



Research Ethics Training

UKRIO Research Integrity Webinar: Research Ethics 5th August 2020

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Research Ethics Support and Review in Research Organisations



<https://ukrio.org/wp-content/uploads/Research-Ethics-Support-and-Review-in-Research-Organisations-UKRIO-ARMA-2020.pdf>



COVID-19 and beyond: The virtuous researcher and the virtuous REC

The pandemic has led to a proliferation of research. Much has been focused on key clinical endeavours in searching for effective treatments and vaccines, but there has been a massive growth across all disciplines. COVID-19 research has posed challenges for researchers and RECs alike. Some well established principles are readily called in to question; for example, can research ethics, based on philosophical individualism, where autonomy seems to trump most other considerations, be defended in the context of a global pandemic which can be argued to favour the common good? RECs face a difficult challenge; virtue ethics might help in providing a theoretical framework for exploring this challenge.

John will be covering the theory underpinning virtue ethics and its application in research contexts. I will cover:

1. Key issues arising during the training I have been providing
2. Virtue ethics examples related to COVID-19 research



COVID-19 and beyond: Key ethics challenges

The UK has led the world in its research efforts

- Big ones
 - Clinical trials
 - Vaccine studies
 - Immunological studies
 - Data bases
- Hastily prepared documents and rapid ethics review
- New approaches to information and consent
- Blurred boundaries of confidentiality
- Adjustments to pre-COVID trials
- Opportunism



UKRIO Training – Key Themes

- What is the role of RECs?
- What is the scope of ethics review?
- From compliance / regulation to ethics review
- Ethical Research –design, delivery and dissemination
- What should RECs look for?

Research virtues and vices

RESPECT PARTICIPANTS

Phase	Defect (vice)	Mean (virtue)	Excess (vice)
<i>(Re)framing</i>	cowardice	courage	recklessness
<i>Negotiating</i>	manipulativeness	respectfulness	partiality
<i>Gathering</i>	laziness	resoluteness	inflexibility
<i>Creating</i>	concealment	sincerity	exaggeration
<i>Disseminating</i>	boastfulness	humility	timidity
<i>Reflecting</i>	dogmatism	reflexivity	indecisiveness

REVIEWING PHASES

Phase

Meaning

Understanding	research rationale, primary and secondary objectives, methods, design
Empathising	with.... researcher, participants, sponsors, funders, peers, supervisors
Focusing	on ... worthwhileness, benefits and burdens, risks, researcher consideration of participants, impact / wider benefits
Clarifying	key ethical issues, researcher intentions, researcher ability
Deliberating	to... find committee consensus, identify significant ethical issues
Concluding	by arriving at an opinion, establishing clear reasons to support opinion
Reflecting	on the decision and process, consistency with other decisions

THE VIRTUES AND VICES OF ETHICAL REVIEW

TRUST RESEARCHERS

Phase	Vice (deficit)	Virtue	Vice (excess)
Understanding	Ignorance	<i>Intelligence</i>	ostentatiousness
Empathising	Inconsiderateness	<i>Sensitivity</i>	Emotionality
Focusing	Distractibility	<i>Discernment</i>	Narrow-mindedness
Clarifying	Vagueness	<i>Perspicacity</i>	Punctiliousness
Deliberating	Self-absorption	<i>Cooperation</i>	Collusion
Concluding	Aberrance	<i>Reasonableness</i>	Pedantry
Reflecting	Inconsistency	<i>Reflexivity</i>	Rigidness



Participant Information and Consent

- **Capacity / competence**
 - Vulnerable participants
- **Voluntariness**
 - Easy to withdraw
 - Inducements
 - coercion
- **Information**
 - Adequate and fit for purpose
 - Comprehensive and comprehensible

Information

- Purpose
- Comprehensibility
- Format / Medium
 - Written
 - Verbal
 - Pictorial
 - Video
 - App

PARTICIPANT INFORMATION SHEET

You are being invited to take part in a research study. Before you make your decision, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. You may want to talk to others about the study before taking part.

Part 1 tells you the purpose of this study and what will happen to you if you take part.

Part 2 gives you more detailed information about the conduct of the study.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.



Respectful PIS

We are sorry that you have been admitted to hospital with a diagnosis of COVID-19; this must be very worrying for you and your family. It is difficult to ask anything of you at the moment but we really need your help. In truth we know little about the virus which is why we are conducting research. This is where you could help.....

(Form to be on headed paper)

IRAS ID:

Centre Number:

Study Number:

Participant Identification Number for this trial:

CONSENT FORM

Title of Project:

Name of Researcher:

Please initial box

1. I confirm that I have read the information sheet dated..... (version.....) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.



Legal and Ethical Use of Data

- Ethics
 - **Privacy and confidentiality** nb s 251 restrictions have been temporarily lifted with regard to accessing confidential data in order to process confidential patient information without consent for COVID-19 public health, surveillance and research purposes. **Normally consent would be required**
- GDPR
 - Regulations related to the processing of personal data. The legal basis for this processing in public institutions such as NHS Trusts and Universities is 'tasks in the public interest'. **Transparency statements are required**

Police disperse crowds at illegal rave in Forest of Dean due to Covid risk

Gloucestershire police say they have broken up event and warned people to stay away

