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Mapping Normative Frameworks of Ethics and Integrity of Research

# D.5.2 Delivery of the First Tagged RE+RI Cases as Input for the Platform


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| **Project details** | |
|---|---|
| **Project:** | Mapping Normative Frameworks of Ethics and Integrity of Research |
| **Project acronym:** | EnTIRE |
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| **Project number:** | 741782 |
| **Project Coordinator:** | Vrije Universiteit Medisch Centrum (VUmc) Amsterdam |

| **Deliverable details** | |
|---|---|
| **Work Package:** | WP 5 Cases, Casuistry and Scenarios |
| | |
| **Work package leader:** | Dublin City University |
| **Authors:** | Anna Catharina Armond, Kristóf János Bodnár, Bert Gordijn, Søren Holm, Mohammad Hosseini, Péter Kakuk, Afroditi Kalambouka and Jonathan Lewis |
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# 1. Summary

This report confirms that the first tagged cases in research ethics and research integrity have been made available on the Staging Platform. For details regarding the methods employed to search for, retrieve and tag RE+RI cases, please refer to our previous deliverable (**'D.5.1. Protocol for Systematic Searches and Tagging of RE+RI Cases'**). For details of the results of the pilot searches for RE+RI cases and any substantial changes made to the methodologies described in D.5.1, please refer to our **'Report on Task 5.2 Pilot Collection of Data on Cases'**.

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## 2. Description of Work

As part of Task 5.1, WP5:

1. Identified potential sources of RE+RI cases: a) academic literature; b) reports by RE+RI committees and regulatory bodies; c) grey literature; d) media outlets; e) the blogosphere; and f) online repositories;
2. Developed appropriate systematic methods to conduct searches within these sources so as to gather RE+RI cases;
3. Developed a system of categories for tagging cases so as to enhance the user experience on the online platform.

The output of task 5.1 was **D.5.1 ('Protocol for Systematic Searches and Tagging of RE+RI Cases'**).

The deliverable was submitted to the European Commission on 1st December 2017.

In terms of Task 5.2, WP5:

1. Conducted pilot searches within each of the potential pools of RE+RI cases to see whether the search methodologies were adequate and feasible;
2. Conducted structuring, posting and testing activities on the web platform;
3. Adjusted the system of tagging based on the results of the pilot searches and the normative framework defined in the focus groups (WP2).

Task 5.2 was carried out between 1st November 2017 and 30th April 2018. The task put the protocol into practice by conducting pilot searches for RE+RI cases to see whether the search methodologies and tagging system detailed in the initial protocol were adequate and feasible.

WP5 produced a report explaining how the protocol has been adjusted according to the results of the pilot searches, the development of the online platform and the input from WP2's stakeholder consultation.

As part of Task 5.2, WP5 delivered the first tagged cases as input for the Staging Platform, thereby fulfilling the requirements of D.5.2.

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# 3. Tagging, Uploading and Presenting Cases on the Online Platform

## 3.1 The Development of the System for Tagging RE+RI Cases

Details of the proposed system of categories for tagging cases are provided on pp. 77-85 of the D.5.1 protocol with adjustments to the system outlined in pp. 36-39 of the report for task 5.2.

At the time of producing the D.5.1 protocol, it was noted that the proposed system for tagging cases presents an idealised model, one that is, ultimately, dependent on decisions made by the EnTIRE project's executive committee, consultants, stakeholders and work packages in collaboration with the end-users.

Discussions regarding the tagging and presentation of data on the platform have taken place across work packages. Furthermore, the IT structures facilitated by WP6 have developed in response to cross-consortium discussions.

WP5 stated in its protocol that the proposed tagging 'system' should remain open to adaptation and innovation. The system for tagging and presenting data is still being developed and an updated semantic form has, at the time of writing, not yet been implemented on the Staging Platform. Regardless, we expect the next iteration of the semantic form to be revised as the project develops in response to cross-consortium discussions, stakeholder consultation and user engagement.

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## 3.2 The Current Tagging System

The system for tagging cases that is currently available on the Staging Platform is structured as follows:

**CASE**

**Title**
**Type** Fictional/Factual/Factual Anonymized
**Year/Date**
**Organization Involved**
**Research Area**
**Country**

**SOURCE REFERENCES**

**Form**
**Source Type** Book/Conference/Court/Journal/Web
**URL**
**Title**
**Author 1 First Name Author 1 Last Name**
**Author 2 First Name Author 2 Last Name**
**Author 3 First Name Author 3 Last Name**
**Date**
**DOI**
**Outcome**
**Description**
**Implicit Dimensions**
**Explicit Dimensions**
**Main Ethical Principles**
**Types of Violation**
**Questions Published?**
**Comments Published?**
**Discussion Points Published?**
**Advice Published?**
**Current Tags**
**Current Categories**
**Word Count**

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## 3.3 The Next Iteration of the Tagging System

The tagging system detailed in section 3.2 has been updated. Details of these updates are outlined in pp. 36-39 of the report for task 5.2. WP6 is due to facilitate the following tagging system on the Staging Platform:

**CASE**

**Title**
**Type** Fictional/Factual/Factual Anonymized
**Year/Date**
**Affiliation**
**Research Area**
**Country**

**SOURCE REFERENCES**

**Source Type** Book/Conference/Court/Journal/Web
**URL**
**Source Title**
**Author**
**Publication Date**
**DOI**
**Abstract**
**Description**
**Outcome**
**Mentioned Regulatory Document**
**Principle, Virtue and Value**
**Type of Violation**
**Discussion Point?**
**Question for Trainer?**
**Comment?**
**Advice?**
**Tag**
**Word Count**

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## 3.4 Details of Uploaded Cases

WP2's stakeholder consultation identified *three* groups with specific research ethics and research integrity interests:

- Researchers
- Policymakers (including Research Ethics Committees and Research Integrity Offices)
- Administrators in the Scientific Community

The stakeholder consultation revealed that researchers tend to be interested in RE+RI cases based on everyday scenarios. Policymakers tend to be interested in complex cases and case analyses. Finally, administrators in the scientific community appreciate high-profile cases of both good and bad research practice.

The cases made available on the Staging Platform fall are aligned to these three types:

| **Case Type** | **Number of Cases on the Staging Platform** |
|---|---|
| Everyday Scenarios | 4 |
| Complex Cases | 5 |
| High-Profile Cases | 10 |
| **TOTAL** | 19 |

Of these 19 cases, 16 are factual and 3 are fictional.

Currently, 5 of the cases available on the Staging Platform have been identified through Google News, 1 case via the LexisNexis database, 4 via online repositories, 2 via reports from research ethics committees and research integrity offices and 7 via academic and grey literature.

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## 3.5 Presenting Cases on the Online Platform

Tagging cases according to the system outlined in section 3.3 should allow users to search for, retrieve and identify cases according to key terms. However, the EnTIRE consortium is not seeking to produce an encyclopedia or a database. As a result, cases should be presented in a way that allows users to engage meaningfully with the content. A mere list of different tags would not, on its own, facilitate such an engagement. On that basis, WP5, in collaboration with WP1, 3, 4 and 7, developed a template ('the identification document') for presenting case content on the platform (May-July 2018). WP5 tested the identification document ('ID') on three different cases (July-August 2018). Following feedback from WP1, 3, 4 and 7 (September 2018), WP5 revised the ID document and tested it on three additional cases (September 2018-Present).

The aim of the ID document is to provide a standardized template that users can draw upon to input, amend and develop cases on the online platform. The standardized template has been created not only to allow more passive users to obtain a snapshot of a case and useful regulatory, resource and analytical information pertinent to that case, but to facilitate dialogue between different users on questions and issues that arise from a particular case.

In the coming weeks, different versions of the ID document will be assessed by stakeholders of the EnTIRE project. Following feedback, the consortium will determine the form the template should take so that WP5 can develop the 19 cases already available on the Staging Platform and, in earnest, begin the process of scaling-up the collection of RE+RI cases.

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## 3.6 Example Case Presentation

WP5 have proposed the following structure for the ID document:

**1. Title**

Research vs. Practice: A Complex and Multifaceted Case for Research Ethics Committees

**2. Synopsis (In no more than 75 words, how would you pitch this case to a fellow ambassador?)**

An Institutional Review Board assesses a proposal that blurs the boundaries between research and practice. The IRB discusses issues concerning the disclosure of identifiable health information, informed consent, principles of beneficence and maleficence, coercion of research subjects and the intrusiveness of surveys. More importantly, the IRB acknowledges that in order to come to decisions regarding these issues, it must be able to discern those activities that are research-based from those that are practice-based.

**3. Useful Information (What other tools and resources available on this website or any other website would help a fellow ambassador understand this case or deal with cases like this?)**

- Links to WP3's guidelines
- Links to WP3's particular descriptions of important guidelines
- Links to WP4's particular resources (MOOCs/journal articles etc.)
- Links to pertinent case analyses/scenarios

**4. Questions (Do you have any questions about the case that you would like a fellow ambassador to answer?)**

**Jonathan Lewis (Dublin City University) has a question for the Embassy:**
"This case demonstrates the importance of being able to make the distinction between research and practice in order to assess a researcher's proposal according to the correct US regulations. Does anyone have any information regarding whether such a distinction applies in a European regulatory setting? If it does, are there any guidelines available for making such a distinction?"

**5. Comments (Do you have any ideas about the case that you would like to discuss with fellow ambassadors?)**

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**Jonathan Lewis (Dublin City University) has started a discussion:**

"The case indicates that disclosure of identifiable health information for the purposes of public health *practice* does not require informed consent. However, in the case of public health *research*, a waiver of consent is required from an IRB. Furthermore, the case also demonstrates that, for situations where information would be used for both practice and research, the demands for consent fall 'either under the research provisions or the public health provisions, as appropriate'. Does this latter situation not present the possibility of moral hazard? In effect, it allows the researcher to intentionally discharge (to a certain degree) their commitment to the principle of respect for autonomy on regulatory grounds. If we are to avoid the possibility that a researcher might unjustifiably avoid seeking informed consent, would it not be more reasonable to demand that a waiver of consent must always be sought in cases where an activity straddles the divide between research and practice?"

## 6. Tags

**Title** Public Health Practice vs. Research
**Type** Factual
**Affiliation** Department of Public Health; Human Investigations Committee; Department of Health and Human Services; National Bioethics Advisory Commission
**Research Area** LS 07.09 - Public health and epidemiology
**Country** United States
**Source Type** Web
**URL** https://bioethics.yale.edu/research/irb-case-studies/irb-case-public-health-practice-vs-research
**Source Title** Yale Interdisciplinary Center for Bioethics
**Mentioned Regulatory Document** 45 CFR 46; Code of Federal Regulations Part 45; Connecticut General Statutes Section 19a-2a; Public Health Code Section 19a-36-A2; Health Insurance Portability and Accountability Act of 1996; HIPAA; Standards for Privacy of Individually Identifiable Health Information; 45 CFR 160; 45 CFR 164; Clinical Laboratory Improvement Amendment; 45 CFR Part 46; 45 CFR Part 160; 45 CFR Part 164
**Principle, Virtue and Value** Beneficence; Harm; Respect for Participants; Autonomy; Informed Consent; Coercion; Aggression; Intrusiveness; Maleficence
**Type of Violation** Data Protection; Informed Consent
**Discussion Point?** No
**Question for Trainer?** No
**Comment?** Yes
**Advice?** No

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# 4. Conclusion

This report confirms that the first tagged cases in research ethics and research integrity have been made available on the Staging Platform, thereby fulfilling the requirements of D.5.2.