Research reporting: from principles to practicalities

Iveta Simera

The EQUATOR Network

Centre for Statistics in Medicine, Oxford, UK

What we learned so far

- **A published research article (research report) is the only tangible evidence that the study was done**

- **General principle for reporting experimental studies**
  - Experiment should be described in a way that makes it possible for the reader to repeat it
  - Statistical analysis should present enough details to allow reader with access to original data to verify reported results

    (Ranstam 2010, quoting paper by Festing & Altman, 2002)

- **Scientific manuscripts should present sufficient data so that the reader can fully assess reliability and relevance of the presented information**

Declaration of Helsinki

- **Basic principles for all medical research**

"Authors, editors and publishers all have ethical obligations with regard to the publication of the results of research. Authors have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. They should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results should be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest should be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication."

Where to find information

- **What are the ‘rules’ I need to observe to successfully publish my research?**

- **Where to find help on how to apply these ‘rules’ in practice?**

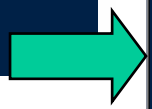
…. Good starting point

– Your research institution website – University of Oxford

– Your research funder’s website – MRC, Wellcome Trust, NIHR,..

University of Oxford: Research services http://www.admin.ox.ac.uk/rso/

Property (IP)
- Research Integrity
- Clinical Trials & Research Governance
- FAQs



UNIVERSITY OF OXFORD

- Research Services
- About Us
- Contact Us
- Research Income and Activity
- News*
- Review and Improvement Programme
- Consultations*
- Knowledge Exchange*
- Sponsor Information
- Find Funding
- Applying for Funding
- Preparing your Budget
- Research Contracts
- Consulting Activity
- Post-award Administration
- Intellectual Property (IP)
- Research Integrity
- Clinical Trials & Research Governance
- FAQs
- Links

SEARCH ADMIN WEB Search Go!

Welcome to the Research Services Website

Research Services

News: Successful Impact Summaries revealed by Freedom of Information Act
The Times Higher Education recently published impact summaries submitted to AHRC, ESRC, EPSRC and STFC that they obtained by Freedom of Information Act requests. The documents include all successful impact summaries submitted to the Councils from the date of introduction of the impact requirements until 4th November 2009.

For further details please see our Knowledge Exchange page.

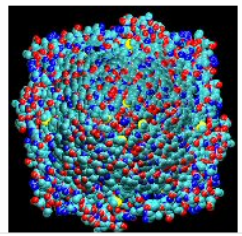
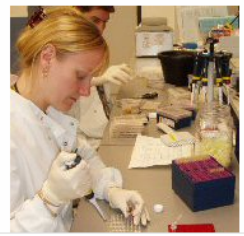
Research Services works in partnership with academic divisions, departments/faculties, University Administration and Services (UAS) and Isis Innovation Ltd to support Oxford's researchers and facilitate world-class research and knowledge exchange.

Our major responsibilities include supporting the grant process, including advice and information on funding opportunities, reviewing and authorising research grant applications, accepting new awards, and sponsor liaison; negotiating research-related contracts; advising on the costing and pricing of research at Oxford; supporting University and Divisional research-related planning; promoting the responsible conduct of research and compliance with regulatory and sponsor requirements; facilitating knowledge transfer; and the continuous improvement of research administration at Oxford.

Please use the menu on the left-hand side to access specific parts of the website, including About Us (about our remit and the help and support we can provide) and our Contact Details.

Please visit the University website for information about Oxford's research, research training, and enterprise development activities.

*Access to some parts of this site is restricted to members of the University of Oxford who are logged on to the ox.ac.uk network. These pages are identified by an asterisk next to the relevant link.


equator network

UNIVERSITY OF OXFORD

- Research Services
- About Us
- Contact Us
- Research Income and Activity
- News*
- Review and Improvement Programme
- Consultations*
- Knowledge Exchange*
- Sponsor Information
- Find Funding
- Applying for Funding
- Preparing your Budget
- Research Contracts
- Consulting Activity
- Post-award Administration
- Intellectual Property (IP)
- Research Integrity
- Clinical Trials & Research Governance
- FAQs
- Links

Research Integrity

Research Services

The University of Oxford is dedicated to the highest standards of research integrity. As set out in its Academic Integrity in Research: Code of Practice and Procedure, it expects all members of the University including staff and students, and those who are not members of the University but who are conducting research on University premises or using University facilities, to observe the highest standards in the conduct of their research.

This website provides links to the relevant University policies, guidelines and procedures which are intended to promote the responsible conduct of research in the University's ongoing research activities.

****New** Research Integrity Seminar Series**

A seminar series for Oxford staff and students and NHS colleagues, with a range of top speakers.

Free. Lunch provided. Commences 22 September.

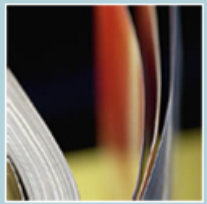
Please see the training page for details of the program.

Supported by the Biomedical Research Centre

- Conflict of Interest
- Data Management
- Health and Safety
- Human Subjects Research
- Intellectual Property
- Mentoring
- Peer Review
- Publication and Authorship
- Research involving Animals
- Research Misconduct
- Research funders' policies
- Training

OUR RESEARCH

Ethics and research guidance



MRC-funded research must comply with these guidelines to ensure work is of a high scientific standard, is conducted safely, and respects the wishes and integrity of any patients or volunteers involved.

MRC policy: Good Research Practice
6. Reporting the results

The policy states as unethical:

Delay publication

Not to report results or exaggerate their importance

Reports should contain basic information about ethical acceptability of the work and about the scientific methods

Authorship

Coherent publication (not in small parts)

Quality is paramount not quantity

Authors must not publish the same data in more than one journal

Less than 2 pages!

Just basic principles

… where to find more information?

6 Reporting the results

Once any issues of confidentiality and ownership have been addressed (see 7), research findings should be disseminated so that they can be assessed by scientific peers and more widely. This is essential if scientific knowledge is to be used appropriately and effectively. Accordingly, researchers should publish their data in a timely fashion in a peer-reviewed journal or in other equally reputable publications and/or present their results at scientific meetings.

It is equally unethical not to report results, or to exaggerate the importance of results for medical practice or policy. Both are areas in which a researcher's desire for advancement or recognition may conflict directly with the public interest in a complete, balanced, and rigorous account of the scientific evidence.

6.1 Publication policy

- The person with overall responsibility for the research programme should authorise publication of results; authorisation should cover both the before the research is initiated to cover the free dissemination of research findings; this is especially important where funding has been secured from industry.

- Published reports should normally contain basic information about the ethical acceptability of the work and/or its legality, as well as information about the scientific method.

- The leader of the research team should authorise any release of the results on the Internet. Releasing information in this way may well compromise intellectual property rights, so there should be a suitable mechanism to monitor information placed on the web.

6.2 Authorship

- Authorship of papers should include those individuals who have made a

Journals' Instructions to Authors

- **Vary greatly in length and content of advice they give to authors**
  - Some provide very clear and specific guidance on how they want researchers to describe their study in the manuscript, including methods, analyses and findings
  - Some focus only on 'technical' side of the paper (references and pictures format)
    - Schriger et al. Ann Emerg Med 2006; 48:743-9

- **"Uniform requirements for manuscript submitted to biomedical journals: writing and editing for biomedical publication"**
  - Developed by the International Committee of Medical J Editors
  - Endorsed by a large number of journals
  - Should be basic reading for all authors – good general guidance

Reporting guidelines

- **More specific guidance for reporting different types of research studies or particular aspects of research is provided by reporting guidelines**
- **Reporting guidelines specify a minimum set of items required for a clear and transparent account of what was done and what was found in a research study, reflecting in particular issues that might introduce bias into the research**
- **Evidence-based & reflect consensus opinion**
- **Benefits of using RG:**
  - Improved accuracy and transparency of publications
  - Easier appraisal of reports for research quality and relevance
  - Improved efficiency of literature searching

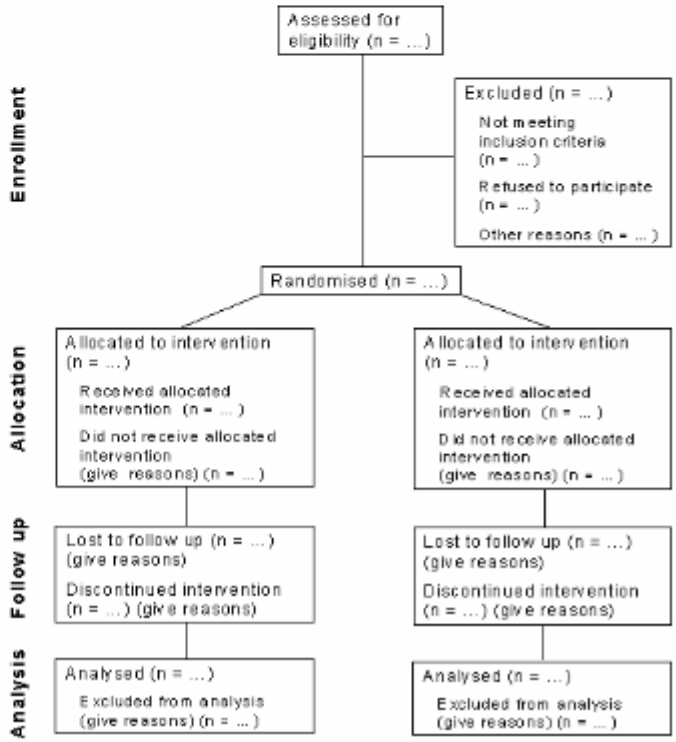
CONSORT 2001 Checklist

www.consort-statement.org

Section / topic	#	Descriptor	Reported on page #
TITLE & ABSTRACT			
Title & abstract	1	How participants were allocated to interventions (*e.g.*, "random allocation", "randomized", or "randomly assigned").	
INTRODUCTION			
Background	2	Scientific background and explanation of rationale.	
METHODS			
Participants	3	Eligibility criteria for participants and the settings and locations where the data were collected.	
Interventions	4	Precise details of the interventions intended for each group and how and when they were actually administered.	
Objectives	5	Specific objectives and hypotheses.	
Outcomes	6	Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (*e.g.*, multiple observations, training of assessors).	
Sample size	7	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules.	
Randomization -- Sequence generation	8	Method used to generate the random allocation sequence, including details of any restrictions (*e.g.*, blocking, stratification)	
Randomization -- Allocation concealment	9	Method used to implement the random allocation sequence (*e.g.*, numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned.	
Randomization -- Implementation	10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups.	
Blinding (masking)	11	Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment. If done, how the success of blinding was evaluated.	
Statistical methods	12	Statistical methods used to compare groups for primary outcome(s); Methods for additional analyses, such as subgroup analyses and adjusted analyses.	
RESULTS			
Participant flow	13	Flow of participants through each stage (a diagram is strongly recommended). Specifically, for each group report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome. Describe protocol deviations from study as planned, together with reasons.	
Recruitment	14	Dates defining the periods of recruitment and follow-up.	
Baseline data	15	Baseline demographic and clinical characteristics of each group.	
Numbers analyzed	16	Number of participants (denominator) in each group included in each analysis and whether the analysis was by "intention-to-treat". State the results in absolute numbers when feasible (*e.g.*, 10/20, not 50%).	

Section / topic	#	Descriptor	Reported on page #
Outcomes and estimation	17	For each primary and secondary outcome, a summary of results for each group, and the estimated effect size and its precision (*e.g.*, 95% confidence interval).	
Ancillary analyses	18	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those pre-specified and those exploratory.	
Adverse events	19	All important adverse events or side effects in each intervention group.	
DISCUSSION			
Interpretation	20	Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision and the dangers associated with multiplicity of analyses and outcomes.	
Generalizability	21	Generalizability (external validity) of the trial findings.	
Overall evidence	22	General interpretation of the results in the context of current evidence.	

CONSORT 2001 Flow Diagram



From: Moher D, Schulz KF, Altman DG. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomised trials. Lancet 2001; 357(9263):1191-1194.

Other reporting guidelines

- **PRISMA (SR / meta-analyses of RCTs)**
- **STARD (diagnostic studies)**
- **STROBE (observational studies)**
- **STREGA (genetic association studies)**

… and many others (over 90 identified by EQUATOR)

EQUATOR (Enhancing the QUAlity and Transparency Of health Research)

- Enhance the value of health research literature by promoting responsible reporting of research studies
- Free online resources and training

Welcome to the EQUATOR Network website – the resource centre for good reporting of health research studies

Too often, good research evidence is undermined by poor quality reporting.

The EQUATOR Network is an international initiative that seeks to improve reliability and value of medical research literature by promoting transparent and accurate reporting of research studies.

Highlights

Seeking funding and support

We appeal to research funders, publishers and other organisations to support responsible research reporting. Find out how

Promote good reporting

Find out how you can help

EQUATOR Newsletter

New reporting guidelines, events, and other news. **Subscribe** now

Latest news

more news

Guidance for developers of health research reporting guidelines

PLoS Medicine has published a guidance paper written by the EQUATOR team.

Read the full story

Reporting guidelines

Library for Health Research Reporting

Authors

Information for authors of research reports

Editors

Resources for journal editors and peer reviewers

Developers

Resources for developers of reporting guidelines

The EQUATOR Network is funded by:

MRC Medical Research Council | CIHR IRSC | NHS

Resource Centre

- Library for health research reporting
  - Reporting Guidelines
  - Reporting guidelines under development
  - Guidance on scientific writing
  - Guidance developed by editorial groups
  - Medical writers – additional resources
  - Research ethics, publication ethics and good practice guidelines
  - Development and maintenance of reporting guidelines
  - Editorials introducing RGs
  - Examples of guidelines for peer reviewers
  - Case studies: RG implementation

Library for health research reporting

The EQUATOR Network library currently contains:

- An introduction to reporting guidelines
- Comprehensive lists of the available reporting guidelines, listed by study type:
  - Experimental studies
  - Observational studies
  - Diagnostic accuracy studies
  - Systematic reviews
  - Qualitative research
  - Economic evaluations
  - Quality improvement studies
  - Other reporting guidelines
  - Sections of research reports
  - Specific conditions or procedures.
- Reporting guidelines under development
- Guidance on scientific writing
- Guidance developed by editorial groups
- Medical writers – additional resources
- Research ethics, publication ethics and good practice guidelines
- Resources related to development and maintenance of reporting guidelines
- Editorials introducing reporting guidelines
- Guidelines for peer reviewers
- Case studies: How journals implement reporting guidelines
- Examples of good research reporting
- Useful and interesting presentations
- EQUATOR 'pick' – comments, discussion and other thought provoking articles and interesting quotes

Download the most frequently–used reporting guidelines:

- CONSORT checklist
- CONSORT flowchart
- CONSORT extensions
- STARD checklist & flowchart
- STROBE checklists
- PRISMA checklist
- PRISMA flow diagram

Download:

- Catalogue of reporting guidelines (Jan 2010)

Resource Centre

Library for health research reporting

Authors of research reports

Editors and peer reviewers

Reporting guidelines developers

Promote responsible reporting

Monitoring use of our resources

Links

Resources for authors

The following resources will help you to produce high quality research publications:

- Planning and conducting your research
- Writing up your research
- Medical writers – additional resources
- Ethical guidelines and considerations
- Other resources

- What can I do to support the EQUATOR Network's effort

Planning and conducting your research

It is important to be aware of reporting requirements and think about reporting when you are planning and conducting your research study:

- UK National Health System Research Flowchart (tool providing resources and points for consideration for all stages of the research process: from formulating a research question to the reporting and dissemination of new findings)
- UK MRC Route Map (Medical Research Council guidance through the legal and good practice requirements when designing conducting and disseminating experimental medicine studies)

Writing up your research

A good scientific article combines clear writing style with a high standard of reporting of the research content:

- Guidance on scientific writing
- Reporting guidelines (comprehensive lists of the available guidelines appropriate to each study type)
- Examples of good research reporting (specific examples showing why and how to correctly describe important aspects of your trial or other types of research studies)

equator network

Search: Go

Enhancing the QUAlity and Transparency Of health Research

Home | About EQUATOR | Resource Centre | Courses Events | Research Projects | Contact | News | Forum

- Resource Centre
- Library for health research reporting
- Authors of research reports
- Editors and peer reviewers
- Reporting guidelines developers
- Promote responsible reporting
- Monitoring use of our resources
- Links

Resources for authors

The following resources will help you to produce high quality research publications:

- Planning and conducting your research
- Writing up your research
- Medical writers – additional resources
- Ethical guidelines and considerations
- Other resources

- What can I do to support the EQUATOR Network's effort

Planning and conducting your research

It is important to be aware of reporting requirements and think about reporting when you are planning and conducting your research study:

- UK National Health System Research Flowchart (tool providing resources and points for consideration for all stages of the research process: from formulating a research question to the reporting and dissemination of new findings)
- UK MRC Route Map (Medical Research Council guidance through the legal and good practice requirements when designing co
medicine studies)

Writing up your research

A good scientific article combines clear writing
the research content:

- Guidance on scientific writing
- Reporting guidelines (comprehensive lists
each study type)
- Examples of good research reporting (specific examples showing why and how to correctly describe important aspects of your trial or other types of research studies)

Knowing what information you need to include in the research report will help you to organise your research methods, notes and findings for publication

Writing up your research

A good scientific article combines clear
the research content:

- Guidance on scientific writing
- Reporting guidelines (comprehen
  each study type)
- Examples of good research reporting (specific amples showing why and how to correctly describe important aspects of your t or other types of research studies)

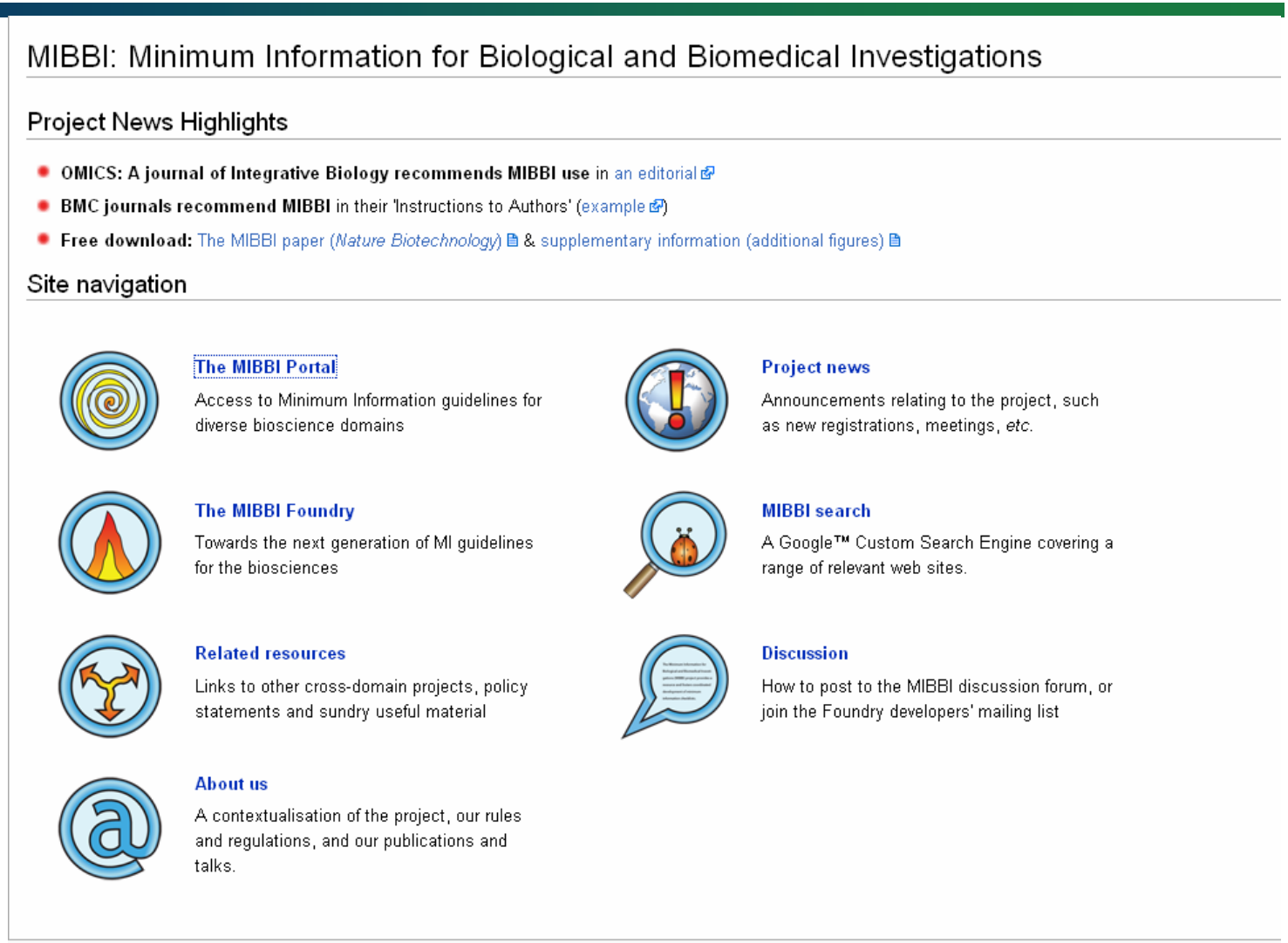
Another important point:

Have reader (users) of your article in mind when writing your manuscript

Tip: **When you finish your writing ...**

When published, your article will start a new independent life – it will be read and critically appraised, and it may contribute to systematic reviews, inform clinical guidelines, and influence clinical practice, etc. So, before you submit your paper to a journal, try to consider whether the article is 'fit for purpose' and able to pass this future scrutiny, e.g. will a Cochrane reviewer be able to identify your study's methods to assess risk of bias (Cochrane handbook, Table 8.5.a); can numerical results be extracted from your paper without any ambiguity; have you provided enough details about your intervention to allow its use in clinical practice; etc.

Reporting biological and biomedical laboratory studies (focus on data)



MIBBI: Minimum Information for Biological and Biomedical Investigations

Project News Highlights

- **OMICS: A Journal of Integrative Biology recommends MIBBI use** in an editorial
- **BMC journals recommend MIBBI** in their 'Instructions to Authors' (example)
- **Free download:** The MIBBI paper (*Nature Biotechnology*) & supplementary information (additional figures)

Site navigation

The MIBBI Portal
Access to Minimum Information guidelines for diverse bioscience domains

Project news
Announcements relating to the project, such as new registrations, meetings, *etc.*

The MIBBI Foundry
Towards the next generation of MI guidelines for the biosciences

MIBBI search
A Google™ Custom Search Engine covering a range of relevant web sites.

Related resources
Links to other cross-domain projects, policy statements and sundry useful material

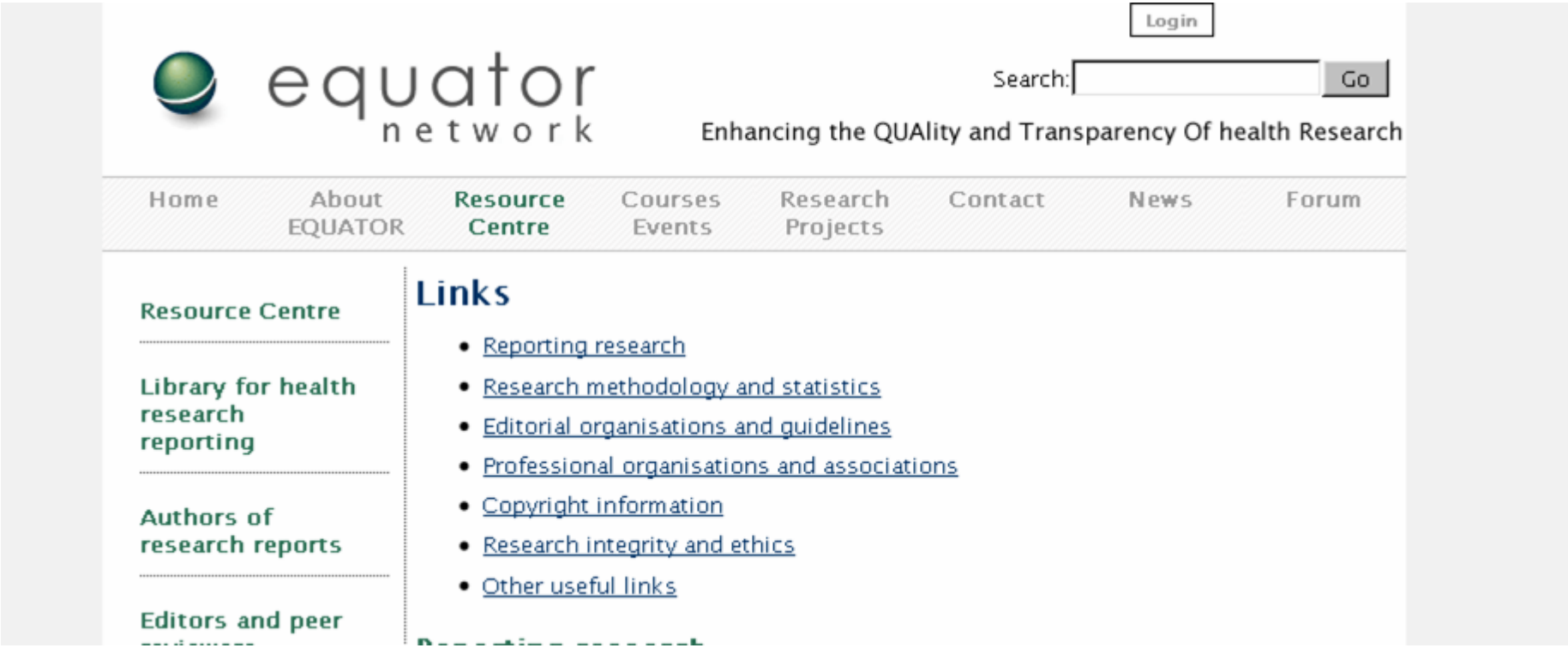
Discussion
How to post to the MIBBI discussion forum, or join the Foundry developers' mailing list

About us
A contextualisation of the project, our rules and regulations, and our publications and talks.

MI projects registered with MIBBI

CIMR	Core Information for Metabolomics Reporting
MIABE	Minimal Information About a Bioactive Entity
MIACA	Minimal Information About a Cellular Assay
MIAME	Minimum Information About a Microarray Experiment
MIAME/Env	MIAME / Environmental transcriptomic experiment
MIAME/Nutr	MIAME / Nutrigenomics
MIAME/Plant	MIAME / Plant transcriptomics
MIAME/Tox	MIAME / Toxicogenomics
MIAPA	Minimum Information About a Phylogenetic Analysis
MIAPAR	Minimum Information About a Protein Affinity Reagent
MIAPE	Minimum Information About a Proteomics Experiment
MIARE	Minimum Information About a RNAi Experiment
MIASE	Minimum Information About a Simulation Experiment
MIASPPE	Minimum Information About Sample Preparation for a Phosphoproteomics Experiment
MIATA	Minimum Information About T Cell Assays
MIENS	Minimum Information about an ENvironmental Sequence
MIFlowCyt	Minimum Information for a Flow Cytometry Experiment
MIGen	Minimum Information about a Genotyping Experiment
MIGS	Minimum Information about a Genome Sequence
MIMIx	Minimum Information about a Molecular Interaction Experiment
MIMPP	Minimal Information for Mouse Phenotyping Procedures
MINI	Minimum Information about a Neuroscience Investigation
MINIMESS	Minimal Metagenome Sequence Analysis Standard
MINSEQE	Minimum Information about a high-throughput SeQuencing Experiment
MIPFE	Minimal Information for Protein Functional Evaluation

Other useful resources



- **COPE (Committee on Publication Ethics)**

EQUATOR Network

www.equator-network.org

Contact: iveta.simera@csm.ac.ox.uk