the
embassy
of good
science
Research integrity and research ethics: Mapping overlapping jurisdictions

Presentation by Raymond de Vries

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I need your help to solve this puzzle
Our challenge

The moral problems of research

Research ethics

Research integrity
My RIO just called to inform me about a researcher here at our university who falsified her data...
I told him that we research ethicists don’t really care. It’s *not ethics*, it is just people behaving badly.
A research ethicist just called to ask me about using surrogate consent to enroll people with dementia in a clinical trial...
I told her that was an ethics question and that she should call me if the researcher ignores the decision of the REC.
The problem of jurisdiction

Conceptual problem:
- What is an ethics question?
- What is an integrity question?
- What is the difference?

Jurisdictional problem:
- Whose expertise is needed?
- What body of knowledge applies?
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Your platform for research integrity and ethics
Whose jurisdiction?
Or this?

...but then, what is this? Who works here?
EnTIRE – Mapping the Normative Framework for Ethics and Integrity of Research
Four work packages

- **Stakeholders’ experiences** and perspectives regarding research integrity and ethics

- **Normative documents** – laws, regulations, codes and guidelines on RE+RI in European countries

- Committees, **training courses, educational resources**, and expert contacts

- **Cases**, methods of case analysis, actual case analyses and a set of scenarios.
In each area we found confusion

1: Stakeholders’ experiences and perspectives regarding research integrity and ethics
“I find it strange to make this distinction. When you have two terms you want to know the difference, and then you come with this kind of reasoning that is mostly leaning towards some absurdity. Because you separate these things. What does it mean to be ethical without integrity? It is just playing with words.”

“Ethics and research have different dimensions… One [ethics] is looking at the 'what', the 'why', and the other one [integrity] is looking at the 'how' you're doing it.”
In each area, we found confusion

2: Normative documents – laws, regulations, codes, and guidelines on RE+RI
2. Normative documents – laws regulations, codes and guidelines on RE+RI in all European countries

In our review of national guidelines and policy documents on RI + RE, we found:

- A relatively strict separation between RE and RI. Documents that regulate RI do not regulate RE and RE documents do not regulate RI.

- RE policy documents were published much earlier than RI policy documents. The Helsinki Declaration was published in 1964 while policy documents concerning RI were published much later: 2000 (USA Federal Research Misconduct Policy), 2010 (Singapore statement), and 2011 (European Code of Conduct).

- RE policy documents often have legal force. Guidelines on research integrity are typically self-regulatory codes of conduct, similar in legal status and content to codes of conduct for professions.
In each area, we found confusion.

3: Training courses and educational resources
3. Committees, training courses, educational resources, and expert contacts

We performed a systematic search for training opportunities using databases PubMed and Scopus, as well as RRI Tools, Netherlands Research Integrity Network, and grey literature.

We retrieved 32,198 results, 28,108 after removing the duplicates. After screening, 123 articles were selected for full text assessment. 70 articles were excluded at that step, leaving 53 articles for analysis.

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<th>Label</th>
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<tr>
<td>RE</td>
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<tr>
<td>Other/No label</td>
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Examples

Research integrity:


*Definition:* No definition of RI given. The intervention is a part of The Professionalism and Integrity in Research Program.

*Topics covered:* informed consent best practices, effective data management, strategies, or proper citation practices, poor time management, communication, or data management practices; inadequate leadership on matters of compliance failure to use good professional decision-making strategies.
Examples

Research ethics:

Danowitz AM, Taylor CE, Integrating a peer-taught module on practical research ethics into the graduate student orientation curriculum. Journal of Chemical Education. 2011;88/8;1090-1093.

Definition of RE: no definition given. The need for the program is emphasized through “inappropriate decisions can lead to unethical behavior and scientific misconduct”

Topics covered: authorship, fabrication, falsification, plagiarism, resolution of intralab conflict, and data integrity
In each area, we found confusion.

4: Cases, case analysis, and a set of scenarios
4. Cases, case analyses and a set of scenarios

We conducted a search using PubMed, Web of Science, SCOPUS, JSTOR, Ovid, and Science. To include both RE cases and RI cases, we did two parallel searches. The terms used in the databases: ("research ethics") AND (violation OR unethical OR misconduct) and ("research integrity") AND (violation OR unethical OR misconduct).
Results

Records identified through the Research Ethics search (n = 11641)
- Duplicates identified (n = 1837)
- Records of RE+RI after duplicates removed (n = 10556)
  - Records screened (n = 10556)
  - Full-text articles assessed for eligibility (n = 806)
  - Studies included in qualitative synthesis (n = 392)

Records identified through the Research Integrity search (n = 3078)
- Duplicates identified (n = 1093)
- Records excluded (n = 9750)
- Full-text articles excluded for not describing consistently a case (n = 414)

Venn Diagram:
- RE: 159
- RERI: 146
- RI: 87

507 Case descriptions
- 250 descriptions from 50 prominent cases
Example: Is informed consent RE, RI, or RE+RI?

Case description retrieved in the RE string only
Violations/Ethical issues tag: Informed consent / Patient safety

*Discusses the challenges around participation in HIV vaccine research in low-income settings such as sub-Saharan Africa*

Case description retrieved in both RE+RI search strings
‘A Reflection on Fraud and Misconduct in Biomedical Research.’ *Pharmaceutical Medicine* October. 2009;23(5-6):269-72. Violations/Ethical issues tag: Informed consent / REC approval

*An account of two separate but connected trials without the approval of a REC or the consent of patients.*

Case description retrieved in the RI string only

*Pathologists in the United Kingdom routinely taking organs and other samples from children's bodies without asking parents for permission. The doctor involved was banned from practising medicine in the United Kingdom. One paper retracted.*
The *ethics – integrity – compliance* continuum
The nature of the work

Puzzles  Policing
The source of the problem

(Lack of) Knowledge  (Lack of) Character
The object of concern

Information  

Know what is right

Behaviour  

Do what is right
Response to the (potential) problem

Prospective review  

Training and Retrospective review
Responding to conflicts of interest
Characteristics of the work

“Clean” Work

“thought” work

“Dirty” work

personnel work
Further questions:

- Why the sudden growth of interest (and work) in Research Integrity?
- Where are the boundaries between RE and RI?
- Who are the workers in this new field?
- What preparation is required to work in the field of research integrity?
We need to:

Think about **what** we do,

how we **organize** what we do, and

whether the work we are doing actually **achieves our goals**
Both RE and RI wish to promote, foster, and protect *good science* but...
the relationship between the two remains unclear, resulting in *confusion, lack of synergy, and overlapping efforts.*

*Our examination of the varied understandings of RE and RI is a necessary first step toward better and seamless cooperation between these two areas of inquiry and practice.*
Thank you
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