



Curriculum Guide for Undergraduates and New Researchers



This curriculum guide is designed to help you get the best out of Research to Publication, taking you through the concepts you need to develop mastery in the areas of investigation and research.

Simply click on the titles below to get started:

[Developing and reporting good research questions](#)

[Making the best start to your research and publishing](#)

[Picking the best study designs and methods](#)

[Ensuring and reporting research ethics](#)

[How to write research papers that can be trusted and used](#)

[Special considerations for conducting clinical trials](#)

[Submitting research to a journal and achieving publication](#)

[Understanding and avoiding scientific misconduct](#)

Developing and reporting good research questions

Course introduction and the research question

Learning outcomes:

- 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
- Describe several sources from which good research questions arise
- Draft a one-sentence research question and 1/2 page describing the significance of your research question.

The introduction: presenting the research question

Learning outcomes:

- 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
- Understand what makes a good research question
- Use evidence based, effective writing to introduce the study
- Use references/literature review effectively and sparingly.

Additional Resource:

[Video/webinar by Trish Groves](#): How to develop and communicate good research questions

Making the best start to your research and publishing

How to write and publish a study protocol

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
- Evaluate examples of published protocols
- Understand importance and limitations of trial registration
- Choose the correct guideline for writing a protocol paper
- Describe key features of ICH GCP E6 and SPIRIT guidelines for reporting clinical trial protocols
- Understand how to prepare a real study protocol for publication in a journal.

Good medical writing

Learning outcomes:

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

Choosing and citing references

Learning outcomes:

- Search published literature for appropriate references
- 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.

Picking the best study designs and methods

Study design

Learning outcomes:

- 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.

Enhancing causal inference

Learning outcomes:

- 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.

The methods: matching study designs to research questions

Learning outcomes:

- 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
- How to use reporting guidelines for different study types.

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
- Describe several strategies for recruiting a sample of subjects.

Sample size and power

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 information

Statistics

Learning outcomes:

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

Questionnaires and qualitative research

Learning outcomes:

- 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.

Ensuring and reporting research ethics

Ethical considerations in research

Learning outcomes:

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

Introduction and overview of regulations

Learning outcomes:

- Identify the key features of the US federal regulations for human subjects research
- Identify the types of research that are subject to the Common Rule
- List six criteria that must be satisfied for institutional review board approval prior to a study
- Describe how you would evaluate and optimize risks and benefits for a study in your research area
- Identify five important ways to discuss benefits and risks with study participants.

Informed consent and related issues

Learning outcomes:

- Define informed consent
- List six information elements researchers must disclose to participants
- Describe at least three examples of vulnerable populations or participants
- Define the HIPAA Health Privacy Rule
- Discuss an ethical rationale for exceptions to consent.

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).

Ethics aspects of study methods

Learning outcomes:

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

Conflicts of interest

Learning outcomes:

- Define conflicts of interest
- Discuss the association between conflicts of interest and bias in research projects
- Discuss how and under what circumstances disclosure, management, and prohibition are appropriate responses to conflicts of interest.

Reporting conflicts of interest

Learning outcomes:

- Why it is necessary to declare conflicts of interest (COI)
- Definitions of COI
- Potential COI in health services research
- 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.

Ethics in Big data and ‘precision medicine’

Learning outcomes:

- Discuss potential ethical opportunities and challenges in “precision medicine” and data sharing
- Discuss authors’ ethical obligations regarding sharing research materials and data
- Discuss researchers’ ethical obligations regarding the return of results to participants.

Research in resource-poor environments

Learning outcomes:

- Describe how research in resource-poor countries differs from research in the US
- 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.

How to write research papers that can be trusted and used

Reporting statistical methods and analyses

Learning outcomes:

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

The results: reporting all findings succinctly

Learning outcomes:

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

Scientific transparency: the pitfalls of selective reporting

Learning outcomes:

- Why selective reporting of research is wasteful and unethical
- How research waste is bad for health
- Why clinical trial registration is so important
- 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.

The discussion: using structure and balance

Learning outcomes:

- Understand the purpose of the discussion section
- Understand the elements of a structured discussion
- Appreciate the need for a balanced, self critical discussion
- Discuss the results of “negative studies” and observational studies
- Explain what was known, and what the study’s results add
- Use evidence based, effective writing to interpret the results and recommend next steps

Optimising the abstract and title

Learning outcomes:

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

Quick refresher:

[The introduction: presenting the research question](#)

[The methods: matching study designs to research questions](#)

[Ethics aspects of study methods](#)

Special considerations for conducting clinical trials

Introduction to randomized blinded trials

Learning outcomes:

- Define randomized blinded trials
- Explain how to design RBTs
- Describe how to choose the intervention and control conditions
- Describe how to define outcomes and adverse effects
- Describe how to select participants
- Describe how to measure baseline and outcome variables
- Evaluate approaches to randomizing and blinding.

Course overview and trial designs

Learning outcomes:

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

Selection of participants

Learning outcomes:

- 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.

Recruitment

Learning outcomes:

- Describe two goals of recruitment
- Identify two study design issues
- Identify three strategies to recruit appropriately
- Identify four recruitment methods.

Choosing the interventions and controls

Learning outcomes:

- Describe aspects of the experimental intervention that should be defined in the planning stages of a trial
- 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.

Randomization

Learning outcomes:

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

Blinding

Learning outcomes:

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

Outcome measures

Learning outcomes:

- 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.

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.

Adherence and complete follow up

Learning outcomes:

- Describe two important reasons for adherence to the protocol
- Describe five ways that adherence can be measured
- Identify two ways to maximize adherence to the protocol
- 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.

Ethical issues in clinical trials

Learning outcomes:

- 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
- 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
- Define contributions needed to qualify as an author on manuscript.

Regulatory issues

Learning outcomes:

- Define regulations that apply to clinical trials
- Describe good clinical practice.

Submitting research to a journal and achieving publication

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.

Compliance with journal and ICMJE requirements

Learning outcomes:

- Why journals vary widely and have different editorial policies
- 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)
- 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.

Patients' consent for publication

Learning outcomes:

- Why consent to publication about potentially identifiable living patients matters
- 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
- Policies, regulations, and laws that protect study participants' privacy.

Surviving peer review

Learning outcomes:

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

What to do with rejections and appeals

Learning outcomes:

- Why journals reject research
- Evidence on what might lead to rejection

- How to interpret rejection letters
- What to do after rejection
- Waste in research and how to avoid it
- When and how to appeal against rejection.

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

Understanding and avoiding scientific misconduct

Authorship and research misconduct

Learning outcomes:

- Describe the purpose of and criteria for authorship
- Explain how disputes over authorship might be resolved
- Define the federal standards for research misconduct
- Describe at least three warning signs of research misconduct
- Discuss how institutions should respond to allegations of research misconduct.

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
- Attribution for shared datasets.

How and why to avoid plagiarism

Learning outcomes:

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

How journals uncover scientific fraud

Learning outcomes:

- Scientific fraud as data fabrication and deliberate falsification
- The extent and harms of scientific fraud
- Techniques journals may use to uncover fraud: statistical analysis, image checking, linguistic analysis, investigative journalism, peer review (pre- and post-publication), data sharing.
- Barriers to tackling fraud
- Principles of research integrity.

How journals act on scientific misconduct

Learning outcomes:

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

About Research to Publication:

Research to Publication is a research methodology programme for early career academics in healthcare research, brought to you by BMJ in collaboration with University of California, San Francisco (UCSF).

The programme is focused entirely on medical research; BMJ's research editors and UCSF's academics guide learners through the entire process from designing a study, to seeing it published in an international journal.

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