researchers to get papers published in high-quality journals. Table 1 summarizes the courses from the specific modules must completed before starting the two-week research block. Please refer to Appendix 1 for specific course learning outcomes.

Modulo Namo	Course Title		
Moulie Name			
Module 1: How to develop and report	t Course 1: Developing a good research question		
good research questions	Course 2: Reporting the research question in your paper		
	Course 1: How to write and publish a study protocol: overview		
Madula 2. Developing and uniting	Course 2: Clinical trial protocols: how to write and publish them		
module 2: Developing and writing	Course 3: How to write a research protocol for a grant application	105	
protocols	Course 4: Good medical writing	240	
	Course 5: Choosing and citing references	150	
	Course 1: Study design	225	
	Course 2: Studies of medical tests	105	
	Course 3: Enhancing causal inference	105	
Madula 2. Changing the bast study	Course 4: The methods: matching study designs to research	225	
Module 3: Choosing the best study	questions		
uesign	Course 5: Subjects and variables	105	
	Course 6: Sample size and power	135	
	Course 7: Statistics	225	
	Course 8: Questionnaires and qualitative research	90	
	Course 1: Ethical considerations in research	105	
	Course 2: History of research ethics	45	
Module 4: How to do ethical research	Course 3: Institutional review board (IRB) and informed consent	60	
	Course 6: Principles of research ethics	45	
	Course 7: Ethics in Big data research	75	
Module 5: How to write a research	Course 2. Scientific transmouster the nitfollo of colorities rementing	220	
paper	Course 3: Scientific transparency: the pitfalls of selective reporting		
Module 6: The essentials of running a	Course 10: Ethical issues in clinical trials		
clinical trial			
Module 7: Picking the right journal	Course 3: Patients' consent for publication		
and getting published			
Module 8: Avoiding scientific	Course (1) How and why to avoid plaginging		
misconduct		255	

#### Select a Research Topic and supervisor

After you complete the above modules, you will have an idea of how to formulate a research question. You can identify interesting, unanswered questions to address by reading the literature. You can access resources from Al Maktoum Medical Library and seek the assistance of the Library Team to help you identify relevant resources. Once your research question is finalized, you can discuss it with your program director and research supervisor. You are required to obtain your program director approval for your chosen topic.

A supervisor can be chosen from your specialty or any specialty that is relevant to your research topic. This can be done by consulting with your program director who can identify potential research supervisors or you can select a supervisor from the PgME Research Supervisor Database. The role of your research supervisor includes *You must complete all of the above tasks before starting the research block.* 

#### Two-weeks research block

During the two-week research block, you are expected to write a research proposal. The research design stage is critical for the success of any research project. If a wrong study design is selected, the data will be of no value even if the research question is important and interesting.

You must plan your time accordingly and arrange a consultation with the Biostatistician, to ensure you appropriately collect data that will answer your research question (such as calculating the collected sample size and designing the data collection tool). It will also be beneficial to meet with the library team to assist you with the literature review and referencing while writing the research proposal. You can consult with the research team for any additional support that is required.

#### Apply for MBRU IRB approval

Research studies with human subjects must be submitted to the MBRU Institutional Review Board (IRB) for review. A written approval must be obtained before initiating a study. You will be guided on the application process and will be expected to apply at the end of your two-week research block. You can also refer to the IRB Application Guide in the Research Section of the GME Website.

# Research Milestones for PGY 3

#### Complete the Online research training -Phase 2

Complete the remaining courses from modules 4 to 8 in the BMJ Research To Publication online training listed below.

Module 4: How to do ethical research	Course 5: Data and safety monitoring	75
	Course 8: Research in resource-poor environments	45

Module 5: How to write a research paper	Course 1: Reporting statistical methods and analyses	
	Course 2: The results: reporting all findings succinctly	330
	Course 4: The discussion: using structure and balance	225
	Course 5: Optimising the abstract and title	360
Module 6: The essentials of running a	Course 1: Course overview and trial design	
clinical trial	Course 2: Selection of participants	60
	Course 3: Recruitment	60
	Course 4: Choosing the intervention and controls	60
	Course 5: Randomization	45
	Course 6: Blinding	60
	Course 7: Outcome measures	90
	Course 8: Assessing safety	45
	Course 9: Adherence and complete follow up	75
	Course 11: Regulatory issues	30
	Course 12: How to write up industry-sponsored trials	225
Module 7: Picking the right journal and	Course 1: Navigating journal and peer review processes	270
getting published	Course 2: Compliance with journal and ICMJE requirements	120
	Course 4: Surviving peer review	195
	Course 5: What to do with rejections and appeals	225
	Course 6: Resubmission inquiries and cover letters	90
Module 8: Avoiding scientific	Course 1: Scientific misconduct, authorship, and conflict of interest	60
misconduct	Course 2: Reporting conflicts of interest	195
	Course 3: Journal rules on authorship	325
	Course 5: How journals uncover scientific fraud	330
	Course 6: How journals act on scientific misconduct	360

### Complete Data Collection

the data collection for your specific study and share the data with the biostatistician to ensure that the specific research data is completed.

# Research Milestones for PGY 4

## Scientific Writing Workshop

To complement the BMJ RtoP online training, you will attend one of the scientific writing workshops to guide you on the principles of medical writing and the process of publishing a paper in a medical journal.

# Four-weeks research block

During this block, you will finalize the data analysis with the biostatistician, agree on the major findings and data that will be presented in your paper, and have a manuscript ready by the end of the block. Your manuscript should be revised by your supervisor once completed and shared with the Writing Center in MBRU to guide you on the submission process. Evidence of submission to a journal will be required to complete the requirements of your residency training.

Task	Description	Responsible Team	Completed
			Yes/No
PGY2			
Research orientation attendance	Half-day orientation session on the research tasks and timeline	<ul> <li>Program Coordinators</li> <li>Program Director/Faculty</li> <li>Research Team</li> <li>Al Maktoum Medical Library (AMML)</li> </ul>	
Al Maktoum Medical Library and BMJ RtoP access Complete the required modules from BMJ RToP	Access will be granted to all residents and the library team will guide them on how to access resources and the online training. The modules are self-paced and can be accessed on demand. It is mandatory that the modules are completed and the completion certificate is shared with the program coordinator.	<ul> <li>AMML</li> <li>Residents</li> <li>Program Coordinators</li> <li>Research Coordinator</li> </ul>	
Choosing the research topic and selecting a supervisor	Residents are required to discuss the topic of their research with the Program Director who will be responsible for assigning them a research supervisor. The supervisor could be the program director or faculty or an expert in the field of the research topic chosen.	<ul> <li>Resident</li> <li>Program</li> <li>Director/Faculty</li> </ul>	
Meet with the biostatistician Writing the research	All residents are required to meet with the biostatistician in the first week of the research block before writing their research proposal. It is necessary to plan ahead and book an appointment to ensure the availability of an appointment slot. Residents will work on writing the proposal with	<ul> <li>Program         <ul> <li>Coordinator</li> <li>Research</li> <li>Coordinator</li> <li>Resident</li> </ul> </li> </ul>	
proposal	the help of the supervisor during the two-week block	<ul> <li>Program</li> <li>Director/Faculty</li> <li>Supervisor</li> </ul>	

# Section 3: Residency Research Tasks and Timeline Checklist

Obtaining Ethical Approval	The residents should apply for ethical approval by submitting the proposal and required forms and documents. After ethical approval, the research can be conducted and data collection can start.	<ul> <li>Program coordinators</li> <li>Resident</li> <li>Program Coordinators</li> <li>Research Coordinator</li> </ul>
PGY3		
Complete remaining modules from BMJ RToP	It is mandatory that the modules are completed and the completion certificate is shared with the program coordinator.	<ul> <li>Residents</li> <li>Program</li> <li>Coordinators</li> <li>Research</li> <li>Coordinator</li> </ul>
Data Collection	Residents will work on their data collection on the allocated time provided by the program faculty.	<ul> <li>Resident</li> <li>Program</li> <li>Director/Faculty</li> </ul>
PGY4		•
Data Analysis	Residents are required to meet with the biostatistician to guide them through the data analysis phase	<ul> <li>Resident</li> <li>Program</li> <li>Coordinators</li> <li>Research</li> <li>Coordinator</li> </ul>
Writing the research paper/Thesis	Residents will be guided on the writing process and a workshop on publication will be conducted A research paper/thesis (if required) should be completed and submitted to a reputable journal. Proof of submission to a journal is required for residency completion	<ul> <li>Resident</li> <li>Program <ul> <li>Director/Faculty</li> </ul> </li> <li>Supervisor</li> <li>Research <ul> <li>Coordinator</li> </ul> </li> </ul>

# Section 4: Research Support Contact Details

- General inquiries and biostatistics consultation fnahli@dubaihealth.ae
- Al Maktoum Medical Library and Writing Center
   <u>library@mbru.ac.ae</u>
- IRB Submission Inquiries
   <u>srenold@dubaihealth.ae</u>

# Appendix 1: BMJ Online Modules learning outcomes.

#### Module 1: How to develop and report good research questions

#### Course 1: Developing a good research question

Learning outcomes:

- $\rightarrow$  Identify and describe the characteristics of a good research question
- → Explain three key ingredients for developing a research question
- → Name and briefly describe the FINER criteria
- $\rightarrow$  Describe several sources from which good research questions arise
- $\rightarrow$  Draft a one-sentence research question and 1/2 page describing the significance of your research question

#### Course 2: Reporting the research question in your paper

Learning outcomes:

- ightarrow Understand the purpose of the introduction section
- → Explain what was known, and not known about the study's topic and about the specific research question
- → Report the study's research question clearly
- $\rightarrow$  Understand what makes a good research question
- $\rightarrow$  Use evidence based, effective writing to introduce the study
- → Use references/literature review effectively and sparingly.

#### Module 2: Developing and writing protocols

#### Course 1: How to write and publish a study protocol: overview

Learning outcomes:

- → Understand different meanings of the term "protocol"
- → Communicate the value of planned research
- → Appreciate the characteristics of a good research question
- → Match research questions to appropriate study designs
- $\rightarrow$  Identify strengths and weaknesses of published protocols.

#### Course 2: Clinical trial protocols: how to write and publish them

- → Understand the importance and limitations of trial registration
- → Choose the correct guideline for writing a protocol paper
- → Understand the key features of ICH GCP E6 and SPIRIT guidelines for reporting clinical trial protocols
- → Prepare a real clinical trial protocol for publication in a journal.

#### Course 3: How to write a research protocol for a grant application

Learning outcomes:

- $\rightarrow$  Understand when a research grant is needed
- $\boldsymbol{\rightarrow}$  Know how to prepare a grant application
- $\rightarrow$  Understand the principles of grant review
- → Appreciate why a research plan for funding must be based on a high quality study protocol
- $\rightarrow$  Use simple language when writing the research plan.

#### Course 4: Good medical writing

Learning outcomes:

- $\rightarrow$  How to tell the story of the study using IMRaD format
- ightarrow How to use structure, style, and language to write well
- → Writing in an evidence based style
- → "House style" at journals
- ightarrow Templates to facilitate writing and submission
- $\rightarrow$  When and how to use medical writing and translation services.

#### **Course 5: Choosing and citing references**

Learning outcomes:

- → Search published literature for appropriate references
- $\rightarrow$  Pick and read relevant references to support key statements
- → Cite accurately and fully, avoiding plagiarism
- → Beware of web references
- → Ignore or contest journal requests for "self-citation"
- → Follow journal advice, using Vancouver or Harvard style.

#### Module 3: Choosing the best study design

#### Course 1: Study design

Learning outcomes:

**Observational Studies** 

- → Define cohort studies
- → Distinguish between prospective and retrospective cohorts
- → Explain the nested case-control design and strategy
- → Describe the multiple-cohort design
- → Define cross-sectional studies
- → Explain why cross-sectional studies yield weaker evidence for causality than cohort studies
- → Define case-control studies and their benefits and problems
- → Describe case-crossover studies.

#### **Course 2: Studies of medical tests**

Learning outcomes:

→ Understand the definition of studies of medical tests and how these studies differ from therapeutic intervention trials or studies to assess causality

- $\rightarrow$  Explain how to select subjects for a study of a medical test
- → Understand how to measure reproducibility of a test including use of kappa and the coefficient of variation
- → Define key metrics to use in studies that assess the accuracy of a diagnostic test including sensitivity, specificity, predictive value, ROC curves, and likelihood ratios
- $\rightarrow$  Understand how to design studies of clinical prediction rules and the associated limitations and challenges with this design.

#### **Course 3: Enhancing causal inference**

Learning outcomes:

- ightarrow Describe cause-effect relationships and enumerate the four rival explanations
- → Identify ways to minimize chance
- → Discuss bias and identify ways to avoid bias
- → Identify ways to make confounding less likely
- → Offer several suggestions or strategies for incorporating opportunistic observational designs
- → Explain how causal inference can be enhanced by positive evidence.

#### Course 4: The methods: matching study designs to research questions

Learning outcomes:

- ightarrow Why the methods section is the most important part
- → How to report study methods accurately and fully
- → How to report methods to minimise bias and confounding
- $\rightarrow$  How to use reporting guidelines for different study types.

#### Course 5: Subjects and variables

Learning outcomes:

- → Define sample and population, and describe how sample and population inform all clinical research
- → Identify criteria for a target population
- → Compare and contrast approaches to sampling
- $\rightarrow$  Describe several strategies for recruiting a sample of subjects.

#### Course 6: Sample size and power

- $\rightarrow$  List the steps for estimating sample size for an analytic study
- → Explain other considerations in calculating sample size for analytic studies

- $\boldsymbol{\rightarrow}$  List the steps for estimating sample size for descriptive studies
- → Identify strategies to minimize the required sample size
- → Explain other strategies for estimating sample size when there is insufficient information

#### **Course 6: Statistics**

Learning outcomes:

- → List the steps for estimating sample size for an analytic study
- →Explain other considerations in calculating sample size for analytic studies
- →List the steps for estimating sample size for descriptive studies
- →Identify strategies to minimize the required sample size
- →Explain other strategies for estimating sample size when there is insufficient informatio

#### **Course 7: Statistics**

Learning outcomes:

- → Define and describe box models
- → Define and describe standard error
- → Define and describe p-values
- → Define null hypothesis
- $\rightarrow$  Select the appropriate statistical tests for your study.

#### **Course 8: Questionnaires and qualitative research**

Learning outcomes:

- $\rightarrow$  Describe steps an investigator can take to ensure that questionnaires and interviews are as valid and reproducible as possible
- → Define open-ended questions and closed-ended questions and devise several examples of both types of questions
- → Identify desirable question elements as well as pitfalls to avoid
- → Design a one-page instrument that is easy to read, easy to understand, and suitable for data entry.

Module 4: How to do ethical research

#### Course 1: Ethical considerations in research

Learning outcomes:

- → Discuss a brief history of research oversight
- → Review ethical principles and federal regulations
- $\rightarrow$  Explain institutional review board (IRB) approval
- → Define informed consent
- → Discuss scientific misconduct, authorship, conflicts of interest, and ethical issues in specific types of research.

#### **Course 2: History of research ethics**

Learning outcomes:

→ Identify the ethical code of principles for clinical research that has been adapted worldwide

 $\rightarrow$  Describe 3 key principles of clinical research identified in the Nuremberg Code

→ List the 4 ethical principles included in the 1964 Declaration of Helsinki (beyond the Nuremberg Code)

→ Describe what the 1966 NIH Ethical Review Policies obligated US research institutions to develop and institute.

#### Course 3: Institutional review board (IRB) and informed consent

Learning outcomes:

- → Discuss which types of clinical studies need institutional review board approval.
- → List 5 purposes of informed consent
- ightarrow Discuss how the Facebook case used or did not use the informed consent process
- ightarrow Discuss current problems with informed consent process and forms
- → Discuss 3 common misconceptions that participants may have even after the completing informed consent process
- $\rightarrow$  Discuss 3 different types of informed consent that might be used for studies with genetic materials.

#### Course 4: Ethics aspects of study methods

Learning outcomes:

- ightarrow Why and how ethics issues can affect study methods
- → How international guidelines on research ethics can affect study methods
- $\rightarrow$  How to report ethics aspects in the methods section of a research paper
- $\rightarrow$  Why medical journals mandate prospective registration of clinical trials, protection of patient confidentiality, and other ethics issues that affect study methods.

#### Course 5: Data and safety monitoring

Learning outcomes:

- → Identify potential safety issues related to your study
- →List at least three important duties of a quality control coordinator and/or data and safety monitor
- → Describe the function and operation of a Data and Safety Monitoring Board (DSMB).

#### **Course 6: Principles of research ethics**

Learning outcomes:

- → Describe 4 ethical principles for clinical trials
- $\rightarrow$  List 3 ethical principles that were violated during the Tuskegee Study.
- → Describe issues of beneficence in the TGN 1412 Study.

#### Course 7: Ethics in Big data research

- $\rightarrow$  List the four core values that are at stake in Big Data Research
- → List 7 fields of study included in Big Data Research

 $\rightarrow$  Discuss researchers' ethical obligations regarding the return of results to participants

→ Describe the Ten Simple Rules regarding responsible conduct of research in your country.

#### Course 8: Research in resource-poor environments

#### Learning outcomes:

- → Explain why use of placebos in clinical trials may be unethical in developing countries
- → Discuss issues related to provision of background and ancillary care, informed consent, access to the study intervention after the trial, and collaboration with host-country stakeholders.

#### Module 5: How to write a research paper

#### Course1: Reporting statistical methods and analyses

Learning outcomes:

- ightarrow Report statistical methods and analyses clearly
- → Follow the Statistical Analyses and Methods in the Published Literature (SAMPL) guidelines on reporting statistics
- $\rightarrow$  Better understand journal resources and policies on statistical methods
- → Learn from examples of good reporting.

#### Course 2: The results: reporting all findings succinctly

Learning outcomes:

- ightarrow Why the results section is less important than you think
- $\rightarrow$  How to report study results accurately and fully
- ightarrow Pitfalls of reporting results on associations and risks
- ightarrow How to use reporting guidelines for the results of different study types
- $\rightarrow$  Using tables and figures
- → Using supplemental files
- → Options for data sharing.

#### Course 3: Scientific transparency: the pitfalls of selective reporting

Learning outcomes:

- → Why selective reporting of research is wasteful and unethical
- $\rightarrow$  How research waste is bad for health
- → Why clinical trial registration is so important
- $\rightarrow$  How to make research reproducible
- → What we can all do to make research more transparent: research funders and governments; ethics

committees; drug, devices, and diagnostics industries; journals; authors.

#### Course 4: The discussion: using structure and balance

Learning outcomes:

→ Understand the purpose of the discussion section

- $\rightarrow$  Understand the elements of a structured discussion
- $\boldsymbol{\rightarrow}$  Appreciate the need for a balanced, self critical discussion
- $\boldsymbol{\rightarrow}$  Discuss the results of "negative studies" and observational studies
- $\rightarrow$  Explain what was known, and what the study's results add
- $\boldsymbol{\rightarrow}$  Use evidence based, effective writing to interpret the results and recommend next steps

# Course 5: Optimising the abstract and title

Learning outcomes:

- ightarrow Why abstracts of research papers must be accurate and clear
- ightarrow How to use international, evidence based guidelines on preparing abstracts for different study designs
- $\rightarrow$  How to report the PICO elements of a study in the abstract
- $\rightarrow$  How to write an informative, effective title for a research paper.

Module 6: The essentials of running a clinical trial

# Course 1: Course overview and trial designs

Learning outcomes:

- ightarrow Define randomized controlled trial
- ightarrow Identify three alternative study designs to randomized controlled trials
- ightarrow Identify five reasons for not conducting randomized controlled clinical trials
- ightarrow Identify four reasons for conducting randomized controlled clinical trials
- ightarrow Describe four randomized trial designs.

# Course 2: Selection of participants

Learning outcomes:

- $\rightarrow$  Explain why it is important to develop detailed and specific eligibility criteria in a clinical trial
- →Describe advantages and disadvantages of defining a broader versus narrower population in a trial
- → Describe at least three appropriate reasons for excluding participants from a clinical trial.

# Course 3: Recruitment

Learning outcomes:

- $\rightarrow$  Describe two goals of recruitment
- ightarrow Identify two study design issues
- ightarrow Identify three strategies to recruit appropriately
- → Identify four recruitment methods.

# Course 4: Choosing the interventions and controls

- ightarrow Describe aspects of the experimental intervention that should be defined in the planning stages of a trial
- ightarrow Identify at least three important functions of a control or comparator intervention in a trial

→ Assess the strengths and weaknesses of common controls for pharmacologic, surgical, or behavioral interventions.

#### **Course 5: Randomization**

Learning outcomes:

- → Describe the importance of randomization in clinical trials
- → Describe simple randomization
- → Describe randomized permuted blocks.

#### Course 6: Blinding

Learning outcomes:

- → Define blinding and identify ways to blind many interventions
- ightarrow Identify three ways that blinding minimizes potential bias for
- ightarrow Identify four types of interventions that cannot be blinded
- $\rightarrow$  Describe strategies to implement if the study cannot be blinded.

#### Course 7: Outcome measures

Learning outcomes:

- $\rightarrow$  Describe at least two reasons for using one primary outcome
- → Identify two types of data that support that a measure is a 'valid' surrogate marker for treatment
- → Identify the main criterion for determining whether a marker is a valid 'surrogate' endpoint
- → Describe two pros and cons for using composite outcomes.

#### Course 8: Assessing safety

Learning outcomes:

- → Define a serious adverse event
- → Describe one pro and con of elicited vs volunteered adverse events
- → Describe reasons for using a formal adjudication process for clinical outcomes
- → Identify one disadvantage of adjudication.

#### Course 9: Adherence and complete follow up

- $\rightarrow$  Describe two important reasons for adherence to the protocol
- ightarrow Describe five ways that adherence can be measured
- ightarrow Identify two ways to maximize adherence to the protocol
- $\rightarrow$  Identify four ways to maximize follow up
- → Describe three analytic techniques to use for poor compliance during a trial
- → Describe two effects of non-adherence.

#### **Course 10: Ethical issues in clinical trials**

Learning outcomes:

- $\rightarrow$  Identify ethical issues in clinical trials
- → Describe factors for acceptability of random assignment to a treatment
- → Define interim monitoring
- → Describe two basic goals of interim monitoring in a blinded trial
- $\rightarrow$  List four reasons to stop a trial early
- → List four components of a data monitoring plan
- → Describe conflict of interest issues in clinical trials
- → Describe three ways of performing scientific misconduct
- $\rightarrow$  Define contributions needed to qualify as an author on manuscript.

#### **Course 11: Regulatory issues**

Learning outcomes:

- $\rightarrow$  Define regulations that apply to clinical trials
- → Describe good clinical practice.

#### Course 12: How to write up industry-sponsored trials

Learning outcomes:

- $\rightarrow$  The evidence on misreporting of industry trials
- $\rightarrow$  Potential pitfalls of using composite end points in trials
- → Reporting of authorship for industry studies
- $\rightarrow$  How to report industry trials transparently
- $\rightarrow$  Good publication practice (GPP3) for industry studies.

Module 7: Picking the right journal and getting published

#### Course 1: Navigating journal and peer review processes

Learning outcomes:

- → Key points to consider when choosing a journal
- → Tips on choosing between local, and national, and international journals
- → What the term "indexed journal" means
- → Measures of impact, particularly journal impact factor
- → Publishing with open access
- → Typical peer review process
- → How journals try to minimise bias in peer review
- → Research evidence for different kinds of peer review
- → How to avoid predatory journals.

#### **Course 2: Compliance with journal and ICMJE requirements**

- ightarrow Why journals vary widely and have different editorial policies
- $\rightarrow$  Core requirements for all medical journals
- → The Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals from the International Committee of Medical Journal Editors (ICMJE)
- → Importance of key ICMJE policies (on authorship, conflicts of interest, clinical trial transparency)
- $\rightarrow$  Overview of the authorship rules and the role of the corresponding author
- → The rules on clinical trial registration
- → Examples of specific journal policies eg The BMJ's patient review of research.

#### **Course 3: Patients' consent for publication**

Learning outcomes:

- $\rightarrow$  Why consent to publication about potentially identifiable living patients matters
- $\rightarrow$  Circumstances in which journals need such consent to publication
- → How journals handle consent, and what they do when consent is unavailable or privacy is breached
- $\rightarrow$  Policies, regulations, and laws that protect study participants' privacy.

#### **Course 4: Surviving peer review**

Learning outcomes:

- $\rightarrow$  How to submit an article
- → Typical author journey through the peer review process
- → Roles and responsibilities of authors, editors, and reviewers during peer review
- $\rightarrow$  Why ORCID (open researcher and contributor ID) is useful
- → What peer reviewers do
- ightarrow How to respond to comments and revise the manuscript
- → What happens after manuscript acceptance
- $\rightarrow$  How to approve proofs
- $\rightarrow$  Working with the media
- → Using social media to disseminate research
- $\rightarrow$  When to respond to post publication peer review.

#### Course 5: What to do with rejections and appeals

- $\rightarrow$  Why journals reject research
- → Evidence on what might lead to rejection
- $\rightarrow$  How to interpret rejection letters
- $\rightarrow$  What to do after rejection
- $\rightarrow$  Waste in research and how to avoid it
- $\rightarrow$  When and how to appeal against rejection.

#### **Course 6: Pre-submission inquiries and cover letters**

Learning outcomes:

→ Why a presubmission inquiry can increase the efficiency and success of peer review for both authors and editors

- $\rightarrow$  When to make a presubmission inquiry
- $\rightarrow$  Key elements of a presubmission inquiry
- ightarrow How to write the cover letter when submitting research
- → When and how to disclose overlapping and prior publication
- $\rightarrow$  When and how to request fast track peer review.

#### Module 8: Avoiding scientific misconduct

#### Course 1: Scientific misconduct, authorship and conflict of interest

Learning outcomes:

- ightarrow Describe the purpose of and criteria for authorship
- → Explain how disputes over authorship might be prevented and/or resolved
- → Define conflicts of interest
- → Discuss how failure of reproducibility may indicate scientific misconduct
- → Discuss how research misconduct may introduce bias into the research findings.

#### **Course 2: Reporting conflicts of interest**

Learning outcomes:

- $\rightarrow$  Why it is necessary to declare conflicts of interest (COI)
- → Definitions of COI
- $\rightarrow$  Potential COI in health services research
- ightarrow Potential COI in industry-sponsored research
- → Public reporting of industry payments to health professionals
- → Handling COI for other types of journal article
- → Potential COI for editors, journals, and publishers.

#### Course 3: Journal rules on authorship

Learning outcomes:

- → Authorship: how it is defined, and why it matters
- → How MEDLINE and journals list authors
- → Journal policies and practices to safeguard authorship
- → Guest, gift, and ghost authors and other authorship problems
- $\rightarrow$  Attribution for shared datasets.

#### Course 4: How and why to avoid plagiarism

- ightarrow How plagiarism and text recycling are defined
- → How common plagiarism is
- → Factors associated with plagiarism
- $\rightarrow$  Use of plagiarism detection tools by publishers
- $\rightarrow$  How to avoid plagiarism and how to respond if caught.

#### Course 5: How journals uncover scientific fraud

Learning outcomes:

- ightarrow Scientific fraud as data fabrication and deliberate falsification
- ightarrow The extent and harms of scientific fraud
- → Techniques journals may use to uncover fraud: statistical analysis, mage checking, linguistic analysis,

investigative journalism, peer review (pre- and post-publication), data sharing.

- → Barriers to tackling fraud
- $\rightarrow$  Principles of research integrity.

#### Course 6: How journals act on scientific misconduct

- ightarrow How and why journals respond to suspected misconduct that relates to submitted and published articles
- $\rightarrow$  The role of the Committee on Publication Ethics (COPE)
- → The roles of authors' institutions and research integrity organisations in investigating possible misconduct
- $\rightarrow$  Reasons for, and impacts of, retractions in biomedical and health research
- → How MEDLINE corrects the literature.