EU Funding of research:
A need for Ethical Governance

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DG Research & Innovation/Health, E1

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Research and Innovation

Overview

- Ethics and the EU experience
- Background
- How ethics affects your research
- Protection Legislation?
- Governance and EU-hPSCReg
- Opportunities for Funding

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Ethics review: 2 visions

Risk treated as a legal hazard

Ex-post process

- Implies large budget provisions for lawsuits/litigations.
- Internal review processes have NO VALUE in court.
- Risk for researchers of being blocked by third parties – even at publication stage (cf. avian flu case)

Risk anticipation and mitigation

Ex-ante process

Identifies the issues, the risks,
Offers processes/solutions to mitigate them,
Protects the researcher, the project and the funding bodies,
Minimizes adverse impact,

Risk is inherent to research

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Attorneys for Plaintiffs

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

----------X

THE AUTHORS GUILD, INC., THE AUSTRALIAN SOCIETY OF AUTHORS LIMITED, UNION DES ÉCRIVAINES ET DES ÉCRIVAINS QUÉBÉCOIS, PAT CUMMINGS, ANGELO LOUKAKIS, ROXANA ROBINSON, ANDRÉ ROY, JAMES SHAPIRO, DANIÈLE SIMPSON, T.J. STILES and FAY WELDON,

Plaintiffs,

- against -

HATHITRUST, THE REGENTS OF THE UNIVERSITY OF MICHIGAN, THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, THE BOARD OF REGENTS OF THE UNIVERSITY OF WISCONSIN SYSTEM, THE TRUSTEES OF INDIANA UNIVERSITY and CORNELL

Defendants.

U.S.D.C. S.D. N.Y.
CASHIERS

Civ. No.

COMPLAINT

The Chronicle | The Independent Daily at Duke University

NEWS SPORTS OPINION RECESS TOWERVIEW BLOGS PHOTOS

HEALTH & SCIENCE RESEARCH

Updated: Anil Potti, Duke Cancer Researcher Accused of Misconduct, Resigns

By Zachary Tracer, Taylor Doherty | November 19, 2010

Updated 6:30 p.m. with comments from Dr. Anil Potti, IGSP Director Huntington Willard and Dr. Michael Cuffe, DUHS vice president for medical affairs.

The Duke cancer researcher who has been under investigation for research misconduct since this summer has resigned.

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NEWS

US board says censuring research on avian flu was necessary to prevent a potential catastrophe

BMJ 2012; 344 doi: 10.1136/bmj.e840 (Published 2 February 2012)
Cite this as: BMJ 2012;344:e840

http://www.bmj.com/content/344/bmj.e840.short

COLORADO CASUALTY INSURANCE COMPANY, a Colorado corporation,

Plaintiff,

vs.

PERPETUAL STORAGE, INC., a California corporation; UNIVERSITY O UTAH, a body politic and corporate of th State of Utah, on behalf of UNIVERSITY OF UTAH HOSPITALS AND CLINICS and UNIVERSITY OF UTAH HEALTH SCIENCES CENTER,

Defendants.

According to the lawsuit, the University of Utah incurred 3.3 million in costs to remedy the security breach

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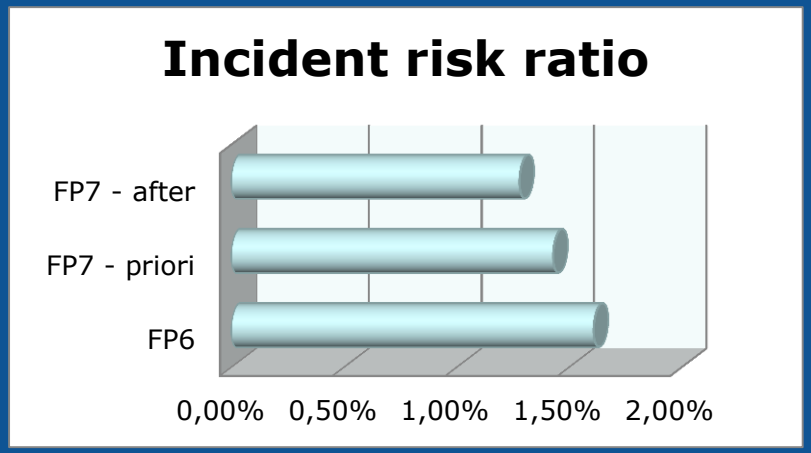
Impact on Risk Management

- Issue not identified
- Issue identified - no ER required
- Issue identified + ER
- Issue identified + info required
- Special Requirement included

Health ER FP7 and Risk

Framework	Corrected risk occurrences
FP6	1.6%
FP7 – prior screening	1.4%
FP7 – after screening	1.3%



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Results of the EU Experience

OUT OF THOUSANDS OF FINANCED Projects

- *(basic research to the Product, huge Cooperative Projects+ Translational+Funding Vaccination Clinical Trials)*
- ***ONLY ONE CRITICAL situation***
- *FP7: 1019projects,* ***thanks to the Ethical Review process, both the Researchers and the Commission could offer satisfactory answers and safeguards to the EP.***
  - **No court action followed**

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Once Upon a Project

- *EU funded research on behaviour patterns*
- *Though scientifically sound, circumstances raised queries: both subject AND id of researchers*
- *Queries became Political – involved MEPs, EC, news media – "**How COULD you fund such an outrage?"***
- *BUT – prior to financing, ER had identified risks and mitigation, preventive measures requested,*
- *And implemented the framework for ethics,*
- *Due dilligence was proved, turmoil decreased*

Why is Ex-ante ethical scrutiny important?

- Proactive, preventive, thoughtful
- Huge projects many issues and Countries
- **Common legislation-**Local sanctions through local authorities

Make the ER effort useful

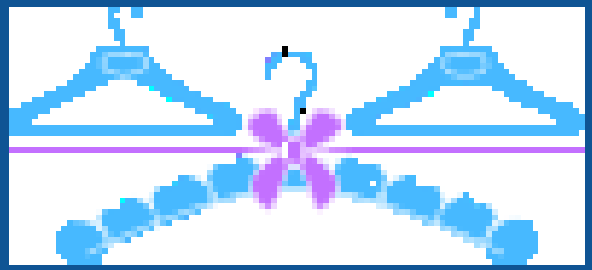
- All **proposals** ER(2 stage process)(Time, money)
- Proposals have ethics info from end of selection
  - ER –Immediate action
  - All Projects start with ethics framework set-up
- Ethics as regulatory "passport" throughout research to ML

Ethics: In Practise

What does the Science have to gain?

Budget and Ethics

The Full picture



Issues that require Ethics Review

- Informed Consent
- Research on Humans,
- Human embryos/foetus (EU-hPSCReg)
- Privacy
- Data Protection
- Research on Animals
- Research developing countries
- Dual Use

Governance:Rules and legislative basis

- Responding to public concerns
- Ensuring the EU funds Ethical Research
- Rules are Common to EU culture
- Robust Ethics Procedure as signature
- Proven method for Trust
- First line of Patient defense
- Preventive Ethics, traceable Regulatory conformity

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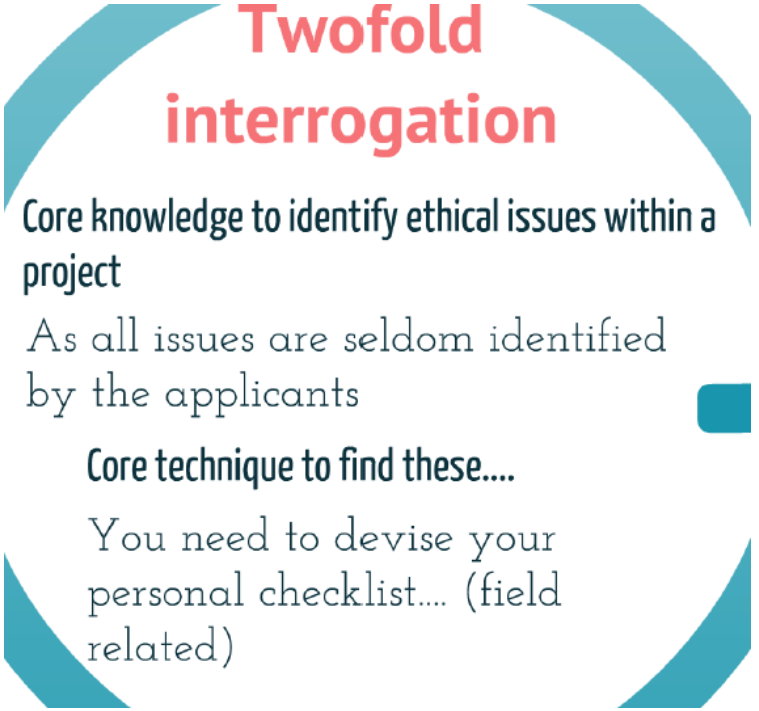
Why is Ethics useful

- ***Ethics is central to EU Research***
- ***Ethics is not Law***
- ***Ethics is not JUST for Health***
- ***Ethics is NOT just paperwork***
- ***Risk Managemenet tool***
- ***Regulatory Conformity paper trail***



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Why is foolproof ER important for Cellular Therapy

- Proactive, preventive – Confronts the difficulty
- Huge stakes, many issues – Make it work for you
- **Common legislation-**Local sanctions through local authorities

Make this effort work for you

- All **products can have traceable regulatory "ID Card"**
- Proposals have regulatory conformity from selection
  - ER – Time to put the regulatory framework in place
  - All Projects start with ethics framework
  - **Ethics as regulatory "passport" throughout research to ML**

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Remember

NTK (need to know)...and remember

It is not because the issues are not identified that they are no issues (e.g : conferences).

It is not because the "vocabulary" used in the different assessment forms seems far away from the research field that the topic must be waived.

Research is built in an environment, the environment (political situation, risks such as litigation risks & potential costs....) must be considered when assessing ethics...

The EU and MEPs do not want research money to go to lawyers.....

"Paying my fee will also help as evidence for our insanity defense."

Ethics contributes to Quality

Quality: Research that demonstrates scientific, technical and managerial quality will have Ethics on equal level.

Ethics in Science and Health Research:
all the projects need to have a uniformly excellent ethics from beginning to end of the research.

Input for future patents
The Ethics Reports **MUST** be incorporated into the technical specifications from Phase I

The indications by Ethics can be vital for successful product

Maintain an updated « ethics » file requires a constant effort but also gives project leader time to focus

Main focus on Consent (CT+data+ ...)

(Examples:
personal data, medical interventions, interviews, observations, tracking, secondary use of information provided for other purposes, e.g. other research projects, officially collected information, social media sites...)

Data Protection

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Human/Patients involvement

Most of the research project include humans

(Examples:
personal data, medical interventions, interviews, observations, tracking, secondary use of information provided for other purposes, e.g. other research projects, officially collected information, social media sites...)

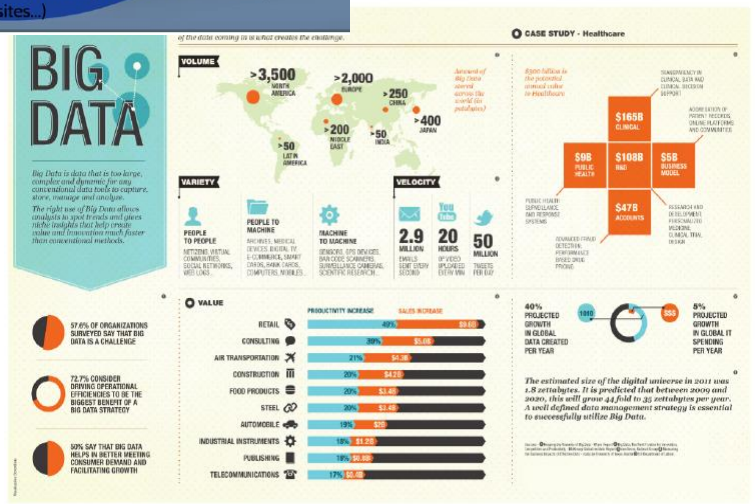
As a foreword, the ethics assessment in H2020

What do you need to know

Ethics is now embedded within the treaty (no longer an Annex) - article 14, etc...

Responsible research = responsible data usage

Data exchange is under pressure (Snowden Case) - Risk of data exchanges protective measures being repelled.



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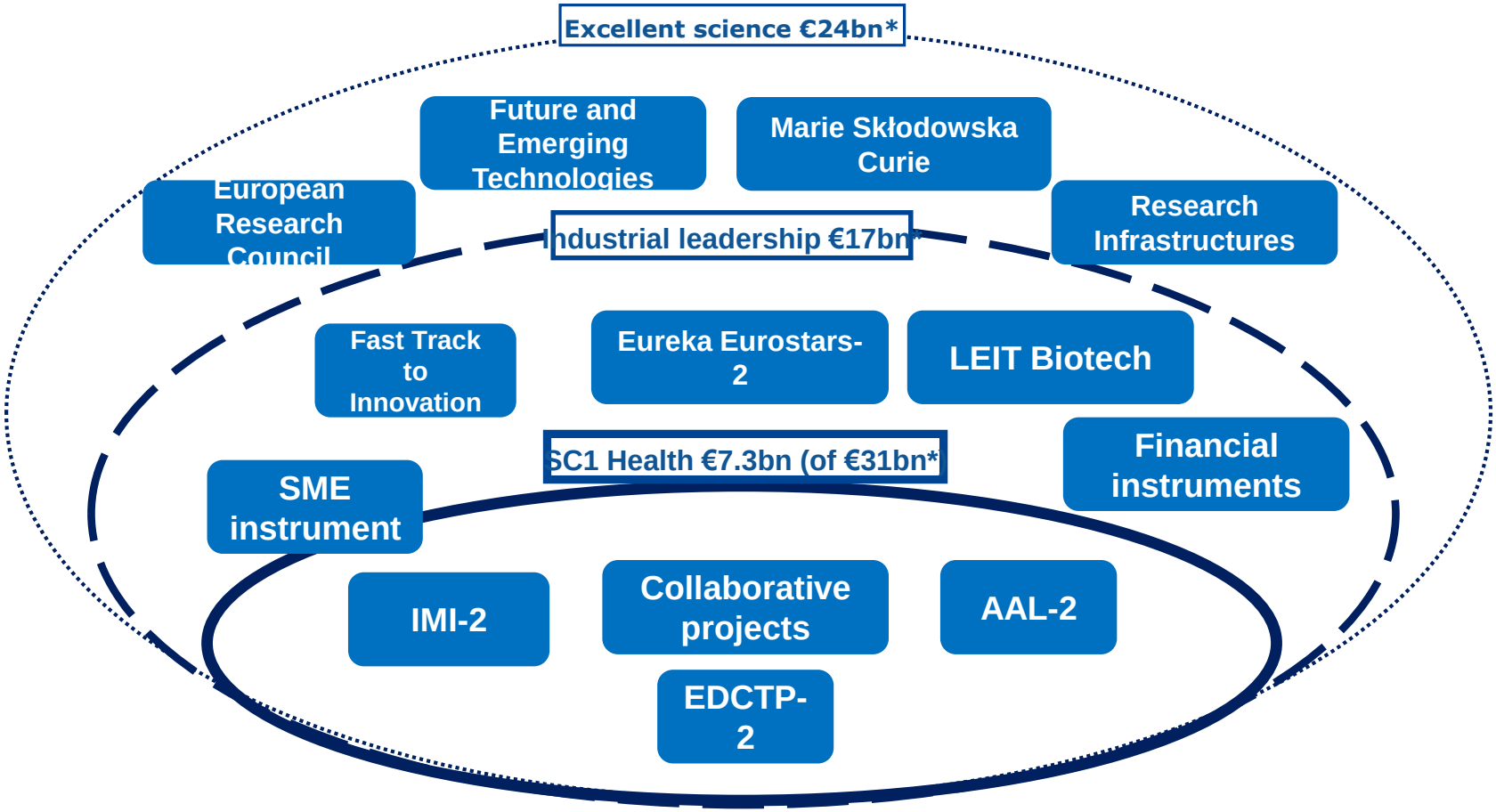
Funding opportunities



*** Figure to be updated following EFSI investments in 2015**

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The SC1 Work Programme 2016-17 in brief

Call 'Personalised Medicine'
21 topics (34 in 2014-2015): 10 in 2016, 10 in 2017, 1 open in 2016 & 2017

including 'coordination activities'
15 topics (17 in 2014-2015): 12 in 2016, 3 in 2017

€ 935 million

SME Instrument : 2 Topics
Other Actions: 12 items
(incl. InnovFin ID & "Birth Day Prize")
Focus Area Digital Security: 1 Topic
Focus Area Internet of Things: 1 Topic

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innovative medicines initiative

THE INNOVATIVE MEDICINES INITIATIVE

The Innovative Medicines Initiative (IMI) is Europe's largest public-private initiative aiming to speed up the development of better and safer medicines for patients.

IMI supports collaborative research projects and builds networks of industrial and academic experts in order to boost pharmaceutical innovation in Europe.

IMI is a joint undertaking between the European Union and the pharmaceutical industry association EFPIA.

efpia

IMI 2: ~€3.2 b

EC: €1.6b+ EFPIA €1.4b + other (€0.2b)

IMI2:

- Covers the entire medical research and innovation value chain
- Strategic Research Agenda is based on the WHO Priority Medicine Report renewed in July 2013
- Involves pharmaceutical industries as well as others (diagnostics, imaging, animal health, ICT **etc.**)
- Supports World class research and innovation leading to breakthrough vaccines, medicines and treatments

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Thank you

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Ethics Review in H2020

- Health and ERC similar management of Ethics
- Ethics management for all projects
- All **proposals** to undergo ER
- Faster road to Market licence
- All proposals will have
  - Ethics report
  - Technical follow-up /Ethics audit conducted by the Ethics Unit

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Regulation Follows Science

Legislation

- *Clinical Trials*
- *GMP*
- *Data Protection**
- *ATMP*

Ethics environment

Scrutiny from Public

Ethics Declaration

Ethics Review

Review+Follow-up

Health Research: Issue of Consent

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The background and Environment