



National Centre  
for the Replacement  
Refinement & Reduction  
of Animals in Research

# MultiPART WP4

11-13 March 2015

2004 – 2014 | Ten Years of  
Pioneering Better Science

# Differences between countries

UK:

- High level information
- Focus on harm/benefit analysis for a whole stream of work (5 years)
- Description of individual protocols but not actual experiment
- Covers a range of models and interventions

Germany, Switzerland, Spain, Netherlands? France?

- Approval given on specific experimental protocols
- Detailed experimental design
- Exact description of procedures

**What level of information is appropriate for a multi-centre trial?**

	Approval per protocol	Approval for stream of work
PROs	<ul style="list-style-type: none"> <li>▪ Justification for choice of intervention can vary</li> <li>▪ All centres approved for same protocol (extra check)</li> <li>▪ Easy for experimental design</li> <li>▪ External feedback on protocol</li> <li>▪ Link with trial pre-registration</li> </ul>	<ul style="list-style-type: none"> <li>▪ Several studies covered by same licence</li> </ul>
CONs	<ul style="list-style-type: none"> <li>▪ New application for each study, may incur delays</li> <li>▪ Level of standardisation</li> </ul>	<ul style="list-style-type: none"> <li>▪ Difficult to provide justification for interventions to test in advance</li> </ul>

# Level of detail in application and SOPs

How much is standardised? – when different labs are allowed to do different things, cover all possible options or just one example?

Would regulatory authorities allow deviation from SOPs at that level?

- Anaesthesia
- Rehydration, pre and post surgery care
- Methods of euthanasia
- Measurements during anaesthesia
- Material and supplies

Experimental design

- Are we still considering introducing systematic heterogenisation?
- Will previous variability data be used to inform power calculations?

# Not covered in ethical approval (in UK, establishment licence and law)

- Minimum cage size and stocking density
- Environment (ventilation, temperature, humidity, lightning, noise)
- Education and training in the killing of animals
- Provision of adequate care and accommodation appropriate to the species
- Daily check of health, well-being and environmental conditions
- Establishment appropriately staffed
- Conditions of transport
- Source, use and final disposal of animals

Study sites to agree to comply to minimum standards? E.g. guidelines for accommodation and care of animals ETS 123 from Council of Europe