Scientia et PRAXIS

e-ISSN: 2954-4041

For research ethics, anonymity, and consent in science, technology, and medicine

- It is crucial that all subjects, whether human or animal, whether living or deceased, are accorded dignity and respect within the realm of academic research. Ethical research practices demand that researchers remain vigilant in their efforts to minimize potential risks and prevent harm. Moreover, researchers carry an ethical responsibility to ensure transparency in their research methodologies, enabling editors, peer reviewers, and readers to fairly and comprehensively evaluate their work.
- It's important to note that when conducting interdisciplinary and mixed-methods research, researchers should carefully assess and select the relevant guidelines that apply to their specific research type. This ensures that ethical standards are appropriately tailored to the nature and scope of their research endeavors.

Research involving humans

- **Thorough Research for Journal Selection:** Just like your overall research, conducting comprehensive research is crucial when deciding which journal is the best fit for publishing your work. Given the extensive array of academic journals available, it's essential to employ various methods to narrow down your options to a shortlist of potential journals.
- **Ethical Considerations in Human Research:** All studies involving human subjects, whether individuals, samples, or data, must adhere to the principles outlined in the **Declaration of Helsinki.**
- **Reporting Ethical Approval for Non-Interventional Studies:** In cases of non-interventional studies, such as surveys, where ethical approval is not mandated due to national laws or has been exempted by an ethics committee, this information should be explicitly stated in the manuscript along with a detailed explanation. If an exemption has been granted, the manuscript should include the name of the ethics committee responsible for this decision. However, if there is any uncertainty, researchers should always seek guidance from the relevant department before initiating the study.
- **Sensitivity in Describing Groups:** When referring to various groups based on factors like race, ethnicity, age, disease, disability, religion, sex, gender, or sexual orientation, it is essential to use language that is respectful, non-stigmatizing, and non-discriminatory. Studies categorizing humans into such groups should also provide explanations of the definitions and categories used, including whether any specific categorization was mandated by the funding agencies involved.
- **Mandatory Ethical Approval:** Ethical approval must be obtained for all research studies before being carried out. Authors should be prepared to furnish additional information to the journal's editorial office upon request.
- **Confirmation of Ethical Approval:** In essence, before commencing the study, it is imperative that ethical approval has been secured for all research protocols from the local institutional review board (**IRB**) or the appropriate ethics committee to ensure that the study aligns with both national and international guidelines for human research.
- **A statement to confirm this must be included within the manuscript, which must provide details of the name of the ethics committee and reference/permit numbers where available.**

Ethical considerations for different human study designs

Prospective studies on humans

- Particularly in cases involving interventions, such as clinical trials, it is essential for participants to offer informed consent in written form to participate in the study.
- The manuscript should contain a statement verifying this requirement.
- Authors should be ready to supply the journal's editorial team with dated copies bearing the signatures of both the participants and the author(s) upon request. In situations where verbal informed consent has been obtained instead of written consent, this should be clarified and documented within the manuscript.

Clinical trials

- Aside from the necessary informed written consent mentioned earlier, it is also imperative that clinical trial protocols are recorded in a publicly available database before enlisting participants. This database should be accessible to all potential registrants and administered by a registry that adheres to specific standards like **WHO standards**.
- You can locate a compilation of acceptable registries at the **WHO International Clinical Trials Registry Platform (ICTRP).** Trials can be additionally registered with Clinical Trials.gov and other principal registries **WHO primary registries network.**
- Manuscripts must include the trial registration number and provide explanations for any deviations from the original trial protocol, particularly changes related to primary outcomes.
- Clinical trials should ideally be registered prospectively, meaning before participant recruitment. However, for trials that were not registered prospectively, **Scientia et PRAXIS Journals** may consider those that were registered at least before data analysis. This is crucial to ensure the comprehensive and transparent dissemination of all clinical trial results that impact human health.
- Authors of retrospectively registered trials should be ready to furnish additional information to the journal editorial office upon request.
- Please be aware that some instances may not permit accepting retrospectively registered trials. Authors must consult with the journal's Editor before submitting their work.
- Additional information regarding both prospective and retrospective registration can be found in the provided resources like **AllTrials campaign** and the **ICMJE.**

We follow the **WHO** and **ICMJE** description of the clinical trial, which is described as:

- Any research investigation that proactively assigns human participants or groups of humans to one or more health-related interventions to assess their impact on health outcomes. This assessment may involve the presence or absence of concurrent comparison or control groups.
- Health-related interventions encompass various interventions aimed at modifying biomedical or health-related outcomes. This category includes items such as medications, biological products like cells, surgical procedures, radiological treatments, medical devices, behavioral therapies, dietary changes, alterations in the care process, and so forth. This classification encompasses all stages of the trial, including Phase 1.
- Health outcomes refer to any measurements or assessments related to biomedical or health aspects that are collected from patients or study participants. This encompasses a variety of data, including pharmacokinetic measurements and records of adverse events.

- Studies that are purely observational, where the decision to administer a medical intervention is not under the investigator's control, do not necessitate registration.

Scientia et PRAXIS Journal maintains the prerogative to decline submissions before publication or withdraw already published articles if the authors cannot sufficiently address concerns regarding the registration status or the execution of clinical trials. Authors should be ready to furnish additional supporting materials, such as the original data, to the journal's editorial office when requested.

Clinical Case reports

- A clinical case report provides an extensive clinical account of an individual patient. Since the level of information disclosed in the manuscript might reveal the patient's identity, obtaining explicit Consent to Publish is essential before publishing the case.
- Authors are responsible for obtaining this consent from the patient directly (or from their legal guardians if they are minors or lack the capacity to give informed consent, or from next of kin if the patient is deceased). This requirement remains in place even if the authors have redacted direct identifiers.
- Authors are recommended to follow **CARE guidelines** to guarantee the inclusion of all crucial information about the case, it is important for authors to report comprehensively.

Consent to publish is a journal requirement, and cannot be exempted by an ethics committee.

- Authors have the option to utilize this **Consent to Publish form**. This document should be filled out, signed, and securely stored. Authors should be ready to provide it to the journal's editorial office upon request.
- A statement affirming that consent to publish has been obtained must be incorporated into the manuscript.

Organ or tissue transplants

- **Scientia et PRAXIS Journal** supports the ethical guidelines outlined by the **World Health Organization (WHO)** and the **World Medical Association (WMA).** Specifically, all studies involving transplantation of donated human organs should be conducted with ethical approval from an appropriate committee, and all sources of donor tissue must be provided in the submitted manuscript.
- Authors are responsible for ensuring that donated organs have been acquired with the explicit informed consent of the donor, the donor's legal guardian (if the donor is a minor), or the next of kin (if the donor is deceased). This consent should have been willingly given, free from any form of coercion or inducement.
- Authors of research articles reporting the utilization of donated organs must include a statement affirming the acquisition of informed consent. Special attention should be given to assessing the risks associated with research involving vulnerable populations, and authors should be prepared to furnish details regarding the informed consent process.
- These requirements apply to all studies, including follow-up research, that involve donors or patients who have undergone organ or tissue transplantation.
- **Scientia et PRAXIS Journal** retains the right to decline submissions before publication or retract published articles related to transplantation if authors are unable to provide substantiated proof of informed consent. Authors should also be ready to provide additional supporting documents

related to their study (such as ethical approvals and informed consent forms) upon request from the journal's editorial office.

Human embryos and human stem cells

- Authors conducting research involving human embryos, human embryonic stem cells (including clinical stem cell applications), and associated materials must incorporate a statement within their manuscript confirming the adherence to safety protocols, ethical principles, and relevant regulations during all experiments.
- Authors should be capable of providing evidence that all individuals who either donated or received stem cells or tissues (or their next of kin in the case of a deceased donor) granted informed consent.
- **Scientia et PRAXIS Journal** supports the ethical guidelines for stem cell research as delineated in the **ISSCR Guidelines for Stem Cell Research and Clinical Translation**.
- **Consent for research involving children, adolescents, and vulnerable or incapacitated study participants**
- For participants who are unable to provide informed consent themselves, written consent must be obtained from their parent or guardian. The age at which individuals attain legal adulthood is determined by the participant's home country, usually falling within the range of 16 to 18 years.
- The manuscript should contain a statement confirming the acquisition of informed consent.

Retrospective studies

- Researchers are required to validate that they have secured ethical approval for their study and have obtained permission from the owner of the dataset to utilize the information contained in databases or repositories for their research purposes.
- If information from a database or repository can be used without the need for explicit permission (for example, when it is publicly available and allows unrestricted re-use through an open license), the manuscript should include a statement clarifying this.
- In cases where verbal informed consent has been obtained instead of written consent, this practice should be detailed and explicitly mentioned within the manuscript.
- Following the guidelines outlined in the **Nuremberg Code** and the **Belmont Report**, Informed consent must have been voluntarily provided without any form of coercion or inducement.
- Data obtained should be anonymized unless otherwise instructed by the content owners of the database. In cases where participant details do not need to be anonymized, authors must be able to furnish proof that they obtained written informed consent, which includes consent for publication, from the participants.
- **A statement to confirm this must be included within the manuscript.**

Survey studies

- Researchers must ensure that they have provided all participants with clear information regarding the purpose of the research, whether anonymity is guaranteed or not, and the procedures for data storage. It is vital to respect the participant's right to confidentiality, offer comprehensive insight into the research objectives, and address any associated risks. Recording the participant's voluntary consent to participate is crucial, and compliance with legal data protection requirements is mandatory.
- In situations where national law or the researcher's institution mandates obtaining ethical approval before commencing the study, researchers must adhere to this requirement. For survey

studies in settings where ethical approval is not obligatory, authors should include a statement to clarify this within the manuscript.
- When conducting survey studies in environments where there is no mandatory requirement for ethical approval, authors should provide a statement within the manuscript to elucidate this fact.
- **A statement to confirm this must be included within the manuscript.**

Covert observational research

Conducting concealed observational research demands specific ethical and legal deliberations but may be permissible in exceptional instances with compelling justification. Researchers should also consider the evolving legal structures of privacy rights, which can vary significantly worldwide. Authors engaged in covert research should refer to applicable guidelines, such as those delineated in the provided resource like **British Sociological Association's Statement of Ethical Practice.** All studies that include covert research must include the following:

- Within the manuscript, there should be a statement that thoroughly justifies the covert nature of the research and includes the names of the ethics committee(s) that granted approval for the study, along with reference or permit numbers if applicable.
- When the study is conducted on a social-media platform like Tinder, researchers should refer to the platform's code of conduct and/or terms of use to ascertain whether they require the platform's authorization to incorporate user data in their research.
- The employment of aliases or online personas should be disclosed.
- Ideally, researchers should endeavor to obtain informed consent from the study participants after the study's conclusion.
- **Please note that journal editors, scholarly societies and associations, and the publisher reserve the right to deem covert research unsuitable for consideration in their journal.**

Research on Indigenous communities

Authors should remain cognizant of any distinct research ethics clearance and informed consent protocols mandated for conducting research within communities where unique authorization procedures are in place. Additionally, authors should be mindful of cultural considerations and any constraints linked to content dissemination, which encompass the inclusion of images in their manuscripts. In several indigenous communities, additional approvals may be requisite from community leaders or an Elder.

Authors working with indigenous communities are advised to consult appropriate guidelines for ethical research and publishing (including requirements for authorship) such as:

- **Communication research.** Communication scholars should be mindful of any limitations regarding using copyrighted material in their research. Authors are encouraged to seek guidance from relevant sources such as the Code of best Practices in Fair Use for Scholarly Research in Communication published by The International Communication Association.
- **Social media research.** Scholars who utilize data sourced from social media platforms such as Twitter, Facebook, and others should be mindful of national laws and ethical guidelines concerning data collection and publication.
- When researchers engage with individuals or access private information, they should secure ethical approval before commencing their study. Researchers should also ensure adequate

anonymization measures and obtain informed consent from individuals who could potentially be identified.

- It's important to note that not all data can be gathered under the umbrella of fair use or a copyright exception. Authors must review the user policy or terms of service of the social media platform in the region where the research was conducted to ascertain whether permission is required from the platform.
- Authors are encouraged to consult appropriate guidance such as the **ethics statement** and **framework** from Social Data Science Lab the **ethical guidelines for digital research** from the British Sociological Association.

Participant /patient privacy and informed consent

- **Scientia et PRAXIS Journal** supports the **recommendations of the International Committee of Medical Journal Editors (ICMJE)**, the importance of respecting the privacy rights of patients and study participants, which should not be violated unless informed consent has been obtained. Following the guidelines delineated in the **Nuremberg Code**, the **Belmont Report** and the **American Anthropological Association** , informed consent must be willingly obtained from the participant, who should receive comprehensive information about the study, including its potential benefits and risk.

Consent to participate

- In all research involving human participants, written informed consent must be obtained before the study commences.
- A statement affirming the acquisition of informed consent should be incorporated into the manuscript.
- If only verbal informed consent was secured, a comprehensive explanation for why written consent was not obtained should be provided, along with the name of the **IRB**/local ethics committee that granted approval for verbal consent. Additionally, a description of how this verbal consent was documented must be included in the manuscript.
- In cases involving non-adults, vulnerable individuals, or those unable to provide informed consent, consent must be obtained from their legal guardians or, in the case of deceased participants, from their next of kin.
- When participant data have been anonymized, this should be explicitly stated within the manuscript, accompanied by a note confirming that such modifications have not distorted the scholarly content.

Consent to publish identifiable information

- For any submissions containing potentially identifiable information about an individual, including their online alias or social media handles, authors must confirm that they have obtained written informed consent to disclose such details. This consent should be obtained from the affected individual directly or from their parents/guardians if the individual is a minor or unable to provide informed consent. In cases where the participant is deceased, consent should be obtained from their next of kin.
- Identifiable information encompasses various forms, such as written descriptions, photographs, illustrations, recordings, videos, family pedigrees, and information related to rare diseases, physical traits, or disorders. The process of securing consent for publication should involve sharing the article with the individual (or their designated representative) so that they are fully informed about the article's content before it is published.

- Consent to Publish statements should explicitly verify that the information, as well as any accompanying images, videos, recordings, etc., can be made public. Additionally, these statements should confirm that the individuals granting consent have reviewed the article's content intended for publication. Authors are encouraged to use this **Consent to Publish form**. This document should be filled out, signed, and securely stored.
- **A statement to confirm that Consent to Publish has been obtained must be included within the manuscript**.
- Authors must also state who granted consent to publish.
- Consent to publish is mandatory for the journal and cannot be waived by an ethics committee. Authors should be ready to furnish copies of signed consent forms to the journal's editorial office if requested.

Research involving animals

- Research involving vertebrates, regulated invertebrates (e.g., cephalopods), field studies, and other non-experimental animal investigations must have received approval from the appropriate institutional ethics committee or the institutional committee responsible for animal use and care. The research procedures must align with relevant national or international guidelines. In the case of field studies, authors must also secure any required permits for land access.
- In the context of experimental studies that involve animals owned by clients, authors should additionally maintain records of informed consent from the client or owner and ensure adherence to veterinary care best practices.
- Authors engaged in animal research are encouraged to refer to relevant guidelines regarding the proper care and management of laboratory animals, such as those provided by **the Guide for the Care and Use of Laboratory Animals: Eighth Edition**. In the case of research involving laboratory-based animals (vertebrates or regulated invertebrates), submitted manuscripts should encompass information about the animals' housing, care, and efforts undertaken to minimize distress. For submissions that entail the sacrifice of experimental animals, it is imperative to furnish specific information regarding humane endpoints. This includes outlining the planned behavioral observations or physiological measurements employed to establish these humane endpoints. Researchers engaged in this kind of research are recommended to refer to the guidelines provided by the **NC3Rs guide on Humane Endpoints** and **the American Veterinary Medical Association Guidelines for the Humane Slaughter of Animals**.
- Comprehensive descriptions of euthanasia or anesthesia techniques, including details about the substances employed, must be provided. These procedures should align with relevant veterinary standards, as outlined in guidelines like those found in the **American Veterinary Medical Association**
- **Authors must include a statement within the manuscript to provide details of the name of the ethics committee(s) that approved the study and include the permit or animal license numbers where available.**
- In cases where a study has been exempted from the necessity of ethical approval, authors should explicitly mention this exemption, along with the name of the ethics committee responsible for granting it, and provide the reasons for the exemption.
- **Scientia et PRAXIS Journal** also supports the ethical principles of animal research and adheres to the ethical guidelines provided by **the International Council for Laboratory Animal Science (ICLAS).**

Research involving plants

- Research involving plants, whether cultivated or found in the wild, including the gathering of plant material, should be conducted in alignment with the regulations set forth by the authors' institutions and national or international governing bodies. Field studies must adhere to local laws, and the manuscript should include a statement confirming the acquisition of necessary permissions and/or licenses.
- Specimens must be placed in a publicly accessible herbarium or another public repository that grants access to the deposited material. The manuscript should contain details about the voucher specimen and the individual responsible for its identification.

Research involving protected heritage sites

- Researchers operating within protected heritage sites must adhere to all essential ethical directives, encompassing the methods of data collection and the handling of specimens. They must also secure all required permits from the pertinent authorities for access to the sites and/or specimens before commencing their work.
- **Authors must include a statement within the manuscript to confirm that all necessary permits were obtained, and must include the name of the authority which provided it.**

Research in paleontology and archaeology

- Authors should ensure the inclusion of comprehensive details regarding their research methods and analyses, including phylogenetic aspects. Additionally, they must provide thorough information about the specimens, including quantities and repository specifics, mention the museum's name if applicable, and specify the geographic location.
- If, in accordance with national or international regulations, permits are obligatory for the research and/or the publication of the study, authors must acquire these permits from the appropriate authority. Any findings from local sites must be reported to the relevant authorities as stipulated by local regulations before submitting the manuscript.
- Authors who report on archaeological investigations involving human remains must adhere to all essential ethical standards, which encompass best practices in data collection, documentation, and deposition. They should also secure all required permits from the relevant authorities for site access and the handling of human remains before initiating their research.
- Authors are encouraged to consult the **Guidelines to the Standards for Recording Human Remains.**
- Authors should incorporate a statement in the manuscript to affirm that they have obtained all requisite permits, and this statement should include the name of the issuing authority.

Biosafety, biosecurity and emerging biotechnology

Scientia et PRAXIS Journal will solely review research that has been conducted in accordance with institutional policies on biosafety and biosecurity. These policies, in turn, should be guided by national or international recommendations.