News and Views

Biomedical Research and Human Research Subject Protection:
Is There Need for Action in Germany and Austria?¹

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Abstract
Biomedical research and international collaborations in biomedical research become more and more important — economically and politically, making harmonised legislation for human research subject protection indispensable. The European Convention on Human Rights and Biomedicine is the first binding contract under international law to protect human rights in the field of biomedical research. Almost 10 years after its entry into force neither Germany nor Austria have signed or ratified the Convention. Research involving incapacitated adults is one of the key issues in this context. This paper analyses the Convention and other European, US and international legislation, focusing on research involving incapacitated adults in “non-therapeutic” trials. It shows that a ban of “non-therapeutic” research involving incapacitated adults leads to an unjust exclusion of this patient group, leading to uncertainty and disadvantages in medical treatment.

Keywords
European Convention on Human Rights and Biomedicine; EC GCP Directive; Belmont Report; Universal Declaration on Bioethics and Human Rights; incapacitated adults; non-therapeutic research

1. Introduction

1.1. Scope

The judges’ response at the “Nuremberg Doctors’ Trial” to the horrific human experimentation in the Third Reich was a ten point code, the so-called “Nuremburg Code”.² This code makes the well-being and protection of the individual the

¹ This paper is largely based on the doctoral thesis by V. Stühlinger entitled: “Standardized International Legislation for Biomedical Research — shall Research Involving Incapacitated Adults pose an Obstacle?”, 2008, UMIT, the Health & Life Sciences University. Further references on topics discussed in this paper are to be found therein.
² On 20 August 1947 the US judges in the Nuremberg Doctors’ Trial not only rendered a judgement but also proclaimed ethical guidelines for physicians and medical research, the so called “Nuremberg Code”. The
centre-point of medicine and medical research. Neither progress nor benefit for society as a whole should be determinants for scientific research. Thus, the legacy of the Nuremburg trials is the strongly demanded link of medicine and medical research to individual ethics and the rejection of every collectively orientated research ethic.

With this in mind the Council of Europe treaty on biomedical research (European Convention on Human Rights and Biomedicine) has been strongly criticized in Germany and Austria.

The Convention is the first binding contract under international law to protect human rights in the field of biomedicine. However, not all Member States of the Council of Europe have signed or implemented the Convention so far. The main point of criticism in Germany and Austria is article 17 (2) of the Convention, which — under certain circumstances — permits research for the benefit of others, i.e. research without individual benefit for the participants themselves, so-called “non-therapeutic” research, on research subjects without the capacity to consent.

So far, the German Ethics council, advising the German Bundestag as well as the Federal Government in questions of ethics, in particular in the field of the life sciences, did not issue any opinion on the ratification of the Convention. In a briefing regarding the status of ratification of European Agreements and Conventions, the German Government declared that the opinion-forming process concerning the ratification of the Convention is not completed in Germany, — leaving any decision open.

judges hereby admitted that research or medical misconduct has not only been conducted during World War Second, but is relevant for the future also. The Nuremberg Code can be seen as the beginning of bioethics and ethical guidelines regarding biomedical research. See e.g., G.J. Annas, “American Bioethics and Human Rights: The End of All Our Exploring, International and Comparative Health Law and Ethics: a 25-Year Retrospective”, Journal of Law, Medicine & Ethics, 2004: 658-663, at 658: “Both American bioethics and international human rights were born from World War II, the Holocaust, and the Nuremberg tribunals”; and M. Grodin, G.J. Annas, “Medicine and Human Rights”, Hastings Center Report; 23, No 4, (1993): 8-13, at 9: “Although the Nuremberg Code has not been adopted as a whole by the United Nations, its consent principle did become an important part of the United Nations International Covenant on Civil and Political Rights, which was promulgated in 1966 and adopted by the United Nations General Assembly in 1974.”


Signature and Ratification (total number:21): Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Georgia, Greece, Hungary, Iceland, Lithuania, Moldova, Norway, Portugal, Romania, San Marino, Slovakia, Slovenia, Spain, Turkey; Signatures not followed by Ratification (total number: 13): Finland, France, Italy, Latvia, Luxemburg, Montenegro, Netherlands, Poland, Serbia, Sweden, Switzerland, former Yugoslav Republic of Macedonia, Ukraine. Status as of 14/5/2008, retrieved November 10, 2008 <http://conventions.coe.int/> (Treaty Office).

Deutscher Bundestag, 16. Wahlperiode, Unterrichtung durch die Bundesregierung, Bericht der Bun-