

## Research Project

### Ethical issues of cutting edge biotechnology: Embedded interdisciplinary risk benefit evaluation of first-in-human trials in synthetic biology and nanomedicine

#### Third-party funded project

**Project title** Ethical issues of cutting edge biotechnology: Embedded interdisciplinary risk benefit evaluation of first-in-human trials in synthetic biology and nanomedicine

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**Organisation / Research unit**

Ethik / Bio- und Medizinethik (Elger)

**Department**

**Project Website** <http://ibmb.unibas.ch/phd-program/current-phd-projects/ethical-issues-of-cutting-edge-biotechnology/>

**Project start** 01.08.2012

**Probable end** 29.02.2016

**Status** Completed

#### BACKGROUND OF THE RESEARCH MODULE

Embedded research related to existing or planned projects is urgently needed in synthetic biology and the field of nanomedicine. During the past 5 years, several US and European bodies have issued separate guidelines on the ethical issues of (a) synthetic biology and (b) nanotechnology and/or nanomedicine. These recommendations remain rather general and of limited help to researchers in these fields. Indeed, although many guidelines acknowledge the heterogeneity of research projects in the fields of both synthetic biology and nanotechnology and the need for individual ethical assessment of different research projects, they tend to address ethical issues in global terms. Most of these reports do not provide specific guidance to stakeholders who have to decide whether and under which circumstances a first-in-human trial is justified using any of the two new and promising technologies. Decision making concerns patients, scientists, policy makers and the public because of the various risks and benefits of these technologies. Possible risks are relevant not only for patients, factory worker and scientists in contact with the new devices and materials, but also for the wider population and the environment. In light of the considerable range and the complexity of the ethical questions, an interdisciplinary evaluation of present and future research projects is required bringing together the expertise of ethicists and scientists while taking into account patient values.

#### AIMS OF THE RESEARCH MODULE

(a) Obtain data from the literature and the analysis of guidelines to compare decisions and criteria related to first-in-human trials using nanomedical or synthetic biology devices. Identify consensus and disagreement of guidelines and develop a synopsis about accepted and not accepted trials where the cut-off points become visible.

(b) Obtain comprehensive facts on benefits and harms as well as data on how experts and patients balance the conflicting values and what are their perceived needs for information and safeguards.

(c) Develop transparent strategies how to balance benefits and harms in 4 projects in Basel and in general. Propose evaluation steps that are helpful for researchers who plan FIH studies, funding sources and REC members who evaluate them, patients who make decisions to participate or not in these trials, as well as policy makers and society.

## METHODS OF THE DIFFERENT PROJECT PARTS

Both subprojects will evolve in parallel and contain 3 parts. The 1st part (a.) consists of a literature review of guidelines, of FIH trials in the two domains, and of studies on patient attitudes and informed consent. In the 2nd part (b.) data about knowledge and attitudes of 40 experts, 20 gout patients (i.), 100 other patients and 200 other possible participants of FIH trials (ii.) will be obtained through semi-structured interviews (i.) and a questionnaire study (ii.) using established social science methods of quantitative and qualitative research. The 3rd part (c.) uses classical methods of ethical analysis of FIH trials in general and of four specific projects in particular, and integrates stakeholders' views examined in the previous parts.

## IMPORTANCE AND IMPACT OF THE MODULE AND OF THE LINKS BETWEEN ITS TWO PROJECTS

The present study fills an important gap and is unique in that it combines, within one research module, the ethical evaluation of existing and planned cutting edge biotechnology studies in two departments and fields. The objective is to profit from the synergic effects of carrying out simultaneously the ethical evaluation of human trials concerning both D-B SSE research projects and future studies using nanomedicine devices. This is advantageous, first, because the so called converging technologies have some aspects in common when it comes to first-in-human trials. Second, the interaction and linkage of the two projects within the planned research module will be crucial to ensure comprehensive data collection on these important ethical issues and to realise a truly interdisciplinary endeavour necessary to find realistic and ethically acceptable solutions to the existing problems.

The project will permit to collect important new data and to cross-link results from the ethical analysis of FIH in both subprojects. It presents a unique opportunity to disseminate solutions and recommendations that have been developed in an interdisciplinary context, taking into account expert knowledge and opinions of different stakeholders.

### **Financed by**

Swiss National Science Foundation (SNSF)

## **Add publication**

### **Published results**

1462940, Genske, Anna; Engel, Sabrina; Elger, Bernice, Synthetische Prothese gegen Gicht? : ein möglicher Beitrag der hausärztlichen Praxis zur ethischen Beurteilung von klinischen Versuchen, 1424-3776, Primary care, Publication: JournalArticle (Originalarbeit in einer wissenschaftlichen Zeitschrift)

3289185, Genske, Anna; Engel-Glatzer, Sabrina, Rethinking risk assessment for emerging technology first-in-human trials, 1386-7423, Medicine, health care and philosophy, Publication: JournalArticle (Originalarbeit in einer wissenschaftlichen Zeitschrift)

3373085, Satakar, Priya; Shaw, David, Not fit for purpose: the ethical guidelines of the Indian Council of Medical Research, 1471-8731, Developing world bioethics, Publication: JournalArticle (Originalarbeit in einer wissenschaftlichen Zeitschrift)

3669405, Satakar, Priya; Elger, Bernice Simone; Shaw, David, Naming it 'nano': Expert views on 'nano' terminology in informed consent forms of first-in-human nanomedicine trials., 1748-6963, Nanomedicine (London, England), Publication: JournalArticle (Originalarbeit in einer wissenschaftlichen Zeitschrift)

3699854, Satakar, Priya; Elger, Bernice Simone; Shaw, David., Stakeholder views on participant selection for first-in-human trials in cancer nanomedicine, 1198-0052, Current Oncology, Publication: JournalArticle (Originalarbeit in einer wissenschaftlichen Zeitschrift)

**Add documents****Specify cooperation partners**

<b>ID</b>	<b>Kreditinhaber</b>	<b>Kooperationspartner</b>	<b>Institution</b>	<b>Laufzeit - von</b>	<b>Laufzeit - bis</b>
1548683	Engel Glatter, Sabrina	Bedau, Mark Prof.	Reed College	01.08.2012	01.08.2015
1548685	Engel Glatter, Sabrina	Andorno, Roberto	University Zurich	01.08.2012	01.08.2015
2288769	Elger, Bernice Simone	Blume, Stuart, Prof. (second su- pervisor)	University of Amsterdam	01.08.2012	01.08.2015