ETHICAL RISK

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Funding: European Commission, Marie Curie Fellowship (€ 209'033)

About the research: Major stakeholders in research – including the OCED, European Commission, and regulators in the U.S., U.K., France, and Switzerland – are currently promoting more risk-adapted approaches to regulating biomedical research. These approaches aim to calibrate key subject protections, including ethical review and safety monitoring, to the risks that studies pose to participants. **"**ETHICAL RISK - An ethical framework for the risk-based regulation of biomedical research" has two objectives. 1) To analyze the ethical questions that are raised by risk-adapted systems of research regulation and oversight, including the stratification of research risks and the relation between risk, ethical review, consent, and the scientific and social value of the research. 2) To develop an ethical framework for risk-adapted approaches to regulating research based on this analysis. The project combines conceptual and normative analysis, policy analysis, and expert consultation.

Publications

Rid A: Rethinking risk-benefit evaluations in biomedical research. In: Strech D, Mertz M (Eds): *Ethics and Governance in Biomedical Research. Concepts, Methods, Case Studies*, Springer: Dordrecht, Heidelberg, London, New York *(in press)*

Bromwich D, Rid A: Can informed consent to research be adapted to risk? *Journal of Medical Ethics (in press)*

Rid A (2014): Setting risk thresholds in research: Lessons from the debate about minimal risk. *Monash Bioethics Review* 32(1): 63-85

Rid A (2014): How should we regulate risk in biomedical research? An ethical analysis of recent policy proposals and initiatives. *Health Policy* 117(3): 409-420

Other publications are in preparation

Presentations

Title TBD. ETHOX Centre, University of Oxford, May 2015

Title TBD. Workshop, "Risk-adapted approaches to regulating health research: Ethical challenges", King's College London, April 2015

Evaluating risk in phase 1 oncology research. Brocher Foundation Symposium, "Phase 1 oncology trials: implications for ethics, palliative care, and society", Geneva, Switzerland, July 2014

Conceptualizing the social value of research and its relationship to risk. 12th World Congress of Bioethics, International Association of Bioethics, Mexico City, June 2014

Risk-adapted regulation in the UK: Recent developments. 12th World Congress of Bioethics, International Association of Bioethics, Mexico City, June 2014

Evidence-based research regulation: two approaches. 12th World Congress of Bioethics, International Association of Bioethics, Mexico City, June 2014

Stratifying risk in research regulation and oversight. 12th World Congress of Bioethics, International Association of Bioethics, Mexico City, June 2014

Stratifying risk in research regulation and oversight. Stanford Center for Biomedical Ethics, Stanford School of Medicine, Stanford, April 2014

Risk-adapted regulation of research: ethical commentary. European Forum for Good Clinical Practice (EFGCP) Annual Conference, "Benefits and Risks of Research: How Do We Redress the Current Imbalance?", Brussels, January 2014

What are the true risks of research? European Forum for Good Clinical Practice (EFGCP) Annual Conference, "Benefits and Risks of Research: How Do We Redress the Current Imbalance?", Brussels, January 2014 (workshop moderator, with Tim Sprosen)

Theory and Rationale for a Risk-Adaptive Approach to Clinical Trial Monitoring. Workshop on Risk-Based Clinical Trial Monitoring, European Forum for Good Clinical Practice / University College London, June 2013 (with Hugh Davies)