Stem Cell Research
Regulatory and Ethical Challenges at the Threshold of Application

Short Talks & Interdisciplinary Panel Discussion

April 26, 2017
5:00 p.m.

Münchener Kompetenzzentrum Ethik (MKE)
an der Ludwig-Maximilians-Universität München
Geschwister-Scholl-Platz 1, Room M210

Talks:

European Regulations and their Effects on Clinical Trials
Christine Hauskeller, Philosophy and Sociology, University of Exeter; Member of Zentrale Ethikkommission für Stammzellenforschung (ZES); Principle Investigator BAMI EU-FP7: *Ethical Harmonization in European Clinical Trials*

Balancing Social Justice and Risk Management in the Regulation of Clinical Stem Cell Research
Achim Rosemann, Social Anthropology, University of Warwick; Postdoctoral Researcher at the *Bionetworking in Asia* Project*; Co-Developing the Research Cluster on Life Sciences, Society and Education* at Warwick

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Klaus Tanner, Theology, University of Heidelberg; Chairman of ZES; Principle Investigator in the BMBF-project *The Patent System as a Medium of Ethicisation and Politicisation of Stem Cell Research*

Translational Research using induced Pluripotent Stem Cells (iPSC) between Patients' Expectations and Ethical Regulations
Zacharias Kohl, Senior Physician, Department of Molecular Neurology, University Clinic Erlangen; Principle Investigator in the Bavarian Research Network *Induced Pluripotent Stem Cells* (ForIPS)

Interdisciplinary Panel Discussion with all Speakers:

Stem cell technology is rapidly moving into applications with large numbers of ongoing clinical trials, experimental medical treatments and uses of stem cells for pharmaceutical tests. The emerging clinical and commercial application challenges regulatory agencies worldwide. Among those challenges are international harmonization or standards, the formation of different marketing practices, and disagreements about evidence criteria between lab and clinical researchers. The guidelines for safe clinical translation by the International Society for Stem Cell Research (ISSCR) have been criticized as impeding rapid progress because they prescribe time-consuming and costly procedures and built upon the infrastructure provided by big pharmaceutical companies, disadvantaging other routes to clinical innovation and poorer countries. There is huge diversity in how governments implement international standards and adjust them to local conditions and needs. A complex web of regulations must be navigated to avoid over-regulation and allow enough flexibility for local economic and scientific development. The tensions between ethical, legal and practical demands are the topic of this pubic conference.

This public event is free of charge, but please register in advance via e-mail to: anja.pichl@elkb.de

Organized by: Arne Manzeschke and Anja Pichl Institut TTN an der LMU Munich Members of the Bavarian Research Network ForIPS **In Cooperation with:** Münchener Kompetenzzentrum Ethik an der LMU	**Funded by:** The German Ministry of Education and Research