



### **How ethics, law and philosophy of science can help make progress in the development and use of alternative methods**

The German research unit *R2N – Reduce and Replace based in Lower Saxony* aims at “developing scientifically-sound alternative methods on all levels of biomedical science to either minimize the quantity of animals used, or to fully replace existing animal experiments” (<https://r2n.eu/home-2/>). It is well known by now that the development and use of alternative methods is not only dependent on scientific and technological aspects. A number of non-scientific, “normative” aspects are additionally involved that, in many cases, have an inhibiting effect on progress. Examples include legal barriers, status quo biases in the scientific community, and conflicting value judgements of stakeholders at different levels (e.g., researchers, authorities).

To gain a deeper understanding of these and related issues and how to address them, *R2N* has included two research groups that investigate the normative aspects of the development and use of alternative methods as integrated parts of the research unit. These groups are conducting ethical, legal and social issues (ELSI) research on the development and use of alternative methods. ELSI research has been instrumental in analyzing normative aspects of cutting-edge life science research and novel health technologies, such as personalized medicine and genome editing. It uses a wide variety of approaches and methods from philosophy (e.g., conceptual analysis), law (e.g.,

policy analysis) and the social sciences (e.g., empirical social research) to explore the normative landscapes in which science and technological development takes place. In line with ELSI research, the normative research groups in *R2N* explore topics related to the ethics of animal research and the 3R principle, the legal framework for alternative methods in conjunction with regulatory practice, and social aspects of scientific (self-)regulation, including the social epistemology of scientific research.

One research group, led by Marcel Mertz and Hannes Kahrass, focusses on analyzing the decision-making processes of researchers for using or not using alternatives, shedding light especially on ethically relevant, but in many cases “hidden”, value judgments that affect decisions both consciously and unconsciously. These value judgments can be influenced by a plethora of epistemic, ethical, legal, or practical considerations that stem from, e.g., scientific reasoning, internal and legal regulations, funding practices, processes of publishing and peer review, disciplinary culture and academic traditions, career perspectives, or personal moral standpoints. The ELSI research of this group will ethically assess the way such value judgments are constituted, with the final objective of providing a decision aid tool for supporting decisions regarding the possible use of alternative methods.

The second normative research group, led by Simon Lohse and Nils Hoppe, integrates ELSI research with a philosophy of science approach. It focuses on mechanisms in the broadly construed regulation of

alternative methods, i.e., including self-regulation in basic science. The group aims at analyzing factors that influence the development and use of alternative methods at the interface of science and policy-making. These factors include legal requirements in translational research settings, social and infrastructural aspects of research, and “socio-epistemic” issues in science – such as different criteria for the validity of new approaches. The final goal of this analysis is to identify potential for improvement of the existing regulatory regime in basic and applied science.

Both groups work in close cooperation with each other and use conceptual methods (ethical or legal analysis) as well as empirical methods (social-scientific qualitative interviews). In doing so, they attempt to achieve three main goals: (1) A deeper understanding of ethical, legal, and social (including socio-epistemic) factors that influence the development and use of alternative methods achieved by close scrutiny of actual regulatory and scientific practices, as opposed to a purely theoretical analysis; (2) knowledge transfer between science and decision-/policy-making by way of direct engagement; (3) sound policy advice and support of decision-making, which will be based on the groups’ empirical findings and conceptual work. All three of these goals can be considered as important steps in making progress in the development and use of alternative methods.

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