HERE SEMINAR

NEEDS AND INSTRUMENTS DEVELOPMENT ABOUT RESEARCH & INNOVATION ETHICS IN ALBANIA

20-21 NOV 2024 TIRANA

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Overview

Different Understanding of Ethics

The terms ethics in research, ethical research, and ethical researcher are closely related but focus on different aspects of ethical practice in the context of scientific inquiry. Here's how they differ:

Activity 1: Brainstorming in groups

Ethics in Research

- **Definition**: This refers to the set of principles and guidelines that govern how research should be conducted to ensure it adheres to ethical standards.
- **Focus**: Ethics in research addresses the rules and norms that researchers must follow to protect human participants, animals, the environment, and the integrity of the research process.
- **Key Elements**:
- Informed consent.
- Privacy and confidentiality.
- Avoiding harm to participants.
- Transparency and honesty in reporting results.
- Compliance with legal frameworks like the GDPR or animal welfare regulations in the EU.

Ethical Research

- **Definition**: This term refers to research that is conducted in a manner that actively incorporates ethical considerations throughout the entire research process.
- **Focus**: Ethical research is about the process and outcomes of the research being morally sound, focusing not only on adherence to rules but also on the social responsibility and the positive impact of the research.
- **Key Elements**:
- Research that seeks to avoid harm and contribute to the well-being of society.
- The research methodology is aligned with ethical norms (e.g., fair treatment of all subjects, ethical use of data).
- Promotes equity and avoids discrimination or exploitation of vulnerable populations.
- Engages in responsible research that minimizes environmental harm and addresses societal challenges.

Ethical Researcher

- **Definition**: An ethical researcher is an individual who demonstrates personal commitment to ethical values in their conduct, decision-making, and professional practices in research.
- **Focus**: This term centers on the behavior and attitude of the researcher themselves, emphasizing personal integrity, accountability, and ethical reflection.
- **Key Elements**:
- Adherence to ethical guidelines but also going beyond compliance by embodying moral responsibility.
- Demonstrates honesty, fairness, and transparency in all research-related activities.
- Takes responsibility for the potential impact of their research on society, the environment, and individuals involved.
- Proactively addresses ethical dilemmas, including issues like potential conflicts of interest, biases, or the ethical implications of research findings.

Summary of Differences

- Ethics in research focuses on the guidelines and principles that must be followed in research.
- Ethical research emphasizes conducting research that is intrinsically moral, socially responsible, and ethically designed from the outset.
- Ethical researcher refers to an individual's personal integrity and their consistent commitment to moral values throughout the research process.

Each of these concepts highlights a different dimension of ethics in the context of research, ranging from formal rules to the personal responsibility of the researcher.

Case studies

Ehical principles and EU guidelines applied in various research contexts

Case studies

Clinical Trials Involving Vulnerable Populations

Context: An EU-funded study on a new medication for Alzheimer's disease involves elderly participants who may have impaired decision-making capacity.

Ethical Issue: Protecting vulnerable populations who might not fully understand the risks involved in participating in clinical trials.

EU Ethical Guidance:

Directive 2001/20/EC: ensures that clinical trials on human subjects, especially those involving vulnerable groups like the elderly, are conducted with the utmost care and oversight.

Informed Consent and Legal Representatives: In cases where participants cannot provide informed consent, legal representatives must provide consent on their behalf.

Case studies

Clinical Trials Involving Vulnerable Populations

Researchers must ensure that the participants' autonomy and well-being are respected at every stage.

Ethical Review Boards: All clinical trials involving vulnerable populations require approval from ethics committees, which ensure that risks are minimized and the research is justified.

- **Outcome: The trial was designed with additional safeguards, such as regular oversight from independent medical professionals and ethics monitors, ensuring the protection of participants' rights and dignity.**

Case studies

Use of Animals in Medical Research

- **Context**: A biomedical research project funded by the EU aims to test new treatments for neurological diseases using animal models.
- **Ethical Issue**: The use of animals in research raises ethical concerns about animal welfare, particularly when it involves invasive procedures.
- **EU Ethical Guidance**:
  - Directive 2010/63/EU: This directive outlines strict regulations for the protection of animals used for scientific purposes. It promotes the 3Rs principle—**Replace, Reduce, Refine**—to minimize animal suffering.

Case studies

Use of Animals in Medical Research

- **Ethics Committees**: Every project involving animals must be approved by institutional animal ethics committees, ensuring that animal use is scientifically justified, and that alternatives are considered.
- **Transparency**: Researchers are required to publicly disclose the number of animals used and the measures taken to minimize their suffering.

- **Outcome: The research team adopted alternative methods to reduce the number of animals used, including computer simulations and in vitro testing, in line with the EU's 3Rs principle.**

Case studies

Data Privacy in Social Science Research

- **Context**: A large EU-funded social science study aimed at understanding public attitudes toward immigration collects personal data from thousands of European citizens, including sensitive demographic information.
- **Ethical Issue**: Protecting participants' privacy and complying with the General Data Protection Regulation (GDPR), especially when handling sensitive personal data.
- **EU Ethical Guidance**:
- **GDPR**: The regulation requires that all personal data be processed lawfully, transparently, and securely. Researchers must obtain explicit consent for data collection and ensure that individuals can withdraw their consent at any time.

Case studies

Data Privacy in Social Science Research

- **Data Anonymization**: Researchers must anonymize or pseudonymize data to prevent identification of individuals, particularly when publishing results.
- **Data Protection Impact Assessment** (DPIA): For high-risk data processing activities, such as large-scale collection of sensitive data, a DPIA must be conducted to identify and mitigate risks.

- **Outcome: The research team implemented robust anonymization techniques, conducted a comprehensive DPIA, and ensured that participants had control over their data, in full compliance with GDPR regulations.**

Case studies

Dual-Use Research: AI in Security Applications

- **Context**: An EU-funded project develops AI technologies to improve national security, including facial recognition software for identifying potential security threats.
- **Ethical Issue**: Dual-use research, where AI developed for beneficial purposes (e.g., security) could potentially be misused for surveillance, violating privacy and human rights.
- **EU Ethical Guidance**:
- **EU Dual-Use Regulation**: Projects involving dual-use technologies are required to assess the potential for misuse and take steps to prevent unethical applications.

Case studies

Dual-Use Research: AI in Security Applications

- **Ethics Advisory Boards**: The EU mandates that dual-use research undergo review by ethics advisory boards to evaluate the potential risks and ensure safeguards are in place.
- **Security and Privacy by Design**: Researchers are encouraged to incorporate privacy-enhancing technologies and design security systems that are aligned with human rights standards.

- **Outcome: The project incorporated stringent security measures to prevent unauthorized use of the AI software and consulted with human rights experts to ensure the technology would not violate privacy or civil liberties.**

Case studies

Environmental and Social Responsibility: Climate Change Research

- **Context**: An EU-funded climate change project investigates the effects of industrial pollution on biodiversity in European coastal areas.
- **Ethical Issue**: The need to balance scientific exploration with environmental protection, ensuring that research activities do not further harm the ecosystems being studied.
- **EU Ethical Guidance**:
- Sustainable Research Practices: EU guidelines emphasize minimizing the environmental impact of research projects, including the use of non-invasive techniques and reducing carbon footprints.

Case studies

Environmental and Social Responsibility: Climate Change Research

- **Public Engagement and Social Responsibility**: Researchers are encouraged to involve local communities in the research process, especially when the research affects ecosystems they depend on.
- **Ethics of Environmental Protection**: EU guidelines stress that research projects must contribute to the sustainable development goals and protect the ecosystems under study.
- **Outcome: The research team adopted sustainable practices, including non-invasive data collection methods, and engaged local communities in protecting coastal areas while ensuring that their research results would support conservation efforts.**

Science with and for Society, SwafS

For all research activities funded by the European Union, adhering to the highest standards of research ethics and integrity is pivotal to achieving research excellence in all domains. To this end, the SwafS projects produced a broad array of tools to promote and support compliance including education material, guidelines, toolkits and Standard Operating Procedures frameworks

200 projects

462 mln EUR

18 projects on Eth

Research ethics and research integrity

Ethics is an integral part of all research activities funded by the European Union, and ethical compliance is essential to guarantee research excellence.
All projects carried out must comply with ethical principles and relevant national, EU and international legislation, for example the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights

Research ethics and research integrity

The European Code of Conduct for Research Integrity serves the European research community as a framework for self-regulation across all scientific and scholarly disciplines and for all research settings.

The **2023 Revised Edition** has been updated to ensure that the European Code of Conduct remains fit for purpose and relevant to all disciplines, emerging areas of research, and new research practices.

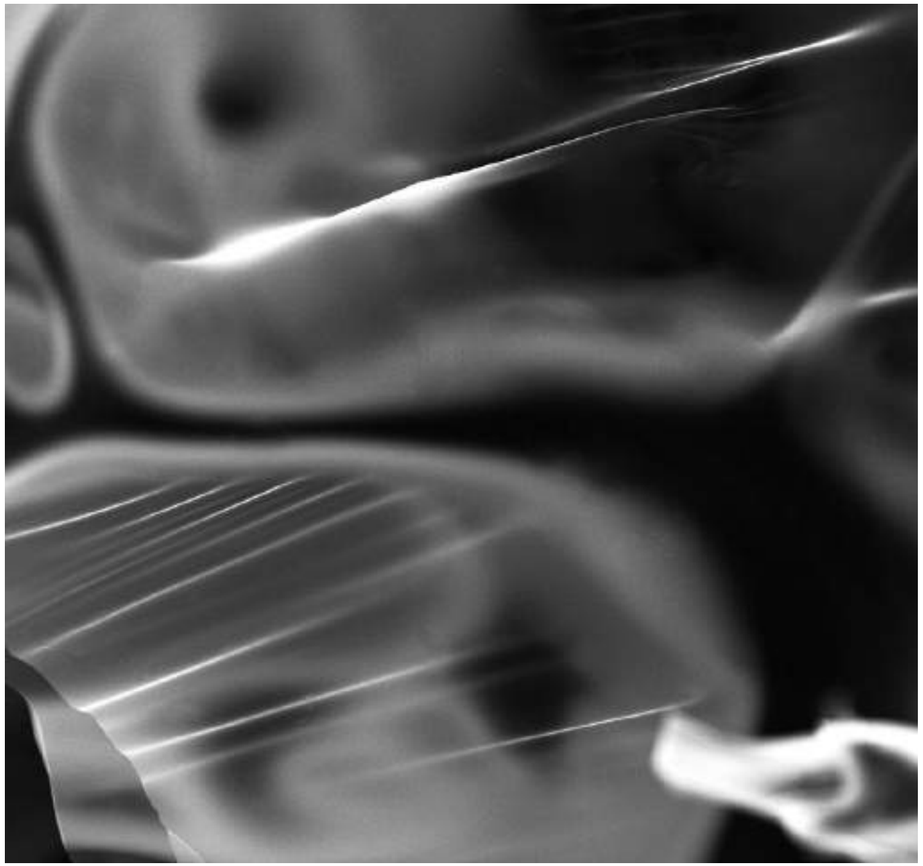
Research ethics and research integrity

The revised version takes account of changes in data management practices, the General Data Protection Regulation (GDPR), and recent developments in Open Science and research assessment.

Complex ethical challenges

genomics, human enhancement and human–machine interaction, artificial intelligence and big data & more...

To strengthen the EU capacity to uphold the highest ethical standards for research carried out in Europe and worldwide, a dedicated **European Network of research ethics committees and research integrity offices (ENERI)** has been set up to strengthen exchanges of good practice and increase collaboration among the main national research integrity and ethics actors



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Research values

ECC changes 2023

Interpretation of the values and principles that regulate research may be affected by social, political, or technological developments and by changes in the research environment.

application of technologies in research in new ways
Open Science
GDPR

the use and impact of social media to share and disseminate research results
citizen science, participatory research

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Fundamental principles in research

Reliability

in ensuring the quality of research, reflected in the design, methodology, analysis, and use of resources

Honesty

in developing, undertaking, reviewing, reporting, and communicating research in a transparent, fair, full, and unbiased way

Respect

for colleagues, research participants, research subjects, society, ecosystems, cultural heritage, and the environment

Accountability

for the research from idea to publication, for its management and organisation, for training, supervision, and mentoring, and for its wider societal impacts

Research Environment

Research institutions and organisations promote awareness and resource incentives to ensure a culture of research integrity.

Research institutions and organisations create an environment of mutual respect and promote values such as equity, diversity, and inclusion.

Research institutions and organisations create an environment free from undue pressures on researchers that allows them to work independently and according to the principles of good research practice.

Example from Albania?

Training, Supervision, and Mentoring

Research institutions and organisations ensure that researchers receive rigorous training in research design, methodology, analysis, dissemination, and communication

Senior researchers, research leaders, and supervisors mentor their team members, lead by example, and offer specific guidance and training to properly develop and structure their research activities.

Researchers across the entire career path, from junior to the most senior level, undertake training in ethics and research integrity.

Example from Albania?

Research Procedures

Research protocols take account of, and are sensitive to, relevant differences among research participants, such as age, gender, sex, culture, religion, worldview, ethnicity, geographical location, and social class.

Researchers make proper and conscientious use of research funds.

Researchers share their results in an open, honest, transparent, and accurate manner, and respect confidentiality of data or findings when legitimately required to do so.

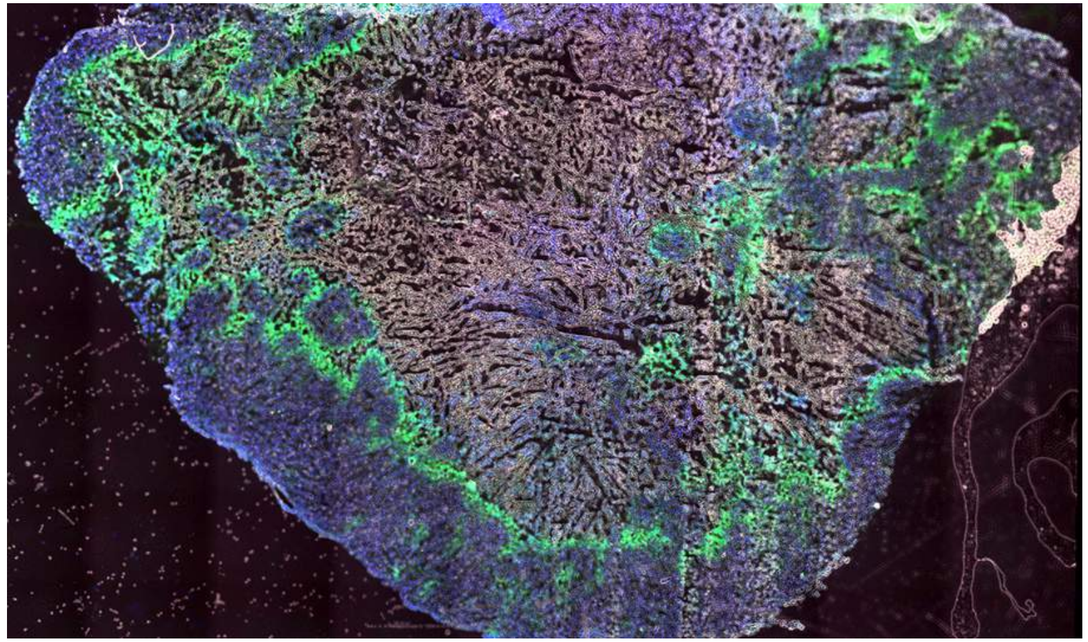
Example from Albania?

Data Practices and Management

Researchers, research institutions, and organisations ensure appropriate stewardship, curation, and preservation of all data, metadata, protocols, code, software, and other research materials for a reasonable and clearly stated period.

Researchers, research institutions, and organisations ensure that access to data is as open as possible, as closed as necessary, and where appropriate in line with the FAIR Principles (Findable, Accessible, Interoperable and Reusable) for data management.

Researchers, research institutions, and organisations are transparent about how to access and gain permission to use data, metadata, protocols, code, software, and other research materials.



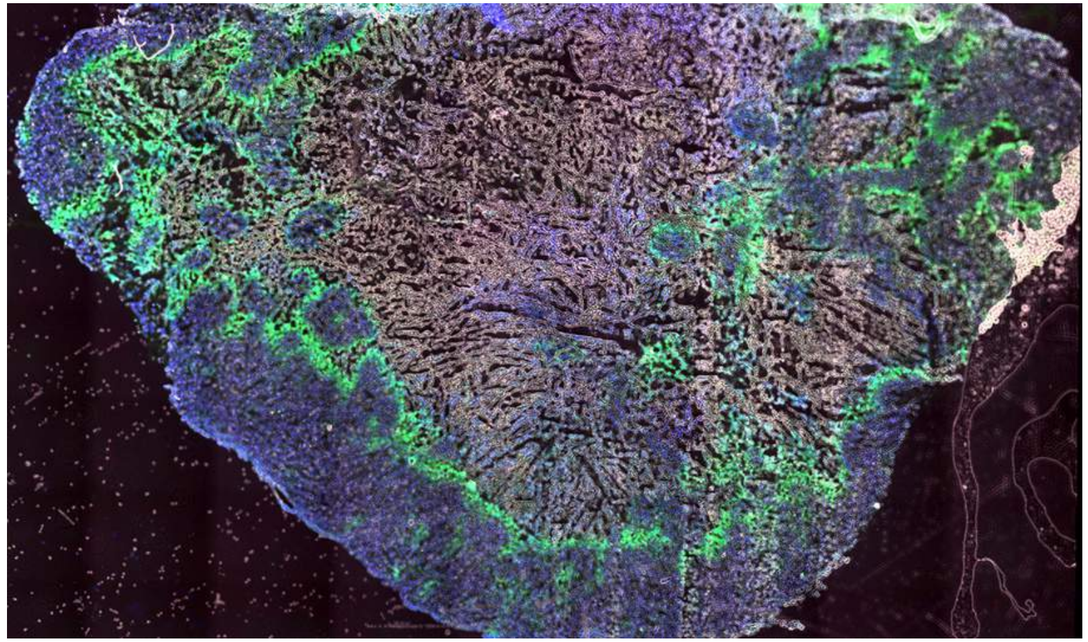
Example from Albania?

Data Practices and Management

Researchers inform research participants about how their data will be used, reused, accessed, stored, and deleted, in compliance with GDPR.

Researchers, research institutions, and organisations acknowledge data, meta-data, protocols, code, software, and other research materials as legitimate and citable products of research.

Researchers, research institutions, and organisations ensure that any contracts or agreements relating to research results include equitable and fair provisions for the management of their use, ownership, and protection under intellectual property rights.



Example from Albania?

Collaborative Working

All partners in research collaborations take responsibility for the integrity of the research and its results.

All partners in research collaborations formally agree at the outset, and monitor and adapt as necessary, the goals of the research and the process for communicating their research as transparently and openly as possible.

Example from Albania?

Collaborative Working

All partners in research collaborations formally agree at the outset, and monitor and adapt as necessary, the expectations and standards concerning research integrity, the laws and regulations that will apply, protection of the intellectual property of collaborators, and procedures for handling conflicts and possible cases of misconduct.

All partners in research collaborations are consulted and formally agree on submissions for publication of research results and other forms of dissemination or exploitation of the results.

Example from Albania?

Publication, Dissemination, and Authorship

Authors formally agree on the sequence of authorship, acknowledging that authorship itself is based on: (1) a significant contribution to the design of the research, relevant data collection, its analysis, and/ or interpretation; (2) drafting and/or critical reviewing the publication; (3) approval of the final publication; and (4) agreeing to be responsible for the content of the publication, unless specified otherwise in the publication.

Authors include an 'Author Contribution Statement' in the final publication, where possible, to describe each author’s responsibilities and contributions.

Authors acknowledge important work and contributions of those who do not meet the criteria for authorship, including collaborators, assistants, and funders who have enabled the research.

Publication, Dissemination, and Authorship

Authors disclose any financial and non-financial conflicts of interest as well as sources of support for the research or the publication.

Authors and publishers promptly issue corrections or retract publications, if necessary, the retraction processes are clear and the reasons stated, and authors are given credit for issuing corrections post-publication.

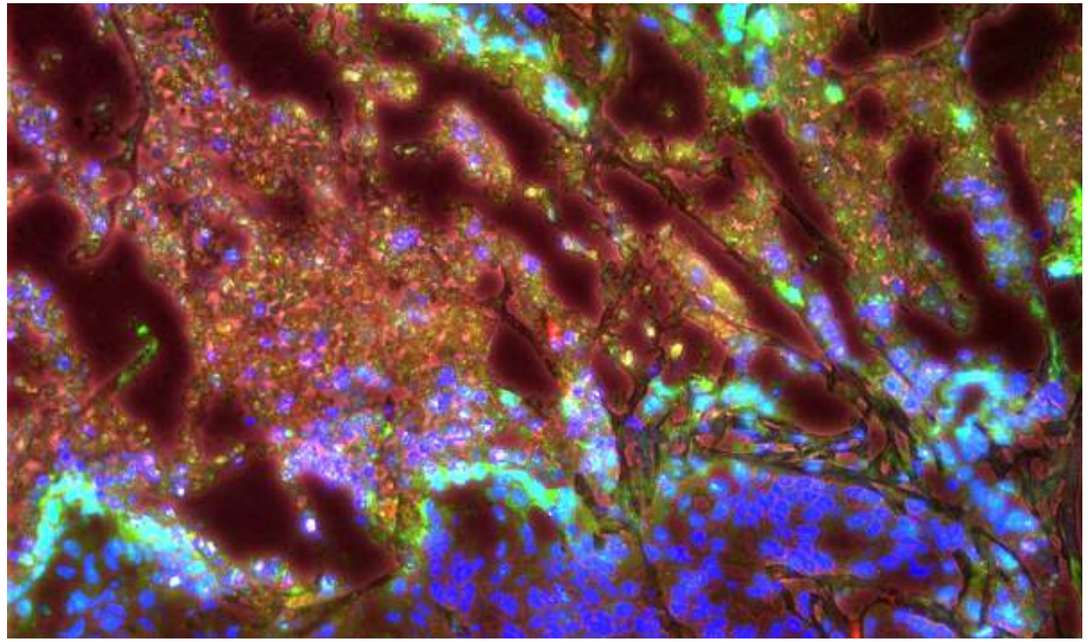
Authors, research institutions, publishers, funders, and the research community acknowledge that negative results can be as relevant as positive findings for publication and dissemination.
Authors are accurate and honest in their communication to colleagues, policy-makers, and society at large.

Authors are transparent in their communication, outreach, and public engagement about assumptio and values influencing their research as well as the robustness of the evidence, including remaining uncertainties and knowledge gaps.

Reviewing and Assessment

Researchers take seriously their commitment and responsibility to the research community through refereeing, reviewing, and assessment, and this work is recognised and rewarded by researchers, research institutions, and organisations.

Researchers, research institutions, and organisations review and assess submissions for publication, funding, appointment, promotion, or reward in a transparent and justifiable manner, and disclose the use of AI and automated tools.



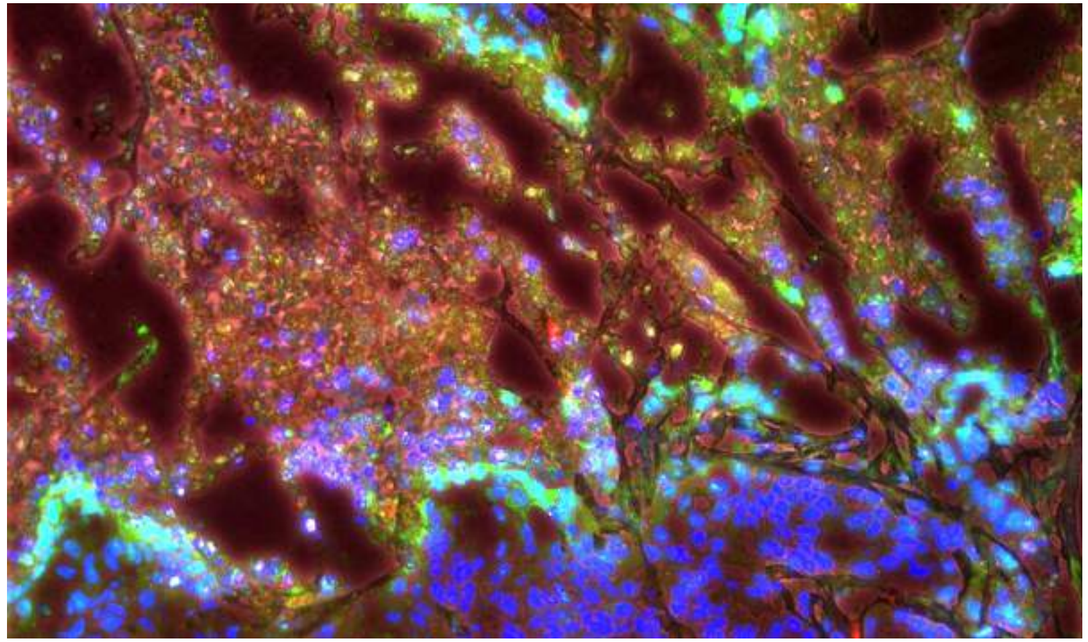
Reviewers and editors declare any actual or perceived conflicts of interest and, when necessary, withdraw from involvement in discussion and decisions on publication, funding, appointment, promotion, or reward.

Reviewing and Assessment

Reviewers maintain confidentiality unless there is prior approval for disclosure.

Reviewers and editors respect the rights of authors and applicants, and seek permission to make use of the ideas, data, or interpretations presented.

Researchers, research institutions, and organisations adopt assessment practices that are based on principles of quality, knowledge advancement, and impact that go beyond quantitative indictors and take into account diversity, inclusiveness, openness, and collaboration where relevant.



Your experience?

Research misconducts and Unacceptable Practices

Research misconduct is traditionally defined as fabrication, falsification, or plagiarism (the so-called FFP categorisation) in proposing, performing, or reviewing research, or in reporting research results

Fabrication is making up data or results and recording them as if they were real

Falsification is manipulating research materials, equipment, images, or processes, or changing, omitting, or suppressing data or results without justification.

Plagiarism is using other people's work or ideas without giving proper credit to the original source.

Other examples of unethical prctices??

Preventing

it is always in the interest of society and the research community that violations are handled in a fair, consistent, and transparent fashion. The following principles need to be incorporated into any investigation process.

Example: Institutions protect the rights of bona fide whistle-blowers during investigations and ensure that their career prospects are not endangered.

Example: General procedures for dealing with violations of good research practice are publicly available and accessible to ensure their transparency and uniformity

Example: Persons accused of research misconduct are given full details of the allegation(s) and are allowed a fair process for responding to allegations and presenting evidence.

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