



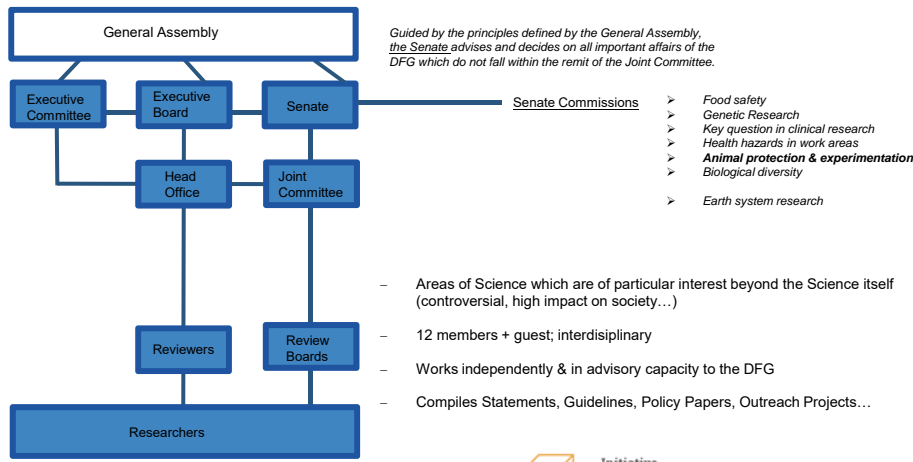
Animal Experimentation in Research: *The 3Rs Principle and the Validity of Scientific Research*

25. January 2022

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DFG Senatskommission für tierexperimentelle Forschung




DFG Ständige Senatskommission „Tierexperimentelle Forschung“ Permanent Senate Commission on Animal Protection and Experimentation of the DFG





Guided by the principles defined by the General Assembly, the Senate advises and decides on all important affairs of the DFG which do not fall within the remit of the Joint Committee.

Senate Commissions

- Food safety
- Genetic Research
- Key question in clinical research
- Health hazards in work areas
- **Animal protection & experimentation**
- Biological diversity
- Earth system research

- Areas of Science which are of particular interest beyond the Science itself (controversial, high impact on society...)
- 12 members + guest; interdisciplinary
- Works independently & in advisory capacity to the DFG
- Compiles Statements, Guidelines, Policy Papers, Outreach Projects...

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DFG Ständige Senatskommission „Tierexperimentelle Forschung“ Contact



<http://www.dfg.de/SKTF>


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Guideline „Animal experimentation in research: The 3Rs principle and the validity of scientific research“

- Reproducibility and Replication
- The 3Rs
- Weighing up ethical issues

Why are these topics important?



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Veröffentlichung 8. Juli 2019

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Reproducibility and Replication

„The Reproducibility Crisis“ and animal research/animal welfare

- The use of animals in research comes with an additional (ethical) responsibility for the researchers
 - => animal welfare
 - => translatability & ethical justification

- Research with animals needs to be ethically justifiable, a lack of translatability from animal to human severely lowers the justifiability:

“At the end of the day, the failure of animals results to translate is arguably the greatest laboratory animal welfare issue of our day and a source of many societal ills.” (Gamer, 2014)

- Improvements of reproducibility/replication may be in conflict with 3R measures

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The 3Rs
A core principle in animal research

- ▶ **Replacement:** replace animals in research with non-animal methods
- ▶ **Reduction:** reduce the number of animals used
- ▶ **Refinement:** refine methods & procedures to reduce harm/suffering

=> *Can the desired scientific gain in knowledge be achieved...*

- (a) *without (sentient) animals (Replace) ?*
- (b) *with fewer animals (Reduce) ?*
- (c) *with less burdensome methods (Refine) ?*

But the 3Rs principle cannot be applied as an end in itself
=> must be in balance with scientific methods and research approaches
=> extent definition/view to include „quality of research“

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Scientific Research**

Guidelines of the Permanent Senate Commission on
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for the Design and Description of Animal Experimental
Research Projects

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**Tierversuche in der Forschung:
Das 3R-Prinzip und die Aussage-
kraft wissenschaftlicher Forschung**

Handreichung der Ständigen Senatskommission
für tierexperimentelle Forschung der DFG zur
Planung und Beschreibung tierexperimenteller
Forschungsprojekte

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Why are these topics important?

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Weighing up ethical issues
Part of the work with animals (harm/benefit analysis)

Ensuring quality as a fundamental requirement of science

Protection of the animal ↔ Ethical responsibility

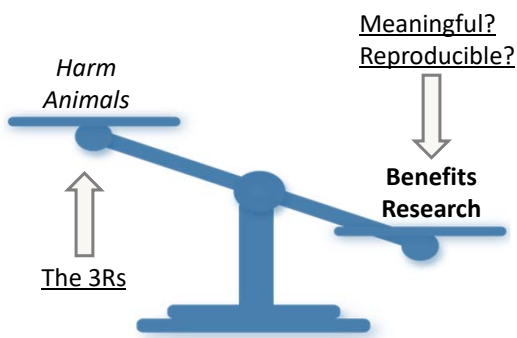
High animal welfare standards ↔ Scientific quality


- Legitimation of animal experiments
- Weighing of goods
(Animal welfare/Animal protection – Freedom of science – Human welfare)
- The 3Rs as guiding principle

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Weighing up ethical issues
Harm/Benefit analysis

Ensuring quality as a fundamental requirement of science
=> Research question „important enough“ to justify harm to animals
=> Research methods **required** to answer research question?
=> Research methods **suitable** to answer research question?



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3Rs and scientific validity

The 3Rs

- ▶ Replacement
- ▶ Reduction
- ▶ Refinement

↔

Scientific validity

- ▶ **Construct validity**
Criterion for the suitability of the model/methods
- ▶ **Internal validity**
Criterion for the suitability of the postulated cause-effect relationship
- ▶ **External validity**
Criterion on the degree of generalisability

The 3Rs are only impactful with existing validity of the project

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3Rs and scientific validity

The 3Rs are only impactful with existing validity of the project

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3Rs and scientific validity

Areas of tension

The 3Rs



Scientific validity

Areas of tension

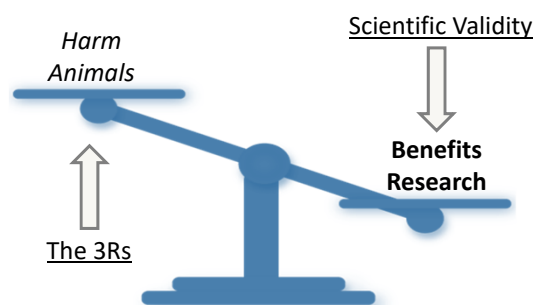
- ▶ Selection of animal species
Active consideration of the choice of the animal model (within of harm/benefit analysis, validity, species-specific capacity to suffer)
- ▶ Determination of the number of animals
Weighing up between efforts to reduce and scientific significance
- ▶ Standardisation
Considering external validity (replicability & generalisability) in the study design
- ▶ Pilot studies and exploratory experiments
Design P. and E. studies in such a way that they lead to focusing of the research and thus an overall reduction in the number of animals.
- ▶ Replicate experiments
Consider replication of experiments from the start

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The 3Rs & scientific validity: Take home message



- Animal research needs careful ethical consideration => harm/benefit analysis
- The 3Rs are only impactful with existing validity of the research
- Areas of tension need to be resolved with highest regards to the animal welfare, but without compromising the science

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Guideline
„The 3Rs principle and the validity of scientific research“

Released (english & german): 8. Juli 2019

- Disseminated to relevant stakeholders (universities, authorities...)
- Included in the DFG application & reviewing process

⇒ *Anchoring the relationship of animal welfare and scientific quality in the application and review process*

⇒ *Contribution to quality assurance in biomedical research*

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Vielen Dank für Ihre Aufmerksamkeit

Weitere Informationen

- ▶ zur DFG: <http://www.dfg.de>
- ▶ zur Senatskommission für tierexperimenteller Forschung: <http://www.dfg.de/sktf>
- ▶ zur „Initiative Transparente Tierversuche“ <https://www.initiative-transparente-tierversuche.de/>

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