



Mapping Normative Frameworks of
EThics and Integrity of REsearch

D 2.2

**Stakeholder Consultation: Definition
of the boundaries of data to be
collected for the mapping exercise**

WP 2 Stakeholder Consultation: Definition of the boundaries of data to be collected for the mapping exercise

Project details	
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Deliverable details	
Work Package:	WP 2 stakeholder consultation
Deliverable description:	Definition of the boundaries of data to be collected for the mapping exercise
Work package leader:	Vrije Universiteit Medisch Centrum (VUmc) Amsterdam
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Description of deliverable

EnTIRE conducts a mapping of the Research Ethics and Research Integrity (RE+RI) normative framework which applies to scientific research conducted in the EU and beyond. The project employs a broad definition of the normative framework informing RE+RI that encompasses both explicit and implicit elements (Box 1).

Box1: normative framework informing RE+RI

The normative framework informing RE+RI consists of explicit rules, formulated in laws, regulations, codes, and guidelines, as well as implicit rules, which structure local RE+RI practice and influence the application of explicit rules. Mapping the normative framework requires identifying explicit rules and showing how they are applied in local practice . Thus, the mapping of the normative framework should pay attention to both explicit elements (e.g. laws, regulations, codes, guidelines) and implicit elements (e.g. addressed in teaching programmes, cases and scenarios).

This deliverable provides a detailed description of the elements of the normative framework, (Table 1).




The broad scope of the framework has implications for data collection and, subsequently, the content of the EnTIRE platform. Implications for data collection work packages (3-5) are outlined (Table 2).

Element	Theme	Sub-theme	Brief description
Explicit	Laws, policies and guidance	Legislation	<ul style="list-style-type: none"> *European, national, and institutional laws *Efforts required to translate into institutional codes, guidelines, and practice
Explicit	Laws, policies and guidance	Codes, guidelines, and standards	<ul style="list-style-type: none"> *European, national, institutional, and discipline/domain specific codes, guidelines, and standards *Efforts (commitment and tools) required to translate into institutional and departmental codes, guidelines, and practice
Explicit	Laws, policies and guidance	Policies	<ul style="list-style-type: none"> * High level strategy or vision documents that outline commitments to good science, RRI, excellence * Institutional and departmental RE+RI policies *Policy development - in response to external developments and internal challenges. *Efforts (commitment and tools) required to enact in practice
Implicit	Support	Research ethics and integrity committees	<ul style="list-style-type: none"> *National organisation and regulation *Institutional organisation *Composition and training of committee members *Limited capacity of RE committees to judge RI cases *Functioning in practice as described by participants (including conflicts of interest and external pressures) *Development of alternative committees/support
Implicit	Support	Expert advice and contacts	<ul style="list-style-type: none"> * Experts who provide RE+RI guidance <i>as one of their main functions</i> <ul style="list-style-type: none"> - Within institutions: Scientific Committee Members; Research Integrity Officers; RE+RI trainers; RE+RI working groups; data protection officers; library staff; research funding officers etc. - Outside of institutions – e.g. RE+RI consultants and advisors
Implicit	Support	Education	<ul style="list-style-type: none"> *RE+RI education initiatives *Target groups *Participants' experiences with, and preferences for, RE+RI education *Evidence of effectiveness
Implicit	Support	Didactical cases, casuistry, and scenarios	<ul style="list-style-type: none"> *Appropriate use of cases, casuistry and scenarios *Tailored approaches for different target groups *Access to cases
Implicit	Support	Technology	<ul style="list-style-type: none"> * Technologies to support RE+RI e.g. software to check for plagiarism, check analyses, check duplicate articles etc. * Initiatives to make research analysis and reporting more transparent made possible by the internet, such as Github, R, and, PubPeer.
Implicit	Support	Data management	<ul style="list-style-type: none"> * Laws, codes, and guidelines related to data management * Record keeping, including documentation of analysis decisions * Storage of data, including privacy/data protection issues * Completeness of data, including metadata * Quality control - auditing * Access to data (open)

Implicit	Support	Research integrity research	<ul style="list-style-type: none"> * Big data * Researchers' awareness of (new) data protection regulations and good practices * Protocols and tools * Effectiveness of RE+RI support * Possibility to conduct research on the content of the EnTIRE platform.
Implicit	Context	National context	Country specific factors, including national history and culture
Implicit	Context	Institution	Institutional infrastructure and culture: <ul style="list-style-type: none"> * Efforts to "turn words into actions" - translate codes, rules, guidelines etc. into change in practice. * the (mal)functioning of regulatory structures within organisations * the influence of codes, rules, guidelines, initiatives on the culture of teams/departments/institutions * the culture of teams/departments/institutions * the influence of country context on the priority given by institutions to RE+RI support
Implicit	Context	Discipline/ domain	Differences in practices in: <ul style="list-style-type: none"> * Different academic disciplines * Academia and industry * Teaching and research within academic institutions
Implicit	Context	Seniors	<ul style="list-style-type: none"> * Seniors and mentors as a source of RE+RI advice * The influence of (good and bad) role models * Deficits in knowledge and poor practices of senior researchers
Implicit	Context	Peer support and behaviour	<ul style="list-style-type: none"> * The influence of peers' practices * The importance of peer support in an open and transparent team/institutional culture
Implicit	Context	Systemic pressures within science	The influences of systemic pressures (e.g. pressure to publish, pressure to obtain funding etc.) and coercion by individuals (politicians, colleagues, committee members) on research practices.
Implicit	Funding and publishing	Funding	<ul style="list-style-type: none"> * The influence of individual funders and funding structures on RE+RI practices, including: European funding; pharmaceutical industry funding; public, national funding; philanthropic funding * The role of funders in promoting RE+RI * Tensions between funders calls for open data and data protection laws and obligations. * The influence of funding structures - e.g. pressure to obtain funding, lack of oversight and guest authorships given to people who attract more funding
Implicit	Funding and publishing	Publishing	<ul style="list-style-type: none"> * Pressure to publish * Commercialization of scientific communication * Publishers' practices that can hinder RE+RI: novel, rather than replication, studies preferred; metrics indicating

			quality and impact; predatory journals; and peer review with potential conflicts of interest * Publishers' practices that can promote RE+RI: promotion of and adherence to COPE guidelines; pre-registration of trials; publishing of protocols; agreements to publish study results; and Open Access and Open Data Initiatives.
Implicit	Individual dispositions, perceptions, and experiences	Individual disposition and values	Personality, values etc. of the individual
Implicit	Individual dispositions, perceptions, and experiences	Perception and awareness of RE+RI	* Researchers' perceptions of problems caused by poor RE+RI practices * The impact of RE+RI problems on public trust in science
Implicit	Individual dispositions, perceptions, and experiences	RE+RI Understanding	* Understandings of the scope of RE+RI
Implicit	Individual dispositions, perceptions, and experiences	Burden of RE+RI	Participants' perception and experience of research ethics and research integrity rules and procedures as a burden hindering the research process.
Implicit	Individual dispositions, perceptions, and experiences	Experiences of poor research practices	* Individual misbehaviours and misconduct * Misbehaviour and misconduct by other people (witnessed and suspected) * Influence of experiences on the perceived need for, and effectiveness of, efforts to promote and support
Implicit	Individual dispositions, perceptions, and experiences	Whistleblowers	* Protections for whistleblowers * Tensions between protections for whistleblowers and protections for researchers against accusations * Trolls - anonymous 'whistleblowers' (also bad faith whistleblowers) hijacking the conversation

Table 1. The normative framework informing RE+RI, including explicit and implicit elements.

 <p>WP3</p>	 <p>WP4</p>	 <p>WP5</p>
1. Information that allows for easy cross-country comparisons and learning	1. Information that allows for easy cross-country comparisons and learning	1. Information that allows for easy cross-country comparisons and learning
2. Good practice examples of translating European, national, institutional, and discipline/domain specific codes, guidelines, and standards into practice within institutions	2. Good practice examples of alternative advisory committees/support for disciplines that do not require ethics approval by law	2. A diversity of cases and scenarios for different target audiences:
3. Collection of discipline/domain specific codes, guidelines, and standards WP3	3. A description of experts who provide RE+RI guidance <i>as one of their main functions</i> within different European countries	- Cases resonate with researchers' day-to-day dilemmas for teaching researchers
4. Laws, codes, and guidelines related to data management	4. Good practice examples of educational initiatives targeted at senior researchers	- Complex cases for and case analyses for teaching RE+RI integrity committees
5. Guidelines on how to set up and run research ethics and integrity committees	5. Information about technologies (particularly open source) to support RE+RI e.g. software to check for plagiarism, check analyses etc.	- 'Big cases' that illustrate the dangers of poor RE+RI oversight to encourage university management to improve oversight and support RE+RI initiatives.
6. Guidelines on how to install research integrity officers standard protocols for data management	6. Information about initiatives to make research analysis and reporting more transparent	
7. Guidance or best practice examples on how to run internal audits	7. Evidence on the effectiveness of measures to promote and support RE+RI	
8. Guidance on supervision	8. Tools for data management	
9. Guidance on conducting audits of funded research	9. Good practice examples of awareness raising initiatives surrounding changes to EU data protection laws	
10. Links to COPE guidelines	10. Good practice examples of embedding RE+RI in institutional priorities, structures, and processes	
11. Guidance for publishers on pre-registration of trials and publishing protocols	11. Good practice examples of a tailored institutional approach for different disciplines	

12.Guidance for storing and assessing authors' data	12.Tools for junior researchers – such as publication agreements
13.Laws and agencies that protect whistleblowers	13.Good practice examples of peer support initiatives
14.Guidance for researchers facing an accusation/harassment	14.Information on movements to tackle perverse incentives
15. Guidance on supervision	15.Examples of RE+RI reporting criteria from different funders
	16.Good practice examples from funders for promoting RE+RI within projects
	17.Examples of alternative evaluation criteria for funders
	18.Educational initiatives aimed at strengthening researchers' values
	19.Educational initiatives that raise awareness of the impact of poor research practices on science and society
	20.Research on scope and understandings of RE+RI

Table 2. Recommendations for additional data to be collected by each data collection work package in order to adequately reflect participants priorities and needs