

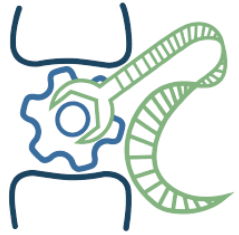
More Ethics in Laboratory, Please!

Scientists' Perspectives on Ethics in the Preclinical Phase

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More ethics in the laboratory, please! Scientists' perspectives on ethics in the preclinical phase

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ABSTRACT

In recent years there have been calls to improve ethics in preclinical research. Promoting ethics in preclinical research should consider the perspectives of scientists. Our study aims to explore researchers' perspectives on ethics in the preclinical phase. Using interviews and focus groups, we collected views on ethical issues in preclinical research from experienced ($n = 11$) and early-stage researchers (ESRs) ($n = 14$) working in a gene therapy and regenerative medicine consortium.

ARTICLE HISTORY

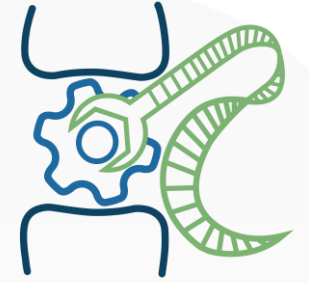
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KEYWORDS

Preclinical research;
bioethics; integrity;
biotechnology; biomedical
research

CARTHAGO Consortium



- Results of **5 focus groups** and **11 interviews** performed within H2020 Marie Curie Action Innovative Training Network consortium.
- Cartilaginous tissue regeneration by gene therapy (CARTHAGO).
- The overall goal is to address the applicability of gene therapy in osteoarthritis and disc degeneration.

Study Aim

“To explore the perspective of researchers at different stages of academic careers and gain insight into their approach to ethics in biotechnologies in the preclinical phase”.

Participants

- Participants from CARTHAGO consortium, **n=25**; 14 females:
- **Early-Stage Researchers/PhD students**. N=14; 10 females. Pre-clinical, lab research.
- **Experienced researchers, Principal Investigators**, N=11, 4 females.

Participants

- Research topics: cell delivery and efficiency gene modulation, tissue/organ delivery tools, repair in tissue and organ culture, in vivo imaging of regeneration, gene therapy efficacy.
- Currently, they work in Finland, Switzerland, Romania, The Netherlands, Sweden, Germany, Portugal, and Denmark.

Ethics

- The protocol, informed consent form, General Data Protection Regulation form, and the information for participants' page were approved by the Bioethics Committee of Jagiellonian University, Krakow, Poland (No. 1072.6120.209.2021 – 29/09/2021).
- Participants were informed about the aims of the study, the risks and benefits of their participation, and that the sessions would be videorecorded.

Methods

Methods. Early-Stage Researchers

- A longitudinal series of five focus groups (FGs) lead by Paola Buedo (online) + 2 questionnaires.
- Questionnaires were self-administred before (September 2021) and after all the FG meetings (May 2022).
- The questionnaires and FGs were piloted among another group of PhD students (n = 10).

Methods. Early-Stage Researchers

- Our research strategy was based on 3 approaches:
 - i) Ethics Parallel Research (Jongsma and Bredenoord 2020),
 - ii) Social Labs (Timmermans et al. 2020),
 - iii) the Responsible Research and Innovation framework (EC 2020).

Methods. Early-Stage Researchers

The aim of focus groups:

- i) to identify bioethical challenges of gene therapy and regenerative medicine and
 - ii) to promote research integrity.
- Every FG was performed following the FG plan.

Methods. Experienced Researchers

- Semi-structured interviews
- Aim: to learn about the knowledge and opinion of the state of ethics and integrity in the preclinical phase.
- Conducted by Paola Buedo between July-September 2022 (45-70 minutes)

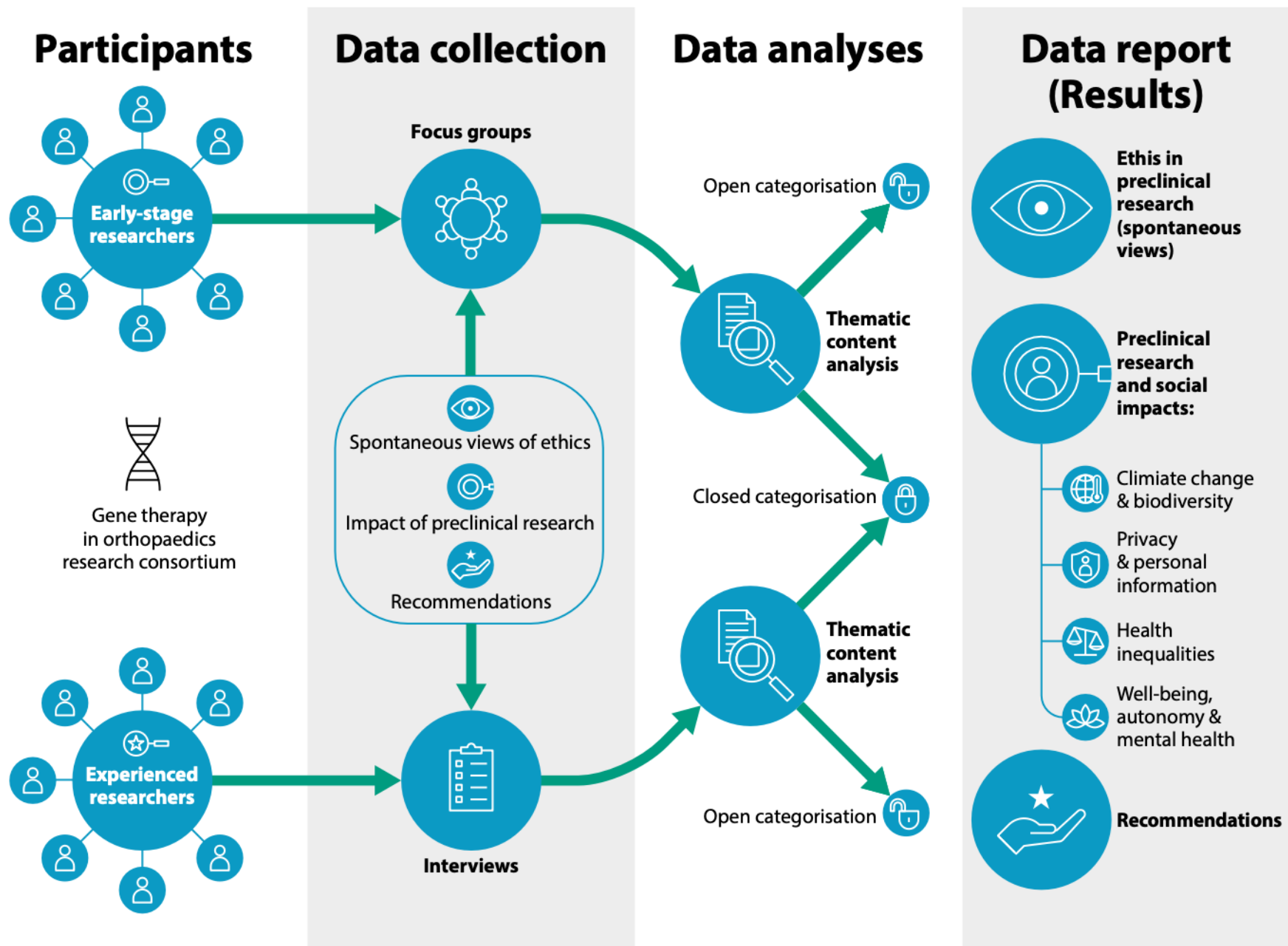


Figure 1. An illustrative synthesis of the methods used in this study.

Results

Table 1. Themes and categories developed from focus groups and interviews.

Themes	Categories in Focus Groups	Categories in interviews
1. Spontaneous views on ethics in preclinical research	<i>Animal experimentation</i> <i>The use of human biological material and how it is obtained</i> <i>Integrity</i> <i>Relationships in scientific community</i> <i>Impact in society</i>	<i>Institutional procedures</i> <i>Standard/no-need ethics</i> <i>Safety, toxicity and long-term effect</i>
2. Preclinical research and social impacts: the case of gene therapy in orthopaedics	<i>Footprint on environment</i> <i>Impact on privacy and personal information</i> <i>Impact on health inequalities</i> <i>Impact on social well-being, autonomy and mental health</i> <i>Impact on climate change and biodiversity</i>	
3. Recommendations or what we can do better in health-related preclinical research	<i>Research integrity strategies</i> <i>Ethics training</i> <i>Avoid sex bias</i> <i>Equity</i> <i>Mental health of researchers</i> <i>Environmentally friendly</i>	<i>Science communication</i> <i>Citizen engagement</i>

Results

- Spontaneous views on ethics in preclinical research
- Two themes that both groups spontaneously associated with ethics in preclinical research:
 - animal experimentation
 - and the use of human biological material and how it is obtained.

Results

- 🌐 Preclinical research and social impact:
- 🌐 Scientists from both groups reflected that preclinical research produces an environmental footprint
- 🌐 Personalized medicine techniques may pose risks of donor identification
- 🌐 Innovative therapies may impact health inequalities

Results

- Preclinical research and social impact:
- Potential positive impact on social well-being, autonomy and mental health.
- Gene therapy research could improve the quality of life, especially in aging societies.
- Increased mobility and the possibility of pain relief could have a positive impact on social life.

Recommendations

- The majority of both groups agreed that:
- more research integrity policies are needed,
- more attention should be paid to the mental health of researchers,
- ethics training should be mandatory.

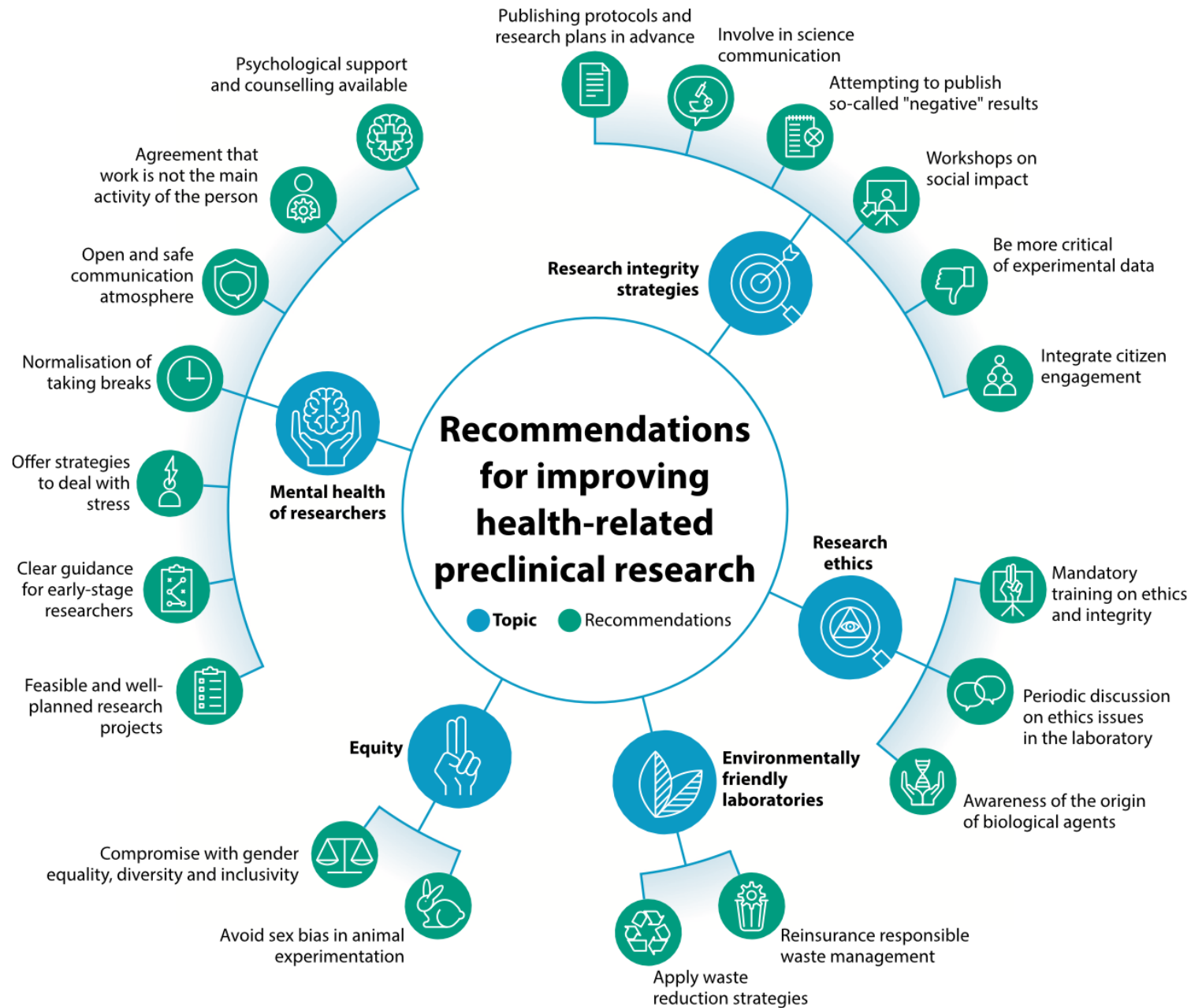


Figure 2. Recommendations for improving health-related preclinical research.

Limitations of the study

- Bias and limitations of qualitative study with small number of participants.
- Participants and moderator/interviewer were from the same research consortium (although different countries).

Conclusion



- The study provides information on ethics and integrity in health-related preclinical research from the perspective of scientists working in laboratories.
- These views help to identify key ethical challenges and, when combined with more data, ultimately lead to informed and evidence-based improvements to existing regulations.

Another study in the series

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How to embed ethics into laboratory research

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ABSTRACT

Health-related innovation in biotechnology requires anticipating potential bioethical implications. In this article, we present a strategy to embed ethics in a group of early-stage researchers performing research in gene therapy and regenerative medicine in the laboratory phase. We conducted a series of focus group meetings with early-stage researchers who work in biotechnology laboratories. The objective was to reflect on the bioethical challenges of their own work and to promote the integration of research ethics with laboratory practice. The

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KEYWORDS

Biotechnology; ethics; focus groups; biomedical research; research ethics

Thank you!

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