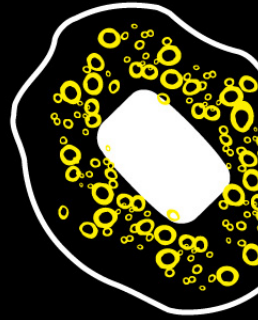


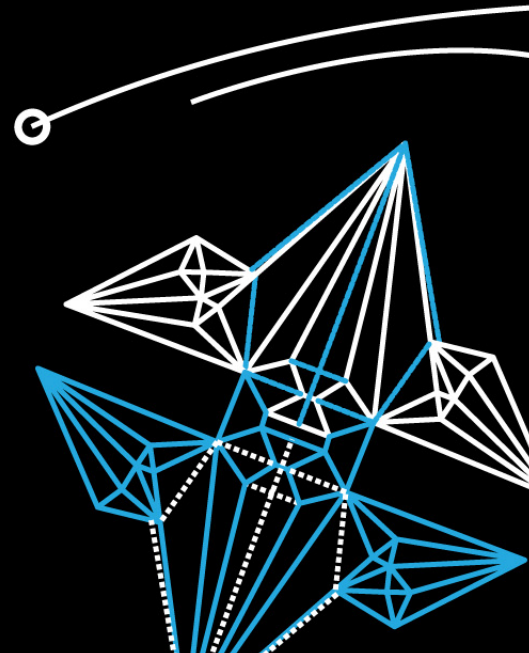
UNIVERSITY OF TWENTE.

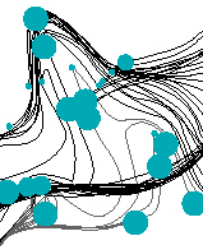


Ethics in Grant Applications

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Importance?

 STOP VIVISECTION



- European Citizens Initiatives
 - One of Us (1.800.000 signatures - 20 countries)
Change financial regulations EU in funding activities involving destruction human embryos
 - Stop Vivisection (1.200.000 signatures - 28 countries)
Support a paradigm shift in the way biomedical and toxicological research are being conducted
- Data Protection Eurobarometer 2015
 - Protection of personal data very important concern EU citizens
- Spending EU tax-payers' money for research in benefit of society...






Horizon 2020

- Ethics Issues Table

- Identification of ethical issues
- 9 topics
- Yes/No items

- Ethics Self-Assessment in proposal

- Section 5



1. HUMAN EMBRYOS/FOETUSES		Page
Does your research involve <u>Human Embryonic Stem Cells (hESCs)</u> ?	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Will they be directly derived from embryos within this project?	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Are they previously established cells lines?	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Does your research involve the use of human embryos?	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Does your research involve the use of human foetal tissues / cells?	<input checked="" type="radio"/> Yes <input type="radio"/> No	
2. HUMANS		
Does your research involve human participants?	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Are they volunteers for social or human sciences research?	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Are they... unable to give informed consent?	<input checked="" type="radio"/> Yes <input type="radio"/> No	



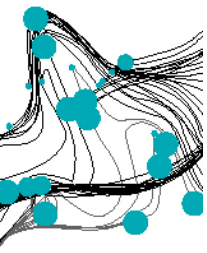
Ethics Self-Assessment

- 9 sections

- Human embryos and fetuses
- Humans
- Human cells/tissues
- Dual use (military applications)
- Environment & Health and Safety
- Personal Data
- Animals
- Third countries
- Dual use

- Comply

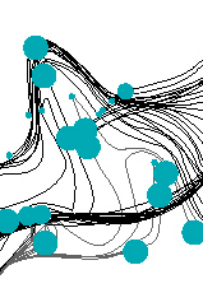
- Ethical principles
- Applicable international, EU and national law



'12 Golden Rules for Research Conduct' 1



- Research projects must:
 1. Respect the integrity and dignity of persons
 2. Do no harm' (clearly communicate risks to participants)
 3. Recognise rights to privacy and freedom of movement, and protect personal data
 4. Meet requirements for informed consent and communication with participants
 5. Treat animals humanely and with respect
 6. Follow the '3 Rs' in animal experimentation design: Replace, Reduce, Refine



'12 Golden Rules for Research Conduct' 2



7. Follow the principle of proportionality (do not impose on participants more than necessary)
8. Treat societal concerns seriously
9. Attempt to prevent dual-use research from being used maliciously
10. Recognise the wholeness of individuals
11. Respect biodiversity and prevent irreversible environmental or ecological damage
12. Recognise that research is for the benefit of society, and that threats to society from research must be considered

(Ethics for researchers, page 24)



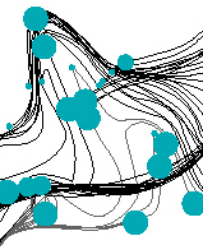
Humans

- Research subjects
 - type
- Intervention
 - Risk assessment
- Medical Research involving Human Subjects Act (WMO)
 - Good Clinical Practice (ICH-GCP)
- MIRA intranet



Personal Data

- Any information which relates to an identified or identifiable natural person
 - Sensitive
- Processing
 - Data Management Plan (Maarten van Bentum)
- Personal Data Protection Act (WBP)
 - Codes of Conduct (VSNU, FMWV, ...)
- EU directive 95/46/EC
- Data Protection Officer: Roderic Winkelhorst



Environment & Health and Safety



- Health and safety of involved researchers
 - Risk assessment
- Health and safety procedures University





Conclusion

- Comply with ethical principles and applicable international, EU and national law
- Advice available within University however depends on research area (sections)
- Proposal level
 - Ethics not directly part of the evaluation
 - Assessed by independent Ethics Committee after proposal is granted
 - Comments can be addressed during grant agreement preparation



Useful links H2020

- How to Complete Your Ethics Self-Assessment
 - http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-self-assess_en.pdf
- Ethics section of H2020 Online Manual
 - http://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/ethics_en.htm



Useful links Ethics

- Ethics for Researchers
 - http://ec.europa.eu/research/participants/data/ref/fp7/89888/ethics-for-researchers_en.pdf
- European Textbook on Ethics in Research
 - http://ec.europa.eu/research/science-society/document_library/pdf_06/textbook-on-ethics-report_en.pdf
- International Ethical Guidelines for Biomedical Research involving Human Subjects
 - http://www.cioms.ch/publications/layout_guide2002.pdf



Useful links University of Twente

- EU Office
 - www.utwente.nl/subsidies
- Environment, Health and Safety department
 - <https://www.utwente.nl/hr/en/health-safety-environment/>
- Data Protection Officer (in Dutch)
 - <https://www.utwente.nl/az/gegevensbescherming/>
- MIRA intranet
 - <https://www.utwente.nl/mira/intranet/researchinvolvinghumansubjects/>
 - <https://www.utwente.nl/mira/intranet/researchinvolvinganimals/>