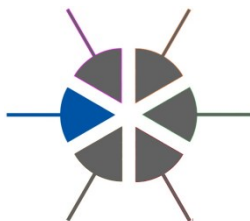
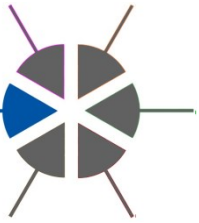




# Multicentre Preclinical Animal Research Team



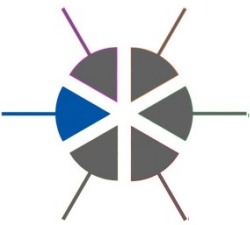
WP4: Regulation and Ethics



# WP Leads

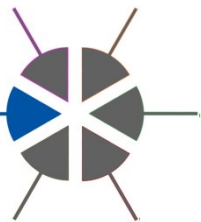
- Dr Nathalie Percie du Sert
- National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs)
  - <http://www.nc3rs.org.uk>
- Professor Stuart Allan
- University of Manchester
  - [www.manchester.ac.uk](http://www.manchester.ac.uk)





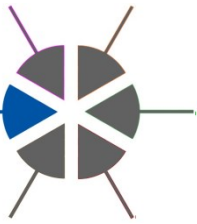
# Deliverables

1. Seek approval from regulatory authorities for ethical review roadmap



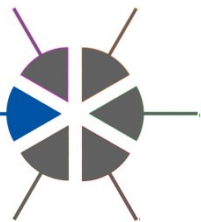
# Milestones

1. Identify relevant regulatory authorities and approval processes across participating countries (month 6)
2. Establish prototype ethical review roadmap for Multi-PART studies (month 12)



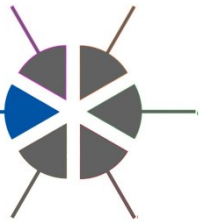
# Tasks

1. Identify relevant regulatory authorities across countries
2. Examine existing ethical approval processes across participating countries
3. Establish ethical review process for Multi-PART studies
4. Co-ordinate with WP2 Task 1 (Stroke models)
5. Explore the potential to establish a single point of contact and approval for preclinical studies
6. Explore the role of other regulatory bodies



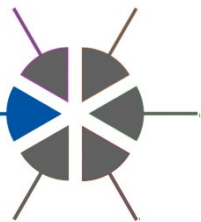
# Identify relevant regulatory authorities

- Initially countries of Multi-PART participants
  - i.e. Australia, France, Germany, Netherlands, Spain, Switzerland, UK
- Collect data through bespoke questionnaire



# Examine existing ethical approval processes

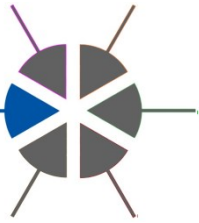
- Consider local vs national
- Identify and engage with most relevant national and international organisations e.g.
  - Federation for Laboratory Animal Science Associations
  - International Council for Laboratory Animal Science
- Effects of directive 2010/63/EU



# Establish ethical review process for Multi-PART studies

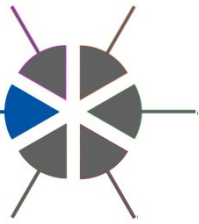
- Define structure and remit of an ethical review committee (ERC) for multicentre animal studies
- Explore feasibility of this ERC being recognised by relevant regulatory authorities





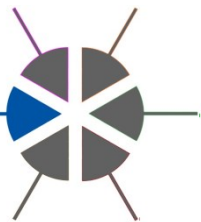
# Co-ordinate with WP2 Task 1

- Review portfolio of rodent stroke models
- Establish acceptance of models across countries from ethical and regulatory perspective
- Ensure highest standards (& adherence to 3Rs)



# Explore feasibility of single point of contact & approval

- Liaise with relevant regulatory bodies (identified in task 1)
  - e.g. Home Office (UK), Ministere de l'Agriculture et de la Foret (France)
- Standardised application process across countries OR approval of application authorised in country of leading institution



# Explore the role of other regulatory bodies

- Establish contacts with other relevant bodies
  - e.g. European Medicines Agency
- Explore whether any interest in being involved in multicentre animal studies – if so in what way?