Mapping Normative Frameworks of Ethics and Integrity of Research

D.5.3 Delivery of the entire set of case deliberation methods and case analyses as input for the platform

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Project details	
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Work Package:	WP 5 Cases, Casuistry and Scenarios
Work package leader:	Dublin City University
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Table of Contents

1. Deliverable Summary

This report includes the entire set of case analysis methods and example case analyses to be uploaded to the online platform. In addition, the report includes:

- A procedure for identifying methods for the analysis of RE+RI cases;
- A description of a systematic review of case analysis methods;
- A description of a survey distributed to the EnTIRE and VIRT2UE consortiums in order to identify additional case analysis methods;
- Details of identified case analysis methods;
- A summary of case analysis methods and associated case analyses.

2. Description of Work

As part of Task 5.4, WP5:

1. Conducted a systematic literature review to identify case analysis methods suitable for the analysis of RE+RI cases;
2. Analysed a set of particularly prominent and/or topical RE+RI cases showcasing relevant case analysis methods.

One of the outputs of task 5.4 is this report (**D.5.3 'Delivery of the entire set of case deliberation methods and case analyses as input for the platform'**).

3. Procedure for Identifying Case Analysis Methods

3.1 Scoping Search for Case Analysis Methods

One of the aims of developing an innovative, user-friendly open access and open source Wiki-platform is to increase awareness of cases and scenarios embodying best practices and create preconditions for scientific excellence. Furthermore, the key unique feature of the EnTIRE project 'is the iterative, "bottom up" approach, making explicit normative experiences of local stakeholders and principles embedded in local rules and practices, and enabling the structuring of data in a way that fits in with research and evaluation practice, providing useful, accessible information for local users' (Widdershoven et al. 2015).

Bearing in mind the 'bottom-up', user-oriented approach to the online platform, WP5's aim was to identify user-friendly, accessible methods for analysing RE+RI cases that can be appropriated by all users, without prior philosophical knowledge, in local contexts. On that basis, WP5 suggested two requirements for an eligible case analysis method:

1) A procedural, 'step-by-step' framework, such as checklist or flowchart, that any user can follow without prior philosophical knowledge for the purposes of analysing RE+RI cases, whereby cases are 'violations' or 'best practice' in a documented form; AND
2) A substantive aspect that is incorporated within the procedural framework in order to supply the normative standards for analysing RE+RI cases, whereby the normative standards can be appropriated by users to meet their local RE+RI requirements.

A scoping search was conducted on 15 October 2018 using Google Scholar. The search terms that were included were: (("research ethics" OR "research integrity") AND ("violation" OR "unethical" OR "misconduct") AND ("analysis" OR "method" OR "procedure")). These are the terms that were included in the systematic review for cases in the academic/grey literature (as detailed in **Report on Task 5.2 Pilot Collection of Data on Cases**) with the addition of ("analysis" OR "method" OR "procedure"). Jonathan Lewis checked the results and screened the content (titles, abstracts) of the first one hundred results, which were ordered in terms of 'relevance'.

It was found that there are no specific methods for analysing RE+RI cases that fulfil both the procedural and substantive requirements.

Normative standards do exist for assessing substantive ethical content in research ethics. These are broadly in line with the standards that have traditionally been employed in biomedical ethics. However, according to the scoping search, these standards are not incorporated within a procedural framework that users can follow without prior philosophical knowledge.

For research integrity, principlist (Steneck 2007; Shamoo and Resnik 2009) and virtue-based (MacFarlane 2008) approaches have been developed to guide researchers in acting with integrity. Again, although these provide normative standards, they do not incorporate these normative standards within a procedural framework that users can follow without prior philosophical knowledge

3.2 The Normative Ethics Approach

One approach we considered was to produce procedures that incorporate normative standards generated by the application of three traditional theories in normative ethics:

- Consequentialism
- Deontology
- Virtue Ethics

There are objections to such an approach.

Firstly, and most importantly, it is unclear how one might turn these normative theories into useable procedural-*cum*-substantive methods (bearing in mind that there is no consensus in contemporary philosophy regarding the scope, application, specification and natures of these respective theories). Note the substantive distinctions between rule-consequentialism, act-consequentialism, perfectionist consequentialism, utilitarianism, and so on. Important subcategory distinctions also exist for deontological and virtue-based approaches.

Secondly, WP2's stakeholder consultation identified three different types of stakeholders: researchers; research ethics committees and research integrity offices; and research administrators (Evans, Veldkamp, Valentini et al. 2018). Even if a method could be produced, stakeholders would need substantial knowledge of each normative theory before they could apply it in the analysis of RE+RI cases. This would undermine the user-oriented, accessible approach of the online platform. We were keen not to dissuade users from engaging with real-life cases in research ethics and research integrity on the basis that the process is seen to be too complex, too confusing and too unreliable with the possibility for too much disagreement or a general lack of consistency.

3.3 The Deontological Approach

A second approach we considered was to adopt a single normative theory and to provide a procedural method that incorporates the normative standards of different subcategories of that theory. For example, were we to focus on deontology in general, we could aim to deliver a procedural method with normative content supplied by Kant's moral philosophy, a second with normative content from intuitionist theories and a third with content derived from *prima facie* duties.

If we take into account the fact that Beauchamp and Childress are now on their seventh edition of their *Principles of Biomedical Ethics*, which attempts to guide ethical decision-making in biomedical settings through the deployment of the principles of autonomy, beneficence, non-maleficence and justice, it is not clear that a single, useful method can be produced for *prima facie* duties (Richardson 2000; Schöne-Seifert 2006; Walker 2009; Paulo 2016). Beauchamp and Childress have iteratively revised and supplemented their brand of principlism in response to contemporary philosophical debates. In doing so, they have sought to integrate other approaches, such as narrative ethics and casuistry. They believe that these traditionally distinct approaches are important and instrumental for principlism's success in the sense that such approaches supplement and enrich their account (Schöne-Seifert 2006). Not only is it questionable whether Beauchamp and Childress' approach is, in fact, a method (Walker 2009), it is difficult to determine the usefulness of their guide to bioethical decision-making bearing in mind that they have sought to converge traditional approaches to ethics into one coherent theory, they have assumed a narrow approach to the norms of common morality and they have deepened and extended their meta-theory through engagement with moral epistemology (Gert, Culver and Clouser 2006; Walker 2009, Paulo 2016).

On that basis, the objections detailed in 3.2 can be seen to apply here as well. Furthermore, bearing in mind that the *prima-facie*-duty approach was developed so as to divest moral philosophy of some of the more controversial concepts and assumptions associated with robust moral theories (Ross 2002), we decided that it is reasonable to expect that the issues raised in section 3.2 cannot be overcome by developing a method for case analyses based on either Kantianism or more intuitionist theories.

3.4 The Framework-Derived Approach

Since the first wave of research ethics scandals occurred in the US and Germany during the 1910s and 1920s, principle- or rule-based frameworks have tended to guide and/or regulate research ethics and research integrity (Pettit 1992; Resnik 1998; Shamoo and Resnik 2009). The development of frameworks has also coincided with the growing regulation of research ethics (Pettit 1992) and, in recent years, research integrity (Resnik 2009). In Europe, the majority of research institutions have their own principle- or rule-based frameworks. The same holds true for national research ethics committees, research integrity offices and funding bodies as well as pan-European funding bodies and institutions (such as ALLEA).

Many codes and frameworks mix specific prescriptions and proscriptions with general principles. No doubt this partly reflects the fact that they have usually been developed by committees and/or through consultation. Consequently, consistency in formulation has been hard to maintain.

Most approaches to research ethics and research integrity are principle-based in that they portray conduct as consisting of adherence to (*prima facie*) rules, duties or responsibilities. For example, the Nuremberg Code (1949) consists of ten directives for human experimentation, the Helsinki Declaration includes thirty-five ethical principles for medical research involving human subjects (World Medical Association 2013), and The Belmont Report articulates three principles for research involving human subjects (National Commission 1979). In 2010, participants in the 2nd World Conference on Research Integrity developed the Singapore Statement on Research Integrity, which includes four principles and fourteen responsibilities pertaining to the conduct of scientific research in various disciplines, not just research with human participants. In addition, the revised European Code of Conduct for Research Integrity (2017) lists four principles and describes a number of responsibilities.

Researchers, research administrators, research ethics committees and research integrity offices (i.e. the three types of stakeholders identified by WP2's stakeholder consultation) will already be (in varying degrees) familiar with these regulatory frameworks and their associated normative standards, especially those that apply to their respective research institutions.

Furthermore, one of the aims of the EnTIRE project (WP3) is to provide a detailed mapping and analysis of the normative documents on research ethics and research integrity that are available within the European Union and to integrate those documents in a meaningful and useful way in the online platform for The Embassy of Good Science.

Bearing in mind that these regulatory frameworks are meant to facilitate integral and ethical conduct, we decided that it is reasonable to believe that they can also be used to analyse RE+RI cases. On that basis, we decided not to 'reinvent the wheel' when it comes to providing the normative standards for case analysis methods. Instead, we decided to incorporate these frameworks and their associated normative standards into procedural methods that can be readily, easily and meaningfully used by all the EnTIRE consortium's stakeholders in local settings without any prior philosophical knowledge. Framework-derived reflection would, thus, be central to these procedural methods. Such an approach would achieve a balance of practical usefulness and substantive normative content necessary for the analysis of RE+RI cases by non-philosophers in different research-oriented roles.

Different procedural methods already exist in the field of bioethics. These include the Nijmegen Method, the four quadrants approach, the case (deliberation) method and various dialogical processes (Gini 1985; Widdershoven 2001; Gracia 2003; Steinkamp and Gordijn 2003; Sokol 2008).

3.5 Procedure Summary

It was decided that a systematic review would be undertaken to check the results of the scoping search (section 3.1). The aim of the systematic review was to identify specific methods for analysing RE+RI cases that fulfil the following requirements:

1) A procedural, 'step-by-step' framework, such as checklist or flowchart, that any user can follow without prior philosophical knowledge for the purposes of analysing RE+RI cases, whereby cases are 'violations' or 'best practice' in a documented form; AND
2) A substantive aspect that is incorporated within the procedural framework in order to supply the normative standards for analysing RE+RI cases, whereby the normative standards can be appropriated by users to meet their local RE+RI requirements.

We refer to these as 'ideal case analysis methods'. We were aware, however, that the systematic review might only identify 'partial methods' (i.e. methods that only meet one of the requirements). As part of the systematic review, we decided to record the details of partial methods, and use these to construct 'ideal case analysis methods' later in the process.

We were also aware that the systematic review might return neither ideal nor partial case analysis methods. To manage this risk, we decided to supplement our procedure for identifying case analysis methods by surveying members of the EnTIRE and VIRT2UE consortiums, which include a number of international experts in research ethics, research integrity, bioethics and medical ethics. We asked consortium members not only to identify procedural, 'step-by-step' frameworks, such as checklists or flowcharts, for the purposes of analysing RE+RI cases, but also to pinpoint any procedures for analysing cases in clinical medicine, medical ethics or other fields of applied ethics. Even if members of these consortiums could not identify procedures for analysing RE+RI cases, they *would* certainly be able to identify 'ethical case analysis' procedures in related areas of applied ethics that might subsequently be adapted to provide procedures for analysing RE+RI cases.

It was decided that even though several independent procedures might be identified and adapted, the normative standards of those procedures should be founded on framework-

derived reflection (section 3.4). Consequently, we decided not to take a position on the normative standards themselves, but allow users to reflect on the basis of the RE+RI frameworks that apply to their institution, national context, funding programme and/or profession.

We decided that once we had identified and suitably adapted the procedural methods, we would analyse a set of prominent/topical cases using those methods. These analyses would function as examples that could inform the users of the online platform.

The criteria we used to determine whether a case is 'prominent' or 'topical' are:

1) It has played an important role in educating students, researchers, RECs, RIOs and practitioners in research ethics and/or research integrity;
2) It has been discussed in the public sphere, including in the media and social media;
3) It can be considered to be a paradigm case of good or bad practice in relation to one or more of the central principles of research integrity (e.g., fraud, fabrication or plagiarism) and/or research ethics (respect for autonomy, harm, beneficence or justice);
4) It is promoted on well-known online platforms, which are primarily concerned with research integrity and/or research ethics;
5) It has motivated changes in major research ethics and/or research integrity guidelines and/or regulations;
6) It is deemed to be of interest to one of the three groups of stakeholders identified by WP2's stakeholder consultation.

So long as a case fulfilled at least one of the six criteria, it would be considered to be 'prominent' or 'topical'.

In summary:

- WP5 decided to undertake a systematic review to check the results of the scoping search;

- By surveying the EnTIRE and VIRT2UE consortiums, WP5 would identify procedural methods that could be suitably adapted for the analysis of RE+RI cases;
- WP5 would create a set of procedural methods that incorporates the framework-derived approach to normative standards for the analysis of RE+RI cases;
- WP5 would analyse a set of particularly prominent/topical cases using the set of procedural methods;
- WP5 would make the entire set of procedural methods and associated case analysis examples available for upload to The Embassy of Good Science.

3.6 Section References

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World Medical Association. Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects. https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/. Published June 1964. Amended October 2013. Accessed November 1, 2018.

4. Systematic Review of Case Analysis Methods

4.1 Systematic Review Structure

To search for case analysis methods, we used the *structure* of a refined systematic review. According to the *Cochrane Handbook for Systematic Reviews of Interventions* (Version 5.1.0), a systematic review 'reduces the impact of authors' biases, promotes transparency of methods and processes, reduces the potential for duplication, and allows peer review of the planned methods' (Higgins and Green eds. 2011). The 'gold standard' for systematic reviews is detailed in the *Cochrane Handbook*, produced by The Cochrane Collaboration. The *Handbook* instructs researchers on the method of full-scale systematic reviews, which, as the Cochrane Collaboration acknowledges, can take several years to produce. Due to time constraints, the *Cochrane Handbook* has been used to produce a refined systematic review for searching for case analysis methods in academic/grey literature. The systematic review structure is derived from the Preferred Reporting Items for Systematic Reviews and Meta-Analyses ('PRISMA') guidelines, an example of which is provided in the *Cochrane Handbook* (see **Figure 4.1**). It is structured as follows:

- Create and refine a set of search terms using Boolean operators;
- Choose the bibliographic and citation databases to search;
- Search the databases and export references to bibliographic software;
- Identify and remove duplicates
- Screen the results according to 'Title' and 'Abstract' in order to identify ideal and partial case analysis methods;
- Produce a refined list of references using appropriate data management software;
- Read the publications in full;
- 'Snowball' for additional publications that are mentioned in the reference lists of the initial set of publications;

- Having read the publications in full, remove references that are unsuitable or 'off topic' according to criteria detailed in section 3.1 above;
- Produce another refined list of references using appropriate data management software;
- Produce two separate lists of case analysis methods, one for 'ideal' methods and another for 'partial methods';
- Report the search.

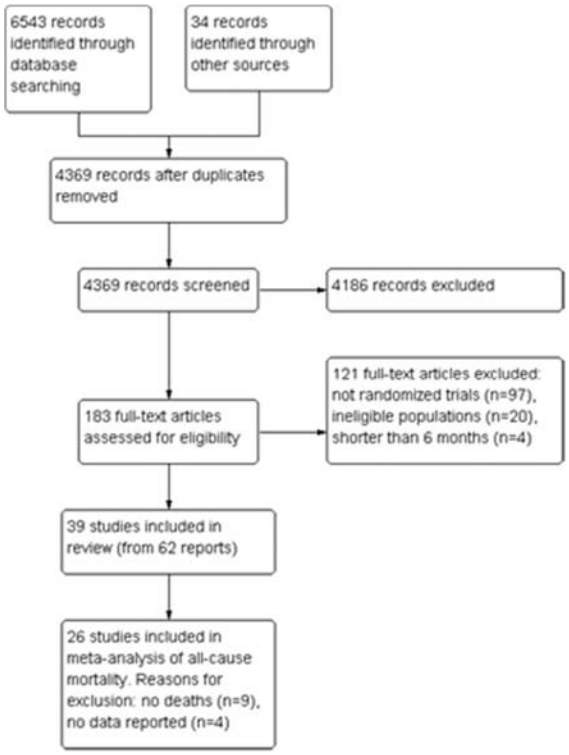

Figure 4.1: Systematic Review Flow Diagram (reproduced from the *Cochrane Handbook*, Fig. 11.2a)

4.2 Account of the Review

- *Create and refine a set of search terms using Boolean operators:*

The search terms that were included were: ((“research ethics” OR “research integrity”) AND (“violation” OR “unethical” OR “misconduct”) AND (“analysis” OR “method” OR “procedure”)). These are the terms that were employed in the systematic review for cases in the academic/grey literature (as detailed in **Report on Task 5.2 Pilot Collection of Data on Cases**) with the addition of (“analysis” OR “method” OR “procedure”). These terms correspond to those used during the scoping search of 15 October 2018.

It should be noted that WP5, as part of tasks 5.2 and 5.3, developed a search methodology for cases in academic/grey literature using two sets of keywords. The purpose was to generate two sets of cases, one for research ethics and one for research integrity. As detailed in **Report on Task 5.2 Pilot Collection of Data on Cases**, these parallel searches will enable WP5 to analyse the overlaps and differences between, and evolution of the representation of, research ethics and research integrity. However, at this stage, we do have sufficient evidence to discern the similarities and differences between RE cases and RI cases.

- *Choose the bibliographic and citation databases to search;*

On the basis that it covers all the citations included in PubMed/MEDLINE and EMBASE from 1966, and some older PubMed citations from 1949-1965, the Scopus database was employed. It is considered to be one of the most widely-used and frequently-cited databases for research associated with the aims, purposes and content of this deliverable.

- *Search the databases and export references to bibliographic software;*

The search was conducted via Scopus on 3 December 2018. The search retrieved 500 items, which were exported to Zotero in a CSV file.

- *Identify and remove duplicates*

Duplicates were identified and removed leaving 499 items.

- *Screen the results according to 'Title' and 'Abstract' in order to identify ideal and partial case analysis methods;*

Following the initial screening process, 21 items were eligible for inclusion.

- *'Snowball' for additional publications that are mentioned in the reference lists of the initial set of publications;*

An additional six items were identified by checking the publications cited in the reference lists of the remaining 21 items.

- *Having read the publications in full, remove references that are unsuitable or 'off topic' according to criteria detailed in section 3.1 above;*

Each of the 27 items was read in full and assessed against the following criteria for inclusion:

1) A procedural, 'step-by-step' framework, such as checklist or flowchart, that any user can follow without prior philosophical knowledge for the purposes of analysing RE+RI cases, whereby cases are 'violations' or 'best practice' in a documented form; AND

2) A substantive aspect that is incorporated within the procedural framework in order to supply the normative standards for analysing RE+RI cases, whereby the normative standards can be appropriated by users to meet their local RE+RI requirements.

Eleven items were identified. Of these, three publications fulfilled at least criteria (1), thereby constituting a 'partial case analysis method'. Although eight publications discussed normative standards, these failed to take account of, specifically, *local* RE+RI requirements as articulated in institutional, regulatory or statutory codes, regulations, laws and frameworks. None of the identified eleven items fulfilled the sufficient criteria to constitute an 'ideal case analysis method'.

- *Produce another refined list of references using appropriate data management software;*

The three items relating to partial, procedural methods were exported to Zotero.

- *Produce two separate lists of case analysis methods, one for 'ideal' methods and another for 'partial methods';*

Two lists were produced; one that included the three items that met the criteria for a partial method; and another that included 0 items that met the criteria for an ideal method.

4.3 Systematic Review Results

Three references were identified that fulfilled the following criteria for a case analysis method:

1) A procedural, 'step-by-step' framework, such as checklist or flowchart, that any user can follow without prior philosophical knowledge for the purposes of analysing RE+RI cases, whereby cases are 'violations' or 'best practice' in a documented form; AND

These references are (in date order):

- Frisch N. Value Analysis: A Method for Teaching Nursing Ethics and Promoting the Moral Development of Students. *Journal of Nursing Education*. 1987;26(8):328–32.

- Valdes D, Giraldo E, Ferrer J, Frey W. Case Analysis: A Tool for Teaching Research Ethics in Science and Engineering for Graduate Students. *2009 Annual Conference & Exposition*, Austin, Texas. https://peer.asee.org/5729. Published 14 June 2009. Accessed 9 April 2019.

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5. EnTIRE and VIRT2UE Survey

5.1 Survey Description

As mentioned above, we decided to supplement the results of the systematic review by surveying members of the EnTIRE and VIRT2UE consortiums.

In the survey, we stressed that our aim was to identify *user-friendly*, *accessible* methods that can be appropriated by all users, *without any significant prior philosophical knowledge*, in order to analyse RE+RI cases *in local contexts*.

The survey was distributed by the coordinator of the EnTIRE consortium on 16 January 2019. A copy of the survey is included in **Appendix 1**.

The results of the survey were provided on 30 January 2019.

5.2 Survey Results

The survey was distributed to 41 members of the EnTIRE and VIRT2UE consortiums.

Ten anonymised responses were received.

Five of the respondents claimed that they are not aware of any procedural, 'step-by-step' frameworks, such as a checklist or a flowchart, for the purposes of analysing RE+RI cases or any procedures for analysing cases in clinical medicine, medical ethics or other fields of applied ethics. As a result, these responses were removed from the results.

For the remaining five responses, the following results were obtained:

Method	Suggested Sources	Philosophical Knowledge Needed?	User-friendly?	Adaptable for RE+RI Cases?
CME-Method	Molewijk B, Engerdahl I, Pedersen R. Two years of moral case deliberations on the use of coercion in mental health care: Which ethical challenges are being discussed by health care professionals? *Clinical Ethics* 2016;11(2-3):87-96.	No	Yes	Yes
Ethics Case Deliberation	Gracia D. Ethical case deliberation and decision making. *Medicine, Health Care and Philosophy* 2003;6 (3):227-33.	Yes	No	Unconfirmed
Seven Step Method	Werhane P, Bowie N, Boatright J, Velasquez M. The Seven Step Method for Analyzing Ethical Situations. [Online]. https://studylib.net/doc/18058307/model-g---the-seven-step-method-for-analyzing-ethical-sit.... Published 1990. Accessed 25 February 2019.	No	Yes	Yes
MCD Framework (Dilemma Method)	Stolper M, Molewijk B, Widdershoven G. Bioethics education in clinical settings: theory and practice of the dilemma method of moral case deliberation. *BMC Med Ethics* 2016;17(1):45.	No	Yes	Yes

EthXpert	Laaksoharju M, Kavathatzopoulos I. EthXpert: The Basic Structure and Functionality of a Decision Support System in Ethics. [Online]. Accessed 9 April 2019.	No	Yes	Yes
A Framework for Ethical Decision Making	Velasquez M, Moberg D, Meyer M, et al. A Framework for Ethical Decision Making. [Online].https://www.scu.edu/ethics/ethics-resources/ethical-decision-making/a-framework-for-ethical-decision-making/. Published May 2009. Accessed 9 April 2019.	No	Yes	Yes
Four Quadrant Approach	Sokol D. The "four quadrants" approach to clinical ethics case analysis; an application and review. *J Med Ethics* 2008;34(7):513-6.	No	Unconfirmed	Yes
Decisions under conditions of clinical uncertainty	McCullough L. The professional medical ethics model of decision making under conditions of clinical uncertainty. *Med Care Res Rev* 2013;70(1 Supp):141S-158S	No	Unconfirmed	Yes

The following condition needed to be satisfied by any appropriate partial case analysis method:

1. A procedural, 'step-by-step' framework, such as checklist or flowchart, that any user can follow without prior philosophical knowledge for the purposes of analysing RE+RI cases, whereby cases are 'violations' or 'best practice' in a documented form;

On that basis, the methods that are not user-friendly, presuppose philosophical knowledge or cannot be adapted to analyse research ethics and research integrity cases were deemed to be ineligible.

As a result, the following revised list of methods was produced:

Method	Suggested Sources	Philosophical Knowledge Needed?	User-friendly?	Adaptable for RE+RI Cases?
Seven Step Method	Werhane P, Bowie N, Boatright J, Velasquez M. The Seven Step Method for Analyzing Ethical Situations. [Online]. https://studylib.net/doc/18058307/model-g---the-seven-step-method-for-analyzing-ethical-sit.... Published 1990. Accessed 25 February 2019.	No	Yes	Yes
MCD Framework (Dilemma Method)	Stolper M, Molewijk B, Widdershoven G. Bioethics education in clinical settings: theory and practice of the dilemma method of moral case deliberation. *BMC Med Ethics* 2016;17(1):45.	No	Yes	Yes
Four Quadrant Approach	Sokol D. The "four quadrants" approach to clinical ethics case analysis; an application and review. *J Med Ethics* 2008;34(7):513-6.	No	Unconfirmed	Yes
CME-Method	Molewijk B, Engerdahl I, Pedersen R. Two years of moral case deliberations on the use of coercion in mental health care: Which ethical challenges are being discussed by health care professionals? *Clinical Ethics* 2016;11(2-3):87-96.	No	Yes	Yes
EthXpert	Laaksoharju M, Kavathatzopoulos I. EthXpert: The Basic Structure and Functionality of a Decision Support System in Ethics. [Online]. Accessed 9 April 2019.	No	Yes	Yes
A Framework for Ethical Decision Making	Velasquez M, Moberg D, Meyer M, et al. A Framework for Ethical Decision Making. [Online].https://www.scu.edu/ethics/ethics-resources/ethical-decision-making/a-framework-for-ethical-decision-making/. Published May 2009. Accessed 9 April 2019.	No	Yes	Yes
Decisions under conditions of clinical uncertainty	McCullough L. The professional medical ethics model of decision making under conditions of clinical uncertainty. *Med Care Res Rev* 2013;70(1 Supp):141S-158S	No	Unconfirmed	Yes

6. List of Case Analysis Methods

Taking into account the results of the systematic review and the survey, the following methods were identified that fulfilled the criteria of a partial case analysis method, specifically:

1. A procedural, 'step-by-step' framework, such as checklist or flowchart, that any user can follow without prior philosophical knowledge;

Method	**Suggested Sources**
Value Analysis	Frisch N. Value Analysis: A Method for Teaching Nursing Ethics and Promoting the Moral Development of Students. *Journal of Nursing Education*. 1987;26(8):328–32.
Teaching Research Ethics Tool	Valdes D, Giraldo E, Ferrer J, Frey W. Case Analysis: A Tool for Teaching Research Ethics in Science and Engineering for Graduate Students. *2009 Annual Conference & Exposition*, Austin, Texas. https://peer.asee.org/5729. Published 14 June 2009. Accessed 9 April 2019.
REalistiC Decisions	Davies H. How we can make better decisions in review and design of research using a simple ethics model. *Journal of Medical Ethics: Blog*. https://blogs.bmj.com/medical-ethics/2018/10/11/how-we-can-make-better-decisions-in-review-and-design-of-research-using-a-simple-ethics-model/. Published 18 October 2018. Accessed 10 March 201.
Seven Step Method	Werhane P, Bowie N, Boatright J, Velasquez M. The Seven Step Method for Analyzing Ethical Situations. [Online]. https://studylib.net/doc/18058307/model-g---the-seven-step-method-for-analyzing-ethical-sit.... Published 1990. Accessed 25 February 2019.
MCD Framework (Dilemma Method)	Stolper M, Molewijk B, Widdershoven G. Bioethics education in clinical settings: theory and practice of the dilemma method of moral case deliberation. *BMC Med Ethics* 2016;17(1):45.
Four Quadrant Approach	Sokol D. The "four quadrants" approach to clinical ethics case analysis; an application and review. *J Med Ethics* 2008;34(7):513-6.
CME-Method	Molewijk B, Engerdahl I, Pedersen R. Two years of moral case deliberations on the use of coercion in mental health care: Which ethical challenges are being discussed by health care professionals? *Clinical Ethics* 2016;11(2-3):87-96.

EthXpert	Laaksoharju M, Kavathatzopoulos I. EthXpert: The Basic Structure and Functionality of a Decision Support System in Ethics. [Online]. Accessed 9 April 2019.
A Framework for Ethical Decision Making	Velasquez M, Moberg D, Meyer M, et al. A Framework for Ethical Decision Making. [Online].https://www.scu.edu/ethics/ethics-resources/ethical-decision-making/a-framework-for-ethical-decision-making/. Published May 2009. Accessed 9 April 2019.
Decisions under conditions of clinical uncertainty	McCullough L. The professional medical ethics model of decision making under conditions of clinical uncertainty. *Med Care Res Rev* 2013;70(1 Supp):141S-158S

7. Summary of Case Analysis Methods and Case Analyses

7.1 D.5.3 and Task 5.4

The EnTIRE proposal demands that WP5 deliver the set of case deliberation methods and case analyses as input for the platform by M24. This constitutes D.5.3. However, the proposal also states that Task 5.4, specifically, the task of *identifying and applying appropriate case analysis methods and building RE+RI scenarios*, should continue until the end of the project (M48).

The case analysis methods and case analyses included in this report fulfil the requirements of the deliverable. However, on the basis of our experiences with previous deliverables, we know that discussions regarding the presentation of these deliberation methods and analyses on the platform need to take place across work packages.

As we have found by identifying, tagging and presenting data regarding RE+RI cases for the online platform, the case deliberation methods and analyses as they are presented here are likely to develop in response to cross-consortium discussions, stakeholder consultation and user engagement.

On that basis, we are presenting six case analysis methods and associated analyses in order to fulfil the requirements of D.5.3. Nevertheless, in the interests of efficiency and in order to remain open to innovation and adaptation, we will apply the remaining four case analysis methods to specific cases once there is better cross-consortium understanding of the structure and content of The Embassy of Good Science in general. By adopting this approach, we are able to reconcile D.5.3 with the demands of Task 5.4.

7.2 Future Case Analyses

To fulfil the requirements of Task 5.4 (to be completed by M48), we will present case analyses using the following methods once there is better cross-consortium understanding of the structure and content of The Embassy of Good Science in general:

Method	**Suggested Sources**
CME-Method	Molewijk B, Engerdahl I, Pedersen R. Two years of moral case deliberations on the use of coercion in mental health care: Which ethical challenges are being discussed by health care professionals? *Clinical Ethics* 2016;11(2-3):87-96.
EthXpert	Laaksoharju M, Kavathatzopoulos I. EthXpert: The Basic Structure and Functionality of a Decision Support System in Ethics. [Online]. Accessed 9 April 2019.
A Framework for Ethical Decision Making	Velasquez M, Moberg D, Meyer M, et al. A Framework for Ethical Decision Making. [Online].https://www.scu.edu/ethics/ethics-resources/ethical-decision-making/a-framework-for-ethical-decision-making/. Published May 2009. Accessed 9 April 2019.
Decisions under conditions of clinical uncertainty	McCullough L. The professional medical ethics model of decision making under conditions of clinical uncertainty. *Med Care Res Rev* 2013;70(1 Supp):141S-158S

7.3 Current Case Analyses

In the remaining sections of the report, we present the following case analysis methods and the associated analyses of the following cases:

Method	Suggested Sources	Case	Principal Case Source
Value Analysis	Frisch N. Value Analysis: A Method for Teaching Nursing Ethics and Promoting the Moral Development of Students. *Journal of Nursing Education*. 1987;26(8):328–32.	Text-Generating AI Technologies	Radford A, Wu J, Amodei D, et al. Better Language Models and their Implications. [Online]. https://openai.com/blog/better-language-models/ Published 14 February 2019. Accessed 15 March 2019.
Teaching Research Ethics Tool	Valdes D, Giraldo E, Ferrer J, Frey W. Case Analysis: A Tool for Teaching Research Ethics in Science and Engineering for Graduate Students. *2009 Annual Conference & Exposition*, Austin, Texas. https://peer.asee.org/5729. Published 14 June 2009. Accessed 9 April 2019.	STAP Case	Cyranoski D. Research integrity: Cell-induced stress. *Nature* 2014;511(7508):140–3.
REalistiC Decisions	Davies H. How we can make better decisions in review and design of research using a simple ethics model. *Journal of Medical Ethics: Blog*. https://blogs.bmj.com/medical-ethics/2018/10/11/how-we-can-make-better-decisions-in-review-and-design-of-research-using-a-simple-ethics-model/. Published 18 October 2018. Accessed 10 March 201.	Grievance Studies Affair	Wikipedia contributors, 'Grievance Studies Affair', *Wikipedia, The Free Encyclopedia,* https://en.wikipedia.org/w/index.php?title=Grievance_Studies_affair&oldid=884101416. Accessed 13 March 2019

Seven Step Method	Werhane P, Bowie N, Boatright J, Velasquez M. The Seven Step Method for Analyzing Ethical Situations. [Online]. https://studylib.net/doc/18058307/model-g---the-seven-step-method-for-analyzing-ethical-sit.... Published 1990. Accessed 25 February 2019.	Legal threats force corrections over a scale measuring medication usage	Marcus A. Legal threats once again force corrections over a scale measuring medication usage. [Online]. https://retractionwatch.com/2019/02/15/legal-threats-once-again-force-corrections-over-a-scale-measuring-medication-usage/#more-86298. Published 15 February 2019. Accessed 10 April 2019.
MCD Framework (Dilemma Method)	Stolper M, Molewijk B, Widdershoven G. Bioethics education in clinical settings: theory and practice of the dilemma method of moral case deliberation. *BMC Med Ethics* 2016;17(1):45.	The Dan Markingson Case	Patient Safety Movement. Patient Story: Dan Markingson. [Online]. https://patientsafetymovement.org/advocacy/patients-and-families/patient-stories/dan-markingson/. Accessed 10 April 2019.
Four Quadrant Approach	Sokol D. The "four quadrants" approach to clinical ethics case analysis; an application and review. *J Med Ethics* 2008;34(7):513-6.	Japanese Fraud Highlights Media-Driven Research Ethic	Normile D. Japanese Fraud Highlights Media-Driven Research Ethic**.** *Science* 2001;291(5501):34-5.

For each case analysis method above, the following sections include a description of the case analysis method. These descriptions have been created so that they can be adopted by the users of the online platform in order to analyse RE+RI cases. Consequently, each description is relatively short, stepwise and systematic, containing little or no jargon, self-explanatory, easy to follow and usable by any potential user of the platform. Each description also includes an account of how the original procedural method has been adapted to ensure that it can be employed to analyse RE+RI cases. Finally, for each case analysis method, there is an associated analysis of a prominent/topical case that demonstrates how the method might be employed in practice to analyse RE+RI cases.

8. Case Analysis Method 1: Value Analysis

8.1 Description

8.1.1 The Author

This case analysis uses a procedure advanced by Jack R. Fraenkel (1976) for the purpose of values education. Fraenkel (1932-2013) earned a PhD from Stanford University in 1966 and subsequently worked at San Francisco State University for more than 30 years. When he retired, he was Professor of Interdisciplinary Studies in Education. Fraenkel published a lot on research methodology, curriculum development and research in education (Obituary, 2014). Guided by the work of Coombs and Meux (1971), Fraenkel (1976) advanced an interesting method to analyse value conflicts meant for teachers "[…] to help students determine for themselves what individuals caught in value dilemmas should do […]" (Fraenkel, 1976, 202).

8.1.2 The Value Analysis Method

Fraenkel's method contains the following seven steps:

1. What is the incident about? (What is the dilemma?)
2. What might (the central character) do to try and resolve the dilemma? (What alternatives exist?)
3. What might happen if he or she does each of these things? (What might be the consequences of the various alternatives?)
4. What might happen to those who are not immediately involved? (What might be the short- as well as the long-range consequences?
5. What evidence, if any, is there that these consequences would indeed occur?
6. Would each consequence be good or bad? Why?

7. What do you think X should do? (What do you think is the best thing for X to do?) (Fraenkel, 1976, 202-203).

Figure 8.1 presents Fraenkel's method as a flowchart:

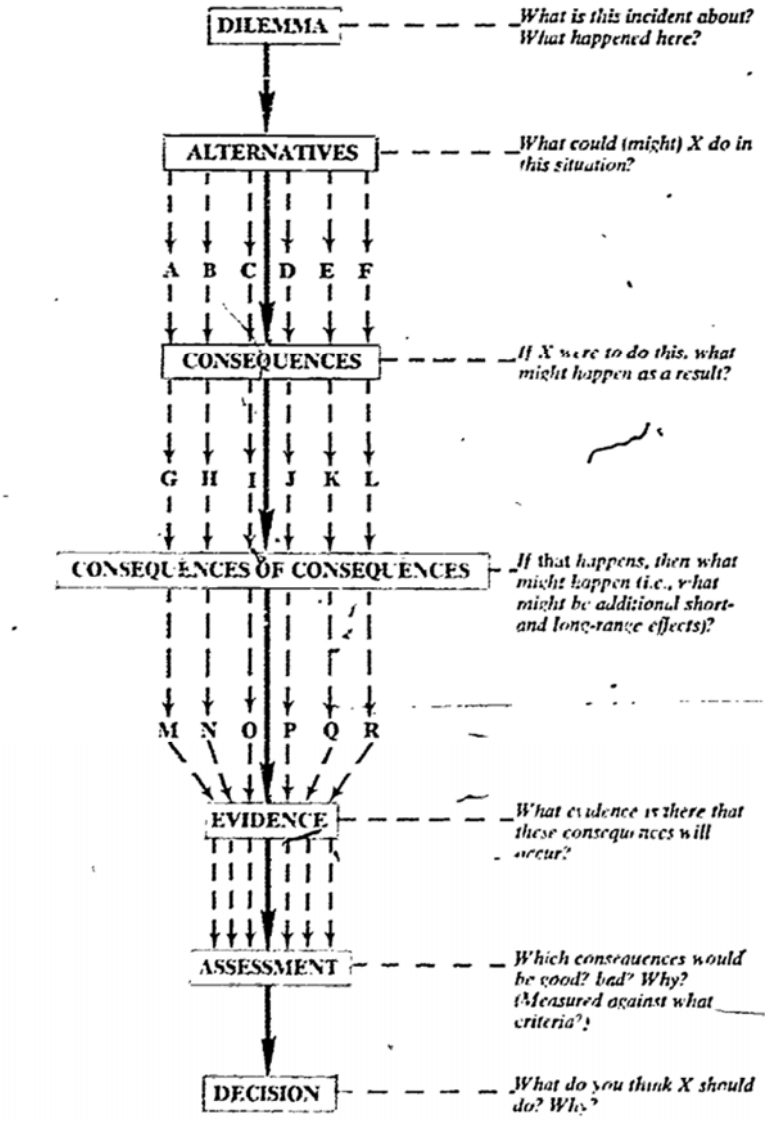

Figure 8.1: From Fraenkel, 1976, 204.

8.1.3 Additional Details

Ad. 1: Fraenkel stresses the importance of identifying whether the conflict is about ends or means to ends that have been agreed upon. Equally important is to establish the factual context of the situation (Fraenkel, 1976, 203).

Ad. 2: This step involves brainstorming for all the available action alternatives for the agent(s) facing the value conflict at hand (Fraenkel, 1976, 203).

Ad. 3 and 4: These questions are focused on the expected consequences of the different alternative actions available to those facing the value conflict. What might be the effects of each alternative respectively? Which parties might be affected? Could the consequences spill over to future generations? It might make sense here to distinguish between short- and long-range effects for the individual and other parties. In order to map these consequences, a Values Information Chart (**Figure 8.2**) could be used (Fraenkel, 1976, 203-5).

Facts	Alternatives	Consequences			
		Short-Range		Long-Range	
		Self	Others	Self	Others

Figure 8.2: Values Information Chart Template

Ad. 5: This question zooms in on the evidence supporting or refuting the potential effects of the alternative actions as identified above. If the case at hand is similar to case studies from the past, it might be useful to study what happened there. Data to that effect should be gathered, and their truthfulness and relevance to the case at hand established (Fraenkel, 1976, 205).

Ad. 6: A discussion of the desirability of the expected consequences is needed. This should happen based on certain criteria. These criteria might be of a moral, legal, aesthetic, ecological, economic, health and safety and/or a completely different nature. A Value Analysis Chart (**Figure 8.3**) could be used to keep track of the assessment of the different consequences along the different criteria. In the last column of this chart the desirability of the different consequences is ranked from the most to the least desirable (Fraenkel, 1976, 205-7).

Ad. 7: Fraenkel does not explain how the answer to this final question should follow from the analysis above. It seems to be implicit in his method that the answer automatically matches the alternative that turns out to be most desirable over all.

Alternatives	Consequences	Desirability from various points of view							Ranking
		Moral	Legal	Aesthetic	Ecological	Economic	Health and Safety	Etc.	

Figure 8.3: Value Analysis Chart Template

8.2 Case Analysis: Text Generating AI Technologies

8.2.1 Introduction

The case study involves the partial release of a new AI text generation model called GPT-2. The model has been developed by OpenAI, a non-profit research organization (see: https://openai.com/). In contrast to the manner in which they handled the release of previous products, OpenAI decided not to release GPT-2 completely due to concerns about potential malicious use (see OpenAi Blogpost, 2019 for the complete case study):

> Our model, called GPT-2 (a successor to GPT), was trained simply to predict the next word in 40GB of Internet text. Due to our concerns about malicious applications of the technology, we are not releasing the trained model. As an experiment in responsible disclosure, we are instead releasing a much smaller model for researchers to experiment with, as well as a technical paper. (OpenAi Blogpost, 2019)

Below follows a nontechnical description of GPT-2' text generating capabilities taken from OpenAI's blogpost (see Radford et al., 2019 & OpenAI Code, 2019 for technical details)

> GPT-2 generates synthetic text samples in response to the model being primed with an arbitrary input. The model is chameleon-like—it adapts to the style and content of the conditioning text. This allows the user to generate realistic and coherent continuations about a topic of their choosing […].
>
> [...] our model is capable of generating samples from a variety of prompts that feel close to human quality and show coherence over a page or more of text. Nevertheless, we have observed various failure modes, such as repetitive text, world modeling failures (e.g. the model sometimes writes about fires happening under water), and unnatural topic switching. Exploring these types of weaknesses of language models is an active area of research in the natural language processing community.
>
> Overall, we find that it takes a few tries to get a good sample, with the number of tries depending on how familiar the model is with the context. When prompted with topics that are highly represented in the data (Brexit, Miley Cyrus, Lord of the

> Rings, and so on), it seems to be capable of generating reasonable samples about 50% of the time. The opposite is also true: on highly technical or esoteric types of content, the model can perform poorly. Fine-tuning offers the potential for even more detailed control over generated samples—for example, we can fine-tune GPT-2 on the Amazon Reviews dataset and use this to let us write reviews conditioned on things like star rating and category.
>
> These samples have substantial policy implications: large language models are becoming increasingly easy to steer towards scalable, customized, coherent text generation, which in turn could be used in a number of beneficial as well as malicious ways. (OpenAi Blogpost, 2019)

OpenAI sketch the policy implications as follows:

> Large, general language models could have significant societal impacts, and also have many near-term applications. We can anticipate how systems like GPT-2 could be used to create:
>
> - AI writing assistants
> - More capable dialogue agents
> - Unsupervised translation between languages
> - Better speech recognition systems
>
> We can also imagine the application of these models for malicious purposes, including the following (or other applications we can't yet anticipate):
>
> - Generate misleading news articles
> - Impersonate others online
> - Automate the production of abusive or faked content to post on social media
> - Automate the production of spam/phishing content
>
> These findings, combined with earlier results on synthetic imagery, audio, and video, imply that technologies are reducing the cost of generating fake content and waging disinformation campaigns. The public at large will need to become more skeptical of text they find online, just as the "deep fakes" phenomenon calls for more skepticism about images.
>
> Today, malicious actors—some of which are political in nature—have already begun to target the shared online commons, using things like "robotic tools, fake accounts and dedicated teams to troll individuals with hateful commentary or smears that make them afraid to speak, or difficult to be heard or believed". We

> should consider how research into the generation of synthetic images, videos, audio, and text may further combine to unlock new as-yet-unanticipated capabilities for these actors, and should seek to create better technical and non-technical countermeasures. Furthermore, the underlying technical innovations inherent to these systems are core to fundamental artificial intelligence research, so it is not possible to control research in these domains without slowing down the progress of AI as a whole. (OpenAi Blogpost, 2019)

Against this backdrop, OpenAI justify their GPT-2 release strategy as follows:

> Due to concerns about large language models being used to generate deceptive, biased, or abusive language at scale, we are only releasing a much smaller version of GPT-2 along with sampling code. We are not releasing the dataset, training code, or GPT-2 model weights. Nearly a year ago we wrote in the OpenAI Charter: 'we expect that safety and security concerns will reduce our traditional publishing in the future, while increasing the importance of sharing safety, policy, and standards research,' and we see this current work as potentially representing the early beginnings of such concerns, which we expect may grow over time. This decision, as well as our discussion of it, is an experiment: while we are not sure that it is the right decision today, we believe that the AI community will eventually need to tackle the issue of publication norms in a thoughtful way in certain research areas. Other disciplines such as biotechnology and cybersecurity have long had active debates about responsible publication in cases with clear misuse potential, and we hope that our experiment will serve as a case study for more nuanced discussions of model and code release decisions in the AI community.
>
> We are aware that some researchers have the technical capacity to reproduce and open source our results. We believe our release strategy limits the initial set of organizations who may choose to do this, and gives the AI community more time to have a discussion about the implications of such systems.
>
> We also think governments should consider expanding or commencing initiatives to more systematically monitor the societal impact and diffusion of AI technologies, and to measure the progression in the capabilities of such systems. If pursued, these efforts could yield a better evidence base for decisions by AI labs and governments regarding publication decisions and AI policy more broadly.
>
> We will further publicly discuss this strategy in six months. If you'd like to discuss large language models and their implications, please email us at: languagequestions@openai.com. (OpenAi Blogpost, 2019)

8.2.2 Analysis

1. *What is the incident about? (What is the dilemma?)*

The main question at stake in the case study is whether OpenAI's GPT-2 release strategy is ethically justified.

2. *What might (the central character) do to try and resolve the dilemma? (What alternatives exist?)*

When it comes to the release of GPT-2 the alternatives available are:

1) No release at all
2) A partial release
3) A complete release

3. *What might happen if he or she does each of these things? (What might be the consequences of the various alternatives?)*

1) In the no-release scenario, nobody outside OpenAI would initially know about the existence of GPT-2. However, leaks might obviously occur. In addition, in the short-to-medium terms other research organizations would probably develop similarly powerful models. Not releasing GPT-2 would thus most likely not avoid the development of similar technologies by others. It would at most postpone the emergence of this technology. In addition, the no-release scenario would not be ideal to facilitate a debate about the ethics of powerful text generating AI systems. After all, there would not be any trigger for such a discussion as nobody outside OpenAI would know about the existence of such potent dual use technologies. Of course, OpenAI could still start such a discussion without releasing anything about GPT-2. However, when asked why they engaged in such a

debate, it would be disingenuous not to reveal anything about GPT-2. If in such a context OpenAI were to disclose the true backdrop of their eagerness to spark a debate, this would prompt the partial-release scenario.

2) The partial-release scenario seems ideal to both postpone the emergence of the full-fledged text generating AI technologies and to trigger a lively discussion of the dual use character of the same. On the one hand, it would postpone the appearance of the technology, thus generating time for solid reflection and the development of policy frameworks, if need be. On the other hand, it would expose enough about the prospects of the technology to make people aware of the need for a substantial discussion of the dual use problems of text generating models without anybody being immediately able to mobilize the potential of the full-fledged model.

3) In a complete-release scenario, everybody would be immediately able to use the full-fledged version of GPT-2. This would trigger the fastest development of the AI technologies. It would not generate any leeway for a discussion to take place and necessary policy frameworks to be developed in advance of substantial societal impacts. Discussion would not be perceived as acute because of the full release.

4. *What might happen to those who are not immediately involved? (What might be the short as well as the long-range consequences?)*

In all three scenarios, full-fledged text generating AI systems would be developed. This means that in all three scenarios one would encounter the likely positive and negative societal impacts of sophisticated, general language models as listed by OpenAI in their blogpost.

Potential benefits are:

- “AI writing assistants

- More capable dialogue agents
- Unsupervised translation between languages
- Better speech recognition systems" (OpenAi Blogpost, 2019)

Potential harms are:

- "Generate misleading news articles
- Impersonate others online
- Automate the production of abusive or faked content to post on social media
- Automate the production of spam/phishing content" (OpenAi Blogpost, 2019)

The only significant difference would be the time and space left in advance for the development of policy and regulatory frameworks to enhance the expected benefits and soften the anticipated harms associated with these systems. As discussed above, the partial-release scenario would optimize conditions for such important work to take place. The consequences could be captured in a values-information chart as follows:

Facts	Alternatives	Consequences			
		Short-Range		Long-Range	
		Self	Others	Self	Others
See case study description above	No release scenario	It would be more difficult for OpenAI to start a debate If they did and would be asked why, they would either have to be disingenuous or move to a partial release scenario	Everybody outside OpenAI would remain in ignorance about the technological development that are about to take place leaving less room for debate and policy development.	OpenAI does not spark any substantial debate; neither can it stop the development of the technology.	Positive and negative societal impacts occur because others develop the AI systems.
	Partial release scenario	This is the ideal scenario to start a debate, which would be in line with OpenAI' charter	Third parties would be better informed about the prospects of powerful text generating AI systems and have some time to discuss and develop policies.	OpenAI can spark substantial debate in order to prepare for these impacts, thereby allowing the development of measures that mitigate the potential harms and enhance the expected benefits.	Positive and negative societal impacts occur. There is a change that the ratio of benefits over harms turns out to be more advantageous than the benefit/harm ratio in the no release scenario.
	Complete release scenario	This would be in breach with Open AI's charter	This would leave others less time for debate and policies to be developed before substantial impacts	Open AI might still play a role in facilitating debate. However, the time frame would not be	This is the fastest pathway for any positive and negative societal impacts to materialize, leaving the least amount of time for

			of the technology would likely occur.	accommodating for the development of effective measures.	debate. Hence the benefit/harm ratio is likely less advantageous than the ratio in the partial release scenario.

5. *What evidence, if any, is there that these consequences would indeed occur?*

OpenAI's forecasts concerning the societal impacts and applications of large, general language models seem highly acceptable. Since the technologies at hand are completely novel, it is difficult to draw analogies with existing technologies. However, the expected benefits and harms as listed by OpenAI are all almost self-evident. The benefits that OpenAI lists, i.e. writing assistants, more capable dialogue agents, unsupervised translation between languages, and better speech recognition systems, would occur because more powerful text generating AI systems would simply enhance already existing technologies and research endeavours in these fields. The expected harms listed by OpenAI, i.e. the generation of misleading news articles, the impersonation of others online, the automated production of abusive or faked content to post on social media, and automated production of spam/phishing content, are equally likely to occur as they are simply extrapolations from existing societal phenomena.

6. *Would each consequence be good or bad? Why?*

OpenAI's assessment of potential benefits and harms seems broadly correct. The applications that are branded as beneficial might, for example, make life easier and work more effective. The malicious applications could lead to erosion of trust, social disruption and reputational damage amongst others. It would therefore be worthwhile to try and create some time and space for the development of appropriate regulatory frameworks and policies. The analysis above leads to the following value analysis chart:

Alternatives	Consequences	Desirability from various points of view							Ranking
		Moral	Legal	Aesthetic	Ecological	Economic	Health and Safety	Etc.	
No release scenario	Positive and negative societal impacts occur because others develop the AI systems OpenAI does not spark any substantial debate	-	-	N/A	N/A	-	-	N/A	Suboptimal
Partial release scenario	Positive and negative societal impacts occur OpenAI can spark substantial debate in order to prepare for these impacts	+	+	N/A	N/A	+	+	N/A	Best scenario
Complete release scenario	This is the fastest pathway for any positive and negative societal impacts to materialize Least amount of time for debate	-	-	N/A	N/A	-	-	N/A	Suboptimal

From a moral point of view, the partial-release scenario is most desirable because it is likely to enhance the expected benefits and reduce the expected harms. From a legal perspective, the same desirability assessment ensues because it is desirable to have a bit more time for the preparation of regulatory frameworks to deal with the impacts. Aesthetic and ecological considerations seem immaterial to the overall assessment. In terms of the economy it seems desirable as well to optimize the benefit/harm ratio as many of the benefits and harms will be of an economical nature. The same goes for health and safety as many of the potential harms are to do with breaches of cybersecurity and disruptions of democratic institutions, which could have severe negative effects on health and safety. Additional assessment criteria seem inconsequential. All in all, partial release seems the most desirable scenario.

7. *What do you think X should do? (What do you think is the best thing for X to do?)*

In all three scenarios, full-fledged text generating models would be developed either immediately (complete-release scenario) or in the short-to-medium terms (the other two scenarios). The partial-release scenario is the only one that optimizes the conditions for a discussion which might prove beneficial when it comes to the development of guidelines and policy frameworks in order to diminish the potential negative and enhance the expected beneficial societal impacts of this emerging technology. That is why OpenAI's release strategy, i.e. partial release, is indeed the best option of the three alternatives.

8.3 Section References

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OpenAi Blogpost, https://openai.com/blog/better-language-models/ posted on February 14th, 2019; Authors Alec Radford, Jeffrey Wu, Dario Amodei, Daniela Amodei, Jack Clark, Miles Brundage & Ilya Sutskever (accessed on March 15th, 2019)

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9. Case Analysis Method 2: The Seven Step Method

9.1 Description

9.1.1 Introduction

The Seven Step Method is a checklist developed to assist with ethical decision making. The method involves responding to the following seven "what" questions:

- What are the facts?
- What are the ethical issues?
- What are the alternatives?
- What are the stakeholders?
- What are the ethics of alternatives?
- What are the practical constraints?
- What is the action to take? (Werhane et al. 1990[1])

These questions are designed to encourage a dialectical way of engaging with an ethical problem, so that (in cases where there is enough time) one can revise previous answers several times during the process. Various versions of this model are suggested for different professions. For instance, the Seven Step Method for ethical decision making in counselling (Miller and Davis 2016[2]) or management (Harold Fogelberg 2018[3]) are slightly different than the above model. Nevertheless, in principle, they all aim to help ethical decision making.

[1] Werhane, P., Bowie, N., Boatright, J., Velasquez, M. (1990), The Seven Step Method for Analyzing Ethical Situations [Online Material]. Retrieved February 25, 2019, from https://studylib.net/doc/18058307/model-g---the-seven-step-method-for-analyzing-ethical-sit

[2] Miller, H. F., Davis, T. E. (2016). Practitioner's Guide to Ethical Decision Making. Published by: The Center for Counseling Practice, Policy, and Research. Retrieved February 26 2019, from https://www.counseling.org/docs/default-source/ethics/practioner-39-s-guide-to-ethical-decision-making.pdf

[3] Fogelberg, H. (2018, August 28). 7 Step model for ethical decision making [Web blog post]. Retrieved February 25, 2019, from https://compassexecutives.com/2018/08/28/7-step-model-for-ethical-decision-making/

9.1.2 The Seven Step Method for Research

A more extensive version of this model is developed to address the ethical issues faced in scientific and academic contexts. In *Ethics and the University*, Michael Davis adds several sub-questions to the original model and fine-tunes it for academic purposes (Davis 1999[4]). Being aware of the complexities of using moral theories for non-philosophers, his version of the model provides a framework for an orderly discussion of ethical issues using common sense. Davis' seven steps include:

1. **State problem**. For example, "there's something about this decision that makes me uncomfortable" or "do I have a conflict of interest?"
2. **Check facts**. Many problems disappear upon closer examination of the situation, while others change radically.
3. **Identify relevant factors**. For example, persons involved, laws, professional codes, and other practical constraints.
4. **Develop list of options**. Be imaginative, try to avoid "dilemma"; not "yes" or "no" but whom to go to, what to say.
5. **Test options**. Employ one or more of the following tests:

    - *Harm test*: does this option do less harm than alternatives?
    - *Publicity test*: would I want my decision published in the newspaper?
    - *Defensibility test*: could I defend my choice before a committee?
    - *Reversibility test*: would I still make my choice if I were adversely affected by it?
    - *Colleague test*: what are my colleagues' responses to the options?
    - *Professional test*: what might my profession's governing body or ethics committee say about my choice?
    - *Organization test*: what does the company's ethics officer or legal counsel say about my choice?

[4] Davis, M. (1999). Ethics and the university. London: Routledge.

6. **Make a choice based on steps 1–5**.
7. **Review steps 1–6.**

    - Are there any precautions you can take?
    - Is there any way to access more support next time?
    - Is there any way to change the organization (for example, suggest policy changes at next departmental meeting)?

9.2 Case Analysis: Legal threats force corrections over scale measuring medication usage

9.2.1 Introduction

Source: Blog sphere, www.retractionwatch.com

Link: https://retractionwatch.com/2019/02/15/legal-threats-once-again-force-corrections-over-a-scale-measuring-medication-usage/#more-86298

9.2.2 Analysis

1. **State problem**

- Should an article using an unlicensed measuring scale be retracted unless the authors pay for a costly retroactive license?
- Is it morally right to use a licenced scale and to change it to a free scale?

2. **Check facts**

➢ The scale is used in a study published by Hale and his colleagues in 2016 and is a pilot study in the field of cardiology (Hale 2016[5]). The scale is based on a copyrighted questionnaire:

> Morisky's scale, copyrighted in 2006, is available for more than 110 health conditions and in more than 80 languages. It asks basic questions, such as: "Have you ever cut back or stopped taking your medication without telling your doctor[…]?" The survey became popular in health research after it

[5] Hale, T. M., Jethwani, K., Kandola, M. S., Saldana, F., & Kvedar, J. C. (2016). A Remote Medication Monitoring System for Chronic Heart Failure Patients to Reduce Readmissions: A Two-Arm Randomized Pilot Study. *Journal of Medical Internet Research*, 18(4). doi:10.2196/jmir.5256

was validated in a 2008 study by Morisky, but other similar tools are available (Marcus 2017[6]).

- Hale et al.'s paper is cited 19 times in February 2019 (See **Table 9.1**). Some of the studies that cited Hale et al. are also cited by other studies. Therefore, retracting the paper will affect many parties.

- If the authors do not retract, the developers of the scale will sue them for not having paid a licence fee.

- Other articles that used this scale without a licence have been retracted:

    - For example, a study by Patel et al. into chronic kidney disease (Patel, Ferris and Rak 2015[7]). The Retraction notice states:

> Due to an unintentional error, the MMAS-8 scale in our article, "Health and Nutrition Literacy and Adherence to Treatment in Children, Adolescents, and Young Adults with Chronic Kidney Disease and Hypertension, North Carolina, 2015", published on August 4, 2016, by Preventing Chronic Disease, **was used without proper permission from Dr Donald E. Morisky and coauthors**. We regret any problems our article may have caused, and we retract it from the literature (Patel, Ferris and Rak 2016[8])

[6] Marcus, A. (2017). Pay up or retract? Survey creators demands for money rile some health researchers. Science. doi:10.1126/science.aap9445

[7] Patel, N., Ferris, M., Rak, E. (2015). Health and Nutrition Literacy and Adherence to Treatment in Children, Adolescents, and Young Adults with Chronic Kidney Disease and Hypertension, North Carolina, 2015. *Preventing Chronic Disease,* 13 (E101). doi: 10.5888/pcd13.160044

[8] Retraction Notice, Vol. 13, August 4 Release. (2016). Preventing Chronic Disease, 13. https://doi.org/10.5888/pcd13.160044r

3. **Identify relevant factors**

Title of the paper:

A Remote Medication Monitoring System for Chronic Heart Failure Patients to Reduce Readmissions: A Two-Arm Randomized Pilot Study.

Authors of the paper:

Timothy M Hale; Kamal Jethwani; Manjinder Singh Kandola; Fidencio Saldana; Joseph C Kvedar

Authors are based in the following institutions:

- Partners Healthcare, Connected Health, Boston, MA, USA
- Massachusetts General Hospital, Boston, MA, USA
- Harvard Medical School, Boston, MA, USA
- Brigham and Women's Hospital, Internal Medicine, Boston, MA, USA

Publishing journal:

Journal of Medical Internet Research (JMIR)

Developers of the scale:

Steven Trubow (The Ohio State University, University of Wisconsin) and Donald Morisky (UCLA Fielding School of Public Health), co-founders of the company called MMAS Research LLC. The U.S. law encourages academic scientists and their institutions to protect and profit from their inventions, including those developed with public funds. According to the *Bayh-Dole Act (BDA)*

passed in 1980, scientists are allowed to patent research that was developed with government funds (Resnik 2007, p.9[9]).

Other parties:

The authors of papers that cite Hale et al.'s paper. According to Google Scholar, these are 19 articles. Retracting this paper will affect all the other papers that used it as a reference and add extra overhead to the journals that published these (see **Table 9.1**):

Article	**Publisher**	**Year**
Innovative Telemonitoring Enhanced Care Programme for Chronic Heart Failure (ITEC-CHF) to improve guideline compliance and collaborative care: protocol of a multicentre randomised controlled trial	BMJ Open	2017
Evaluating utility and compliance in a patient-based eHealth study using continuous-time heart rate and activity trackers	JAMIA	2018
Mobile Phone Apps to Support Heart Failure Self-Care Management: Integrative Review	JMIR Cardio	2018
Associations between Control of Glucose, Diabetes Support Services, New Insulin Initiation and 30 day Hospital Readmission in Diabetes Patients	ProQuest	2017
Extended, continuous measures of functional status in community dwelling persons with Alzheimer's and related dementia: Infrastructure, performance, tradeoffs, preliminary data, and promise	Journal of Neuroscience Methods	2018
Telemonitoring and hemodynamic monitoring to reduce hospitalization rates in heart failure: a systematic review and meta-analysis of randomized controlled trials and real-world studies	Journal of Geriatric Cardiology	2018
Updates in heart failure 30-day readmission prevention	Heart Failure Reviews	2018
Comparative Effectiveness of Disease Management With Information Communication Technology for Preventing Hospitalization and Readmission in Adults With Chronic Congestive Heart Failure	JAMDA	2018

[9] Resnik, D. B. (2007). The Price of Truth: How Money Affects the Norms of Science. New York: Oxford University Press.

Examining the implications of analytical and remote monitoring in pharmacy practice	The Pharmaceutical journal	2017
Extended, continuous measures of functional status in community dwelling persons with Alzheimer's and related dementia: Infrastructure, performance, tradeoffs, preliminary data, and promise	Journal of Neuroscience Methods	2017
Development of a Path to Home Mobile App for the Geriatric Rehabilitation Program at Bruyère Continuing Care: Protocol for User-Centered Design and Feasibility Testing Studies	JMIR Research Protocols	2018
A Novel Intelligent Two-Way Communication System for Remote Heart Failure Medication Uptitration (the CardioCoach Study): Randomized Controlled Feasibility Trial	JMIR Cardio	2018
The Therapist's Role in the Medical and Pharmacological Management of Heart Failure. Current Best Practices	Topics in Geriatric Rehabilitation	2019
The effectiveness of telehealth on self-management for older adults with a chronic condition: A comprehensive narrative review of the literature	Journal of Telemedicine and Telecare	2017
Quality Improvement in Gastroenterology: A Systematic Review of Practical Interventions for Clinicians	Digestive Diseases and Sciences	2018
Timely Interventions for Children with ADHD through Web-Based Monitoring Algorithms	Diseases	2019
Improving the self-management of heart failure in low- and middle-income countries using a standalone mobile health intervention	TSpace	2018
A Guide for the Nurses in Care Management of Heart Failure	Journal of Cardiovascular Nursing	2017
Prevención de reingreso hospitalario del paciente crónico adulto	TAUJA	2017

Table 9.1. List of articles that cited Hale et al.'s paper until the end of February 2019.

4. Develop list of options

- **Option 1**: Pay the retroactive fees for the licence
- **Option 2**: Retract the article
- **Option 3**: Find a similar model that is not licenced and correct the paper

5. **Test options**

Harm test: does this option do less harm than alternatives?

- Option 1: The money has to come from somewhere, and this could mean that the budget for an ongoing project should be reduced.
- Option 2: This is perhaps the most harmful option, not just for the group but also for the scientific community because the paper is cited 20 times. The results of this paper have been used by others.
- Option 3: This seems to be the least harmful, because it involves finding an alternative solution and updating the paper.

Publicity test: would I want my decision regarding this option published in the newspaper?

- Option 1: Probably not. By cutting the budget for one of the current projects, we would be questioned about our commitments. For instance, we might not be able to meet deadlines or deliver the promised quality.
- Option 2: No. Although a retraction notice is, in principle, similar to a newspaper publication, choosing to retract would have a knock-on effect on the other studies that used the results. These studies have to update their references and find alternatives for backing up the claims that are currently backed up by Hale et al.
- Option 3: Yes. It shows that while authors are respecting the law, they are also capable of thinking outside the box.

Defensibility test: could I defend my choice before a committee?

- Option 1: Yes. On the basis that the fees for the licence are reasonable, and there are the means to pay for it.

- Option 2: Yes. On the basis that the fees are not reasonable and there is no alternative model.
- Option 3: Yes. On the basis that a legal dispute will not result and the journal will agree to publish a correction.

Reversibility test: would I make my choice if I were adversely affected by it?

- Option 1: Being adversely affected by this choice would entail paying the fees or sacrificing one of the current projects to cover the fees. None of these outcomes is desirable.
- Option 2: Authors will not be able to publish their article. Besides the authors, those who cited the article would be adversely affected by this choice.
- Option 3: The only one adversely affected by this choice would be the developers of the scale. This is a reasonable option on the basis that the developers had originally suggested others should pay the license fee or retract.

Colleague test: what do my colleagues say when I describe my problem and suggest this option as my solution?

- Option 1: Colleagues are likely to ask: 'Which project are you going to sacrifice and how are you going to defend this choice?', or 'Don't you think that if you use some of the money that was dedicated for another project to this, your future financial decisions will be questioned?'.
- Option 2: Given the stigma around having a retracted article, colleagues are likely to be concerned with academic reputation.
- Option 3: Colleagues are likely to suggest this option if an alternative model delivered the same results.

Professional test: what might my profession's governing body or ethics committee say about this option?

- Option 1: The local research council or academy of sciences would generally aim to prevent controversies in the future in order to support society's trust in science. Hence, their reaction is likely to be: 'In the future, please make sure that when you use resources that are developed by other people, you check whether they are licenced or not. It seems like this time you had the necessary resources to pay for that, maybe this will not be an option next time'.
- Option 2: The local research council or academy of sciences would perhaps not be happy with this option as it has a negative effect on other publications as well as on society's trust in science. Their likely response could be: 'You should contact the corresponding-author of all the other papers that cited yours and inform them that this paper is retracted'.
- Option 3: The local research council or academy of sciences would likely support this choice. Not only does it not involve spending scarce resources on a finished project, it would not affect society's trust in science. They might request that the author publicise the details of the alternative model.

Organization test: what does the company's ethics officer or legal counsel say about this?

- Option 1: There would likely be a concern with institutional reputation. They might advise the author to check their other publications for the appropriation of licensed material and to create awareness of the problems with using licensed material.
- Option 2: There would likely be a concern with institutional reputation. They might even consider this to be negligence. They might advise the author to create awareness of the problems with using licensed material.
- Option 3: Such an option would be viewed positively.

6. **Make a choice based on steps 1–5**

After going through all the steps, **Option 3** seems to be the most reasonable option for several reasons:

- It is the least harmful option;
- It is publicly defensible;
- It adversely effects the fewest number of stakeholders;
- It is likely to be the most plausible option from the perspective of other colleagues;
- It does not negatively affect society's trust in science;
- It does not negatively affect the university's reputation.

7. **Review steps 1–6. How could one avoid such a situation in the future?**

- Check all the previously published material for the use of licenced material;
- Make sure that licenced material is not used unless there is a budget for it.

Are there any precautions you can take?

- Publish a letter to the editors and explain to the scientific community what exactly happened in an open and transparent manner.

Is there a way to access more support in the future?

- Arrange a meeting with other researchers and create awareness.
- Participate in a relevant conference and spread the news in an oral presentation.

Is there any way to change the organization?

- Ask the department to create separate inventories of free-to-use resources and paid resources;
- Ask the department to create an emergency fund should similar issues arise in the future;
- Ask the department to apply for a legal protection insurance to minimize the effects of legal costs, litigations, and so on.

9.3 Section References

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10. Case Analysis Method 3: REalistiC Decisions

10.1 Description

10.1.1 Introduction

This model was proposed by Hugh Davies MB BS, Research Ethics Advisor for the Health Research Authority ('HRA') and former Consultant Paediatrician at Oxford University Hospitals (https://uk.linkedin.com/in/hugh-davies-61029750).

The procedure is founded on the idea that each member of a research ethics committee ('REC'), research integrity office ('RIO') or institutional review board ('IRB') will deliberate based on their initial views and beliefs about a particular case.

The purpose is to move from individual opinions to the underlying reasons for those opinions in order turn *'I think'* claims regarding a particular case into *'We agree'* judgments.

As Davies observes, this procedure is only part of the process of coming to decisions about individual cases. Although the procedure helps members of RECs, RIOs and IRBs to shape and share their deliberations, it cannot make the decision for them. [8, 9, 10]

10.1.2 Changes to the Original Procedure

Although intended to be a procedure for reviewing research ethics proposals, it is flexible enough to be used to analyse research integrity cases.

In the original account, Davies refers to 'ethical theory' as a key structural component of deliberations.

The key aim for the case analysis method described here is *that it can be appropriated by all users, without prior philosophical knowledge, in local contexts.*

In order to fulfil this requirement, we advise RECs, RIOs and IRBs to engage with the regulatory frameworks and normative standards that apply to their respective organizations in the form *of codes of ethics, codes of conduct, funding body standards and, if applicable, broader national and international research ethics and research integrity codes.* On that basis, Davies' reference to 'ethical theory' has been changed to 'normative standards'.

10.1.3 The REalistiC Decisions Method

The procedure for analysing research ethics and research integrity cases can be summarized as follows [8, 9, 10]:

1. Identify and clarify the issue;
2. Early View ('What do I think?');
3. What are my reasons for thinking this?
4. Communicate my Early View and associated reasons;
5. Recognize the Early Views and reasons of other committee members;
6. Review my Early View by assessing it against the standards of:

    - Normative Standards *('How do normative frameworks help us?')*
    - Experience *('How have we approached this issue before?')*
    - Expertise *('What expertise has been applied to this before?')*
    - Empathy *('What views and opinions do other parties have?')*
    - Evidence *('What evidence is there on this issue?')*
    - Expediency *('What is possible or realistic in the circumstances?')*
    - Escape *('What other ways are there to manage disagreement?')*

7. Come up with a more informed judgment;
8. Engage in debate with other members of the committee to reach consensus

The procedure is presented in diagram form in **Figure 10.1**

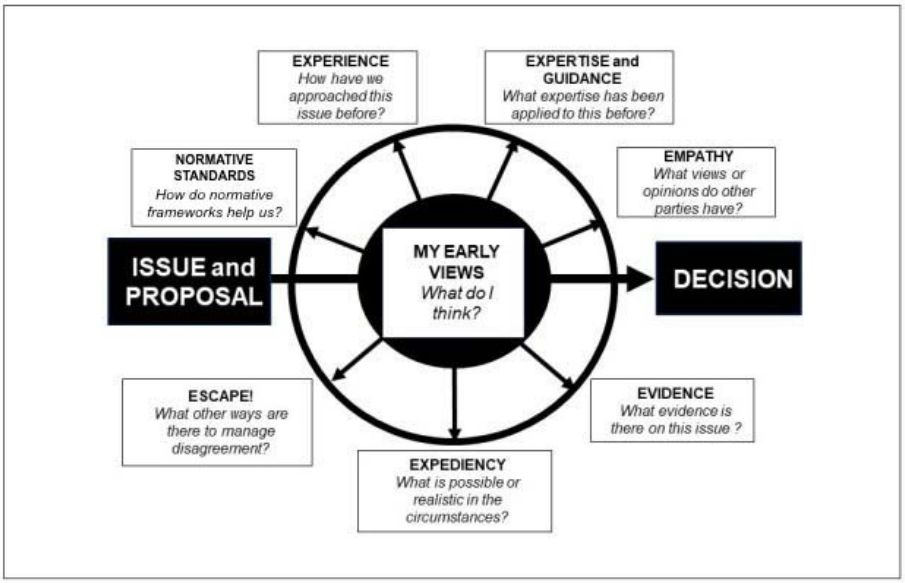

Figure 10.1: Adapted from Davies H. REalistiC Decisions: making judgements in review (and design). [Online]. http://www.reviewingresearch.com/realistic-decisions-making-judgements-in-committee/. Accessed 10 March 2019.

10.1.4 Additional Details

Early View

Once an issue has been identified and clarified, the first steps are to ask:

- '*What do I think?*'
- *'What are my reasons for thinking this*?'

When formulating an Early View and reasons for that view, we need to:

- Assess the strengths and weaknesses of the reasons for our view;
- Know when we can and can't rely on this Early View;
- Ensure our view does not prejudice against diverging opinions.

Normative Standards

- *'How do normative frameworks help us?'*

In order to answer this question, we need:

- A basic knowledge of the appropriate regulations that apply to the issue;
- To be able to use these regulations to analyse our Early View;
- To revise our Early View and to provide reasons for any revisions.

Experience

- *'How have we approached this issue before?'*

In order to answer this question, we need:

- To access past decisions;
- To compare past cases and the current case and determine whether previous decisions are relevant;
- To use disagreement to develop new standards for guiding future considerations;
- To be able to explain why, if relevant, we haven't followed such precedent.

Expertise

- *'What expertise has been applied to this before?'*

To answer this question, we need to:

- Access independent expert review;
- Access an up-to-date library of authoritative guidance;
- Balance guidance documents and judge the relative authority of guidance documents;
- Provide reasons if our decisions run contrary to guidance.

Empathy

- *'What views and opinions do other parties have?'*

We turn to the views of those with a legitimate interest in the case (for example, the accused, the complainant, individuals involved with the case, and the public).

To answer this question, we need to:

- Identify all those with an interest in the case and see it 'through their eyes';
- Recognize limitations to our empathy;
- Confirm or refute any 'empathy-based decisions' using answers to the other questions listed above;

Evidence

- *'What evidence is there on this issue?'*

We turn to any published research concerning similar cases. However, we need to be careful when forming prescriptive conclusions based on factual premises. After all, the quality of the

evidence may be questionable and there may be significant normative and factual differences between the case in question and situations discussed in published research.

In order to answer this question, we need:

- To locate, assess, and apply published evidence;
- To recognize the proper place of facts when making judgments;
- To encourage published research on research integrity and research ethics.

Expediency

- *'What is possible or realistic in the circumstances?'*

We need to ensure that we have not interpreted the case against sets of unrealistic standards. Expediency is built on a realistic evaluation of research constraints and consequences and imposes proportionate and realistic conditions.

In order to answer this question, we need to:

- Understand and accommodate realistic standards when assessing the case;
- Judge when expediency is adequate justification;
- Balance expediency and fair standards when forming a judgment about a case.

Escape

- *"How can we manage this problem of our disagreement?"*

In order to answer this question, we might be required to:

- Agree to disagree (if it will not affect the final judgment);
- Seek elaboration on any of the answers to the questions listed above;
- Vote on a set of judgments;
- Consider alternatives.

Deliberation

Once we have put forward our Early View and associated reasons, recognized the Early Views and reasons of our committee members, re-evaluated our Early View by answering the questions above, we need to come up with a more informed judgment. To do this, we should be aware that:

- Each question listed in section 10.1.3 leads to reasons to justify (or refute) a position;
- No single answer can provide a firm base for judgment;
- Our judgment will involve balancing the answers to the different questions;

The final step is to deliberate with our fellow committee members in order to reach a consensus:

- If we all agree**,** then the decision is made and little needs to be done, although, from time to time, we should critique our views;

If we fail to obtain consensus**,** we can ask for further involvement from interested parties (**Empathy**), outside advice and deliberation (**Expertise**) and new research (**Evidence**).

10.2 Case Analysis: 'The Grievance Studies Affair' and Accusations of Data Fabrication

10.2.1 Introduction

In October 2018, Peter Boghossian, James Lindsay and Helen Pluckrose informed the readers of *Areo* magazine that they had produced 20 academic papers spanning several subdomains of 'grievance studies'. [2] According to the authors, these papers 'featured radically sceptical and standpoint epistemologies rooted in postmodernism, feminist and critical race epistemology rooted in critical social constructivism as well as psychoanalysis'. [2] Their 'method' involved beginning each paper with 'something absurd or deeply unethical (or both) that we wanted to forward or conclude'. [2] They, subsequently, 'made the existing peer-reviewed literature do [their] bidding in the attempt to get published'. [2] Their aim was to undertake 'a kind of reflexive ethnographic study' and 'audit' in order to demonstrate that the language and customs of 'grievance studies' could be successfully learned, leading to publications of peer-reviewed papers in top journals. [2]

With the *Wall Street Journal* and journals demanding that the authors prove their identities, they 'came clean' to the *WSJ* in August 2018 (with several papers still under review). [1-2]

Of the 20 papers submitted, seven were accepted, seven were progressing through the review process and six were 'retired as fatally flawed or beyond repair' [2]. Furthermore, one paper, 'Expression of Concern: Human Reactions to Rape Culture and Queer Performativity at Urban Dog Parks in Portland, Oregon', was recognized by *Gender, Place, and Culture* as a leading piece in feminist geography during the journal's anniversary celebration. [2]

'The Grievance Studies Affair' has garnered international media attention with support and criticisms both inside and outside of academic circles. [3]

Boghossian, an Assistant Professor at Portland State University ('PSU'), is the only member of the collaboration employed by a higher education institution. In a letter dated 12 October 2018, Mark McLellan, Vice President for Research and Graduate Studies, informed Boghossian that a Committee of Inquiry would be convened to determine whether he had engaged in research misconduct. [4] McLellan also referred the case to PSU's Institutional Review Board ['IRB']. [4] The IRB was asked to determine whether or not the audit should have required ethical approval and whether Boghossian had 'intentionally either falsified or fabricated research data'. [4] Although none of the 20 papers involved actual human subjects, the IRB was required to determine whether the editors and peer reviewers for the targeted journals should be considered the subjects of the audit.

In a letter dated 27 November 2018, the Committee of Inquiry stated that it had 'unanimously agreed that the "dog park" article represents an unambiguous example of research data fabrication'. [4]

In a letter dated 17 December 2018, the IRB informed Boghossian that he had failed to secure the necessary IRB approval to participate in the audit. The IRB determined that the project 'met the federal definition of "research" (45 CFR 46.102)' and 'federal definition of "human subject" (45 CFR 46.102)'. [4]

The IRB's investigation into purported fabrication of research data is still ongoing.

10.2.2 Scenario

- You are a member of PSU's IRB.
- You are required to cut through the noise of global and social media attention and the raging culture wars with which this case is enmeshed, and determine whether Boghossian has either fabricated or falsified research data.

- You are required to use the method adapted from Davies' model in order to reach an informed judgment, which you will communicate to the other members of the board.

10.2.3 Analysis

Early View

You have produced a synopsis of the case (section 10.2.1).

- *'What do I think?'*

Your Early View is that Boghossian has neither falsified nor fabricated research data.

- *'What are my reasons for thinking this*?'

You have read the paper, 'Expression of Concern: Human Reactions to Rape Culture and Queer Performativity at Urban Dog Parks in Portland, Oregon', and acknowledge the authors' claim that they examined 10,000 dogs' genitals before interrogating their owners about their sexual orientations. You acknowledge the authors' admission that this did not take place.

You acknowledge that the previous IRB had determined that the project consisted of the 'audit', that is, the submission of 20 papers to peer-reviewed journals with the aim of demonstrating that that the language and customs of 'grievance studies' could be successfully learned, leading to publications of peer-reviewed papers in top journals. Furthermore, you acknowledge the previous IRB's determination that the audit 'met the federal definition of "research" (45 CFR 46.102)' and 'federal definition of "human subject" (45 CFR 46.102)'.

On that basis, you believe that the papers themselves are not the results of the audit. The results of the project are constituted by the judgments elicited by the submitted papers. The judgments

made by editors and peer reviewers seem to have been reported without distortion or embellishment. Furthermore, you recognize that the results of the audit have not been formally published in a peer-reviewed academic publication.

In your view, the submitted papers, and the 'dog park' article in particular, are merely the method for eliciting judgments from the editors and peer-reviewers. You consider these papers to be analogous to the real and hypothetical cases used to elicit and identify judgments in the social and behavioural sciences.

As you believe that these papers constitute the *method* of the audit and not the *results* of the audit, your Early View is that Boghossian has neither fabricated nor falsified research data.

Initial IRB Deliberation

All members of the IRB present their respective Early Views. There is a lot of disagreement.

As a result, you and your fellow board members are required to assess your respective Early Views against the following standards:

- Normative Standards *('How do normative frameworks help us?')*
- Experience *('How have we approached this issue before?')*
- Expertise *('What expertise has been applied to this before?')*
- Empathy *('What views and opinions do other parties have?')*
- Evidence *('What evidence is there on this issue?')*
- Expediency *('What is possible or realistic in the circumstances?')*
- Escape *('What other ways are there to manage disagreement?')*

Normative Standards

You acknowledge that PSU adopts federal standards of research conduct established by the U.S. Public Health Service ('PHS'). According to the PHS's Policies on Research Misconduct (42 CFR 93):

- Fabrication is making up data or results and recording or reporting them;
- Falsification is 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.

Although you believe that the submitted papers constitute the *method* of the audit and not the *results* of the audit, the PHS Policies do not distinguish between the fabrication of results and the fabrication of methodological information.

Based on the PHS's criteria, what matters is that Boghossian made up data and published it in a peer-reviewed journal article.

Conclusion: Normative standards reveal that Boghossian fabricated data.

Experience

You access the IRB's database to locate cases of fabrication. You observe that this is PSU's first 'hoax' case involving accusations of fabrication. All other cases of fabrication have involved data invention in the context of *actual* empirical studies.

The novelty of this particular case leads you to look for precedent elsewhere. You investigate the case of the 'Sokal Hoax'. However, you acknowledge that this case seems to be normatively different because Sokal did not make up empirical data in the context of a fictional study.

You believe that the invention of empirical data for a completely fictional study may be normatively relevant.

You consider the following distinctions between 'fabrication' in a hoax study and fabrication in an empirical study:

- Fabrication in empirical studies tends to involve the *results* of the study. Boghossian did not make up the results of the *study* (when the study is taken to refer to the '*audit*'). Rather, Boghossian made up content that went into the study's *method* for eliciting judgments from editors and peer reviewers. Fabricated *methodological* information like this is normal in the behavioural and social sciences.
- Fabrication in empirical studies tends to make a real difference to the truth-values of hypotheses, theories, and assertions as well as the internal and external validity of the research. If fabrications did not make substantive differences to the relationship between certain empirical phenomena and theories, hypotheses, and assertions, then there would be little reason for them. As the 'dog park' study is fictional, employed as a premise for a conclusion the authors had drawn in advance by making 'the existing peer-reviewed literature do [their] bidding', the invention of data does not make a difference to the truth-value of the fictional results or the truth of the theoretically-presupposed conclusion.
- On the basis that fabrication in empirical studies makes a substantive difference to the truth of theories, hypotheses, and assertions, it is not usual for a researcher who commits such fabrication to intend to reveal the fabrication. By contrast, not only did Boghossian and his co-authors intend to present the 'dog park' study as a fabrication, they also intended to reveal the fabrication when they commenced the 'audit'. [4]

***Conclusion*:** Although **Experience** does not allow you to firmly conclude that Boghossian did or did not fabricate data, you judge that this is a novel case and that there may be differences

between this case and usual cases involving fabrication. However, you are also aware that exceptionally good reasons are needed if a university is to set a precedent whereby they deem that it is acceptable to *publish* fabricated data under certain conditions. You are unsure whether your reasons are good enough.

Expertise

You engage with the cited sources and observe that experts from all fields have been discussing this case in public. You observe that Richard Dawkins, Daniel Dennett, Jonathan Haidt, Jordan Peterson, Steven Pinker, and Alan Sokal have all defended Boghossian's actions. You observe Pinker's claim that finding Boghossian guilty of research misconduct is a misuse of the idea, an affront to academic freedom and fodder for critics of academe. [5] According to Dawkins, Boghossian should not be found guilty of research misconduct because the Grievance Studies Affair should be construed as satire; 'it is the essence of satire that it is not literally true'. [6]

It is likely that these experts have been quoted in the international media because they have actively engaged in the 'culture wars' with which this case is enmeshed. On that basis, you identify some reactions of research ethics and research integrity experts. [7]

According to Elisa Hurley, Executive Director at Public Responsibility in Medicine and Research, 'false data was knowingly submitted for publication and was in fact published'. For Hurley, it does not matter that the authors intended to present the 'dog park' study as a fabrication. She claims that the question of fabrication could have been dealt with had Boghossian sought ethical approval from PSU prior to conducting the audit. [7]

According to Celia Fisher, Director of the Fordham University Centre for Ethics Education, 'they [the authors] allowed this to be published, and therefore, I do think it's appropriate to look at fabrication of data'. Even though the 'dog park' article was retracted, it is still 'misleading to those who would take the data as being valid data'. [7]

For Ivan Oransky, co-founder of *Retraction Watch*, the key point is that the 'dog park' study was published. If the authors had had 'the foresight to prevent accepted studies from being published, there wouldn't have been a huge difference between their fabricated data and, say, a fabricated résumé for a more traditional audit study'. [7]

Conclusion: You acknowledge that research ethics and research integrity experts tend to agree that Boghossian's 'dog park' constitutes data fabrication. You also acknowledge Oransky's point that it constitutes fabrication precisely because the article was published.

Empathy

Due to the amount of international attention this case has received, it is impossible to come up with an accurate picture of the public's views concerning the purported data fabrication.

You are aware that the complainant's view is that 'the "dog park" article represents an unambiguous example of research data fabrication'.

You are aware that Boghossian shares the views of his fellow co-authors. They claim that their papers 'present very shoddy methodologies including incredibly implausible statistics ("Dog Park")'. The data was 'clearly preposterous', intended to be 'clearly preposterous' and intended to be revealed as such. [4]

They claim that accusation of data fabrication misses the point. They go on to argue that the ethical rules about fabrication are 'meant to act as a safeguard against and a sanction for researchers who contrive to promote their own advancement directly by passing off and maintaining bogus data with no intention to reveal the truth'. Consequently, they conclude that the rules governing data fabrication should not apply in this instance. [4]

Conclusion: You acknowledge the disagreement between the different parties. You observe that those who accuse Boghossian of fabrication appeal to the **Normative Standards** discussed above. However, you also observe that Boghossian and his co-authors appeal to the differences between their case and typical cases of fabrication, differences you articulated based on **Experience.**

Evidence

You undertake a Google search to look for published research concerning hoax articles that include made-up data. Due to time and resource constraints, you are unable to undertake a *systematic* review. Consequently, you are reliant on the 'relevance' of the items generated by the search. All the published research pertaining to cases of fabrication seemingly involve *actual* empirical studies.

***Conclusion*:** Although you acknowledge the limitations of your online search, the results seem to affirm the tentative conclusions you came to from **Experience;** specifically, that this is a novel case and that there may be differences between this case and usual cases involving fabrication.

Expediency

Based on the tentative conclusions reached when considering **Experience**, **Empathy** and **Evidence**, you think that the **Normative Standards** cited by a number of commentators may not be a suitable means for assessing this case, bearing in mind that it is *hoax* employing made-up data to elicit certain judgments as part of a broader audit study.

You think that your **Experience**-based claim seems intuitively right; specifically, that fabrication in *actual* empirical studies tends to make a substantive difference to the truth-values of hypotheses, models and theories. On that basis, you arrange a Skype meeting with a retired professor in biomedical research. She is considered to be an expert in experimental design and scientific methods.

You are careful not to disclose any of the particulars of the case. You ask why data fabrication and falsification might be important in the context of research misconduct.

She informs you that although fabrication is distinct from falsification, both should be viewed in the context of *falsifiability* in general. The reason fabrication and falsification are so important is because *falsifiability*, that is, the notion that a theory, hypothesis, or assertion can be experientially shown to be false, has traditionally been employed to demarcate science from non-science. She provides you with details of Karl Popper's falsifiability thesis, specifically, the idea that if a theory, hypothesis, or assertion is incompatible with possible empirical observations, then it is scientific. By contrast, a theory that has been modified to accommodate, or is consistent with, *all* empirical observations is unscientific.

You acknowledge the reason why fabrication and falsification are so important in the context of science. Fabrications and falsifications in scientific studies manipulate the relationship between empirical phenomena and scientific hypotheses. Such manipulations, therefore, impinge upon the compatibility of empirical observations and scientific claims, leading to a distortion of the 'real' relationship between scientific claims and the empirical phenomena. Fabrication and falsification of data, therefore, affect the falsifiability of a scientific theory, hypothesis or assertion. It seems to you that fabrication and falsification undermine the scientific pretensions of the studies in which they occur. Furthermore, fabrication and falsification damage the reputation of science.

By contrast, Boghossian's 'dog park' study is unscientific. Firstly, the hypothesis is supported by a broader theoretically-driven approach that can accommodate all empirical observations, and is, therefore, protected from falsifiability. Secondly, because the study is entirely fictional, there is no way to demonstrate whether his hypothesis, the theory that supports it, and the presupposed conclusion, are incompatible with certain possible empirical observations. As a result, the made-up data relating to the genitals of 10,000 dogs does not affect the compatibility

of empirical observations and scientific claims. Furthermore, as the 'dog park' study is not intended to be scientific (in Popper's sense), the made-up data does not damage the scientific integrity of the study.

***Conclusion*:** Your deliberations lead you to affirm the tentative conclusions reached when considering **Experience**, **Empathy** and **Evidence**. Consequently, you reasonably conclude that those accusing Boghossian of fabrication might be setting unrealistic standards when assessing this case.

Deliberation

You recognize that each question leads to reasons to justify (or refute) a position, no single answer can provide a firm base for judgment, your judgment will involve balancing between the answers to the different questions. Based on your judgments, you conclude that Boghossian did fabricate data for the 'dog park' study. Had he not published the article, but withdrew it once it had been accepted, he would not have committed data fabrication. It seems to you that acceptance alone would have been sufficient to prove the point of the broader audit study. However, you deem that there are significant normative differences between typical instances of fabrication in empirical studies and fabrication of methodological information for the purposes of the broader audit study. Although the 'dog park' study is *technically* an instance of fabrication (on the basis that the data was published), you judge that the normative standards by which this case is assessed are primarily concerned with accounting for fabrication in scientific studies. This study is unscientific and intended to be a 'hoax'. Based on **Experience**, **Empathy**, **Evidence** and **Expediency,** you conclude that fabrication in this case is substantially less unacceptable than those cases of fabrication that take place elsewhere.

You communicate your judgment and reasons to the rest of the IRB. The rest of board does the same and, together, you seek to come to a consensus.

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11. Case Analysis Method 4: Teaching Research Ethics Tool

11.1 Description

11.1.1 Introduction

The method was developed by Ferrer[10] and applied by a group of investigators from Graduate Education in Research Ethics for Scientists and Engineers (GERESE) at the University of Puerto Rico, Mayaguez campus (UPRM). The aim of the project was to integrate research ethics into the graduate curriculum in science and engineering[11]. This method is used as a conceptual tool to guide students though the moral deliberation process in a systematic way.

11.1.2 The Method

The method consists of the following seven steps	
Determination of facts	Identify the situations, people and environment through which the case unfolds. A good understanding of facts is essential for this deliberation procedure.
Identification of morally problematic situations	There are usually several morally problematic situations that require attention. This step provides students with an opportunity to improve their sensibility to ethically problematic situations.
Identification of possible courses of action	Usually, there are several possible courses of action. Some result in misconduct while others effectively and ethically solve the problem(s).
Distinguishing "moral questions", "moral disagreements", and "moral conflicts"	A moral question is a situation in which moral duties are clear to the subject, although they may be in conflict with other issues of interest to the agent such as financial and political interests. These

[10] Ferrer, J.J. (2007), "Deber y Deliberación una Invitación a la Bioética" Cep, Mayagüez, Puerto Rico.
[11] Valdes, D., & Jaramillo Giraldo, E., & Ferrer, J., & Frey, W. (2009, June), Case Analysis: A Tool for Teaching Research Ethics In Science And Engineering For Graduate Students Paper presented at 2009 Annual Conference & Exposition, Austin, Texas. https://peer.asee.org/5729

	situations do not require moral deliberation so much as moral courage. Moral disagreements arise when the agent feels subjectively certain but holds a point of view in conflict with another persons' moral judgments. These situations call for moral dialogue and argumentation. Finally, moral conflicts (or moral problems) arise when agents face conflicting moral duties. These instances call for moral deliberation.
Establish a hierarchy of values related to morally problematic situations	If there are moral conflicts, examination of the relative hierarchy of values is required in order to determine the overriding duty or duties in the situation.
Consequence analysis (if necessary)	If the previous step is not sufficient to identify the preferred course of action, a further step is required consisting of the analysis of foreseeable consequences of each course of action. The analysis of consequences depends on a good determination of the facts. It should include foreseeable consequences related to the persons involved, the working environment, the external environment, and society at large.
Justification of the moral choice	After analysing different possible courses of action, students identify those that are morally justified.

11.2 Case Analysis: The STAP Case

11.2.1 Introduction

In January 2014, Haruko Obokata, a biochemist at the RIKEN Centre for Developmental Biology in Kobe, Japan, published two breakthrough papers in *Nature*. Scholars in the field of stem-cell research and cloning were among the co-authors of the articles. Obokata claimed to have discovered a simple and inexpensive way of producing stem cells; the STAP (stimulus-triggered acquisition of pluripotency) method. The method consisted of converting mouse cells into an embryonic state by inducing them to stress, such as physical pressure or exposure to acid.

Soon after the publication, serious allegations were made. Initially, commentators noted errors in the figures, duplications, and a plagiarized text in the article. Subsequently, many scientists reported their inability to replicate the results and suggested that the cells were not what they were purported to be. Within a few months, an investigation led by officials at the RIKEN Centre found evidence of data falsification and fabrication. The co-authors requested the retraction of the papers. However, Obokata maintained that her findings were real. A few months later, Obokata agreed to retract both papers and she was invited to verify the original findings, under surveillance, at the RIKEN Centre.

11.2.2 Analysis

1. **Determination of facts**

In January 2014, Haruko Obokata, a biochemist at the RIKEN Centre for Developmental Biology in Kobe, Japan, published two breakthrough papers in *Nature*. Scholars in the field of stem-cell research and cloning were among the co-authors of the articles. Obokata claimed to have discovered a simple and inexpensive way of producing stem cells; the STAP (stimulus-triggered acquisition of pluripotency) method. The method consisted of converting mouse cells into an embryonic state by inducing them to stress, such as physical pressure or exposure to acid.

Soon after the publication, serious allegations were made. Initially, commentators noted errors in the figures, duplications, and a plagiarized text in the article. Subsequently, many scientists reported their inability to replicate the results and suggested that the cells were not what they were purported to be. Within a few months, an investigation led by officials at the RIKEN Centre found evidence of data falsification and fabrication. The co-authors requested the retraction of the papers. However, Obokata maintained that her findings were real. A few months later, Obokata agreed to retract both papers and she was invited to verify the original findings, under surveillance, at the RIKEN Centre.

2. Identification of morally problematic situations

- Although Obokata did not confess, the investigation concluded that she had committed data fabrication and falsification.
- The co-authors failed to check the validity and accuracy of the data before the paper was published.
- The quality of the peer review process is also questionable. Some of the issues could have been identified by the journal.

3. Identification of possible courses of action

- Obokata might be investigated in order to assess the validity of her previous studies.
- Obokata might be punished for data fabrication and falsification.
- Obokata might be required to verify the original findings and demonstrate that the data is valid.
- Raise awareness of the case.
- Conduct an investigation into the co-authors of the papers in relation to their responsibility for the studies.
- The journal might develop a policy that requires additional pre-publication precautions and verifications.

- Alternative solutions might be developed in order to prevent similar kinds of cases (e.g. data sharing).

4. Distinguishing "moral questions", "moral disagreements", and "moral conflicts"

The discovery of data fabrication and falsification took place after publication of the results. Nevertheless, Obokata continued to deny the accusations. Disagreement exists between Obokata and her peers regarding the validity of her published results. She may not have intended to commit data fabrication and falsification. However, sloppy data management informed the conclusion. Those conducting the investigation alleged that Obokata was aware of the risks. The journal could have identified the errors prior to publication, but the presence of some of the most trusted names in the field among the co-authors may have affected the reviewers' judgments.

5. Establish a hierarchy of values related to morally problematic situations

1) Honesty
2) Reliability
3) Respect for collaborators

4) Justification of the moral choice

After the journal retracted both papers, Obokata was still able to verify the original findings under close RIKEN surveillance. The STAP case is now closed. However, we can still stipulate about post-case moral choices. One of those choices might involve deciding upon ways in which cases such as this can be prevented. Various stakeholders have been involved in the case (*Nature*, Obokata, her co-authors, the RIKEN Centre, other stem-cell researchers). These stakeholders might reflect on their respective roles and responsibilities and consider raising awareness of the morally-problematic issues associated with the case.

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12. Case Analysis Method 5: Moral Case Deliberation

12.1 Description

12.1.1 Introduction

Moral Case Deliberation (MCD) aims to combine reflection on concrete cases with procedures to foster moral learning. In MCD in health care settings, patients, family members and health care staff discuss a moral question. MCD can be regarded as a form of Clinical Ethics Support (CES) or REC assessment in health care and biomedical research, helping health care professionals to reflect on their actual ethical questions and reasoning, and to find answers in acute cases. MCD is about listening and asking the right questions, rather than convincing the other, and postponing one's own judgements in the interests of being open to other viewpoints.

The validity and reliability of knowledge claims and moral judgments are constructed and examined within the practice itself. In the end, the reliability and validity of the judgments are determined in experience and in the practice of daily life. The MCD facilitator or the MCD participants can refer to existing theories and concepts, as well as existing normative frameworks (such as policies, laws, professional codes etc.). The point is, however, that ethical issues are not defined beforehand, but are derived from practice.

In MCD, the moral problem under consideration is always a concrete moral issue, experienced by one of the participants. This issue is presented as a case (for example, concerning a treatment decision with an individual patient). The case is analysed not by applying general moral concepts or principles but by investigating the values and norms of the stakeholders. In a MCD, different viewpoints are examined. The initial aim is not to decide which perspective or answer is right, but to ask open and critical questions in order to elaborate assumptions behind the perspective and find out how they are applicable to the case at hand.[12]

[12] Stolper M, Molewijk B, Widdershoven G. Bioethics education in clinical settings: theory and practice of the dilemma method of moral case deliberation. *BMC Med Ethics* 2016;17(1):45.

Though MCD is primarily designed to examine clinical cases. However, given that many research ethics deliberations – e.g. the work of RECs when assessing research protocols – take place before the research in question, the methodology could be used to assess research ethics dilemmas as well. Also, an MCD can be undertaken by a single individual – for example, by considering 'imaginary' research ethics committees and other stakeholders as part of a 'virtual' deliberation. Since such imaginary and empathy-based techniques are considered to be important aspects of our ethical thinking – in thought experiments, for example – MCD might be a useful tool for such assessments.

12.1.2 The Moral Case Deliberation Method

Introduction

During the first step, the aim and procedure of MCD is explained by the facilitator. The facilitator addresses issues such as the nature of MCD, the context surrounding the MCD, the aim of the meeting, mutual expectations (e.g. open and honest communication) and the steps in the method.

Presentation of the case

This step focuses on the experience of the case presenter. The presenter is asked to describe a concrete personal situation in which he or she experienced the moral issue at stake. The case presenter is asked to provide a short but thick description of the facts of the situation. Facts can include the 'feelings' he or she experienced since feelings can be a useful indicator of the moral discomfort of the presenter and can often implicitly refer to certain values.

Formulating the moral question and the dilemma

In this step, the case presenter's underlying moral question is made explicit. By formulating his/her moral question, the other participants can better understand what is at stake and what (morally) matters for the case presenter. Furthermore, to make the moral question more concrete, the case presenter is asked to formulate the situation in terms of a dilemma: what are the concrete choices available in this situation?

Clarification in order to place oneself in the situation of the case presenter

The fourth step aims to foster a clear understanding of the situation so that participants can 'put themselves in the shoes' of the case presenter. Clarification aims to (re)construct as clearly as possible the situation presented by the case presenter in order to investigate the moral dilemma. Within MCD, participants try to answer the dilemma with which the case presenter is faced.

Analyzing the case in terms of perspectives, values and norms

The participants make a list of the relevant stakeholder perspectives, and, for each perspective, identify the values related to the dilemma and the possible actions that realize a specific value (we call this value a 'norm'). The analysis of the perspective of the case presenter will lead to the identification of values and norms that support or undermine different options.

Looking for alternatives

The aim of this step is to brainstorm in order to get a view on possible courses or actions which lie beyond the dilemma.

Making an individual choice and making explicit one's considerations:

This step involves the formulation of the personal views, values, norms, arguments and choices in relation to the case. The participants express their own views of what they consider to be right. The facilitator might ask the participants to individually address the following points:

a) It is morally justified that I choose option … (A, B or an alternative).
b) Because of…. (which value or norm?)
c) Despite of…. (which value or norm?)
d) How can you limit the damage of your choice mentioned under (c)?

Dialogical inquiry

In this step, similarities and differences between the individual considerations are examined. Sometimes, two participants make a different choice based on the same value. Alternatively, participants may choose the same option based on different values or norms. Identifying similarities and differences may lead to better understanding and a better insight of what is at stake in a specific case.

Conclusion

In this step, participants are invited to draw conclusions and develop a plan for action. The facilitator returns to the moral question formulated at the start of the MCD and asks the group to make explicit their conclusions. Reaching consensus is not necessary; the conclusion can also be that there is a plurality of ideas with different practical implications.

Evaluation

Lastly, learning experiences and the outcome are evaluated.

12.2 Case Analysis: The Dan Markingson Case

12.2.1 Introduction

The aim of this virtual MCD is to examine whether Dan Markingson's suicide during a clinical trial was a consequence of research ethics violations and whether it could have been prevented by a better oversight mechanism. The participants of the MCD are Dan's mother, Mary Weiss (the case presenter), an independent bioethicist, a representative from the REC that was overseeing the CAFÉ trial and the facilitator.

12.2.2 Analysis

Presentation of the case

The presenter describes her conviction that her son died as a consequence of being enrolled on a clinical trial, the CAFÉ study, that was neither scientifically nor ethically appropriate. She claims that her son's suicide resulted from him not being withdrawn from the study despite her request. She feels that neither her son's nor her own autonomy was respected. She feels that the study leaders did not take her concerns seriously and that the trial and Dan's death involved negligence and professional inadequacy.

Formulating the moral question and the dilemma

Dr. Olson – Dan's psychiatrist at the time of enrolment – informed Dan that participation in the CAFÉ trial was the only way he could avoid involuntary confinement at Anoka Metropolitan Regional Treatment Centre. Though Mary understands this, she believes that this alternative was not a true alternative and that Dan was not able to make important treatment and participation decisions on his own. She, therefore, asks, 'Was Dan's involvement and oversight in the study ethically appropriate?'

Clarification in order to place oneself in the situation of the case presenter

Mary describes her situation as follows:

- She felt that her requests were not taken into consideration.
- She was in contact with Dan during the trial.
- She had concerns about her son's well-being and psychic condition.
- Nobody responded to her concerns.
- Shortly before Dan's enrolment on the trial, his condition was assessed by his physician, who deemed that he was not able to make decisions for himself.
- She would have preferred a process of substituted decision making.
- After Dan was invited to 'consent' to participate, his decision-making capacity 'soon' returned, thereby, excluding her from the decision-making process.
- She feels that Dan was used as a mere means in the trial and that his interests were not taken into consideration.

Analysing the case in terms of perspectives, values and norms

Perspectives	Values	Norms
MARY	Respect for Persons / Informed Consent	Dan's consent should not have been accepted because he seemed to lack appropriate decision-making capacity.
	Respect for Persons / Voluntary Informed Consent	He was not in a position to refute participation. Rather, he was pushed into a 'dichotomy' between being confined or 'choosing' to participate in the study
	Appropriate risk/benefit assessment	She, informed the trial investigators on multiple occasions about her deep concerns that Dan might harm himself and/or others.
BIOETHICIST	Same Concerns as Mary plus Appropriate Oversight	It is questionable whether the pertinent COIs were adequately disclosed and handled.
	Vulnerability	Dr. Olson served as Dan's physician and his enroller. Such a situation generate dependency, making participants such as Dan vulnerable to coercion.

	Appropriate risk/benefit assessment	CAFÉ study coordinator, Ms. Kenney, a clinical social worker, carried out study-related tasks beyond her competency and made serious errors.
REC member	Compliance with research practices and regulations Aiming to comply with the study sponsors requirements	The REC member did not believe the situation (in which the study investigator was also the participant's therapist) to be unprecedented. They did not consider the enrolment of a vulnerable patients onto a clinical trial to be unprecedented. – Since 30 study participants needed to be found, they believed that any patients fulfilling the basic requirements should be enrolled, regardless of their legal capacity (i.e. stay of commitment)

Looking for alternatives

All the members agree that patients not under a stay of commitment might have been more fitting study participants. They agree that participation in the trial was not necessarily a better nor the only alternative to involuntary confinement. However, the REC member does not agree that Dr. Olson violated regulatory and legal standards.

Making an individual choice and making explicit one's considerations

Mary and the bioethicist both claim that:

a) It is not morally justifiable to invite Dan to join the study due to the lack of decision-making capacity and because he was under a stay of commitment;
b) Mary tried to inform the study investigators on multiple occasions about the deterioration of Dan's condition.

The REC representative, contrarily, insists that:

a) Dan's enrolment was morally justifiable because, at the time of enrolment, legislation did not ban the recruitment of patients under a stay of commitment. Furthermore, Dan's decision-making capacity had changed significantly by the time of enrolment. Finally, because of the nature of the study, Dan's participation did not carry a greater risk of harm than any other treatment regimen.

Dialogical inquiry

Though both sides accept that the main question concerns the validity of Dan's consent to participate in the study, the REC representative insists that formally, and from a legislative perspective, Dan had consented and was able to consent. The REC representative does not seem willing to revise this understanding.

Conclusion

No consensus could be reached during the course of the MCD. Mary and the bioethicist still believe that it was ethically inappropriate to enrol Dan onto the study.

Evaluation

At the same time, the REC representative admits that simply being in compliance with the actual regulations might not be sufficient ethical grounds for assessing the problem in question. Thus, all parties welcome the new legislation restricting participation of patients under a stay of commitment.

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13. Case Analysis Method 6: Four Quadrant Approach

13.1 Description

13.1.1 Introduction

In a collaborative effort, three clinical ethicists, a philosopher, Jonsen, a physician, Siegler, and a lawyer, Winslade, developed the 'four quadrant approach' ('4QA') for dealing with difficult cases in clinical settings.[13] The process can be viewed as an "ethics workup," similar to the "History and Physical" skills that all medical students come to use when learning how to "workup" a patient's primary complaints. While this method has deep philosophical roots, what clinicians like about it is the ease with which it fits with how we normally think about tough medical cases.[14]

The full procedure of the 4QA involves three stages and a list of distinctive steps:

1. The first stage identifies and describes our initial perception of the case;
2. The second involves the four quadrants (medical indications, patient preferences, quality of life, contextual features) and the identification of information relevant to a given quadrant;
3. The third involves the application of case-based reasoning to identify and justify the best course of action.

13.1.2 Changes to the Original Procedure

The original version of the 4QA was developed to deal with clinical decisions involving patients and dilemmas or conflicts within the doctor-patient relationship.[15] Therefore, there is little room

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[14] http://depts.washington.edu/bioethx/tools/cesumm.html
[15] Sokol DK. The "four quadrants" approach to clinical ethics case analysis; an application and review. J Med Ethics. 2008;34(7):513-516.

for developing, altering or adapting the method even in clinical settings.[16] Moreover, the four quadrants are said to be responsive to the four principles of biomedical ethics, specifically, autonomy, beneficence, non-maleficence and justice. This is a normative framework originally developed for biomedicine.

Here, we have adapted the "original version" to test its applicability in different research ethics and research integrity scenarios.

The basic structure and the general decision-making procedure embedded in the 4QA approach seem to be adaptable to any cases where various options for decision-making need to be assessed and clarified.

In adapting the 4QA, the aim is to enable a focused discussion around normative standards pertinent to research ethics and research integrity, leading to the application of case-based reasoning to the facts of the particular case at hand.

Consequently, the four quadrants of the procedure have been revised so that they not only are responsive to the regulatory frameworks and normative standards that apply to a user's respective organization in the form of codes of ethics, codes of conduct, and, if applicable, broader national and international research ethics and research integrity codes, but can be applied to non-clinical settings to deal with cases in research ethics and research integrity.

[16] Schumann JH, Alfandre D. Clinical ethical decision making: the four topics approach. Semin Med Pract 2008;11:36–42.

13.1.3 The Four Quadrant Method

STAGE 1: Initial Perception

The user should attend to some general questions in order to identify relevant aspects and major characteristics of the situation:

- What are the morally relevant facts?
- What are the ethical or moral issues at stake in this case?
- Who are the stakeholders?
- What particular normative standards in pertinent regulatory documents apply to the case?
- What possible courses of action are available?
- What are the predictable effects of each action?
- Which set of possible outcomes seem to be better?

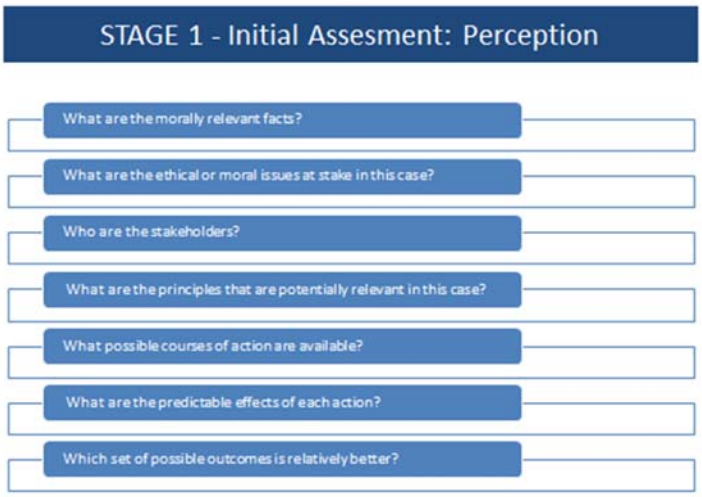
STAGE 2: The Four Quadrant Analysis

I. **Relevant Facts**: What are the most relevant facts concerning the situation?
II. **Uncertainties**: Which features of the situation are uncertain, lacking in clarity, or controversial?
III. **Courses of Action**: What are the practically available options for providing a solution to the case?
IV. **Contextual Features**: What legal, financial and institutional policies and regulations apply to the case?

STAGE 3: Casuistic Reasoning and Justification

Once the details of a case have been outlined according to the four quadrants, there are a series of questions that should be considered:

- What is at issue? Try to list what is the major ethical issue at the case, e.g researchers' dishonesty, negligent conduct, informed consent, rules of data collection etc.)
- Where is the conflict? Is there a conflict between principles of research or principles of research integrity? (e.g. autonomy, justice, beneficence or between honesty, reliability and respect for colleagues)
- What is this a case of? Does it sound like other cases you may have encountered? (e.g. Is it a case of "self-plagiarism", "fabrication of data in a grant application" or "low risk research involving humans without a valid informed consent"?)
- What do we know about other cases like this one? Is there clear precedent? If so, we call this a paradigm case. A paradigm case is one in which the facts of the case are very clear cut and there has been much professional and/or public agreement about resolution of the case.
- How is the present case similar to the paradigm case? How is it different? Is it similar (or different) in significant ways?



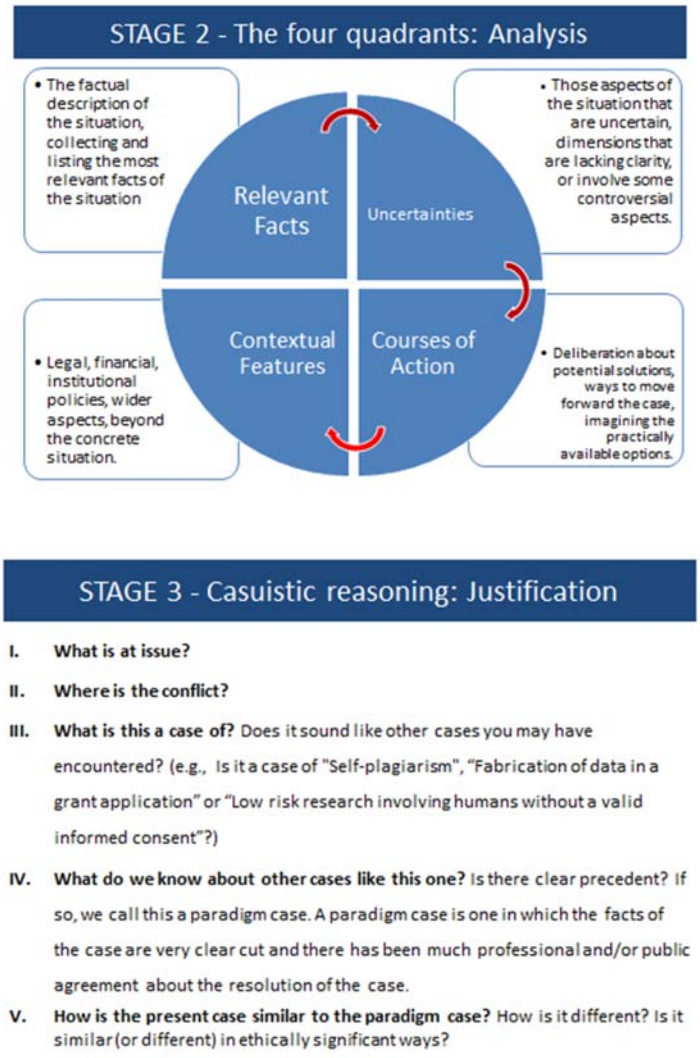


Figure 13.1 Adaptation of the Four Quadrant Approach for the analysis of research ethics and integrity cases

13.2 Case Analysis: Japanese Fraud Highlights Media-Driven Research Ethic

13.2.1 Introduction

Source

Normile D. Japanese Fraud Highlights Media-Driven Research Ethic**.** *Science* 2001;291(5501):34-5. DOI:10.1126/science.291.5501.34.

http://science.sciencemag.org/content/291/5501/34.summary

13.2.2 Analysis

STAGE 1: Initial Perception

- **What are the morally relevant facts?**

An amateur archaeologist, Shinichi Fujimura, secretly transported objects to excavation sites and fabricated archaeological discoveries in several cases. Fujimura was caught by a daily newspaper's reporters who were sceptical about the discoveries and videotaped his escape from the site. Subsequently, in October 2000, Fujimura confessed to committing fraud. Fujimura's discoveries were announced first to the media instead of scientific publications. The scientific community criticized this "publication practice" as well as the "sloppy side of Japanese archaeology".

- **What are the ethical or moral issues at stake in this case?**

Fujimura intentionally misled people, confessed to committing fraud, committed questionable publication practice, and bypassed scientific peer review.

- **Who are the stakeholders?**

    - Fujimura (an amateur archaeologist)
    - *Mainichi Shimbun* (a daily newspaper)
    - Takeoka, (an archaeologist who criticized Fujimura)
    - Sherizawa (a leading archaeologist)
    - Archaeologists
    - Scientific journals
    - The public

- **What particular normative standards in pertinent regulatory documents apply to the case?**

    - If we look at the European Code of Conduct for Research Integrity, developed by ALLEA in response to The Singapore Statement on Research Integrity:
        - Reliability
        - Honesty
        - Respect for colleagues

- **What possible courses of action are available?**

    - Punish Fujimuri for fraud and prevent him from doing it again.
    - Launch an investigation into the validity of his earlier discoveries.
    - Address the questionable "publication practice" that seems to affect the whole field.
    - Raise awareness of the case and support work on preventive measures.

- **What are the predictable effects of each action?**

- Fujimuri will be stigmatized, the research community will be more cautious in accepting his research results.
- Some further misconduct cases of Fujimuri might be discovered that could have a cleaning effect.
- The reputation of Japanese archaeology might be damaged, but as a consequence of higher awareness and the launched reforms it could recover and strengthened in the long term.

- **Which set of possible outcomes seemed to be relatively better?**

- Proactively facing the issue seems to be the better alternative. Punishing Fujimuri individually, but also recognizing co-responsibility with attempting to address the issue at the level of the archaeological community. These are advantageous in the long run for strengthening the fields' integrity and building public trust.

STAGE 2: The Four Quadrant Analysis

I. Relevant Facts: *What are the most relevant facts concerning the situation?*

- An amateur archaeologist, Shinichi Fujimura, secretly transported objects to excavation sites and fabricated archaeological discoveries in several cases.
- Fujimura was caught by a daily newspaper's reporters who were sceptical about the discoveries and videotaped his escape from the site. Subsequently, in October 2000, Fujimura confessed to committing fraud.
- Fujimura's discoveries were announced first to the media instead of scientific publications. The scientific community criticized this "publication practice" as well as the "sloppy side of Japanese archaeology".

II. Uncertainties: *Which features of the situation are uncertain, lacking in clarity, or controversial?*

- Fujimura has confessed to two fabrications. Questions remain with regards to his other discoveries.
- The publication practice of Fujimura has been questioned. Is it a common practice in Japan as well as other countries?

III. Courses of Action: *What are the practically available options for providing a solution to the case?*

- Fujimura's publications and discoveries might be investigated
- Fujimura might be punished for the two counts of fraud to which he confessed
- The publication practices of archaeologists might be investigated and assessed by the scientific community
- The ways in which suspicious discoveries are reported might be investigated and revised

IV. Contextual Features: *What legal, financial and institutional policies and regulations apply to the case?*

- Fujimura responsibility in fabrication of discoveries is certain, but what about the responsibility of his colleagues, his academic community? Miyagi, an archaeologist who worked with Fujimura and did not realize he was planting artefacts on the sites.
- Is he bound by professional duties or academic codes of conduct as an amateur scientist? Who can initiate a misconduct investigation in the case of amateur researchers?
- It seems that the Japanese Archeological Association did not have a Code of Ethics at the time of these events. The development of a Code of Ethics was a result of these events, paragraph 7 reads: "In the conduct of investigation and research as well as in the publication of the results, JAA members must not engage in any fraudulent activity, such

as fabrication or falsification of materials or records, or the plagiarizing of research results." http://archaeology.jp/proceedings/rinrikoryo.html

- Fabrication was clearly prohibited by a number of international documents, and Fujimura's act was an evident form of fabrication.
- Public announcement of research results or discoveries prior to scientific publishing is a more controversial issue.

STAGE 3: Casuistic Reasoning and Justification

I. What is at issue?

- An amateur archaeologist made false discoveries and fabricated findings
- He announced his findings to the media
- He was caught by the media
- He confessed

II. Where is the conflict?

- The fabrication case is straightforward.
- However, the reporting practice has some relevant background conflicts between the goals of research and incentives of researchers (often researchers are incentivized to announce the next spectacular discovery, which compromise the tedious collection of reliable data).
- There is also a potential conflict between the respective agendas of daily newspapers and academic journals.

III. What is this a case of?

- This is a case of research misconduct, specifically, fabrication, committed by an amateur archaeologist in several excavation sites.
- It is also a case of questionable publication practice, bypassing scientific peer review.

IV. What do we know about other cases like this one?

- The fabrication of research results with the researcher admitting to fraud is a simple case consistent with numerous known and investigated cases of fabrication. This is paradigm case of research misconduct with no unique features.
- The reporting of research results prior to academic publication and peer review might be more debatable, and might have some prevalence and acceptability in some fields of scientific research or in some circumstances it could be justified. Potentially similar cases are highly variable and circumstantial. We have no knowledge of well-established cases that could be used as paradigm to evaluate this.

V. How is the present case similar to the paradigm case?

- The case of fabrication is consistent with paradigm cases of fabrication as research misconduct.
- We have no knowledge about paradigm cases in reporting research results to the media prior to scientific publishing. However, reporting of research results prior to peer assessment could be described at least as a problematic practice.

Conclusion

Fujimura's fabrication of research results that he also admitted is a simple case consistent with numerous known and investigated cases of fabrication. This is paradigm case of research misconduct with no unique features. The reporting of research results prior to academic publication and peer review might be more debatable, and might have some prevalence and

acceptability in some fields of scientific research or in some circumstances it could be justified. Potentially similar cases are highly variable and circumstantial. We have no knowledge of well-established cases that could be used as paradigm to evaluate this. However, reporting of research results prior to peer assessment could be described at least as a problematic practice. Fujimura's publications and discoveries must be further investigated. Fujimura must be punished for the two counts of fraud to which he confessed. The publication practices of archaeologists must be investigated and assessed by the scientific community.

13.3 Section References

Jonsen A, Siegler M, Winslade W. Clinical ethics: a practical approach to ethical decisions in clinical medicine. McGraw Hill; 2010.

Normile D. Japanese Fraud Highlights Media-Driven Research Ethic**.** *Science* 2001;291(5501):34-5.

Schumann JH, Alfandre D. Clinical ethical decision making: the four topics approach. *Semin Med Pract* 2008;11:36-42.

Sokol D. The “four quadrants” approach to clinical ethics case analysis; an application and review. *J Med Ethics* 2008;34(7):513-6.

Appendix 1. EnTIRE and VIRT2UE Survey

Dear members of the EnTIRE and VIRT2UE consortium,

As part of WP5 of the EnTIRE project, we are required to identify case analysis methods suitable for the ethical analysis of research ethics and research integrity cases (RE+RI cases). Once identified, these case analysis methods will be detailed on the Embassy of Good Science along with examples of specific case analyses demonstrating their use.

Bearing in mind the 'bottom-up', user-oriented approach to the Embassy, WP5's aim is to identify *user-friendly*, *accessible* methods that can be appropriated by all users, *without any significant prior philosophical knowledge*, in order to analyse RE+RI cases *in local contexts*.

To this end, we are conducting a brief survey about your knowledge of procedural, 'step-by-step' frameworks, such as a checklist or a flowchart, that any user can follow without prior philosophical knowledge for the purposes of analysing RE+RI cases that are used for the ethical analysis of RE+RI cases. In addition, we would be interested whether you know procedures or 'step-by-step' frameworks for the analysis of cases in clinical medicine, medical ethics or any other field of applied ethics, which might be applied to RE+RI cases as well.

We would be immensely grateful if you could take a minute to fill out our simple questionnaire and send it as a response to this e-mail by Friday, the 25th of January.

SURVEY

1. Are you aware of any procedural, 'step-by-step' frameworks, such as a checklist or a flowchart, for the purposes of analysing RE+RI cases? If so, please list the names that these methods commonly go by.

2. Are you aware of any procedures for analysing cases in clinical medicine, medical ethics or other fields of applied ethics? If so, please list the names that these methods commonly go by (for example, 'Four Quadrant Approach').
3. Where can we find useful descriptions of these procedures (as mentioned in the first two questions)? (Please provide us with hyperlinks or journal/book references)
4. Which of these procedures require philosophical (or other specialist) knowledge in order to be useful? (Please list)
5. In your opinion, which of these procedures could be easily followed by any potential user of the Embassy of Good Science? (Please list)
6. In your opinion, which of these procedures could be suitably adapted for the analysis of RE+RI cases? Briefly, how would you adapt them?
7. Would you like to make any further comments?

If you have any questions, please feel free to get in touch via this email address: kakuk.peter@sph.unideb.hu

Thank you very much in advance,

Yours sincerely,

Dr. Péter Kakuk (University of Debrecen, Hungary)
Dr. Jonathan Lewis (Dublin City University, Ireland)
Prof. Bert Gordijn (Dublin City University, Ireland)