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Last updated: January 3, 2025

Ethics Statements of Human, Organ Transplantation, and Animal Research

For research studies using humans and animals, and involving organ transplantations, ethics matter for scientific integrity, human rights and dignity, and collaboration between science and society. These principles make sure that participation in studies is voluntary, informed, and safe for research subjects. So, all manuscripts that are submitted for consideration of publication in a *Baishideng Publishing Group* (*BPG*) journal must follow our ethics policies. For all manuscripts involving human studies, organ transplantations, and animal experiments, author(s) must submit the related formal ethics documents that were reviewed and approved by their local ethical review committee. This is mandatory and is one of the determining factors for whether or not the manuscript will be sent for peer review or finally accepted. If human, organ transplantation, and animal studies received waiver of the approval requirement from the ethics committee, the author(s) must provide an official statement to this effect made by the ethics committee. The ethics policies, guidelines for manuscript type and related ethics and relevant documents/statements are as follows:

1 ETHICS POLICIES

1.1 Human research: For research studies using humans, the study's design, conduct and reporting of results must conform to Good Clinical Practice guidelines [such as the Good Clinical Practice and Clinical Trials in Food and Drug Administration (USA), the Medical Research Council Guidelines for Good Clinical Practice (UK)] and/or to the

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World Medical Association Declaration of Helsinki.

Generally, we suggest that the national standard corresponding to the lead investigator's affiliation be followed. Authors should clearly state the thorough rationale for their chosen experimental approach(es) in the Main Text of the paper. They will also need to provide a concise statement (in the Footnotes section) and accompanying proof of explicit approval given by the appropriate Institutional Review Board (IRB).

All manuscripts describing studies using human subjects that are submitted for consideration of publication in a *BPG* journal must include statement(s) that the appropriate approvals were obtained from the relevant IRB or research ethics committee. In addition, the authors must include a statement that affirms the experiments were performed with prior obtainment of informed consent (written or verbal, as appropriate) from each participant. All personal information must be anonymized prior to publication, unless a record of explicit consent from the involved patient(s) has been provided.

1.2 Organ transplantation research: All procedures and studies involving organ transplantation are required to have been carried out according to WHO Guiding Principles On Human Cell, Tissue And Organ Transplantation outlined by the World Health Organization, abided by the Declaration of Istanbul, and involved no illegal commercial transactions, the use of organs or other material from executed prisoners, or other unethical practices in obtaining donor organs.

All manuscripts involving organ transplantations that are submitted for consideration of publication in a *BPG* journal must include statement(s) of proof that the appropriate approvals were obtained from the relevant IRB or research ethics committee. In addition, the authors must provide a statement that affirms their experiments were performed with prior obtainment of informed consent (written or verbal, as appropriate) from each

participant, along with the name of the institution(s)/clinic(s)/department(s) from which the organ(s)/tissue(s) were obtained (for human organ transplantation studies). All personal information must be anonymized prior to publication, unless a record of explicit consent from the involved patient(s) has been provided.

1.3 Animal research: For research studies using animal subjects, the study's design, conduct and reporting of results must conform to code practice guidelines [such as the The Scientific Basis for Regulation of Animal Care and Use or Code of Practice for the Housing and Care of Animals Used in Scientific Procedures or EU Regulations On Animal Research].

Generally, we suggest that the national standard corresponding to the lead investigator's affiliation be followed. Authors should clearly state the thorough rationale for their chosen experimental approach(es) in the main text of the paper. They will also need to provide a concise statement (in the Footnotes section) and accompanying proof of explicit approval given by the appropriate Institutional Animal Care and Use Committee (IACUC).

In the paper itself, specifically in the Materials and Methods section (or text describing the experimental procedures), all animal studies must include statement(s) that the appropriate approvals were obtained from the relevant IACUC, and a statement that affirms all appropriate measures were taken to minimize pain or discomfort, and details of the animals' care should be provided.

2 ETHICS AND RELEVANT DOCUMENT(S) REQUIRED FOR THE DIFFERENT MANUSCRIPT TYPES

Manuscript type	Name(s) of ethics and relevant documents required	Sample

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3 ETHICS STATEMENTS

3.1 Institutional review board: Any article describing a study (basic research, clinical research) involving human and organ transplantation is required to have the IRB name, whether institutional (part of the author(s)' academic/medical institution, such as the

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Oak Grove Children's Hospital Institutional Review Board) or commercial/independent/private (contracted for-profit organizations, such as the ClinicCare Coalition for Human Rights Institutional Review Board), stated explicitly on the title page.

Sample wording: The study was reviewed and approved by the [Name of Institution or Organization] Institutional Review Board (Approval ID. [####, if available]).

3.2 Institutional animal care and use committee: Any article describing a study (basic research) involving animal subjects is required to have the Institutional Animal Care and Use Committee (IACUC)'s institution name (such as the Genovese Institute) and protocol number (such as 14-9347-39G or EN-21549) stated explicitly in the title page section.

Sample wording: All procedures involving animals were reviewed and approved by the Institutional Animal Care and Use Committee of the [Name of Institution] (IACUC protocol number: [protocol number]).

3.3 Animal care and use statement: Any manuscript describing a study (basic research) that used animal subjects must include a statement in the Materials and Methods section affirming that all appropriate measures were taken to minimize pain or discomfort, and details of the animals' care should be provided.

Example wording: The animal protocol was designed to minimize pain or discomfort to the animals. The animals were acclimatized to laboratory conditions (23 °C, 12 h/12 h light/dark, 50% humidity, *ad libitum* access to food and water) for 2 wk prior to experimentation. Intragastric gavage administration was carried out with conscious

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animals, using straight gavage needles appropriate for the animal size (15-17 g body weight: 22 gauge, 1 inch length, 1.25 mm ball diameter). All animals were euthanized by barbiturate overdose (intravenous injection, 150 mg/kg pentobarbital sodium) for tissue collection.

3.4 Organ transplantation: Any manuscript describing a study involving organ transplantations must include a statement in the Materials and Methods section affirming that their study involved no illegal commercial transactions, the use of organs or other material from executed prisoners, or other unethical practices in obtaining donor organs, and the name of the institution(s)/clinic(s)/department(s) from which the organs/tissues were obtained should be provided.

Example wording: The donor organs/tissues were obtained from [Name of Institution(s)/Clinic(s)/Department(s)]. The study involved no illegal commercial transactions, the use of organs or other material from executed prisoners, or other unethical practices in obtaining donor organs.

3.5 Clinical trial registration: Any research study (clinical trial) that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes must be registered. Authors have 6 mo from the first patient enrollment to register the trial, but BPG recommends registration prior to enrollment. This registration policy applies to prospective/randomized/controlled trials only. Authors must provide the registration identification number and the URL for the trial's registry.

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Sample wording: This study is registered at [URL]. The registration identification number is [registration identification number].

3.6 Informed consent: Any research article describing a study (clinical research and case report) involving humans and organ transplantations should contain a statement in the title page clearly stating that all involved persons (subjects or legally authorized representative) gave their informed consent (written or verbal, as appropriate) prior to study inclusion. In general, the BPG requires that any and all details that might disclose the identity of the subjects under study should be omitted or anonymized. In the rare situation that a study participant's identifiable information is crucial to the case presentation, the statement of informed consent is absolutely necessary, unless the participant is deceased.

Sample wording: All study participants, or their legal guardian, provided informed written consent prior to study enrollment.

Note: Waiver of informed consent for human study subjects may be justifiable under certain rare and specific conditions, such as for a trial with demonstrated minimal risk or cases of emergency care. Authors may petition the BPG for waiver of informed consent, but there is no guarantee that the petition will be granted. In general, the BPG favors the requirement of informed consent for all reports of information (anonymized or identifiable) and reserves the right to refuse publication of such if informed consent was not obtained.

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3.8 Data sharing statement: Basic research and clinical research studies require a data sharing statement. The data sharing statement will be provided in the title page, and will be presented in the form as shown in the sample below.

Sample wording: Technical appendix, statistical code, and dataset available from the corresponding author at [email address or URL]. Participants gave informed consent for data sharing [or ...consent was not obtained but the presented data are anonymized and risk of identification is low... or consent was not obtained but the potential benefits of sharing these data outweigh the potential harms because...]". If no other data, please state: No additional data are available.

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