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embassy
of good
science**



Research integrity and research ethics: Mapping overlapping jurisdictions

Presentation by **Raymond de Vries**

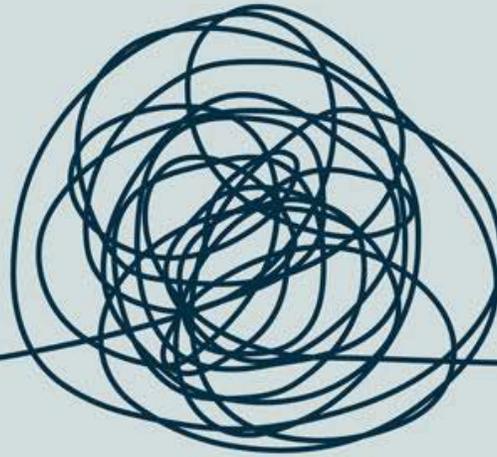
World Conference on Research Integrity, Hong Kong June 2-5



I need your help to solve this puzzle

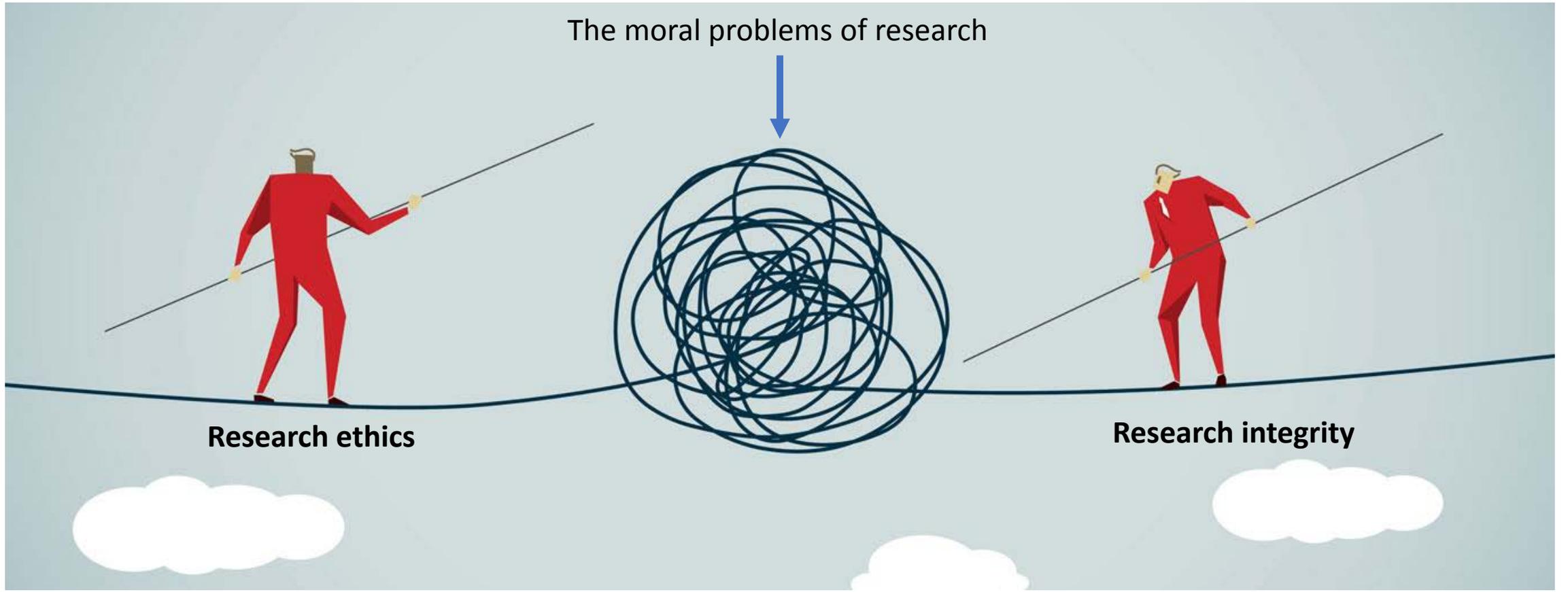
Our challenge

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...

Research ethicist



Research ethicist



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...

Research integrity officer

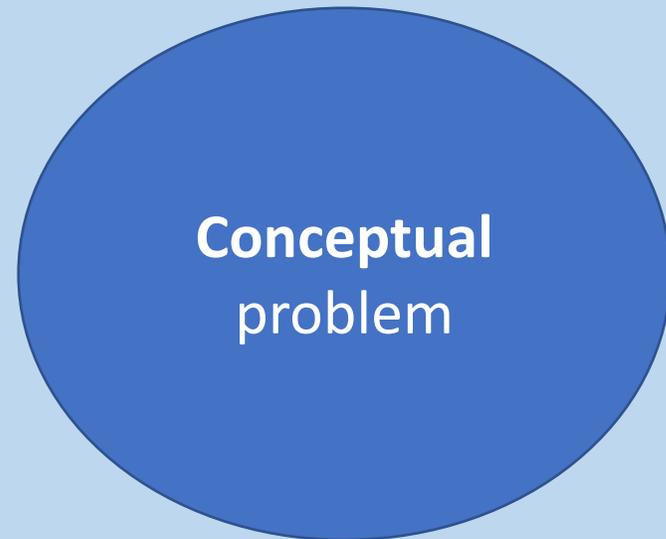


Research integrity officer



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



What is an ethics question?
What is an integrity question?
What is the difference?



Whose expertise is needed?
What body of knowledge applies?

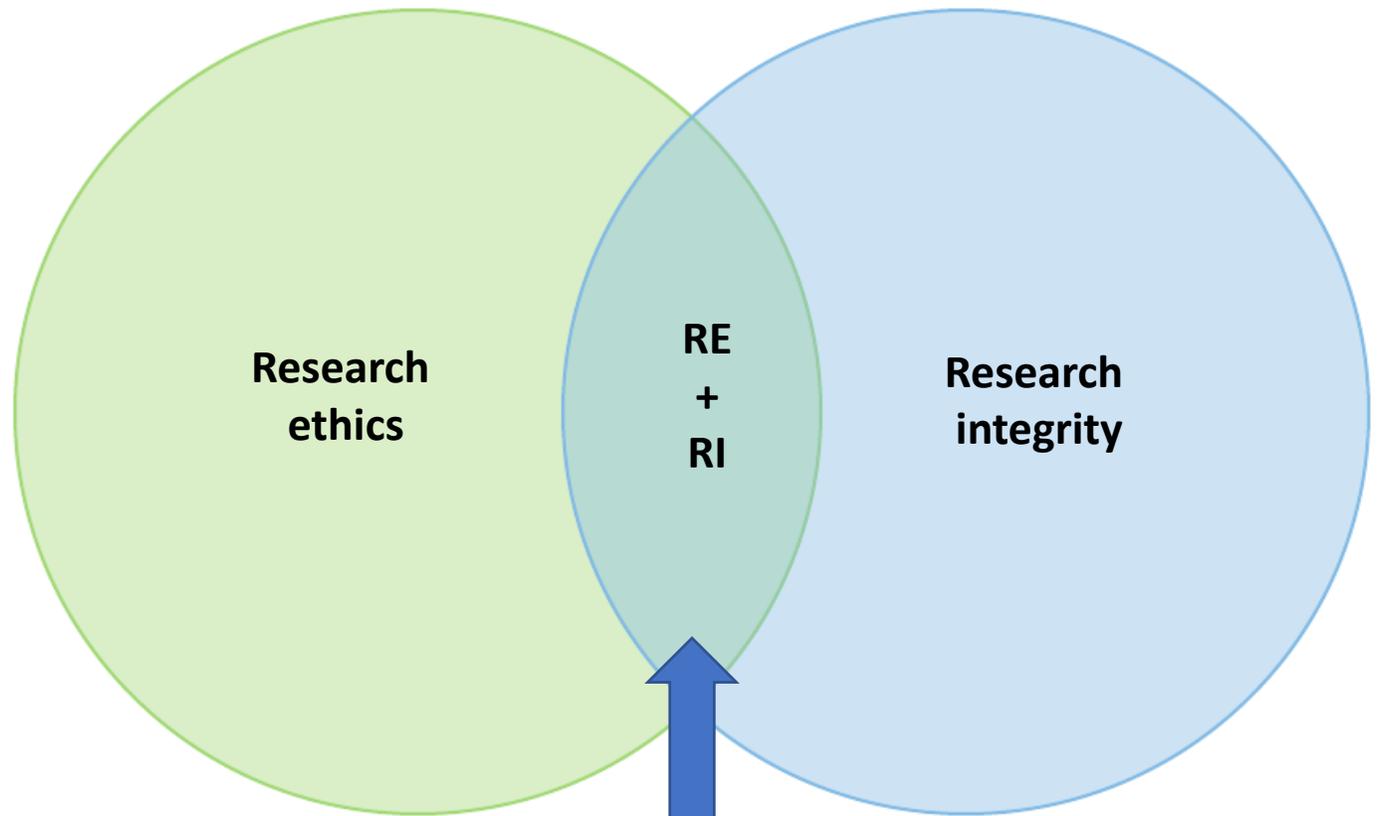
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Your platform for research
integrity and ethics

Whose
jurisdiction?



Or this?



...but then, what is this? Who works here?



EnTIRE – Mapping the Normative Framework for Ethics and Integrity of Research



Mapping

Ethics
&
Integrity

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

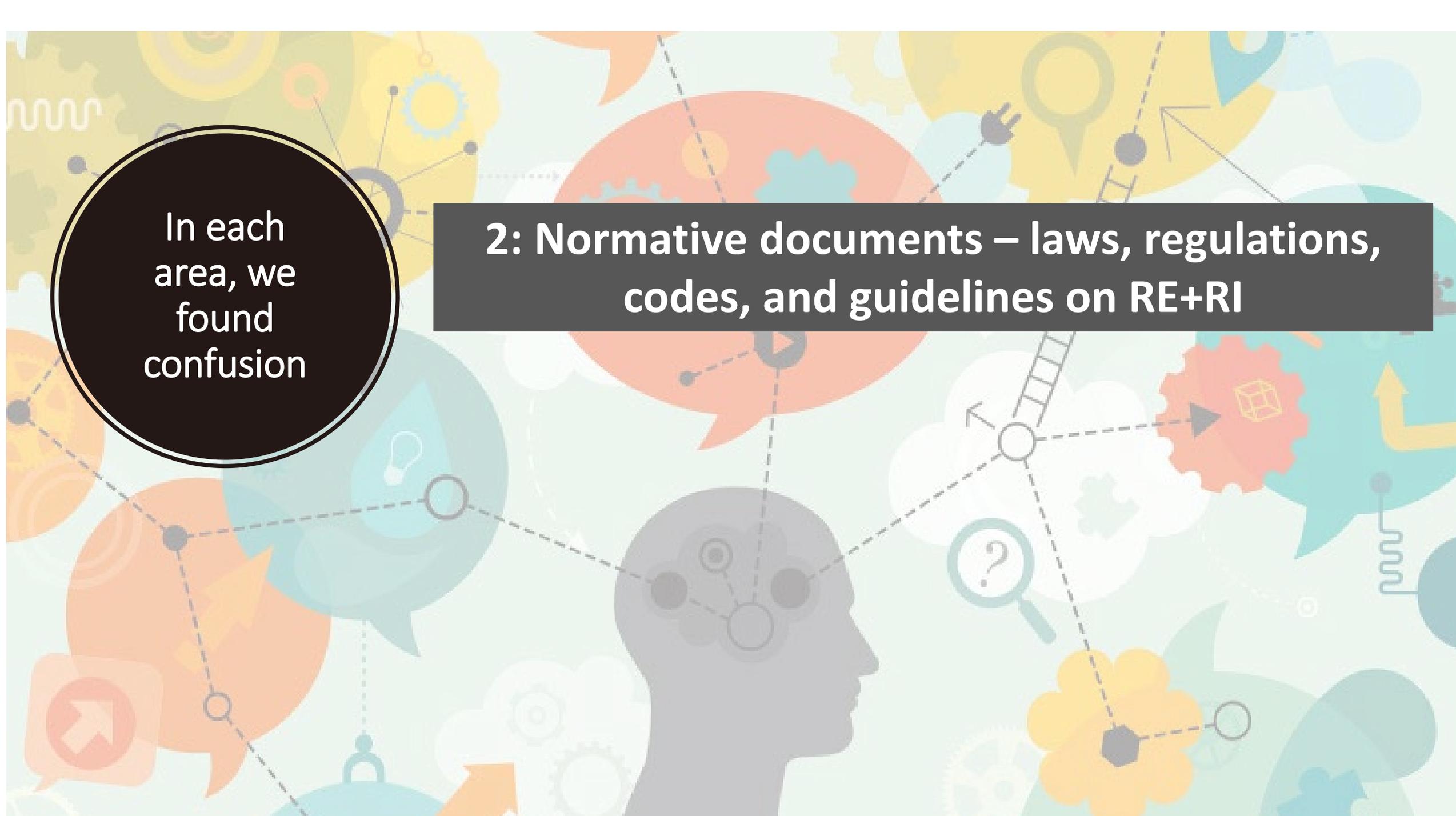
**1: Stakeholders' experiences and perspectives
regarding research integrity and ethics**



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

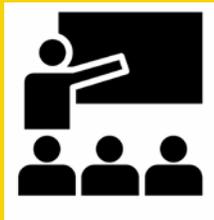
In our review of national guidelines and policy documents on RI + RE, we found:

- ✓ **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.

Label	Number of articles
RE	26
RCR	14
RI	2
RE, RCR, RI	5
Other/No label	6

Examples

Research *integrity*:

DuBois JM, Chibnall JT, Tait R, Vander Wal JS. The Professionalism and **Integrity in Research** Program: Description and Preliminary Outcomes. *Acad. Med.* 2018 Apr;93(4):586-592.

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

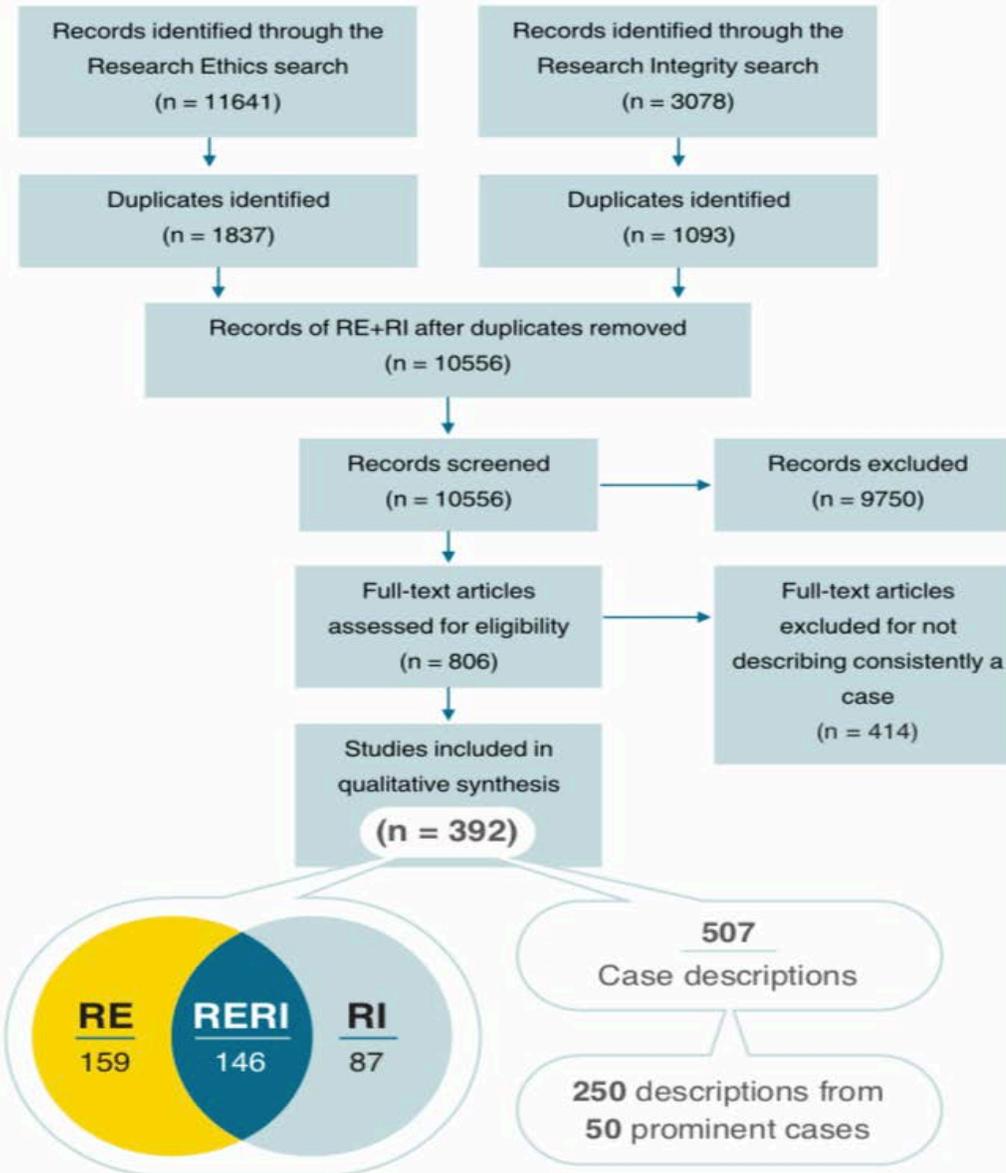
4: Cases, case analysis, and a set of scenarios



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



Example: Is informed consent RE, RI, or RE+RI?

Case description retrieved in the RE string only

'Ethics and human rights and HIV vaccine trials in low-income settings.' *J Med Ethics* 2012;38:286e293.

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

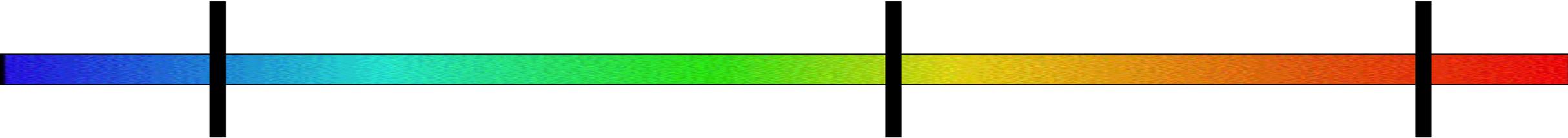
'Flawed infant death papers not retracted.' *Nature* August. 2011;476(7360):263-4. Violations / Ethical issues tag: retractions.

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.

Research ethics

Research integrity

Research compliance



The *ethics – integrity – compliance* continuum

Research ethics

Research integrity

Research compliance

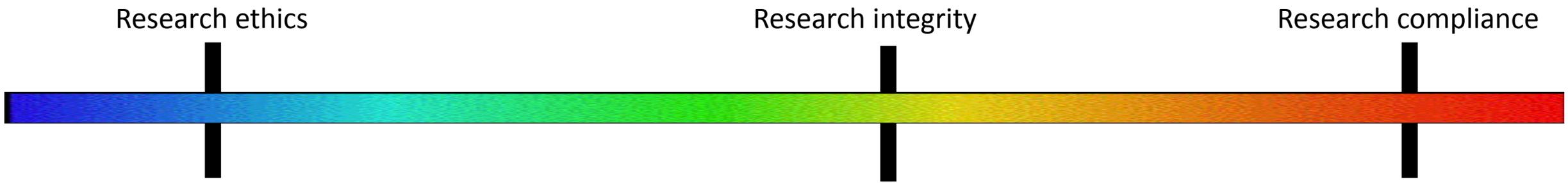


The nature of the work

Puzzles



Policing

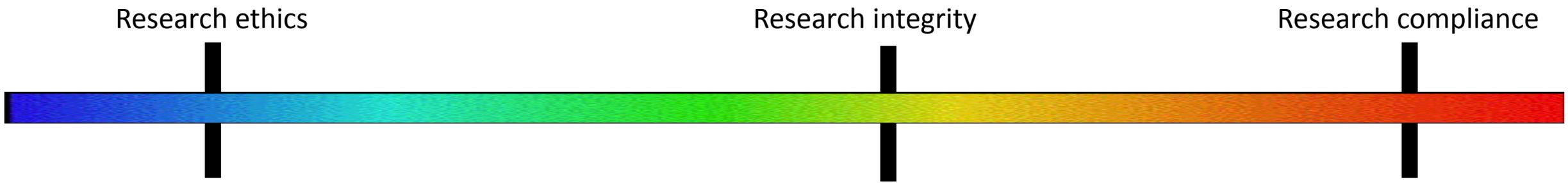


The source of the problem

(Lack of)
Knowledge



(Lack of)
Character



The nature of the work



Research ethics

Research integrity

Research compliance



The object of concern

Information



Behaviour

Know what is right

Do what is right

Research ethics

Research integrity

Research compliance



Response to the (potential) problem

Prospective
review

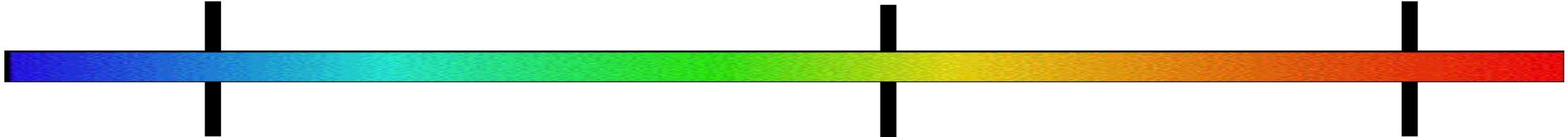


Training and
Retrospective
review

Research ethics

Research integrity

Research compliance



**What is the
nature
of a conflict?**

**Examining nature,
extent, causes and
consequences of
conflicts**

**Managing
conflicts**

**Enforcing
policies**

Responding to conflicts of interest

Research ethics

Research integrity

Research compliance



Characteristics of the work

“Clean”
Work



“Dirty”
work

“thought” 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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