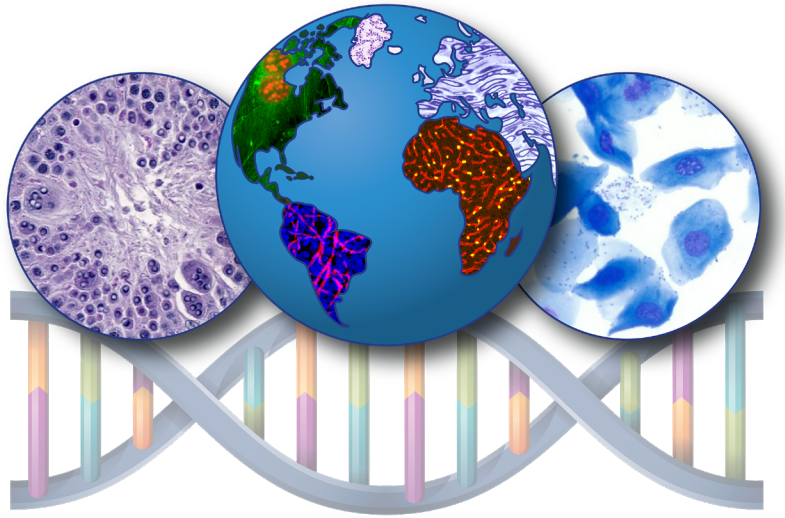
Planning Research and Experimental Procedures on Animals: Recommendations for Excellence (PREPARE) Guidelines



Division of Translational Toxicology Global Toxicologic Pathology Training Program

National Institutes of Health • U.S. Department of Health and Human Services

What are the PREPARE Guidelines?

- **PREPARE** (**P**lanning **R**esearch and **E**xperimental **P**rocedures on **A**nimals: **R**ecommendations for **E**xcellence)
- A voluntary checklist for the **planning stages of animal research** with a focus on **experimental design prior to research occurring**
  - Scientists can use the PREPARE checklist when planning and designing experiments to **improve study quality** and success, **promote animal welfare**, and **increase reproducibility** of research
- The PREPARE guidelines cover the **planning** of an experiment
  - They complement **reporting** guidelines, such as ARRIVE (see *Animal Research: Reporting of In Vivo Experiments (ARRIVE) Guidelines* module)

Who Developed the PREPARE Guidelines?

- Developed by Norecopa, Norway's national 3Rs platform
  - 3R's: Replacement, Reduction, Refinement in animal research
  - Smith AJ, et al. 2018. PREPARE: guidelines for planning animal research and testing. Laboratory Animals. 52(2):135-141. https://doi.org/10.1177/0023677217724823
- The Norecopa website has two important elements
  - A 2-page checklist, available in almost 40 languages, which can be used to generate a Study Plan for an experiment
  - Advice and detailed information on each topic in the checklist, with links to global resources

Why Were PREPARE Guidelines Developed?

- To address the variability in experimental quality across animal studies
  - Addresses concerns about reproducibility and translational reliability
  - Strengthens animal welfare integration into study design
  - Encourages systematic, transparent planning before experiments begin
- To assist with appropriate planning to address animal welfare, reduce resource waste, and increase likelihood of success by creation of scientifically sound studies

Core Purpose of PREPARE

- Improve scientific rigor and internal validity
- Enhance animal welfare standards
- Reduce unnecessary animal use
- Promote collaboration between researchers and animal facilities

Organization of the PREPARE Checklist

- Categorized into major planning domains
  - Formulation of the study
  - Dialogue between scientists and the animal facility
  - Quality control of study components
- Covers scientific, practical, and ethical considerations
- Designed for use before protocol submission
- Encourages dialogue among investigators and animal care staff

Components of the PREPARE Checklist

Categorized into 3 major areas

A. FORMULATION OF THE STUDY

B. DIALOGUE BETWEEN SCIENTISTS AND THE ANIMAL FACILITY

C. QUALITY CONTROL OF THE COMPONENTS IN THE STUDY

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C. QUALITY CONTROL OF THE COMPONENTS IN THE STUDY

PREPARE Checklist: Study Formulation

A. Formulation of the study

1. Literature searches
2. Legal issues
3. Ethical issues, harm-benefit assessment, and humane endpoints
4. Experimental design and statistical analysis

PREPARE Checklist: Study Formulation

A. Formulation of the study

1. **Literature searches**

   - **Ensures the proposed study minimizes animal use by seeking non-animal alternatives, avoiding unnecessary repetition, reducing animal numbers, and refining study procedures**

2. Legal issues
3. Ethical issues, harm-benefit assessment, and humane endpoints
4. Experimental design and statistical analysis

PREPARE Checklist: Study Formulation

A. Formulation of the study

1. Literature searches

2. **Legal issues**

   - **Determine whether the project complies with relevant legislation/guidance and addresses any additional legal or ethical requirements related to the research**

3. Ethical issues, harm-benefit assessment, and humane endpoints

4. Experimental design and statistical analysis

PREPARE Checklist: Study Formulation

A. Formulation of the study

1. Literature searches

2. Legal issues

3. Ethical issues, harm-benefit assessment, and humane endpoints

- **Ensure the proposed study demonstrates:**
  - **Clear scientific rationale and ethical integrity by addressing the 3Rs**
  - **Considers non-animal alternatives**
  - **Avoids unjustified repetition**
  - **Aligns with relevant ethical committee guidance**

4. Experimental design and statistical analysis

PREPARE Checklist: Study Formulation

A. Formulation of the study

1. Literature searches
2. Legal issues
3. Ethical issues, harm-benefit assessment, and humane endpoints
4. **Experimental design and statistical analysis**

- **Design the study to ensure scientific rigor by:**
  - **Defining experimental units**
  - **Determining appropriate animal numbers**
  - **Applying sound statistical, randomization, and bias-prevention methods with clear inclusion and exclusion criteria**

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C. QUALITY CONTROL OF THE COMPONENTS IN THE STUDY

PREPARE Checklist: Dialogue

B. Dialogue between scientists and the animal facility

5. Objectives and timescale, funding, and division of labor
6. Facility evaluation
7. Education and training
8. Health risks, waste disposal, and decontamination

PREPARE Checklist: Dialogue

B. Dialogue between scientists and the animal facility

5. Objectives and timescale, funding, and division of labor

- Write **clear lay summaries** to explain the goals and rationale of studies, helping non-scientists and reviewers understand their purpose
- **Early collaboration** with animal care staff is essential for ensuring welfare, safety, and effective study execution
- **Proper planning** of labor division, costs, and timelines ensures sufficient resources and avoids misunderstandings throughout the project

6. Facility evaluation
7. Education and training
8. Health risks, waste disposal, and decontamination

PREPARE Checklist: Dialogue

B. Dialogue between scientists and the animal facility

5. Objectives and timescale, funding, and division of labor

6. Facility evaluation

- **Scientists should inspect animal research facilities with knowledgeable staff to assess:**
  - **Suitability**
  - **Equipment**
  - **Staffing**
  - **Safety**
  - **Contingency needs**

7. Education and training

8. Health risks, waste disposal, and decontamination

PREPARE Checklist: Dialogue

B. Dialogue between scientists and the animal facility

5. Objectives and timescale, funding, and division of labor

6. Facility evaluation

7. Education and training

- **Assessing staff competence, identifying any training needs necessary to plan animal experiments, and evaluating the facility's readiness**

8. Health risks, waste disposal, and decontamination

PREPARE Checklist: Dialogue

B. Dialogue between scientists and the animal facility

5. Objectives and timescale, funding, and division of labor
6. Facility evaluation
7. Education and training
8. **Health risks, waste disposal, and decontamination**

- **Planning an animal study must include a thorough risk assessment to identify and manage potential health hazards, such as microorganisms, carcinogens, and radiation**
- **This process should be conducted openly and collaboratively with the animal facility to ensure the safety of all people and animals involved**

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PREPARE Checklist: Quality Control

C. Quality control of the components in the study

9. Test substances and procedures
10. Experimental animals
11. Quarantine and health monitoring
12. Housing and husbandry
13. Experimental procedures
14. Humane euthanasia, release, reuse, or rehoming
15. Necropsy

PREPARE Checklist: Quality Control

C. Quality control of the components in the study

9. Test substances and procedures

- **Thorough, detailed information about the substance should be provided to the animal facility**
- **This includes data on origin, purity, preparation, storage, safety, and disposal, as well as any health or environmental risks**

10. Experimental animals
11. Quarantine and health monitoring
12. Housing and husbandry
13. Experimental procedures
14. Humane euthanasia, release, reuse, or rehoming
15. Necropsy

PREPARE Checklist: Quality Control

C. Quality control of the components in the study

9. Test substances and procedures
10. **Experimental animals**
    - **When planning animal studies, researchers must consider the model's suitability, the animals' characteristics, and the ethical implications of their use**
11. Quarantine and health monitoring
12. Housing and husbandry
13. Experimental procedures
14. Humane euthanasia, release, reuse, or rehoming
15. Necropsy

PREPARE Checklist: Quality Control

C. Quality control of the components in the study

9. Test substances and procedures
10. Experimental animals
11. **Quarantine and health monitoring**
    - **The health status of animals should be discussed early**
    - **Planning must address animal sourcing, transport, quarantine, health monitoring, and protective measures for personnel in compliance with relevant regulations**
12. Housing and husbandry
13. Experimental procedures
14. Humane euthanasia, release, reuse, or rehoming
15. Necropsy

PREPARE Checklist: Quality Control

C. Quality control of the components in the study

9. Test substances and procedures
10. Experimental animals
11. Quarantine and health monitoring
12. **Housing and husbandry**
    - **Housing and husbandry conditions play a critical role in animal studies, as poorly managed environments can cause stress and confound scientific results, while animals that adapt well provide more reliable data**
13. Experimental procedures
14. Humane euthanasia, release, reuse, or rehoming
15. Necropsy

PREPARE Checklist: Quality Control

C. Quality control of the components in the study

9. Test substances and procedures
10. Experimental animals
11. Quarantine and health monitoring
12. Housing and husbandry
13. **Experimental procedures**
    - **The division of labor, costs, and responsibilities for recording animal observations should be established early, and all procedures should be clearly described**
    - **Detailed monitoring and welfare assessment plans must be developed to ensure transparency and scientific rigor and should support the use of the most refined methods available**
14. Humane euthanasia, release, reuse, or rehoming
15. Necropsy

PREPARE Checklist: Quality Control

C. Quality control of the components in the study

9. Test substances and procedures
10. Experimental animals
11. Quarantine and health monitoring
12. Housing and husbandry
13. Experimental procedures
14. **Humane euthanasia, release, reuse or rehoming**

- **Early in the planning process, it should be determined whether the animals will need to be humanely euthanized – and if so, when – or if they can instead be released (wildlife studies), rehomed (adopted to the public) or reused in other studies**

15. Necropsy

PREPARE Checklist: Quality Control

C. Quality control of the components in the study

9. Test substances and procedures
10. Experimental animals
11. Quarantine and health monitoring
12. Housing and husbandry
13. Experimental procedures
14. Humane euthanasia, release, reuse, or rehoming
15. **Necropsy**

- **Necropsies should be carefully planned and conducted to prevent bias or material loss during or after the procedure**
- **A standard operating procedure should be applied consistently to all animals, and any unexpected findings of concern should be reported**

Benefits of Using PREPARE

- Improves reproducibility and reliability
- Strengthens ethical and regulatory justification for a study
- Enhances compliance with oversight committees
- Supports strong grant and protocol applications
- Promotes responsible, high-quality animal research

Key Takeaways

- PREPARE is a proactive planning framework that aids scientists through the identification of issues they should consider when planning an animal study
- Integrates scientific rigor and animal welfare
- Encourages collaboration across research teams
- Improves outcomes for both science and animals

Questions

- How does your current planning process align with PREPARE?
  - Where could PREPARE strengthen your protocols?
  - How can early planning improve study reproducibility?

References

- Smith AJ, Clutton RE, Lilley E, Hansen KEA, Brattelid T. 2018. PREPARE: guidelines for planning animal research and testing. Laboratory Animals. 52(2):135-141. https://doi.org/10.1177/0023677217724823
- "NORECOPA, PREPARE for Better Science." *Netlab AS, Bitfarm AS and Thorgate*, https://norecopa.no/PREPARE. Accessed 27 May 2026.

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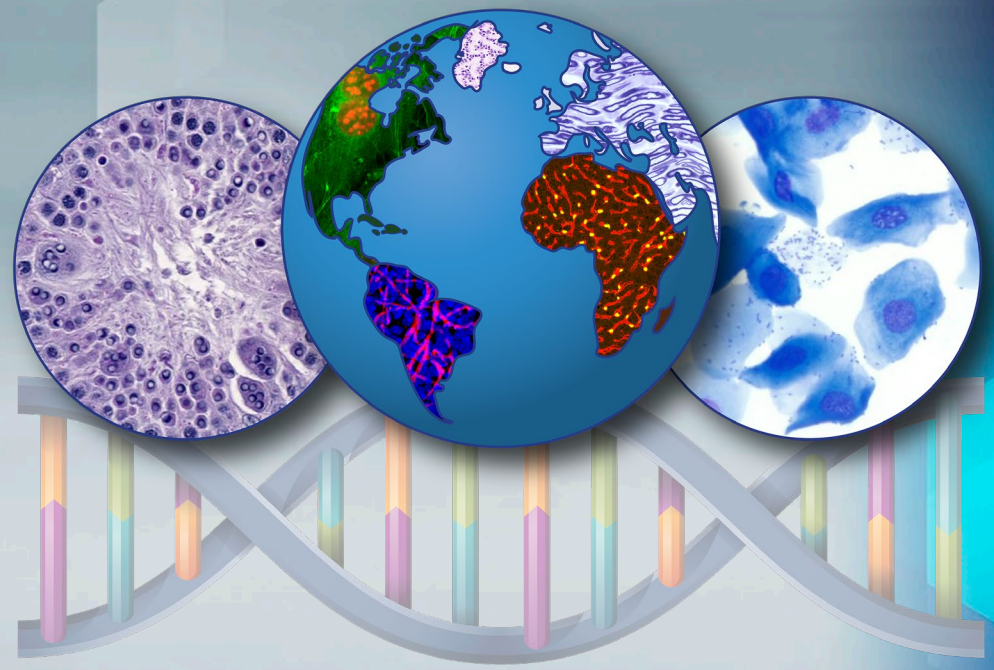

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