Research Integrity Ethics & Questionnaires

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To be considered

Research Integrity & Ethics
Publications & Authorship
Research ethics principles
Informed consent
Relevance to Online Questionnaires

Surely Research Ethics and Research Integrity are two ends of the same coin ?

Or if Not, which comes first ?

Research Ethics (RE)

An examination of the ethics committees/offices of various Irish RPOs, reveals that the primary concern of the majority of committees is research involving human subjects, biological samples and research involving animals.

The European Commission's Horizon 2020 Programme requires all applicants to undertake an ethics self-assessment. The ethics issues identified in the self-assessment include the typical issues of research on humans, human biological samples and animals, but also includes the following:

- Personal Data;
- Research involving countries outside of Europe ("third countries");
- Environment, Health and Safety;
- Dual Use;
- Misuse.

Research Integrity (RI)

The **National Policy Statement** on Ensuring **Research Integrity** in Ireland (2019 & 2014) is guided by the **European Code of Conduct for Research Integrity** (2017) and the **OECD** 2007 Document **Best practices for ensuring scientific integrity and preventing misconduct**".

These identify the most serious breaches of research integrity as: FFPs

Fabrication of Data	**i.e. making up results and recording or reporting them.**
Falsification of Data	i.e. manipulating research, materials, equipment or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
Plagiarism	i.e. the appropriation of another person's ideas, processes, results, or words without giving appropriate credit, including those obtained through confidential review of other's research proposals and manuscripts.

Also practices while not as serious as FFP are probably much more frequent and therefore potentially more damaging ?

Core "Research Misconduct"	Research practice misconduct
FFP normally includes: - **Selectively excluding data from analysis** - **Misinterpreting data to obtain desired results (including inappropriate use of statistical methods)** - **Doctoring images in publications** - **Producing false data or results under pressure from a sponsor**	- Using inappropriate (e.g. harmful or dangerous) research methods - Poor research design - Experimental, analytical, computational errors - Violation of human subject protocols - Abuse of laboratory animals
Data-related misconduct	Publication-related misconduct
- **Not preserving primary data** - **Bad data management, storage** - **Withholding data from the scientific community** **NB: the above applies to physical research materials too**	- Claiming undeserved authorship - Denying authorship to contributors - Artificially proliferating publications - Failure to correct the publication record - Including authors without permission
Personal misconduct in the research setting	Financial, and other misconduct
- **In appropriate personal behaviour, harassment** - **Inadequate mentoring, counselling of students** - **Insensitivity to social or cultural norms**	- Peer review abuse e.g. non-disclosure of conflict of interest, unfairly holding up a rival's publication - Misrepresenting credentials or publication record - Misuse of research funds for unauthorised purchases for personal gain - Making an unsubstantiated or malicious misconduct allegation

Spot the difference?

Typical Research Ethics issues (e.g. research on humans, human tissues or animals, use of personal data) could be considered to be **a sub-set of issues** under the broader heading of **Research Integrity**. Similarly, the **UKRIO *Code of Practice for Research*** mentions research involving human participants, human material or personal data and research involving animals as part of a longer list of issues under **good practice in research and preventing misconduct.**

The European Commission's list of Indicators for **Promoting and Monitoring Responsible Research** and Innovation uses the umbrella term **"Ethics"** to cover both **Research Integrity** and good research practice, and **Research Ethics** for the protection of the objects of research.

The Ethics Section was originally tasked with preserving, ensuring and assessing ethical issues in Framework Programmes. In Horizon 2020, research integrity was added to its portfolio of and it was renamed the Ethics and Research Integrity Section. (out of sink with European code of good practice, & international accepted RI policy)

National Forum RI approach: Research ethics **(RE)** is a **sub-set** of research integrity **(RI).**

National Policy statement on ensuring Research Integrity – State of Mind or awareness

Commitments to foster and ensure research integrity

Commitment 1: Standards

Commitment 2: Good research practice

Commitment 3: Collaboration for continuous improvement

Commitment 4: Action to address misconduct

Commitment 1: Standards

Reliability We are committed to ensuring the highest standards of integrity in all aspects of research in Ireland, founded on basic principles of good research practice to be observed by all researchers, research organisations and research funders

Honesty in developing, undertaking, reviewing, reporting and communicating research in a transparent, fair, full and unbiased way.

Respect for colleagues, research participants and subjects, be they human or animal, society, ecosystems, cultural heritage and the environment

Accountability of the research **from idea to publication**, for its management and organisation, for training, supervision and mentoring, and for its wider impacts.

Commitment 2: Good Research Practice

Culture committed to **maintaining a national research environment that is founded upon a culture of integrity**, embracing internationally recognised good practice and a positive, proactive approach to promoting research integrity.

Training Developing a common approach to **training in research integrity principles and practices** that can be applied across all HEIs and other research performing organisations as part of UG PG PI training

Research Data Practices and Management

Research data should be organised, curated and appropriately stored. It encompasses the methodology used to obtain results, the actual research results and the analysis and interpretation. Primary responsibility for observing good practice in the use, storage, retention and preservation of data sits with the individual researcher, supported by the institution.

Commitment 3: Collaboration for Continuous Improvement

Commitment to working together to reinforce and safeguard the integrity of the Irish research system and to reviewing progress regularly.

– **Support the implementation of research integrity** policies and processes in a harmonised manner across the research performing organisations;

– **Support national research funders** in implementing harmonised research integrity statements in grant conditions and associated assurance processes;

– **Support the development and roll-out of research integrity training** programmes for staff and students in the research performing organisations;

– Monitor international developments and policy in the area of RI

– **Share experiences** on the number and **type of instances of research misconduct** that have been dealt with through formal mechanisms in the RPO

Publications, authorship & predatory journals

Publish or Die! Huge pressure to publish or tweak results for next grant application

Predatory Open access (OA) publishers exploit researchers and the OA system through operating as mock OA journals, willing to publish the work of whoever will pay, and disregarding the peer review system

BOX 1 Definition of Open Access Publications

Open Access Publications

- Are funded by the author
- Are free to the public
- Are peer reviewed
- Are uploaded to online repositories upon publication
- Are correctly attributed to authors[25]
- Make publication part of the cost of doing research

BOX 2 Common Practices of Predatory Open Access Publications

- Cold calling authors through e-mail[19]
- Neglecting the peer review system[11–18]
- Expediting the review process to deliver accepted verdicts faster[11–18]
- Manipulating authors to sign away their rights to the work at the submission stage[20]

Jeffrey Beall's list of ''Potential, Possible, or Probable Predatory Scholarly Open-Access Publishers. This list provides the names—1028 as of May 7, 2016

- **Does Authorship Matter?**
- Authorship confers credit and has important academic, social, and financial implications. Authorship also implies responsibility and **accountability** for published work.

- Because authorship does not communicate what contributions qualified an individual to be an author, **some journals now request and publish information about the contributions of each person** named as having participated in a submitted study, at least for original research.

- Editors are strongly encouraged to develop and implement a contributorship policy. Such policies remove much of the ambiguity surrounding contributions, but leave unresolved the question of the quantity and quality of contribution that qualify an individual for authorship.

International Committee of Medical Journal Editors (ICMJE) Guidelines

- The ICMJE recommends that authorship be based on the following 4 criteria:

1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; **AND**

2. Drafting the work or revising it critically for important intellectual content; **AND**

3. Final approval of the version to be published; **AND**

4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

- In addition to **being accountable** for the parts of the work he or she has done, an author should be able to **identify which co-authors are responsible for specific** other parts of the work. In addition, authors should have confidence in the integrity of the contributions of their co-authors.
- All those designated as authors should meet all four criteria for authorship, and all who meet the four criteria should be identified as authors. Those who do **not** meet all four criteria should be **acknowledged**
- The individuals who conduct the work are responsible for identifying who meets these criteria and ideally should do so when planning the work, making modifications as appropriate as the work progresses.
- Order of authors etc

Non-Author Contributors

- Contributors who meet fewer than all 4 of the above criteria for authorship should not be listed as authors, but they should be **acknowledged**.

- Examples of activities that alone (without other contributions) do not qualify a contributor for authorship **are acquisition of funding**; general supervision of a research group or general administrative support; and writing assistance, technical editing, language editing, and proofreading.
- Those whose contributions do not justify authorship may be acknowledged individually or together as a group under a single heading (e.g. "Clinical Investigators" or "Participating Investigators"), and their contributions should be specified (e.g., "served as scientific advisors," "critically reviewed the study proposal," "collected data," "provided and cared for study patients", "participated in writing or technical editing of the manuscript").
- Because acknowledgment may imply endorsement by acknowledged individuals of a study's data and conclusions, editors are advised to require that the corresponding author obtain written permission to be acknowledged from all acknowledged individuals.

Retraction watch

20K papers

https://retractionwatch.com/the-retraction-watch-leaderboard/top-10-most-highly-cited-retracted-papers/

MMR Controversy

- Measels Mumps and Rubella vaccine
- Administered as a Single dose
- Late 90s reported link to Autism published in Lancet
- Only 12 participants
- Falsified data
- Paper retracted in 2010
- Even now parents reluctant to administer a single 3 in 1 dose
- How many deaths caused ?

Ongoing Implications : Funder Demands for RI

- PIs must undergo certified RI training when applying for grants (digital badge ?)
- RPOs must have Procedures and policies in place to "manage" research misconduct (complicated to integrate misconduct into disciplinary procedures?)
- Cases of misconducted must be reported externally, and to collaborating partners?
- And when a researcher moves to a new Research organisation ?
- CVs based on the **rule of 5**. Candidates present their **best five papers** over the past five years, accompanied by a description of the research, its **impact on society (**not impact factor!) and their individual contribution.
- Quality assurance for publications – especially for external collaborations

- Only papers which have undergone an **approved publication policy quality assessment** (PPQA) audited by e.g. Committee on Publication Ethics (COPE) can be used in grant applications.

Ethics in Social Science and Humanities

Ethics in Social Science and Humanities H2020 Oct 2018

- General principles/underlying ethical principles
  - obligation to protect participants' welfare and safety and to ensure they are treated fairly and with respect.
  - respecting human dignity and integrity
  - ensuring honesty and transparency towards research subjects
  - respecting individual autonomy and obtaining free and informed consent (as well as assent whenever relevant)
  - protecting vulnerable individuals
  - ensuring **privacy and confidentiality**
  - minimising **harm** and maximising benefit
  - respecting and protecting the environment and future generations

Ethical dimensions of research methodology

- Is methodology appropriate, do the expected benefits outweigh the potential risks.
- It must be made clear to prospective research participants that they are free to decide whether or not to take part **(informed consent)**
- **DECEPTION in research**
- deliberately lie or trick the participants in the research setting so that the true purpose of the study remains unknown to them (until it is revealed in a **debriefing** once participation is finished)
- Why ? if disclosing its real purpose would lead participants to modify their behaviour, thereby distorting the research objective.

  Controversial, It violates the principle of informed consent
- **exceptional**, justified where the study addresses important matters and is expected to reveal something of social significance

- *If your research design includes deception,*
- *provide strong justification for the choice of method by showing the importance of the research objective and demonstrating that your research cannot be conducted in any other way*
- *describe how you will debrief your participants and retrospectively obtain their informed consent*
- *show that the use of deception will not harm your participants socially, emotionally or psychologically and that revealing the real nature of the research will not lead to any discomfort, anger or objections on their part, and finally*
- *obtain local ethics committee approval for your study before it gets under way.*

Deception – Miligram experiment (Yale 1961) the participants actually believed they were shocking a real person - Obedience

https://www.simplypsychology.org/milgram.html

Covert research

- goes against the requirements of informed consent and can invade participants' privacy. This type of secret or disguised research is rare.
- requires strong justification and a demonstration of **clear benefits** of the chosen method over any other approach. Matters of social significance must be addressed in the research.
- Covert research should be avoided in principle, unless it is the only method by which information can be gathered.
- **Informed consent** should be sought after the event wherever possible. **Risk** participants may not give their consent retrospectively, which would mean that some or all of the data collected could **not** be used.
- Tea Room Trade 1970s
- https://www.lehmiller.com/blog/2012/10/3/tearoom-trade-and-the-study-of-sex-in-public-places.html

Ethical dimensions of research methodology

- Covert research may be used in settings that pose no particular risk to participants or researchers if the **anonymity** of those being observed is safeguarded. **Observing fully public settings** may therefore not require consent. Such research must be conducted with respect for privacy:

- no personal data are collected (data are fully anonymised at the point and time of collection)
- data are collected unobtrusively and in accordance with local cultural values, and
- data are collected only in situations where people being studied can reasonably expect to be observed by strangers.

- **If illegal activities are observed, are they a witness or an accomplice if they elect not to report.**

Ethical dimensions of research methodology

- **internet** research and social media data
- all data that are available are also public – Is it fair to use them in research
- satisfy free and voluntary informed consent ?
- anonymity
- uncertainty about whether some **users** being studied **are children** or belong to other **vulnerable groups**
- Remember that just because data is publicly accessible, that does not mean that it can be processed by anyone for any purpose.
- Are there reasonable expectations of privacy which the user may have.
- risk of harm through tracing or exposing the social media user's identity and profile - **Ok Cupid! 2019 Denmark**

Internet research and social media data **OK Cupid**

- A student and a co-researcher have publicly released a dataset on nearly 70,000 users of the dating site Ok Cupid, including their sexual turn-ons, orientation, usernames and more.
- Data placed on an open science forum
- It may be possible to work out users' real identities from the published data.
- This was all information available to users of OkCupid once they were signed in. Arguably, the data was public.
- "The data can be used for deanonymization of individuals and very sensitive information, and they can't opt out either,"
- Just because data is sort-of public, doesn't mean that it's ethical to collect en masse.
- NB Ethics Guidelines for Internet-mediated Research 2017 British Psychological Society

Findings outside the scope of the research: ‘unintended/unexpected/incidental’ findings

- Unintended/unexpected/incidental findings may include indications of criminal activity, human trafficking, abuse, domestic violence or bullying. Researchers must inform the participants, or their guardians or other responsible people, of their intentions and reasons for disclosure.

- As a rule, criminal activity witnessed or uncovered in the course of research must be reported to the responsible and appropriate authorities, even if this means overriding commitments to participants to maintain confidentiality and anonymity. There may be a legal obligation to report criminal activity.

Informed consent e.g. BPS Guidelines

No research on a person may be carried out without the informed, free, express, specific and documented consent of the person'. This places a legal obligation on researchers to obtain and record consent from participants or their guardians, on the basis of information that should be given to them before their participation.

No Coercion, Right to withdraw, Anonymity, Additional safeguards for research with vulnerable populations etc

Must provide **information sheet (detailed)** to the intended participants

Get approval from an Appropriate Ethics committee

May be different levels of approval – low or high risk research

Information sheet must (generally accepted by all codes)

Describe Aims, methods, duration and implications of the research, nature of participation, benefits, risks, discomfort that might arise

Give explicit statements that participation is voluntary, right to refuse to participate, and to fully withdraw without consequences.

Provide Information about organisation or funder of research & Provide Full contact details for research team

Identify risk mitigation strategies if appropriate

Outline what will happen to results of the research, whether sharing with or transferred to third parties and for what purposes; retention duration.

State how to handle incidental findings.

Concerning children – Informed Consent (IC)

IC from legally authorised representative, written dated and signed.

Assent of the participants should be obtained.

Must get consent if children reach the appropriate age during the study

IC and information sheets should be comprehensive but different for parents/guardians compared to those for children i.e age/culturally appropriate language – lay terms – **letters in schoolbags ?**

Adequate time for consideration whether to participate or not.

(Online) Questionnaires/ Surveys

- Data collection through an online offers the potential to collect large amounts of data efficiently and within relatively short time frames.

- Online survey approach for collecting data from hard-to-reach populations such as LGB&T or travelers, etc., people with certain conditions, e.g. HIV are often hard to access - stigmatized offline.

- **Preceding information about dignity, respect, informed consent, no harm all apply – all surveys need some form of oversight**

Questionnaires – Harm

- At the level of the individual participant, the duty to do good, and prevent harm, warrants equal vigilance. In instances where the participant is likely to experience discomfort, burden and/or risk, it must be proportionate to the expected gain from the research study – either directly to the participant and/or to society as a whole

- **It doesn't cost anything just to ask, does it? The ethics of questionnaire-based research** (J Med Ethics 2002)

- Breast cancer study - of management expectations and risk-perception

- Harm – Increased anxiety in patients with or without pathology

Online Questionnaires – Consent

- Online administration of surveys raises unique ethical questions regarding **Informed consent.** Establishing that participants have properly engaged with valid consent procedures is not always easy.
- In most online survey tools, it is not possible to explain the study in detail. Researchers must ensure that all information regarding the study, participants' rights and researcher's contact details are provided on the information page of the survey.
- The participant **(remote from the researcher)** must have the capacity to both understand the information and the implications of participation for the individual, and the (cognitive) ability to exercise consent.
- Participants must be assured that their identity will not be divulged – the data-collection, handling and storage processes protect anonymity.

Questionnaires – Consent

- Valid consent can arguably be assumed if the questionnaire has been completed (though it is good practice to include a check box in response to an explicit consent statement)

- Check boxes can be an effective strategy to indicate reading and understanding read of key aspects of the consent information (e.g. their withdrawal rights, how information will be disseminated).

- Avoid making it easy to simply tick all boxes and proceed.
- Care should also be taken not to 'over complicate' consent procedures online, so that participants who wish to proceed and participate in the study can easily do so.
- Overly lengthy consent information pages are more likely to be quickly skimmed, or not read at all

Questionnaires – confidentiality

- There are concerns regarding the privacy and confidentiality where data is stored on the server of a third-party software provider

- Most of these tools rely on the researchers' ingenuity in setting up the survey settings to limit for instance participants' IP addresses. However, tools such as Survey Monkey have been associated with easily accessible data from surveys shared from a common account thereby compromising confidentiality
- One of the key ethical advantages to using Survey Monkey or a similar software tool is that, if IP numbers are not collected, there is no way of tracing respondents.
- If it is not possible to verify identity, people who should be excluded from the survey (e.g., those under 16 years) may in fact complete the survey, or people may submit multiple surveys.

Questionnaires – Withdrawal

- Valid consent requires that participants are aware of their right to withdraw from participation, and withdraw data post-participation.
- Any necessary time limits on data withdrawal should be made clear at the point of valid consent, and any requests from participants to remove their data which are in accordance with these rights should be complied with.
- Two key factors, which make online approaches different to offline modes
  - the typical lack of face-to-face presence between researcher and participants; **and**
  - the automated collection of data during the research process.
- Together, these factors compound the risk that participants might decide to withdraw from a study without this being obvious to the researcher, and after partial (or even complete) data have already been submitted and stored

Questionnaires – Withdrawal

- A participant may decide to exit a survey or experiment part way through, by closing their web browser. Did the participant intended to withdraw their valid consent for the use of any data already stored?
- Such difficulties need to be anticipated, and withdrawal procedures made clear. Displaying a clearly visible ‘exit’ or ‘withdraw’ button on each page of a survey or experiment is often good practice.

- Clicking this would ideally lead to a debrief page and perhaps also a statement asking participants if they require their data to be withdrawn, or whether their partial data can be used

- off-the-shelf online survey software solutions may often not incorporate this functionality.
- A button at the very end of a study confirming consent to use the data or partial data submitted could help here; arguably, but if not verified/checked by a participant then their data should not be used ?

Conclusions

- Ethics is a subset of Research integrity
- Ethical approval is something which is sought and given based on criteria – RI is always on!
- Ethical requirements are well defined and agreed in various national and international codes
- “Informed and continued consent” is a major challenge particularly in online survey Mode
- All surveys/ questionnaires need some form of ethical oversight. (on a scale..)

References

- Guidelines for minimum standards of ethical approval in psychological research ; https://www.abdn.ac.uk/psychology/documents/ethics/BPS_july2004_Guidelines_for_Ethical_Approval.pdf
- 2007 OECD Best Practice Document http://www.oecd.org/dataoecd/37/17/40188303.pdf
- 2009 UKRIO Code of Practice for Research
- 2015 Indicators for promoting and monitoring Responsible Research and Innovation http://ec.europa.eu/research/swafs/pdf/pub_rri/rri_indicators_final_version.pdf
- 2016 National Forum on RI Position paper Research Integrity & Research Ethics https://www.iua.ie/wp-content/uploads/2019/08/Research-Ethics-Integrity-FINAL-April-2016-1.pdf
- 2017 European Code of Conduct for Research Integrity https://allea.org/code-of-conduct/
- 2017 Ethics Guidelines for Internet Medicated research (BPS) https://www.bps.org.uk/news-and-policy/ethics-guidelines-internet-mediated-research-2017
- 2018 Ethics in Social Science and Humanities https://ec.europa.eu/research/participants/data/ref/h2020/other/hi/h2020_ethics-soc-science-humanities_en.pdf
- 2018 EC Guidance notes on Ethics and Data Protection https://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-data-protection_en.pdf
- 2019 Policy Statement of Ensuring Research Integrity in Ireland https://www.iua.ie/wp-content/uploads/2019/08/IUA_Research_Integrity_in_Ireland_Report_2019.pdf