Multicentre **P**reclinical **A**nimal **R**esearch **T**eam

WP4: Regulation and Ethics

WP Leads

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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?