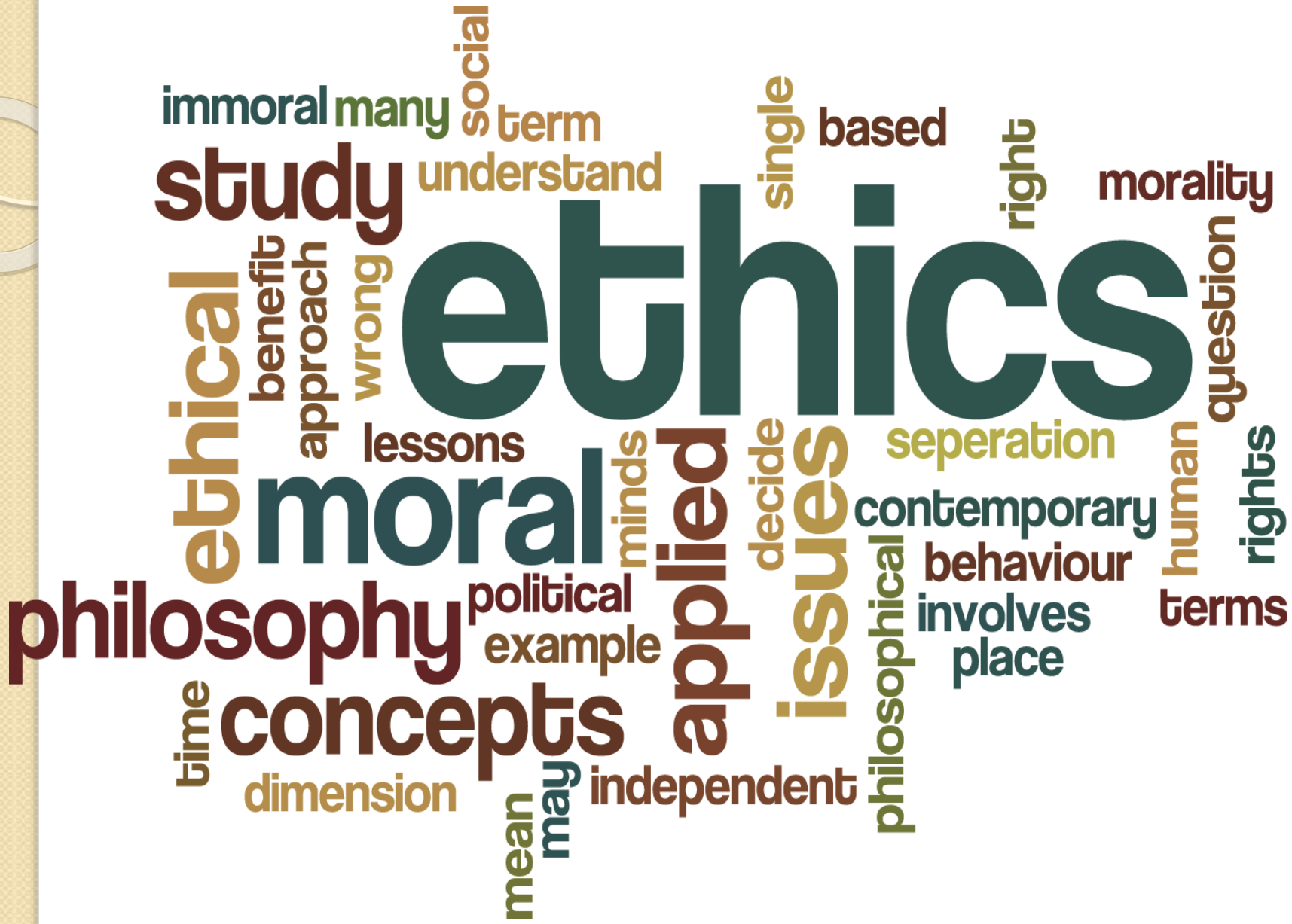
The Ethics Issues table & and the Ethics self-assessment: key messages on content

Dr Mihalis Kritikos

EPRS-European Parliament

Athens, 27/11/2015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human
approval
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medicine
undergraduate
university
patients
data
school
ethical
postgraduate
Medical

Ethics Issues Table

- The applicable legislation is the **Horizon2020 legislative acts;**
- **This Table should be completed as an essential part of the proposal;**
- **"Yes" or "No" approach;**
- **If an answer is "Yes", then the applicant needs to indicate at which page in the proposal further information relating to that issue can be found;**
- As explained in these documents, please note that if you answer YES to any of the questions below, **you are requested to provide additional information and documentation.**

European Research Council Executive Agency

Proposal ID	*Acronym*	*Go to*

4 - Ethics issues table

The applicable legislation is the Horizon2020 legislative acts (i) (see legal references at the end of the section).

This Table should be completed as an essential part of your proposal. Answer "Yes" or "No" to all of the questions below. If an answer is "Yes", then indicate in the adjacent box at which page in your full proposal further information relating to that issue can be found.

For further explanation on the questions see "How to Complete your Ethics Self-Assessment" or, for ERC calls, the "Information for applicants" (Annex 3 - Specific Guidance Related to Ethics).

As explained in these documents, please note that if you answer YES to any of the questions below, you are requested to provide additional information and documentation.

1. HUMAN EMBRYOS/FOETUSES		Page
Does your research involve Human Embryonic Stem Cells (hESCs)?	◉ Yes ○ No	
Will they be directly derived from embryos within this project?	◉ Yes ○ No	
Are they previously established cells lines?	◉ Yes ○ No	
Does your research involve the use of human embryos?	◉ Yes ○ No	
Does your research involve the use of human foetal tissues / cells?	◉ Yes ○ No	
2. HUMANS		**Page**
Does your research involve human participants?	◉ Yes ○ No	
Are they volunteers for social or human sciences research?	◉ Yes ○ No	
Are they persons unable to give informed consent?	◉ Yes ○ No	
Are they vulnerable individuals or groups?	◉ Yes ○ No	
Are they children/minors?	◉ Yes ○ No	
Are they patients?	◉ Yes ○ No	
Are they healthy volunteers for medical studies?	◉ Yes ○ No	
Does your research involve physical interventions on the study participants?	◉ Yes ○ No	

Section 1: HUMAN EMBRYOS/FOETUSES

Does your research involve Human Embryonic Stem Cells (hESCs)?

Will they be directly derived from embryos within this project?

-Research cannot be funded.

Are they previously established cells lines?

-Origin and line of cells.

-Details on licensing and control measures by the competent authorities of the Member States involved.

-Copies of relevant Ethics Approvals.


I'd rather die than allow stem cell research!
funny you should say that...
ED FISCHER
© Original Artist
Reproduction rights obtainable from
www.CartoonStock.com

Section 1: HUMAN EMBRYOS/FOETUSES

- **Does your research involve the use of human embryos?**

-Origin of embryos.

-Details on recruitment, inclusion and exclusion criteria and informed consent procedures

-Copies of relevant Ethics Approvals.

-Informed Consent Forms.

-Information Sheets.

Section 1: HUMAN EMBRYOS/FOETUSES

- **Does your research involve the use of human foetal tissues / cells?**

-Origin of human foetal tissues/cells.

-Details on informed consent procedures

-Copies of relevant Ethics Approvals

-Informed Consent Forms

-Information Sheets

Section 2: HUMANS

- **Does your research involve human participants?**

Are they volunteers for social or human sciences research?

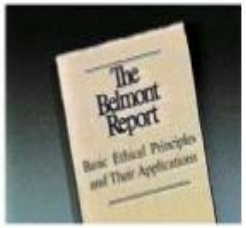
-Details on recruitment, inclusion and exclusion criteria and informed consent procedures

RESEARCH RESOURCES

RESEARCHING WITH HUMAN SUBJECTS (IRB)

The Belmont Report

Ethical Principles and Guidelines for the Protection of Human Subjects of Research



The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

April 18, 1979

Human Subjects Protocol Review & Approval Procedures

Click Here »

Ethical Guidelines

Special Communication

World Medical Association Declaration of Helsinki

Ethical Principles for Medical Research Involving Human Subjects

World Medical Association

Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, and amended by the:
29th WMA General Assembly, Tokyo, Japan, October 1975
35th WMA General Assembly, Venice, Italy, October 1983
41st WMA General Assembly, Hong Kong, September 1989
48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996
52nd WMA General Assembly, Edinburgh, Scotland, October 2000
53rd WMA General Assembly, Washington, DC, USA, October 2002 (Note of Clarification added)
55th WMA General Assembly, Tokyo, Japan, October 2004 (Note of Clarification added)
59th WMA General Assembly, Seoul, Republic of Korea, October 2008
64th WMA General Assembly, Fortaleza, Brazil, October 2013

Section 2: HUMANS

Are they persons unable to give informed consent?

-Details on recruitment, inclusion and exclusion criteria and informed consent procedures

-Details on the procedures to obtain approval from guardian/ legal representative.

-Details on the procedures used to ensure that there is no coercion on participants.

-Informed Consent Forms.

-Information Sheets

Section 2: HUMANS

Are they vulnerable individuals or groups?

-Details on the type of vulnerability.

-Details on recruitment, inclusion and exclusion criteria and informed consent procedures. This must demonstrate appropriate efforts to ensure fully informed understanding of the implications of participation.

-Informed Consent Forms.

-Information Sheets.


PARTICIPATORY
RESEARCH
Working with vulnerable groups
in research and practice
Jo Aldridge


Philip Bielby
Competence and
Vulnerability in
Biomedical Research
Springer


Vulnerable Groups
& Inclusion
COACTION
SOCIAL SCIENCES

Informed Consent
Do you have it?

Section 2: HUMANS

Are they children/minors?

-Details on recruitment, inclusion and exclusion criteria and informed consent procedures. This must demonstrate appropriate efforts to ensure fully informed understanding of the implications of participation.

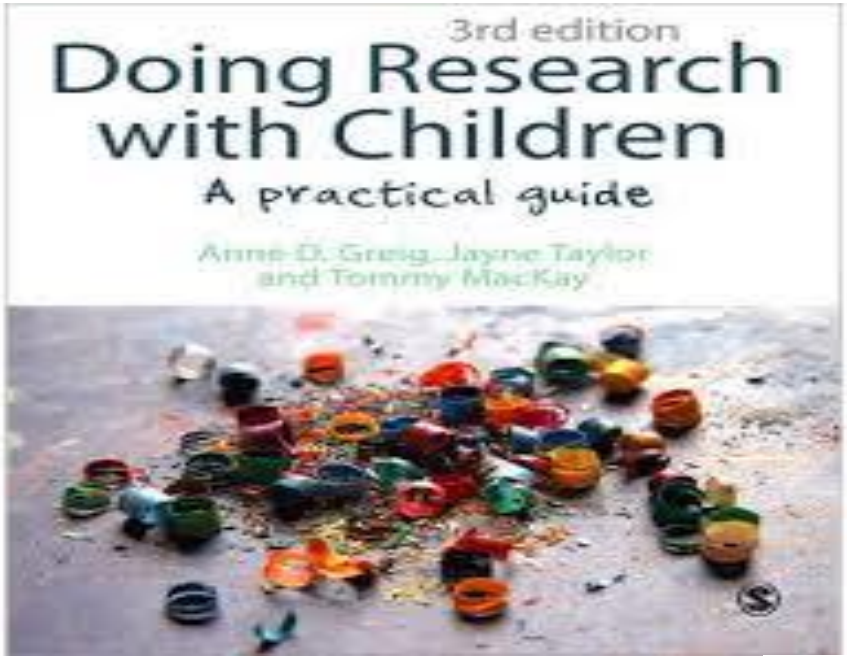
-Details on the age range.

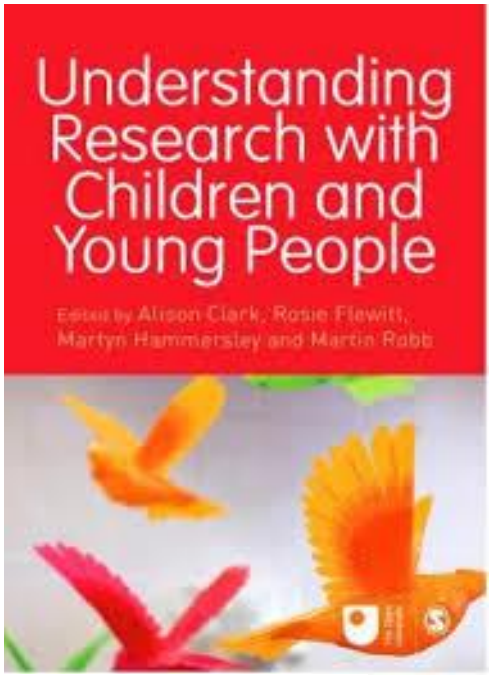
-Details on children/minors assent procedures and parental consent. This must demonstrate appropriate efforts to ensure full informed understanding of the implications of participation.

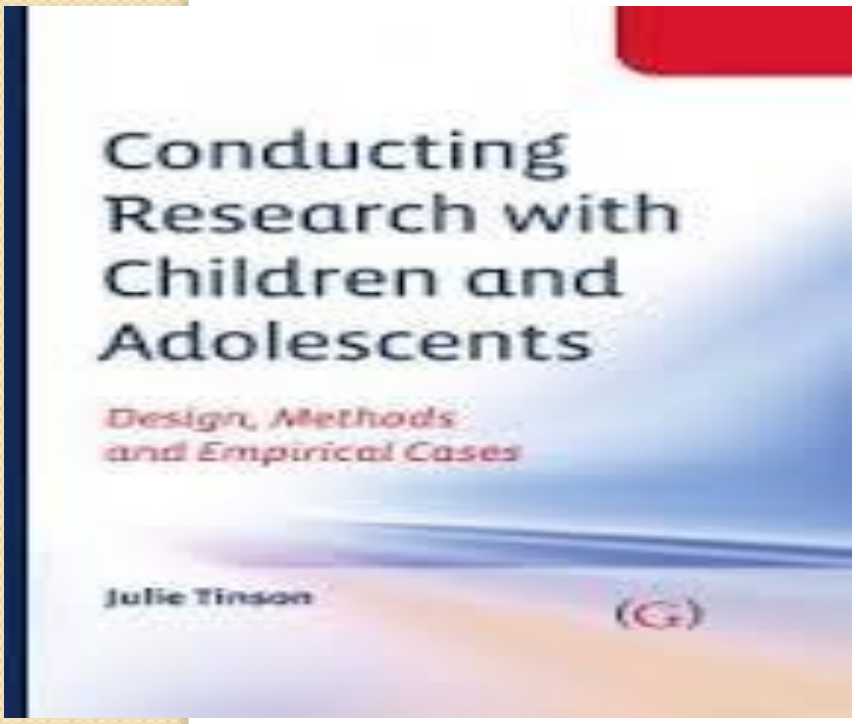
-Describe the procedures to ensure welfare of the child/minor

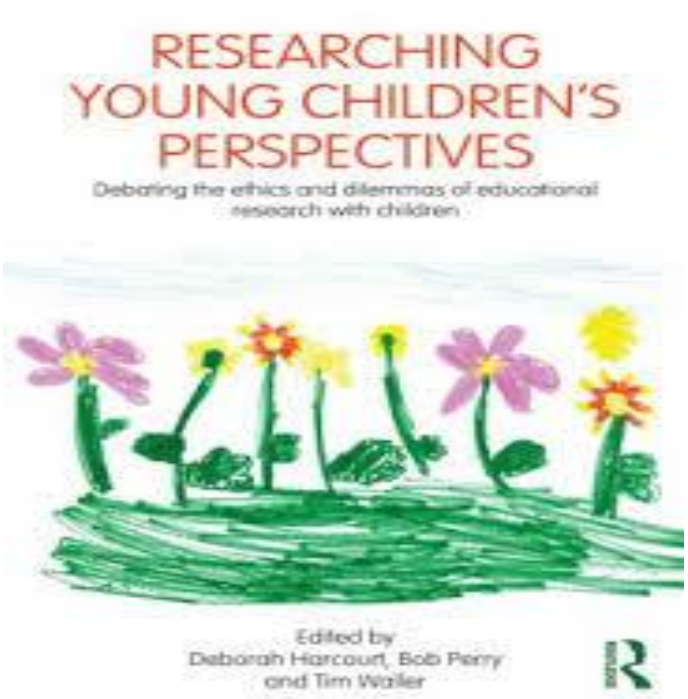
-Informed Consent Forms

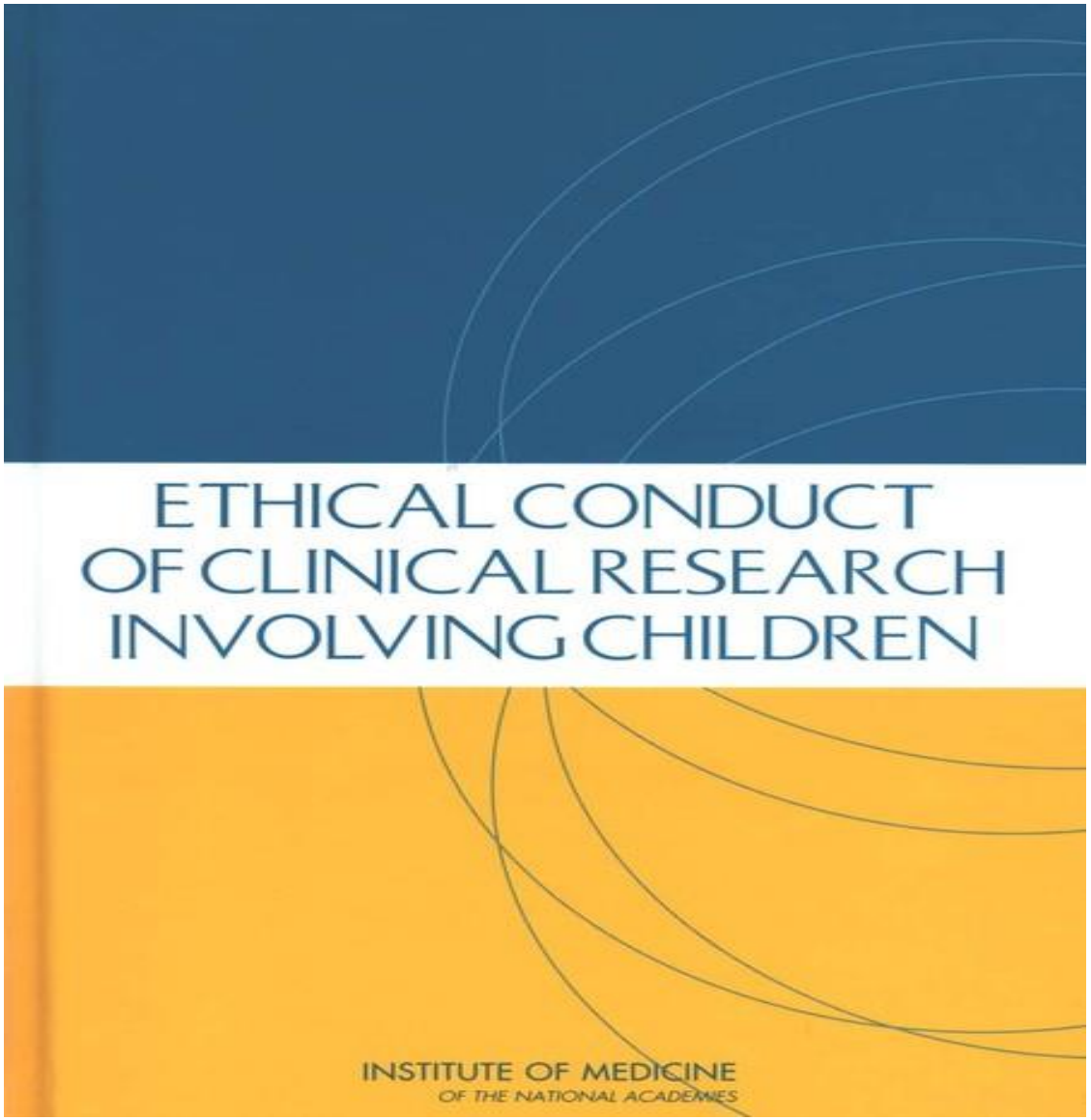
-Information Sheets


3rd edition
Doing Research with Children
A practical guide
Anne D. Greig, Jayne Taylor and Tommy MacKay


Understanding Research with Children and Young People
Edited by Alison Clark, Rosie Flewitt, Martyn Hammersley and Martin Robb


Conducting Research with Children and Adolescents
Design, Methods and Empirical Cases
Julie Tinson


RESEARCHING YOUNG CHILDREN'S PERSPECTIVES
Debating the ethics and dilemmas of educational research with children
Edited by
Deborah Harcourt, Bob Perry and Tim Waller


ETHICAL CONDUCT
OF CLINICAL RESEARCH
INVOLVING CHILDREN
INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

Section 2: HUMANS

Are they patients?

-Details on the nature of disease/condition/disability.

-Details on recruitment, inclusion and exclusion criteria and informed consent procedures

-Details on policy for incidental findings.

-Copies of relevant Ethics Approvals.

-Informed Consent Forms.

-Information Sheets

Are they healthy volunteers for medical studies?

-Details on recruitment, inclusion and exclusion criteria and informed consent procedures

-Details on policy for incidental findings.

-Informed Consent Forms.

-Information Sheet


CLINICAL TRIALS
H.I.T.
BIOBANKS
THINK RESEARCH
DATA
INCENTIVIZE PATIENT PARTICIPATION!
Align research priorities with our needs!
PATIENTS
PATIENTS HELPING DOCTORS
EMPOWER

"It was more of a '*triple-blind*' test. The patients didn't know which ones were getting the real drug, the doctors didn't know, and, I'm afraid nobody knew."

Section 2: HUMANS

- **Does your research involve physical interventions on the study participants?**

Does it involve invasive techniques (e.g. collection of human cells or tissues, surgical or medical interventions, invasive studies on the brain, TMS, etc.)?

-Risk assessment for each technique and as a whole

-Copies of relevant Ethics Approvals.

Does it involve collection of biological samples?

-Details on the type of samples to be collected.

-Details on procedures for collection of biological samples.

-Copies of relevant Ethics Approvals

Section 3: HUMAN CELLS / TISSUES

- **Does your research involve human cells or tissues? (Other than from "Human Embryos/Foetuses" i.e. Section 1)**

-Details of the cells and tissue types involved.

Are they available commercially?

-Details on cell types and provider (company or other).

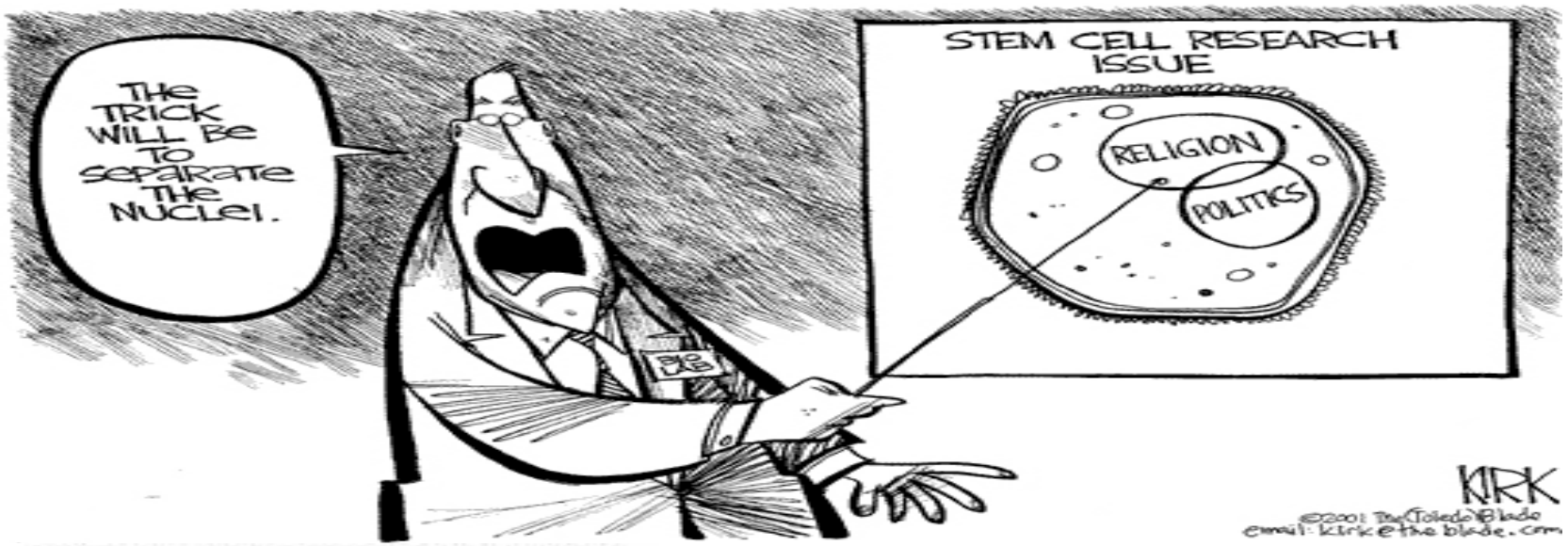
-Any relevant import licences

Are they obtained within this project?

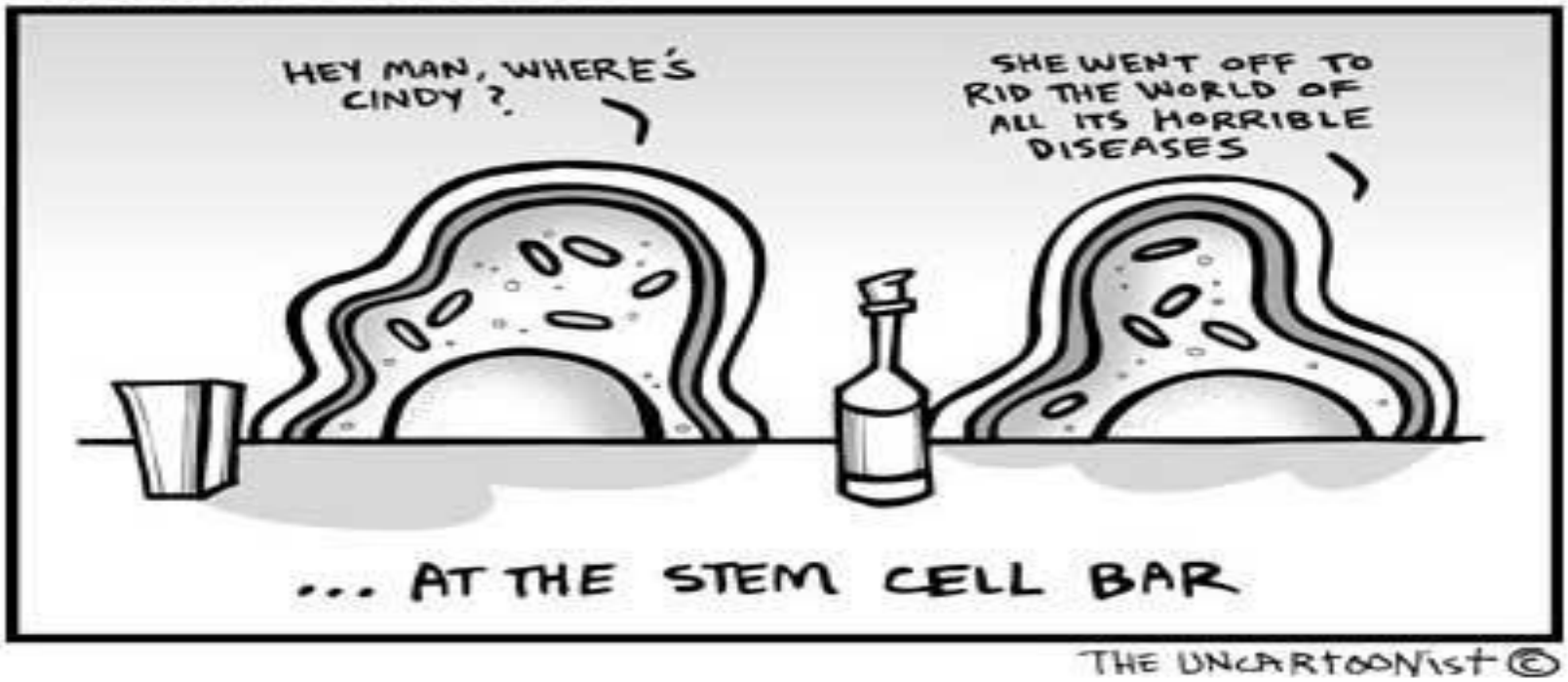
-Details on cell types.

-Copies of relevant Ethics Approvals or regulatory licences.

-Copies of examples of Informed Consent documents.



CARTOON OF THE DAY



3: HUMAN CELLS / TISSUES

Are they obtained within another project?

- Details on cell types.
- Provider of the cell types.
- Country in which the material is located
- Authorisation by primary owner of cells/tissues (including references to relevant licences or ethics approval and evidence of consent for secondary use).
- Copy of any Material Transfer Agreement

Are they deposited in a biobank?

- Details on cell types.
- Name of the biobank.
- Country in which the biobank is located
- Details of the biobank, the legislation under which it is licenced, criteria for access and its data protection policy including any Material Transfer Agreement

Section 4: PROTECTION OF PERSONAL DATA

- **Does your research involve personal data collection and/or processing?**

1. "Personal data" can be defined as identifiers: any information that could, in any way, lead to the specific identification of one unique person, such as name, social security numbers, date of birth, address, mails IPs etc.

2. Any data that you are using should be taken into account, regardless of the method by which they are/were collected: for example, through interviews, questionnaires, direct online retrieval etc.

3. Processing should be understood to not only include data usage, but also merging, transformation, transfer and, more generally, as all actions using data for research purposes

Section 4: PROTECTION OF PERSONAL DATA

Does it involve the collection and/or processing of sensitive personal data (e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)?

It should be noted that this involvement applies, whatever the research topic or Programme. The above list is only indicative. If the type of data that you will be handling in your research is not included the list, it does not mean you should not take into consideration the subject of data processing

-Details of the data safety procedures (compliance with privacy by design and protection of privacy/confidentiality).

-Details of procedures for data collection, storage, protection, retention, transfer if any, destruction or re-use.

-Explicit confirmation of compliance with national and EU legislation.

-Copies of relevant Ethics Approvals for the collection and/or processing of personal data.

-If relevant, Informed Consent Forms or other consent documents (opt in processes, etc.).

-If relevant, Information Sheets or other terms and conditions, factsheets, etc.

-If relevant, notification to, or authorisation from, the relevant Data Protection Authority/Officer.

-If relevant, a copy of authorization to merge the data sets in order to create a novel data set.

Section 4: PROTECTION OF PERSONAL DATA

-Does it involve processing of genetic information?

- **Does it involve tracking or observation of participants?**

It should be noted that this issue is not limited to surveillance or localization data. It also applies to Wan data such as IP address, MACs, cookies etc

Section 4: PROTECTION OF PERSONAL DATA

- **Does your research involve further processing of previously collected personal data (secondary use)?**

It should be noted that this question is threefold. If you answer YES to any of the 3 questions below, you fall within its scope:

1. Are you planning not to collect any data directly but rather to use pre-existing other data sets or sources and/or does your research involve further processing of previously collected data?

2. Does your research involve merging existing data sets?

3. Are you planning to share data with non-EU member states?

Section 5. ANIMALS

- **Does your research involve animals?**

-Are they vertebrates or live cephalopods?

-Are they non-human primates (NHP)?

-Are they genetically modified?

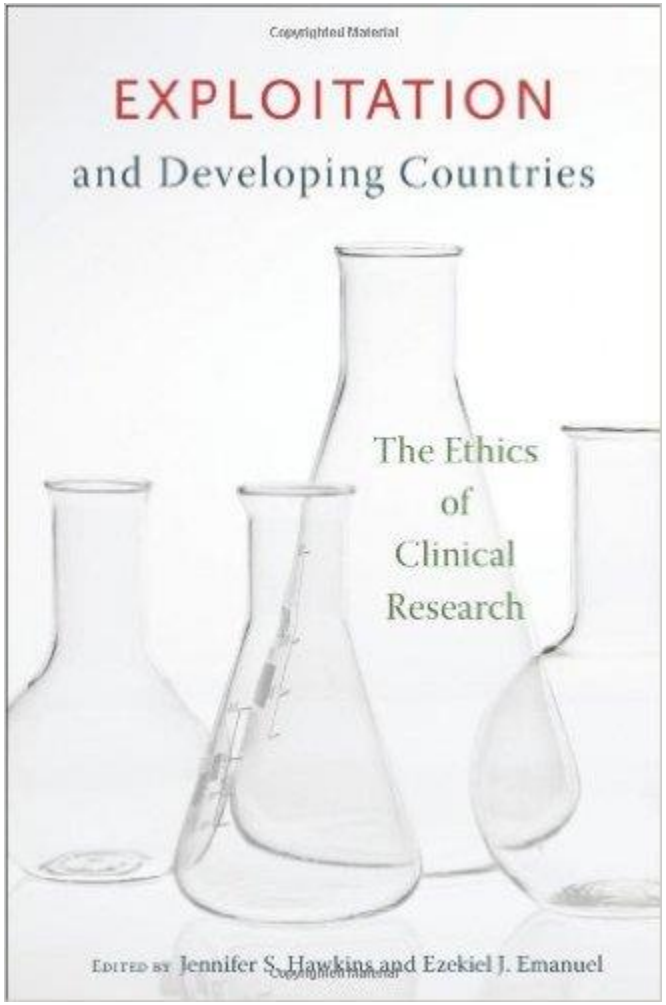
-Are they cloned farm animals?

-Are they an endangered species?

"You mean you're going to test it on a guinea pig *now*?"

Section 6: THIRD COUNTRIES

- **Does your research involve third countries?**
- **Do you plan to use local resources (e.g. animal and/or human tissue samples, genetic material, live animals, human remains, materials of historical value, endangered fauna or flora samples, etc.)?**
- **Do you plan to import any material, including personal data, from non-EU/third countries into the EU? Specify the materials and countries involve**
- **Do you plan to export any material, including personal data, from the EU to third/non-EU countries?**
- **If your research involves low and/or lower-middle income countries, are any benefit-sharing actions planned?**
- **Could the situation in the country put the individuals taking part in the research at risk?**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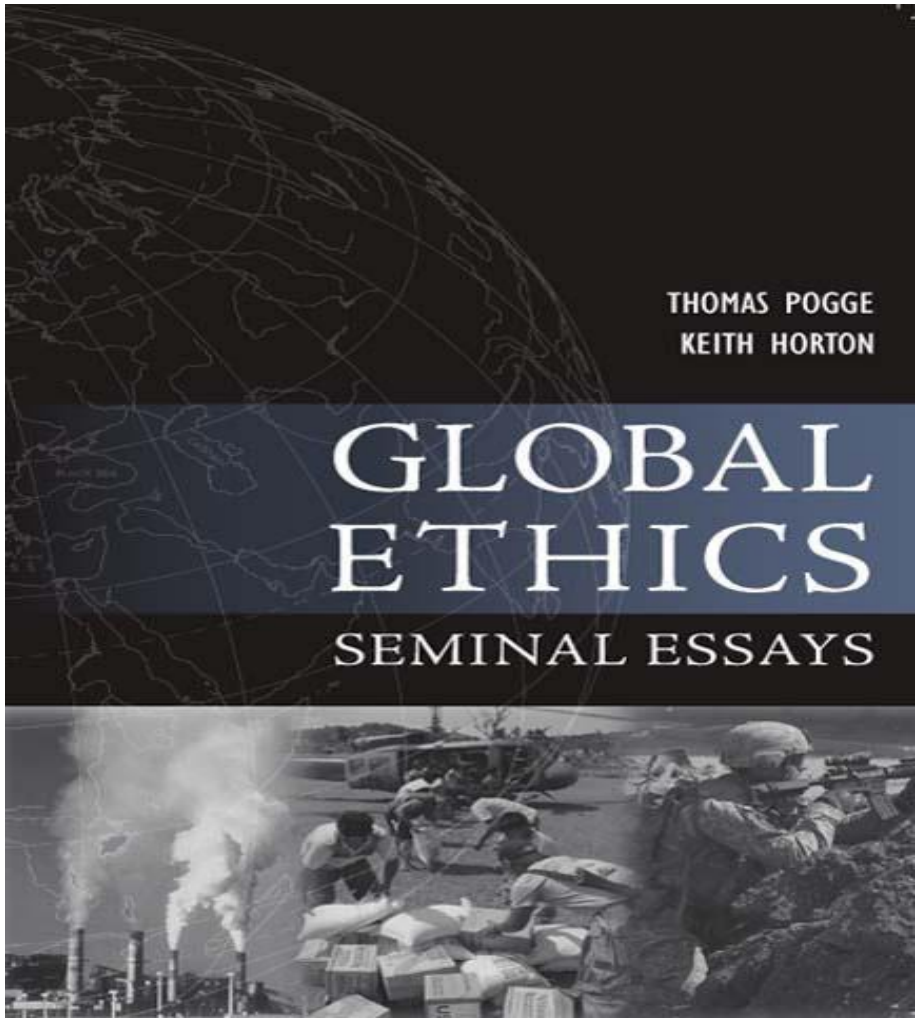
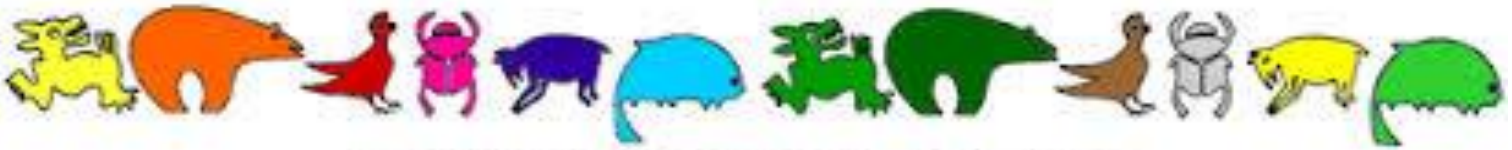
EXPLOITATION
and Developing Countries
The Ethics of Clinical Research
EDITED BY Jennifer S. Hawkins and Ezekiel J. Emanuel


THOMAS POGGE
KEITH HORTON
GLOBAL ETHICS
SEMINAL ESSAYS

Section 7: ENVIRONMENTAL PROTECTION AND SAFETY

- Does your research involve the use of elements that may cause harm to the environment, animals or plants?
- Does your research deal with endangered fauna and/or flora /protected areas?
- Does your research involve the use of elements that may cause harm to humans, including research staff?
- Does your research involve the use of elements that may cause harm to humans, including research staff?



ENVIRONMENTAL ETHICS

WRONG

RIGHT

Section 8: DUAL USE

Does your research have the potential for military applications?

-Does your research have an exclusive civilian application focus?

-Will your research use or produce goods or information that will require export licenses in accordance with legislation on dual use items?

-Does your research affect current standards in military ethics – e.g., global ban on weapons of mass destruction, issues of proportionality, discrimination of combatants and accountability in drone and autonomous robotics developments, incendiary or laser weapons?


virus
H5N1
research
flu
Science
scientists
information
researchers
bird
people
publish
U.S
scientific
journals
work
government
National
University
Fouchier
dangerous
influenza
humans
details
new
one
also
spread
NSABB
published
study
studies
Medical
Health
pandemic
laboratory
Nature
Biosecurity
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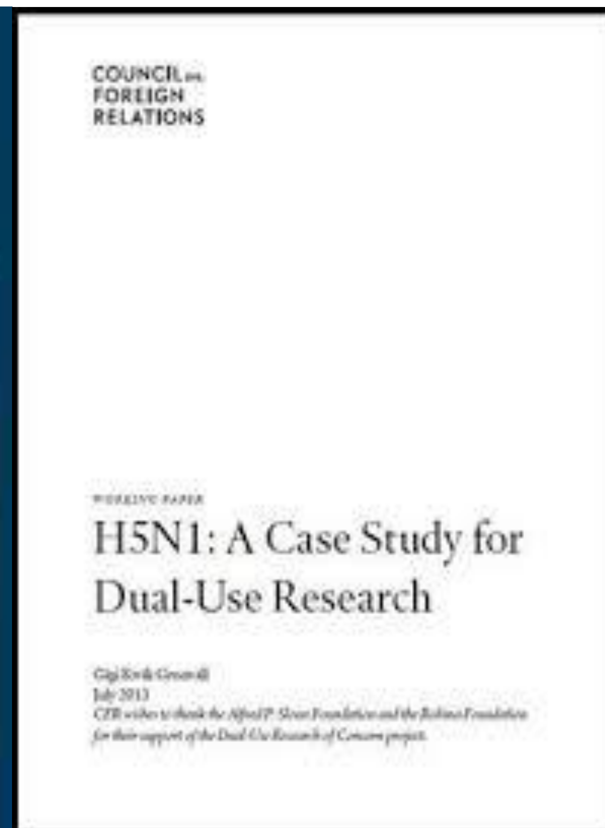
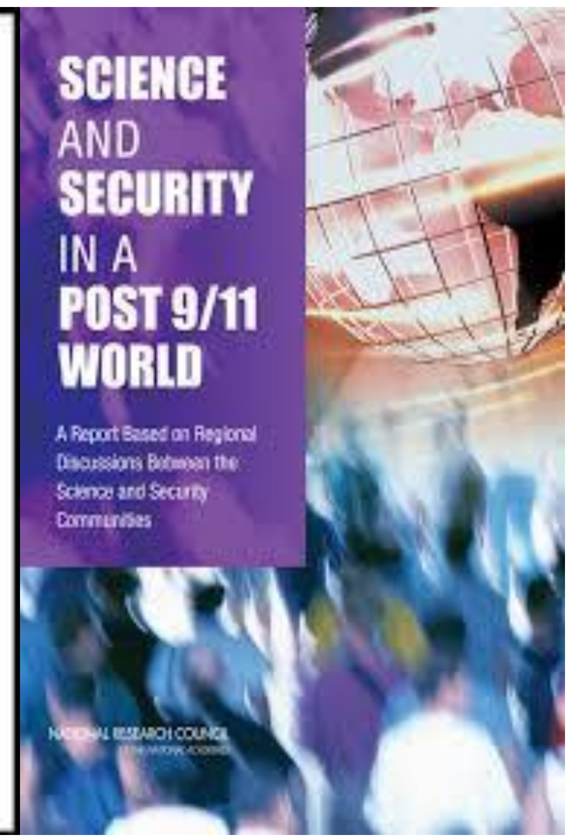
Seumas Miller
Michael J. Selgelid
Ethical and Philosophical Consideration of the Dual-Use Dilemma in the Biological Sciences

COUNCIL on FOREIGN RELATIONS
H5N1: A Case Study for Dual-Use Research

SCIENCE AND SECURITY IN A POST 9/11 WORLD
A Report Based on Regional Discussions Between the Science and Security Communities

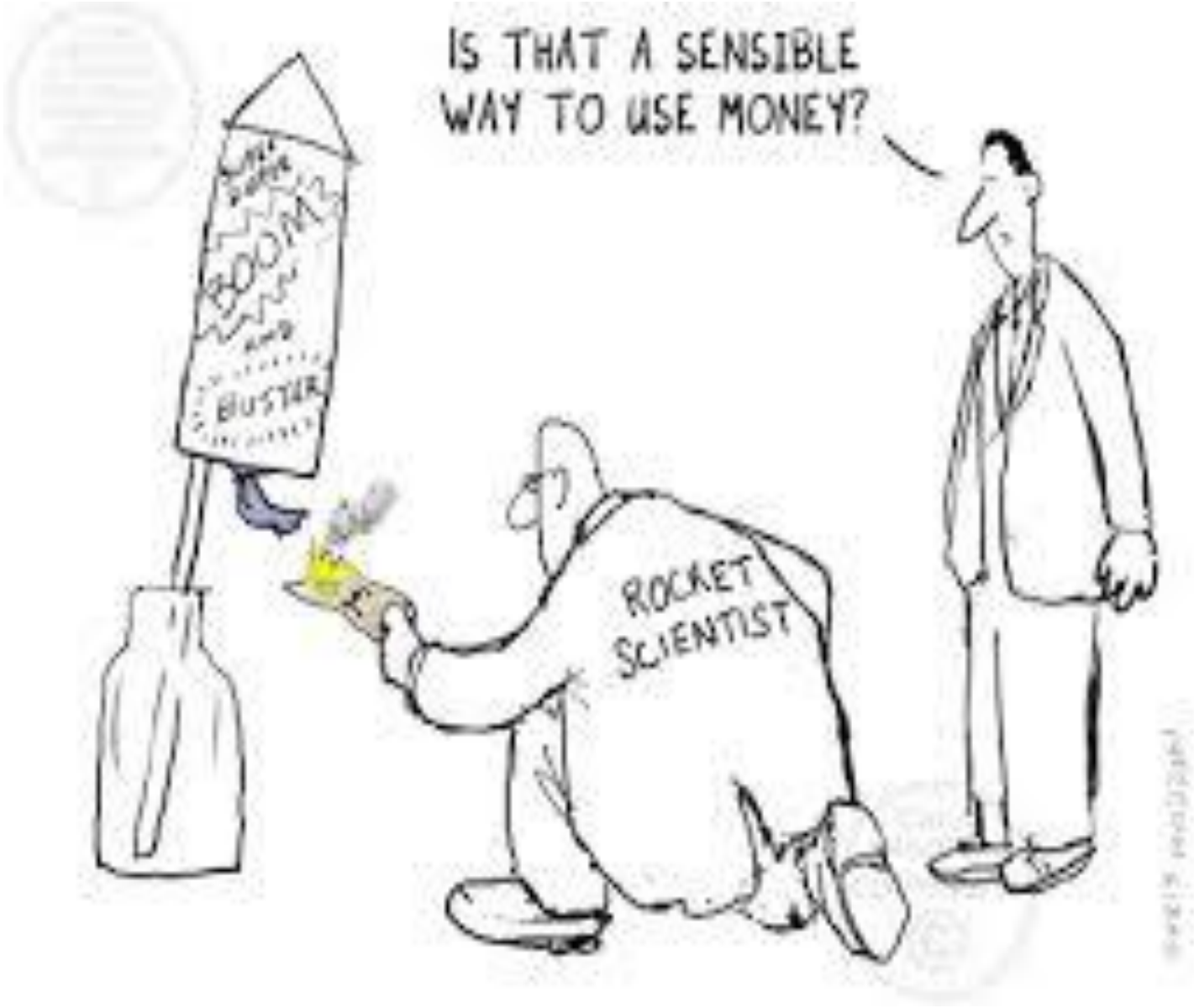
Section 9: MISUSE

- Does your research have the potential for malevolent/criminal/terrorist abuse?

-Does your research involve information on/or the use of biological-, chemical-, nuclear/radiological security sensitive materials and explosives, and means of their delivery?

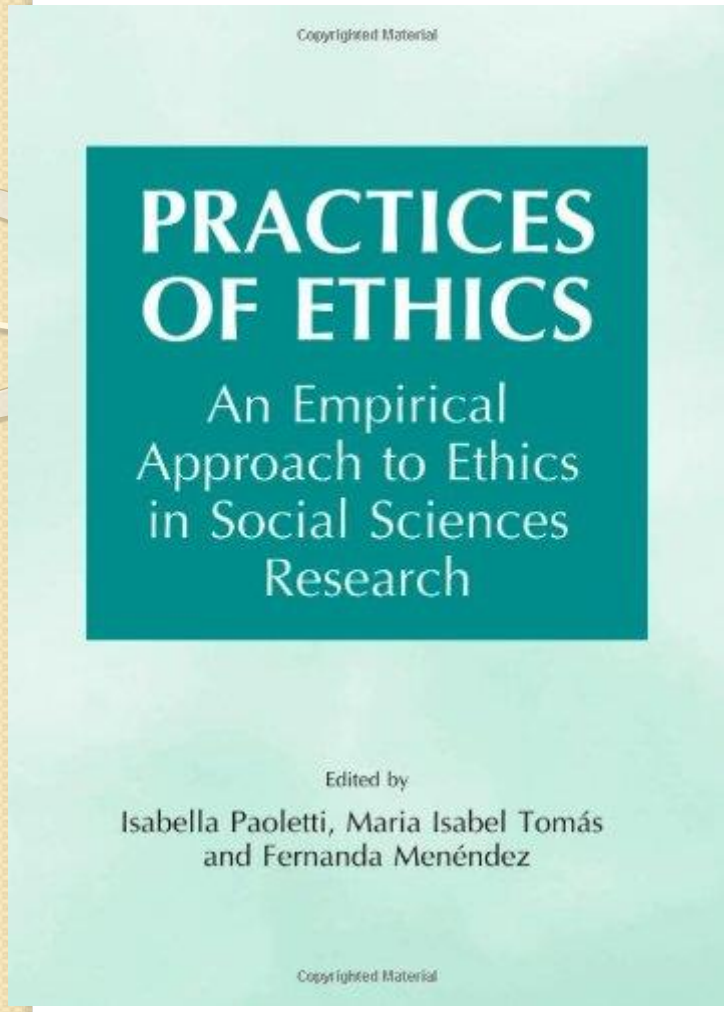
-Does your research involve the development of technologies or the creation of information that could have severe negative impacts on human rights standards (e.g. privacy, stigmatization, discrimination), if misapplied?

-Does your research have the potential for terrorist or criminal abuse e.g. infrastructural vulnerability studies, cybersecurity related research?


IS THAT A SENSIBLE WAY TO USE MONEY?
BOOM
AND
BUSTER
ROCKET SCIENTIST

SECTION 10: OTHER ETHICS ISSUES

- **Are there any other ethics issues that should be taken into consideration?**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An Empirical Approach to Ethics in Social Sciences Research
Edited by
Isabella Paoletti, Maria Isabel Tomás and Fernanda Menéndez
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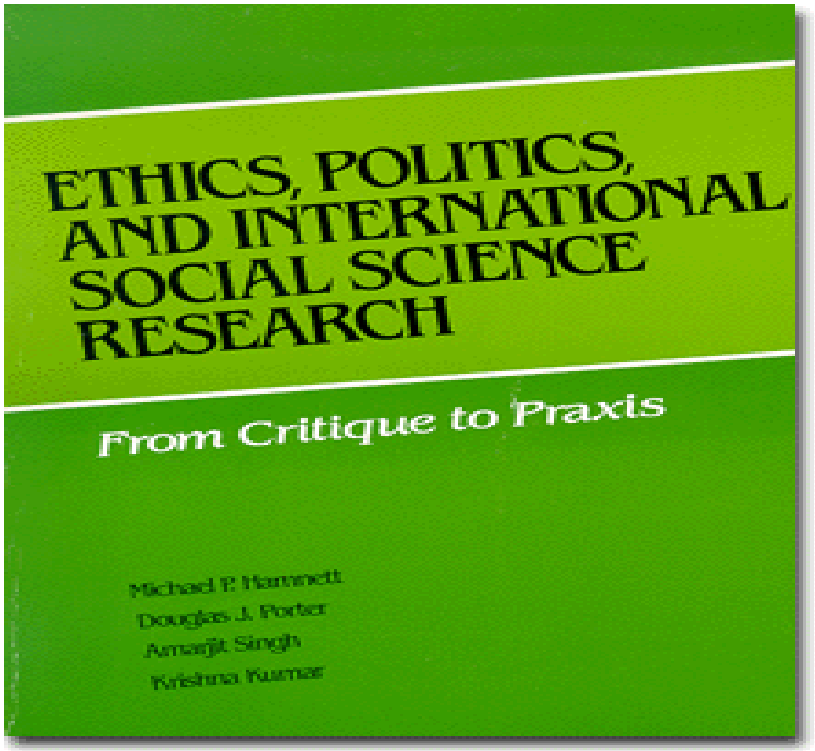
ETHICS IN QUALITATIVE RESEARCH
CONTROVERSIES AND CONTEXTS
MARTYN HAMMERSLEY AND ANNA TRAIANOU


ETHICS, POLITICS, AND INTERNATIONAL SOCIAL SCIENCE RESEARCH
From Critique to Praxis
Michael P. Hammett
Douglas J. Porter
Amarjit Singh
Krishna Kumar

What to look at as an evaluator

- **The proposal as a whole**

Objectives, methodology, impacts

- **The Ethics Issues Table**

- **The Ethics Section**

Context is important!

How to look at ethics:

- Using keywords;
- Tracing methodological tools that raise ethical questions
- Making ethical assumptions about each proposed research action;
- Read the call for proposals carefully;

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1 / 7 100% Fill & Sign Comment

Ethics Issues Table template

Version 1.1
11 July 2014

EN 10:25 08/10/2015

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How to complete your ethics Self-Assessment

Version 1.0
11 July 2014

EN 10:29 08/10/2015

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EUROPEAN COMMISSION
Directorate-General for Research & Innovation

Guidance

How to complete your ethics self-assessment

Version 4.0

8 July 2015

EN 10:33 08/10/2015

Main evaluation benchmarks

- **Horizon 2020 rules;**
- **Fundamental ethical principles and human rights;**
- **European Commission's guidance documents** (informed consent, developing countries, social sciences, food-related research, ethics advisors, ethics committees, dual use/misuse);
- **EU legal framework on research ethics** (data protection, clinical trials, animal welfare, dual use, biosafety, bioterrorism, benefit-sharing, environmental protection);

Main evaluation benchmarks

- International legal framework on research ethics (Council of Europe, UNESCO, UNEP, WHO, etc;
- Sector-specific guidelines;
- Codes of conduct;
- Regional/National/Local legal framework;
- Opinions of ethics committees/advisory bodies;
- Best practices;

Some Tips

- Err on the side of **caution**;

If uncertain, tick YES!

- Be **clear**, **precise and detailed**;

- Make a **legal reference** if possible;

- **Consistency between Ethics Issues Table and Ethics Section analysis;**

Thank you for your attention!

Any questions?

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