

**PRO**moting integrity in the use of **RES**earch results in evidence based policy: a focus on nonmedical research

Document Title: Statement of Ethics Principles for Research Work Package: 3

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## VERSION LOG

Version	Date	Author/reviewer	Change Details
0.1	27 January 2019	RI	
0.2	11 February 2019	JD + HK	
0.3	8 March 2019	RI + comments from	comments in
		Tartu team	response
0.4	1 May 2019	<b>RI</b> after circulation	Format change
		to consortium	and incorporation
			of all comments
			and responses
0.4a	1 May 2019	RD	Minor additions
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#### **REPORT ON THE STATEMENT OF ETHICS PRINCIPLES FOR RESEARCH**

## PREAMBLE

This task entailed building the foundations for the final PRO-RES Framework for Ethics and Integrity in Non-medical research. The first step to this process was to agree basic ethical research *values* to be foundational to the framework. To accomplish this, we have established a statement on research *values* and *virtues* and will draw on resources related to those values in the PRO-RES platform. Following this a statement on research ethics *principles* was built upon those agreed values, again adding to and drawing on resources related to research principles in the platform and to ensure the principles relate to the agreed research values. Online dialogue between all partners will be sustained to propose any additional value bases and the appropriate principles. Ultimately the foundational values and virtues lead to a statement on *standards* in research.

In addition to the work done within the consortium, we will also seek agreement on appropriate values and principles from stakeholder groups. This will done using the PRO-RES survey from the online consultation from WP2. The task output will be a statement of *Ethical Principles for Research* (D3.1) that will be available at the 'entrance' to the framework on the website.

# BACKGROUND

### 1.1 PROCESS AND OUTCOMES

The following statements, which are designed to form the fundamental/foundational assumptions of the PRO-RES Framework, were constructed via an iterative process first within the AcSS team. Each statement/sentence was carefully considered in light of the range of codes, guidelines available internationally and related EC projects. The aim was to incorporate all values, principles and standards considered relevant to a statement of ethical research practice. Note that the background literature that was consulted in this process is to be found in an 'Annotated Bibliography' to be annexed to the PRO-RES Framework. Further clarifications of concepts and careful definitions of terms is to be found in the 'Glossary of Terms and Concepts' also to be annexed. All consortium commentators were asked to read through the complete set of statements prior to making comment on specific sentences. Each of the points are so interrelated that their combined 'message' was what we were seeking.

#### DISCUSSION:

The first set of statements recognises that it is difficult, if not impossible, to separate 'values' from similar and overlapping 'virtues'. Discussion has either neglected or omitted consideration of the importance of virtues in research or assumed them to be subsumed with the stated values. Our discussion led to the need to ensure that both need to be declared in concert.

#### Hence, **STATEMENT 1**:

VALUES and VIRTUES: Throughout most of the existing codes and guidelines there appears a commonly held understanding that the virtuous researcher/scientist holds to certain values. These include a concern to be honest in all the work they do, to cooperate with other scientists in a supportive manner and to show respect for the dignity and diversity of their subjects. They should demonstrate qualities of care, kindness and compassion and take responsibility for all their actions. That includes a responsibility to think through what the consequences of their work might be for society, communities, individuals and even specific groups. At the same time as allowing researchers a reasonable degree of freedom to explore as their discipline dictates, research subjects, participants or respondents and others affected by the research must equally be allowed the freedom not to be harmed by research activities. The freedom to conduct scientific research must be matched by enabling those affected by the research the freedom not to be obliged to be party to it. Nonetheless, engaging in certain research acts and situations requires considerable courage on the part of researchers, this too is considered a virtue of responsible scientific practice. There may sometimes also be an obligation to carry out research in order to determine whether the benefits of an innovation exceed the risks or whether claims of an emerging risk are wellfounded. These values and virtues need to be supported by the cultures and structures of the institutions in which the researchers work.

#### DISCUSSION:

There was a potential source of disagreement over the use of the term 'research subjects' in the statement on values and virtues. The problem is over the application of an appropriate generic term for 'the people being studied'. Some researchers, particularly those engaging in qualitative data collection and analysis, are uncomfortable with referring to the groups or individuals they study as 'subjects'. They regard this as an ethical concern in that the term suggests the kind of objectification of people one finds in more experimental or quantitative forms of research. This is more than a semantic concern and it is worth considering whether the people being studied are referred to as 'participants', 'respondents' or 'subjects' according to the precise nature of their engagement with the research project (Birch and Miller 2002). An additional complexity arises when some ethics reviewers refer to the researchers conducting the study as 'participants' – which they clearly are but this can confuse those 'doing the study' with those who are primarily being studied. If the people being studied are participating in a jointly conceived and disseminated project they are clearly 'participants'. If they are simply answering survey questions delivered on the street they are 'respondents'. When the precise research engagement of those being studied is not known and/or is not central to the discussion the appropriate generic term to use is 'subject'. It is difficult to find a terminologically accurate generic alternative to 'subjects'. The 'people being studied' can be an individual or a group – the term 'subject' encompasses both. Not all people being studied are genuinely 'participating'. Some research designs aim to be truly inclusive (e.g. participative action research) in which case the subjects can be regarded as much as 'participants' as the researchers. In the same way, not all people under study are 'respondents' – giving answers in reply to questions in surveys, interviews, focus groups or questionnaires. Often they are simply being observed and their actions only then regarded as 'responsive' if the researcher's intervention is intended to induce a change (experimentally or quasi experimentally) in their behaviour, thoughts and/or feelings (Iphofen 2011).

One of the reasons the term 'subject' is avoided is to challenge the notion that people need to be 'objectified' when being researched. In fact, it would be inaccurate not to see them as the 'subject' of study – hopefully they are deliberately chosen as the subject or as a route to the subject, they are certainly being 'subjected' to a research intervention and it remains an ethical responsibility of the researcher to ensure they are not 'objectified' in a way that denies their humanity. All things considered, retaining the term 'subject' appears more accurate and does less injustice to those under study than if we were to imagine them as participating when they are not, when they might not see it that way and, in any case, we may be only interested in certain aspects of their life in how it relates to participation in the concerns of our study.

This seems an unduly 'heavy' discussion of what might seem a minor concern. However there are strong feelings and views about this which we cannot ignore. There are fuller discussions of the problem which can be found, for example, in Oliver (2003: 3–9) and in Corrigan and Tutton (2006).

More importantly, it has long been recognised that many values exist in tension if not in direct conflict with each other. Thus 'honesty' and/or 'transparency' could offer a challenge to recognition of the dignity and diversity of participants. Equally one person's freedom to act might curtail another's freedom to act differently. Thus there is no intention in the above values/vices statement to put an inappropriate block on research conducted in public places where there is no reasonable expectation of privacy. Similarly individuals seeking the freedom to opt out from administrative datasets should be reminded of their accountability to civil society; that is, those receiving some benefit from their membership in a society should not expect to opt out of being accountable for what they do with that benefit. The same principle may also apply to early

beneficiaries from an innovation whose risks and benefits will only be fully defined in use. Evidently not all administrative datasets are voluntary, there may be legal requirements for inclusion in some datasets. In countries, for example, where it is not illegal not to register as a voter, some people decide not to do so – either as a form of protest or through simple neglect. A simpler example might be when a transport authority is conducting a survey of passengers and people refuse to take part although knowledge of their use of public transport would be of benefit to themselves as well as to others. (Benefit here has a much broader sense than a financial transfer. It might also apply to the benefits of public order, a stable and predictable legal framework, investments in public health, etc.)

In referring to the "freedom to conduct scientific research", it is important not to understand this as implying that research is an indulgence or privilege. Research is also a moral obligation to establish whether the benefits of an innovation exceed the risks in use or to determine whether apparently emerging risks are causally related to an innovation that has been widely adopted. The absence of research may be as morally challenging as its conduct.

Through the initial discussion, it became clear that a formalised distinction between 'research ethics' and 'research integrity' has taken hold. Our considered view is that 'research ethics' stands as the umbrella term for 'ethical practices in research' such that 'research integrity' ought to be subsumed within that. Further we wished to avoid what has become a narrow convention in linking the lack of integrity to specific forms of research misconduct: fabrication, falsification and plagiarism. Instead we formulated a broader notion for a 'lack of integrity' which is in direct opposition to the values and virtues that we see as fairly established - these are termed research 'vices'.

#### Hence, STATEMENT 2:

**VICES:** The primary concerns of poor research integrity are framed as the corollary of these virtues. These include incompetence, indolence, deceit, the misrepresentation of facts and findings, fraudulent use of data, plagiarism and other forms of corrupt practices – such as harassment, bullying and/or nepotism. Stigmatising or prejudicial language, distortions, or data-gathering biases such as racism/ethnocentrism and sexism are reproved. So too are practices intended to entrench social exclusion or marginalise specific social categories – such as those with a disability or the aged or infirm or ethnic groups. The failure to credit or acknowledge the value of all contributions to a research activity is also to be considered a vice.

#### DISCUSSION:

We are well aware that sometimes any lack of research integrity has structural reasons – when the institutional infrastructure does not allow ethical behaviour, indeed such a structure might even encourage and reward misconduct as long as it cannot easily be disclosed. Such infrastructural 'influences' were outline in the original PRO-RES proposal. We can expand on that analysis within the final Framework – there is no implication as to the source of the vices within this statement – merely that they exist and this is how we propose to define them. There is no implied blame

attached to individuals nor indeed to the institutions of which they are a part. That would depend upon an analysis of specific cases. In fact it is difficult to separate those vices which are 'characteristics', which might more easily be applied to persons, from those 'practices' which are more usually associated with institutions. Thus, while we recognise that we could not accurately apply the notion of 'lazy' to an institution – clearly only individuals can be lazy – their indolence might be either encouraged or not disapproved of by an institution. Once again the primary responsibility for a vice would have to be discerned in specific cases. Similarly while an error in research might be considered a vice, the assessment of intention or motive – neglect or deliberate intent to deceive – requires empirical analysis of the specific case or context.

It became clear during discussion that any statement of ethical principles must be built upon the aforementioned values and virtues and oppose the vices that can occur in research practice. In examining the range of codes and guidelines it is clear that the express statement of a set of principles to quide ethical research practice is commonplace. At the same time, few codes or guidelines declare the same set of principles, necessarily disclose the underlying values, define terms in exactly the same way or clarify the practices that are to be proscribed given the established principles. It is this range and variety of approaches that can be confusing to researchers, research managers, commissioners and policymakers alike. A major goal of the PRO-RES framework is to incorporate as many of the proposed principles as possible and link them to the aforementioned statements of values, virtues and vices. In other words, to reveal the elements of a consensus that can be disclosed if one interrogates those guidelines. At the same time, the PRO-RES team would wish to make it clear that there is no implicit advocacy of what has become known as 'principlism' in commending these statements. Rather there is a need to recognise that dilemmas of ethics and integrity permeate research practice. Compromises frequently have to be made and choices of the 'lesser evil' sometimes required. The problem of a principlist approach is its implied purity of action – for example that in the avoidance of maleficence no harm should be done. Since no one can fully anticipate what might harm others, the best one can hope for is to strive to minimise the potential for harm. Thus the principles we advocate entail the norms to be adopted in order that the promoted values and virtues are maintained.

#### Hence, **STATEMENT 3**:

**PRINCIPLES:** In combining the values and virtues to be sought and the vices to be avoided, most codes and guidelines advocate the applications of certain principles. In order to bear responsibility scientists must participate in open and democratic processes and be accountable for their actions. They need to operate in a collaborative and collegial manner, apply their data collection, findings and research outcomes proportionately, justly and fairly. The larger community – both public and professional – should benefit from and not be harmed by their activities. The involvement of the subjects of research should, as far as possible, be on a voluntary basis – none should be forced to participate nor bear the consequences of a researcher's actions without their informed agreement – though specific principles are necessary to cover those observed in public settings and covert observations of behaviour or phenomena that could not be studied in any other way and that is

necessary for societal benefit. Both researchers and researched need to be accorded a degree of autonomy or independence – both in terms of how the ongoing research is conducted and whether they choose to continue to participate. Reliable research will depend upon a just and equitable selection and treatment of subjects, or participants, or respondents. The diversity of research subjects/participants must be accounted for and their participation in or departure from a research study facilitated.

#### DISCUSSION:

'Standards' are statements about the quality of performance that should be expected from some activity (see the Glossary of Terms and Concepts). These statements may prescribe the technical details of the activity and the process required for the outcome to be recognized as acceptable. Although standards need not have an explicit legal force, they often acquire a moral force, such that individuals and organizations are expected to comply with them in order to be treated as legitimate for relevant social and economic purposes. Clearly such statements are based on the values and virtues listed in Statement 1, must embody the principles outlined in Statement 3 and clearly explain how the vices summarised in Statement 2 can be addressed.

#### Hence, STATEMENT 4:

**STANDARDS:** The standards to ensure that research is conducted ethically and with integrity are contained within sets of rules for good governance. These will include standard operating procedures for the evaluation of projects, proposals and the system of ethics oversight – the form and content of research ethics review committees or any other review, monitoring or ethics approval process. Equally important are the regulated means for safeguarding scientists and researchers, their subjects, their findings and their intellectual property. Sanctions must be available for those researchers that fail to fulfil their obligations without good reason. Results must be auditable and provision made for the honest and constructive critique of malpractice – such as whistleblowing. Standards for due process must include means for resolving conflicts of interest, for mediation and for the redress of grievance.

Taken together these four statements constitute the foundational 'Statement for Ethical Research Practice' that is to be promoted by the PRO-RES Project. Evidently such statements do not fully explain how these practices are to be precisely accomplished. The statements must be backed up by extensive resources that can support the full range of stakeholders with an interest in ethical practices in research. Those resources are to be found in the PRO-RES Framework.

The following pages contain the statements as they should appear on the website. The preceding outline of the construction of these statements and the rationale behind them should be made available as a link for those wishing to pursue such a rationale.

### 1.2 THE FOUNDATIONAL STATEMENTS FOR ETHICAL RESEARCH PRACTICE

The following statements, which are designed to form the fundamental/foundational assumptions of the PRO-RES Framework, were constructed via an iterative process within the Consortium. Each statement/sentence was carefully considered in light of the range of codes, guidelines available internationally and related EC projects. The aim was to incorporate all values, principles and standards considered relevant to a statement of ethical research practice. The background literature that was consulted in this process is to be found in an 'Annotated Bibliography' to be annexed to the PRO-RES Framework. Further clarifications of concepts and careful definitions of terms is to be found in the 'Glossary of Terms and Concepts' also to be annexed. Each of the points are so interrelated that their combined 'message' is what we are seeking.

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Anyone interested in looking further into the rationale that led to these statements can find some background to the full discussion here: [LINK TO **REPORT ON THE STATEMENT OF ETHICS PRINCIPLES FOR RESEARCH**]