Guidelines for Ethical Clearance of Research
Research Ethics Committee
Uva Wellassa University

1. Introduction

Uva Wellassa University Research Ethics Committee (UWU-REC) is the committee which was established to review the ethics of research involving human participants, tissue and data relevant, and both domestic and wild animals used in research activities. Depending on the requirements and situations, plants, their products and environmental aspects are also concerned.

The purpose of the UWU-REC is to safeguard the dignity, rights, safety and wellbeing of all actual or potential research participants and ensure that animals, if used for research, are treated humanely. The UWU-REC ensures the full review and evaluation of all ethical aspects of the research proposals it receives before they are carried out to make sure they follow ethical guidelines.

The UWU-REC has the authority to demand research protocol modifications, enforce and monitor all informed consent or patients' rights issues and to suspend or stop any research that present problems. The UWU-REC serves as the conscience of the scientific research community of the university and other relevant parties and the protector of the human (or animal) participants.

The UWU-REC expects to provide independent, competent and timely review of the ethics of the proposed studies. The UWU-REC is responsible for acting in the interests of potential research participants and the concerned communities, taking into account the interests and needs of the researchers, and having due regard for the requirements of relevant regulatory agencies and applicable laws. The "Procedure for Review of Ethical Issues in Research" is given by the Figure 01.

2. Terms of Reference

The UWU-REC, in principle, expects to involve in following activities. Accordingly, the UWU-REC;

(a) considers written applications and provides independent ethics review of research, as specified;
(b) enforces high ethical standards on research undertaken on human and animal participants;
(c) protects the interests of researchers who are conducting research following the approved protocols/proposals;
(d) monitors the approved research project to ensure ethical compliance;
(e) be available to researchers for consultation on ethical issues;
(f) develops standard operating procedures (SOP) for ethics review and ethical conduct of research in the given fields, if needed, within the limits of national/international guidelines;
(g) conducts and promotes education and training in research ethics for applicable researchers and others;

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Note: It is the responsibility of the person who is leading the Research Project to consider the possible ethical implications.

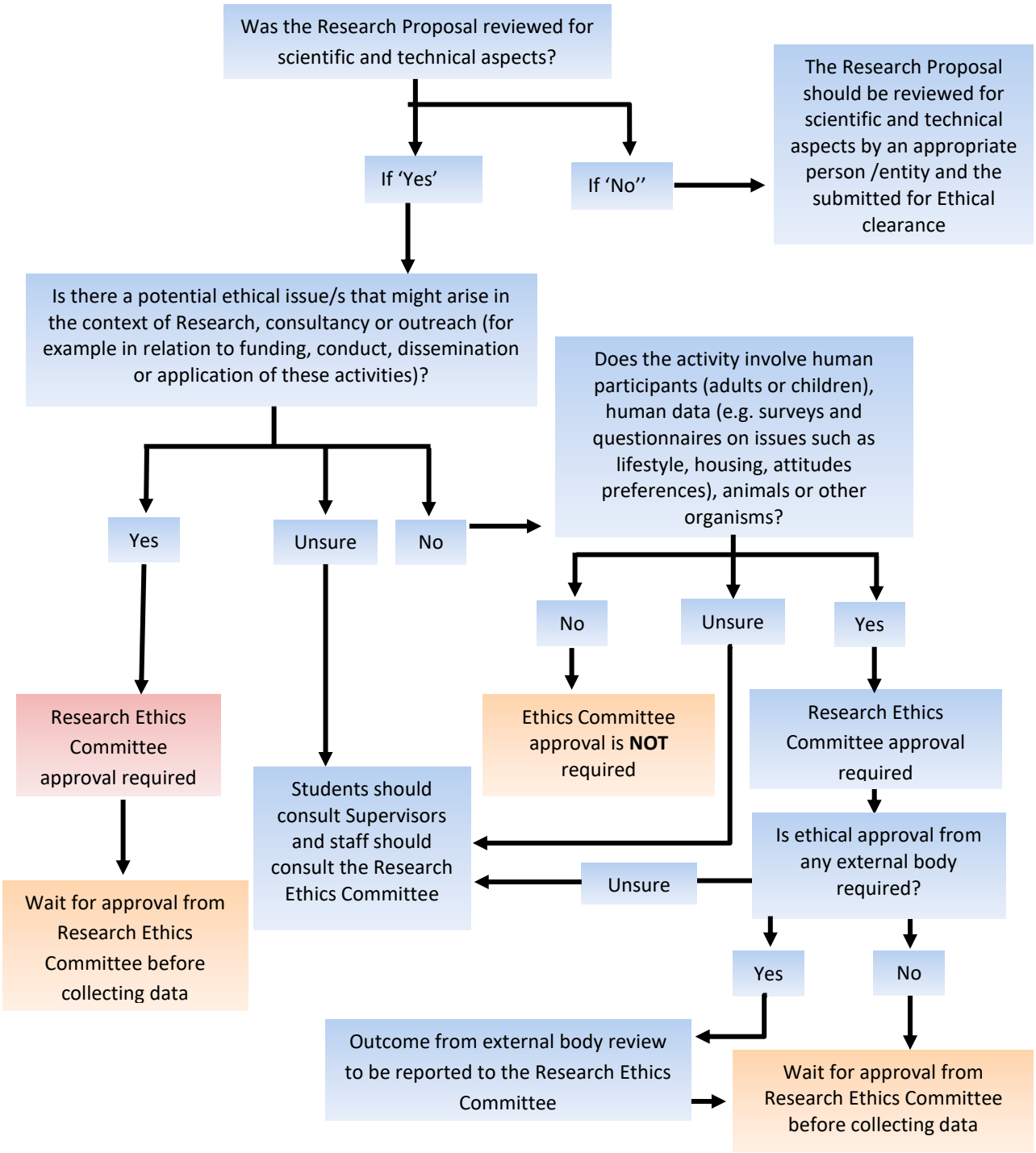

Figure 01: Procedure for Review of Ethical Issues in Research, Uva Wellassa University

(h) educates and trains research ethics committee members and potential reviewers to ensure the quality and consistency of ethics review and/or sensitisation of staff and students in research ethics;
(i) liaises with other Ethics Review Committees in matters of common interest;
(j) informs relevant government agencies of matters that may have policy implications that come to their notice during ethics review;
(k) promotes community awareness and consults with individuals, communities and government on ethics issues relating to research on human subjects;
(l) keeps abreast with international developments in relation to health and ethics issues and liaises with relevant international organisations and individuals.

3. Appointment, Composition and Disciplines of UWU-REC

Appointment

The membership of the UWU-REC is formed representing the following where Chairman/Chairperson and the Secretary will be appointed by the Vice Chancellor on the recommendation of the Research Committee of Uva Wellassa University for a period of three (03) years.

Composition

(a) Chairman/Chairperson
(b) All Deans (*Ex-Officio*)
(c) Research Experts representing the fields, as given below
(d) One Senior Academic Staff member representing each Degree Programme
(e) A Representative/Ministry of Health
(f) A Representative/Ministry of Agriculture
(g) A Representative/Ministry of Livestock Production

Number of Disciplines

Basically, expertise personnel for the UWU-REC are appointed representing following disciplines. However, additional members may be appointed depending on new requirements, if any, on the recommendation of the Research Committee and approval of the Senate of Uva Wellassa University.

(a) Medical Science
(b) Environmental Science
(c) Animal Science
(d) Socio-economic and Humanities Perspectives
(e) Psychology

4. Ethics Reviewing Process

Any proposed research should be scientifically sound if it is to be ethically acceptable. Therefore, it is essential to have a Scientific Review Committee previously reviewed the proposal and find it scientifically valid.

Under UWU context, the research proposals recommended by the Research Committee, having undergone reviewing according to the guidelines provided, will be considered. For the outside proposals, recommendation of a given and acceptable Scientific Review Committee/Authority for the scientific validity is required.

A proof/evidence should be accompanied with the application package to convince the UWU-REC that the given proposal has been already evaluated for its scientifically validity.

However, where there is no such separate review, UWU-REC will consider scientific value and validity (justification, methodology, proposed analytical methods, etc.) as well as ethical issues. In this situation, the applicant should provide a justification for not evaluating the scientific validity of the submitted proposal.

Submitting Application for Ethical Clearance

Principle Investigator (PI), deemed by the UWU-REC to be suitably qualified and experienced to be responsible for the ethical and scientific conduct of the research, should apply for ethics review of the proposed research on a prescribed application form with all relevant information required by the UWU-REC to reach a decision.

Dully completed application together with all other documents (see the Check List) should be submitted to the **Chairman, Research Ethics Committee, Uva Wellassa University** through proper channel.

Three (03) applications are required together with a Covering Letter. Applications can be handed over physically and also can be sent by post (external applicants).

General Considerations

The UWU-REC aligns with relevant and appropriate to the ethical principles of research, taking into consideration the basic ethical principles of respect for persons, beneficence, non-maleficence and justice, without compromising the scientific merit and quality of research.

Relevance for Ethics Review

Any research involving human participants, tissue, data, or animals should undergo ethics review before commencement. All research that involves the use of animals should undergo ethics review to ensure that animals are humanely treated. Depending on the requirements and situations, plants, their products and environmental aspects are also concerned.

Research requiring ethics review can be considered under two heads.

(a) Research that is non-intrusive or non-invasive: such research involves making observations only without any direct interference. Such studies are entitled for waiver of the requirement for obtaining informed consent but ethics review is essential.

(b) Research that is intrusive or invasive: such research involves physical invasion (such as use of diagnostic or therapeutic products, vaccines, and venepuncture), psychological intrusion, invasion of privacy, etc. Such studies require both informed consent and ethics review.

Exemption from Review

Ethics review is not required for studies that amount to quality control, method validation, or medical audit provided that the results are not made available in a form that identifies the participants from whom the information was obtained.

Use of personal medical records without approaching or involving the patients concerned is, in principle, ethically acceptable provided confidentiality and anonymity are preserved. Such

studies are entitled for waiver of the requirement for obtaining informed consent, but ethics review is essential.

International Collaborations

In the case of a collaborative research project involving one or more foreign institutions, ethical approval shall be sought both from UWU-REC where the research will be carried out and from the Institutional Review Board (IRB) or equivalent of the collaborating institutions.

Assigning Reviewers

The UWU-REC appoints three (03) reviewers, including one UWU-REC member, considering the discipline of the research proposal. Two (02) weeks-time period is given for evaluating the proposal and the reviewers have to convey their decision to the UWU-REC, as per the format in the application form.

Granting Ethical Clearance

Once the reviewers' reports are received to the UWU-REC, decision on the given proposal is taken by 2/3 basis at its subsequent meeting. A decision made as to whether the proposal meets the required ethical standards; needs to be further clarified or revised; or is rejected. Accordingly, the decision can be one of the followings and it is communicated in writing under the signature of the UWU-REC Secretary.

(a) Positive Decision: In the case of a positive decision a statement of the responsibilities of the applicant is communicated.

(b) Conditional Decision: In the case of a conditional decision, i.e. where ethics clearance is not granted for the original proposal but a revised proposal would be accepted for consideration, any requirements stipulated by the UWU-REC including suggestions for revisions and the procedure for re-reviewing the application is communicated to the researcher. Two (02) weeks time period is provided for replying by the applicant.

(c) Negative Decision: In the case of a negative decision a clear statement of the reason(s) for the negative decision is communicated to the researcher including whether it may be submitted as a new proposal with appropriate changes. However, the applicant has right to appeal providing justifiable reasons, if any. Under such a situation, the UWU-REC will have the authority to initiate procedure for re-review under new reviewers if the provided reasons are considerable.

5. Ethics Issues for Consideration by Researchers

(a) Informed consent: Informed consent is a voluntary decision taken by an individual to participate in research and is essential for all research involving human participants, tissue and data. The principal investigator has responsibility to obtain voluntary informed consent - (preferably) written - from all prospective participants or in the case of individuals who are not capable of giving informed consent, the permission of their guardians.

(b) Ethical justification and scientific validity: Research involving human participants, including research with identifiable human tissue and data, is considered justified and valid only when the design of the research is scientifically sound and the PI and the other research personnel are competent. The methods to be used should be appropriate to the objectives of the research and the field of study. It should include a thorough

knowledge of the scientific literature and other relevant sources of information. These should be adequately reflected in the research proposal submitted for review and approval to the UWU-REC.

(c) Compromised capacity for giving informed consent: Certain individuals or groups may have limited capacity to give informed consent either because they have limited cognitive capacity or because they have limited autonomy. In this situation, the risk of an intervention should not exceed those associated with routine medical or psychological examination of such persons. A small increase above such risk may be permitted by the UWU-REC, but only when there is an overriding scientific or medical rationale for such increase.

(d) Benefit and risks to study participants: The investigator must ensure that risks are minimised and any anticipated risks are reasonably balanced against the potential benefits in all research involving human participants.

(e) Research participants from populations and communities in which resources are limited: It is unethical to conduct research in a country or community if there is good reason to believe that a product developed or knowledge generated as a result is unlikely to be made generally available or applied for the benefit of the population of that country or community.

(f) Equitable distribution of burdens and benefits in the selection of participants/groups: Groups/communities to be invited to participate in research should be selected in such a way that the burdens and benefits of research will be equitably distributed.

(g) Research involving children: Before undertaking research involving children the investigators must ensure that: the research might not equally well be carried out with adults; the purpose of the research is to obtain knowledge relevant to the health needs of children; a parent or guardian has given permission; the consent of each child has been obtained after the child has been informed to the extent that the child's maturity and intelligence permits; a child's refusal to participate or continue in research will be respected; the research is conducted in a setting in which the child and parent can obtain adequate medical and psychological support; and the parent or guardian is given the opportunity to observe the research as it proceeds, so as to be able to withdraw the child if they decide that it is in the child's best interest to do so.

(h) Research involving pregnant women: Before undertaking research on pregnant women the investigators must ensure that: prospective participants are adequately informed about the risks and benefits to themselves, their pregnancies, the foetus and their subsequent offspring and their fertility; the purpose of the research is to obtain knowledge relevant to the particular health needs of pregnant women, their foetuses or to the health needs of pregnant women in general; and where appropriate, such research is supported by reliable evidence from animal experiments regarding risks of teratogenicity and mutagenicity.

(i) Safeguarding confidentiality: The investigator must establish secure safeguards to ensure the confidentiality of participants' research data.

(j) Right of compensation: Investigators should ensure that research participants who suffer accidental injury as a result of procedures or interventions performed exclusively to accomplish the purpose of research are entitled to free medical treatment for such injury as well as financial or other assistance.

6. Research Ethics Committee Meetings

(a) Conduct of Meetings

Meetings of the UWU-REC is held monthly basis, depending on the proposals submitted for ethical clearance and matters to be brought to the discussion; otherwise, the frequency of meetings is decided, as per the need.

Meetings are formal, presided over by the Chairman/Chairperson (or a senior member if the Chairman is absent), and with minutes of the previous meeting confirmed and time provided for other matters to be discussed. The Secretary has the responsibility of recording minutes and other relevant activities related to meetings conductance and communications.

(b) Operational Details

- Appointments to the Committee which are not ex-officio will be for up to 3 years
- Reporting line – through Research Committee to the Senate
- Quorum for business items – (~1/3) rounded up to the next whole number of the total actual membership
- Quorum for research ethics applications – (~1/3) of the whole number of the total actual membership, including at least one external member
- Frequency of meetings - as required normally 6 times a year
- Decisions on business items can be taken by correspondence, virtual meetings and/or emails provided at least 30% rounded up to the next whole number of the total actual membership.
- Decisions on research ethics applications can be taken by correspondence, virtual meetings and/or emails provided at least 10 members (~1/3) of the whole number of the total actual membership, including at least one external member take part in the decision

Under Exceptional Circumstances of Urgency

The Chairman/Chairperson of the UWU-REC in consultation with another two members may give expedited approval, always reporting these approvals to the next meeting of the committee (e.g. a patient with some rare or ill understood condition, epidemics, etc.). Wherever there is doubt, an application should go to the full committee.

7. Elements of the Review Process

The UWU-REC reviews ethical issues only if the research is of good scientific quality. The framework below is proposed to ensure quality and consistency of the ethics review process relevant to any of the disciplines, as applied:

(a) Social or Scientific Value: To be ethical, the research must be valuable. The UWU-REC ensures that there is a plan whereby results of scientific value will be disseminated.

(b) Scientific Validity: To be ethically acceptable, research must be conducted in a methodologically rigorous manner. Scientifically unsound research in human participants is ipso facto unethical, in that it may expose participants to risks or inconvenience to no purpose.

(c) Fair Participant Selection: The recruitment protocol should ensure fair participant selection. Selection of participants should be carried out so that stigmatised and vulnerable groups such as those who are socially disadvantaged or those who have limited autonomy are not targeted for risky research and the rich and socially powerful are not favoured for potential research benefits.

(d) Favourable Risk/Benefit Ratio: Within the context of standard clinical practice and research protocol, risks must be minimised, potential benefits enhanced and the potential benefits to the individuals and knowledge gained for society must outweigh risk.

(e) Informed Consent Process: Participants should be informed about the research and should provide their voluntary consent. Consent on behalf of those with compromised capacity to consent should be obtained from parents, guardians or next of kin as the case may be.

(f) Respect for Potential and Enrolled Participants and Communities: Research participants should have their privacy protected and their wellbeing monitored.

8. Conflict of Interest

Conflict of interest is present and interferes with ability to make an objective evaluation when UWU-REC members are investigators in the research proposals to be reviewed or, for example, when a member is an advisor to a company whose product is being tested. In such an instance the member/s should disclose conflict of interest and refrain from participating in the review process.

Other than that, the applicants have the freedom to mention about any reviewer/s who should not be used for reviewing their proposals due to any conflict of interest.

9. Notification

The UWU-REC makes provision to require researchers to keep the committees informed of:

(a) all cases of protocol amendments (other than amendments involving only logistical or administrative aspects of the study);

(b) all cases of amendments to the recruitment material (research participant information sheets or the informed consent forms);

(c) serious and unexpected adverse events related to the conduct of the study, for example adverse effects of drugs, and the response taken by the investigator; and

(d) any new information that may affect the risk/benefit ratio of the study.

10. Documentation and Archiving

All working procedures are recoded in writing. The UWU-REC makes provision for archiving all material relating to its work for a minimum five years from the date of granting approval.

The material to be archived includes, but does not be limited to: the agendas of UWU-REC meetings; the minutes of UWU-REC meetings; one copy of all material submitted by applicants; correspondence by UWU-REC with applicants or concerned parties regarding applications, decisions, and follow-up; a copy of the decisions and any advice or requirements sent to applicants; all correspondence and other material received during the follow-up; UWU-REC membership; UWU-REC standard operating procedures (Guidelines); records on income and expenditure, if any; and - annual reports, if any.

11. Ethical Clearance Fee

Ethical clearance fee of Rs. 5000.00 is applied to the applications which are submitted by external parties for obtaining the service of the UWU-REC. However, the fee is waived for external undergraduate/postgraduate students when they do not have a financial support for their research work. In such a case, evidence should be provided for justifying the situation.

12. Specific Guidelines Related to Animal Research Ethics

It applies to any research work that involves animals, including research on live animals, or animal products or parts (i.e. tissues, cells, organs, embryonated eggs, secretions, etc.). All types of animals such as Livestock and Companion Animals (except Wild Animals) are considered here. Applicants are advised to follow the details given below issued by the Guidelines for Ethics Review of Research Proposals Involving Animals in Sri Lanka (2009) of Forum of Ethics Review Committees, Sri Lanka.

(a) Experimental Procedure - Pain and Discomfort

- The research team personnel must treat the animals with kindness, respect and great care, understanding that the animals have sufficient organization to have their own basic drives, desires, and intentions and by this research we interfere with their effort to fulfil their destinies.

- When granting ethics clearance;

  The study must be conducted in a manner which would avoid discomfort, pain, illness and trauma to animals. If this is unavoidable, the discomfort and pain must be minimized with the assumption that procedures that would produce pain in humans will also do so in other animals. Therefore, alternative methodological and procedural techniques, which avoid or minimize illness, pain, trauma and discomfort, have to be considered always.

  Procedures which cause pain, stress, privation or death should be used only when an acceptable alternative procedure is unavailable.

  Procedures involving more than momentary pain or slight aversive stimulation, which cannot be relieved by medication or other acceptable methods, can be undertaken only when the objectives of the research cannot be achieved by any other method. These will be performed with appropriate pain management (including sedation, analgesia or anaesthesia - relevant to the species, etc.) compatible with the goal of the research.

  Research studies which require prolonged aversive conditions or produce tissue damage or metabolic or psychological disturbances are strongly discouraged. These include prolonged exposure to extreme environmental conditions, experimentally induced prey killing, or infliction of physical trauma or tissue damage, etc.

  When conducting a study, which is intentionally designed to examine aversive conditions with greater justification, the parameters of stimulation of pain should be optimized to minimise pain, without affecting the objective(s) of the research.

- If a researcher detects signs of pain on experimental animals, which were not anticipated, he/she should immediately inform the UWU-REC for necessary guidance.

(b) Surgery and Anaesthesia

- Any surgical procedures on and anaesthetization of large animals should be conducted only by a veterinarian. Approval may be given for others who are scientifically qualified and

trained to do so, under the direct supervision of an attending veterinarian.

- Multiple surgical procedures on the same animals are strongly discouraged. However, approval may be given with valid scientific justification considering the nature of the research, the nature of the surgery and the wellbeing of the animal.

- Description of pre-surgical planning and evaluation procedures (including the individual responsibilities of the members of the surgical team according to their level of competence), surgical technique(s) and equipment to be used have to be incorporated in the proposal. Proper aseptic methods must be used.

- Special considerations regarding anaesthetic agents.

  Best suited anaesthetic methods should be selected appropriate to the species, clinical and humane aspects and research needs.

  Procedures involving the use of paralytic agents without reduction in pain sensation should be avoided as far as possible.

  Use of muscle relaxants or paralytics alone during surgery, without general anaesthesia, is unacceptable and is to be avoided.

  Studies of pain on animals paralyzed with a neuromuscular blocking agent cannot be carried out without a general anaesthetic or an appropriate surgical procedure that eliminate sensory awareness.

- When the surgical procedure is likely to cause greater discomfort beyond the provided analgesia/anaesthesia, and unless there is a specific justification not to do so, animals should be maintained under general anaesthesia during the whole surgical procedure.

- Proper postoperative monitoring and care, in addition to food and housing, analgesics and antibiotics should be provided (if necessary) to animals in order to minimize discomfort and pain and to prevent infection and other undesirable consequences.

(c) Animal House/Facility and Research Environment

A structurally well designed animal house/facility in keeping with current international standards should be available to ensure welfare of animals and of the research team and to ensure good quality research.

- Animals have to be provided with adequate quantity of palatable, uncontaminated and nutritionally balanced food and uncontaminated drinking water to provide for their daily requirements and in keeping with research goals. In addition attention should be paid to providing sufficient number of containers for food and water to the animal house/facility and on their filling, refilling and cleaning and their arrangement within the animal house/facility taking into consideration the eating habits of the animals.

- The food for all animals (unless it is required and ethical approval obtained) should be free from medicines, antibiotics, etc. and should be given according to a time table.

- The animal house/facility must contain sufficient space, ventilation, proper instrumentation and mechanisms for noise management to ensure that animals are provided with humane care and health conditions during the research, and may have the service of a veterinarian.

- The animal house/facility has to be cleaned regularly to maintain animal and human hygiene.

- Records of the animal house/facility should be maintained to ensure that it has been inspected by an officer designated by the authorities under who the animal house/facility is maintained, on a regular basis.

(d) Acquisition of Animals – Law and Rights

- All animals, which are not bred in the same animal house/animal facility, must be acquired lawfully. Sourcing and identification of animals must be transparent.

- During the course of research involving animals, the person in charge (if applicable) of an animal has the liberty to bring the experiment to an end at any point if he/she believes that continuation of the experiment is harmful.

- The use of wild animals for research purpose needs justification and permission from the Department of Wildlife Conservation.

- Animals to be captured from the wild should be trapped in a humane manner.

- The retention and use of animals shall in every case in compliance with laws that are in effect at that time.

(e) Post Research Procedures

- The research should be terminated when, the goal is reached or continuation will result in injury or suffering to the animals.

- When the use of an animal is no longer required by an experimental protocol or procedure alternative uses of the animals should be considered. Such uses should be compatible with the welfare of the animal.

- If death occurs, the carcass has to be disposed in an acceptable way considering relevant legislation, health issues, environmental, and aesthetic concerns.

- Animals caught from the wild that do not carry substantial risk to them and to the ecosystem may be released at the point of capture based on the recommendation of the Department of Wildlife Conservation.

- Animals bred and reared in the laboratory should not be released.

(f) Transportation of Animals

- Acquired animals should be transported in a humane way by providing sufficient food, water, ventilation, space and facilities to prevent unnecessary discomfort and pain to the animals, according to the species, breed, caging/housing needs, mode of transport and climatic conditions, etc.

- Other factors to be considered:
    a. Optimize transit time to include or to ensure rest for animals
    b. Health certificate should be obtained at the point of transportation and destination (if healthy animals are used)
    c. Quarantine procedures and Convention on International Trade in Endangered Species of Wildlife Fauna and Flora (CITES) must be strictly adhered to if animals are brought into the country.
    d. Newly received animals must be allowed time to stabilize and acclimatize.
    e. Certificate of transportation should be obtained from relevant authorities.

(g) Euthanasia

- If the study requires the death of an animal or painful or stressful outcome or irreparable injury is anticipated at the conclusion of the research the most humane, reliable and safe euthanasia method (appropriate for the species to ensure immediate death) consistent with the study must be used.

- Euthanasia must be carried out quickly and painlessly in an environment, in which the animal is free from fear and anxiety, under the supervision of an attending veterinarian where appropriate.

- Any animal that is subjected to procedures in which the animal is anaesthetized and made insensitive to pain throughout the experiment must be euthanized before regaining consciousness.

- Any animal observed to be in a state of severe distress or chronic pain that cannot be relieved should be euthanised immediately.

- No large animal shall be discarded until its clinical death is confirmed by a veterinarian.

- Euthanasia should be performed in a separate location in the animal house/facility.

(h) Field Research

- Any field research should not disturb human or animal populations, sensitive ecosystems and normal interactions between populations in the community. Every effort should be made to minimize potential harmful effects of the study on the populations and on other plant and animal species in the area.

- Research conducted in populated areas should be done with respect for the property and privacy of the inhabitants of the area.

(i) Animals used for Routine Diagnostic Work and Vaccine Production

- A certificate of ethics conformity should be obtained from a suitable authority by all laboratories and organisations with respect to the use and treatment of animals used by them for routine diagnostic work or vaccine production; such certificates should be renewed annually.

- Such laboratories and organisations should follow the standards of animal care contained in this document as well as any specific directives given by the UWU-REC as a condition upon which the certificate is issued.

14. Specific Concerns Related to Wildlife Research Ethics

Research on wildlife, in the field and in the laboratory, is carried out using a range of techniques, from the purely observational to more intrusive studies, including handling, tagging, killing and collection of individual plants and animals for scientific studies. There is now a growing recognition that even in research that is likely to benefit the species under study, such as conservation biology research, the individual organisms subject to research affected in many ways etc. This raises many ethical issues related to justification for the research and appropriate welfare standards for the individuals concerned. If concerns of animal welfare need to be integrated, not overlooked, in wildlife research and conservation a number of questions arise that deserve better consideration.

- Is having a valuable research question sufficient to justify the use of methods that may cause pain, harm, and suffering to individuals?

- Are having required legal permits for lethal collection of animal or plant specimens' sufficient to endorse and carry out the related research?

- When and where do ethical issues arise, and how can we take them into proper consideration?

- What are the roles that individual researchers, their peers, institutions, and ethics review committee play?

Wildlife Research Ethics Related to Plants and Habitats

A key component of wildlife research is the study of plants and habitats, such as vegetation surveys, floristic inventories and studies, habitat assessments, regeneration and restoration, habitat manipulation and experimental studies. As in studies of animals, these may range from purely observational or documentation studies, to research that may involve use of standard methods of plot or plot-less sampling designs, tagging, marking, and measuring, collecting of soil, plant, tissue samples and specimens, and experimental interventions such as use of fire, invasive removal, and other such research.

UWU-REC believes that well-designed research and conservation interventions in all such areas involving plants and its habitats, including experimental studies and restoration, are valuable for science, conservation, and communities. Such research and conservation efforts can also be carried out in an ethically informed and appropriate manner, under the 4Rs framework (Replacement, Reduction, Refinement and Refusal) as applied to plants and habitats. In addition, considerations of human participants may apply in the case of projects that may involve plant or habitat resources that are shared or used by local communities.

Wildlife Research Ethics Related to Wild Animals

Wildlife research is taken to include research on free ranging and captive wild animals, all introduced and indigenous species and feral domestic animals, and their habitats. This type of research includes studies that focus on different levels of organization from individual animals (including molecular studies) to ecosystems.

4Rs Principles

The principles of the 4Rs had been developed as a framework for humane animal and plant-based research. They have subsequently become embedded in national and international legislation regulating the use of animals and plant in scientific procedures. The need to improve the design, conduct and analysis of research using animals is also gathering momentum, with greater emphasis from the scientific community on minimising use and improving animal welfare. Knowledge about animals' physical and behavioural requirements is expanding rapidly and translating this into practical information is critical to minimise pain and suffering as well as ensuring the robustness and reproducibility of the experiments they are used for. The 4Rs provide a framework for examining how decisions should be made about animals in science, especially in the face of increasing use of animals in fundamental and applied research.

(a) Replacement

Methods that avoid or replace the use of animals in a study or experiment where they would have otherwise been used. Replacement may include the use of mathematical and computer models, non-invasive samples, archived tissues and tissue cultures, use of natural experiments, using photographic and multi-media recording as alternative to specimen collection for rare and endangered species.

(b) Reduction

Methods that minimise the number of animals used per experiment or study, either by enabling researchers to obtain comparable levels of information from fewer animals, or to obtain more information from the same number of animals, thereby avoiding further animal use. Examples include improved experimental design and statistical analysis, sharing data and resources (e.g. animals, specimens, and equipment) between research groups, museums, and organisations, and the use of technologies, such as imaging, to enable longitudinal studies in the same animals.

(c) Refinement

Methods that minimise the pain, suffering, distress or lasting harm that may be experienced by the animals. Refinement applies to all aspects of animal use, from the housing and husbandry used to the scientific procedures performed on them. Examples of refinement include, using appropriate anaesthetics and analgesics, choice of better and lighter tags, less obtrusive observation methods, minimal habituation to humans, minimising or avoiding stress by training animals to cooperate with procedures such as blood sampling, and providing animals retained in captivity with appropriate housing that allows the expression of species-specific behaviours.

(d) Refusal

Reject the use of methods that are considered to be inhumane and unethical based on the best extant knowledge, even if it involves the inability to answer the research question(s) at the present time. Rejection is likely to apply to a number of situations ranging from biomedical research and cosmetics testing on animal species such as chimpanzees, unwarranted lethal collection of specimens, particularly critically endangered species at high risk from any further population depletion, using methods that cause irredeemable pain and suffering, methods or interventions that involve discrimination or violation of basic human rights, use of force on local human communities etc.

15. Conditions Applied related to Research Ethics Clearance granted by UWU-REC

The approval given by the UWU-REC is only for the purpose of conducting the research, as per the research proposal originally submitted for obtaining research ethics clearance. Thus, the proposed study should be in accordance with the guidelines/conditions stated in the letter of approval issued by the UWU-REC. This approval should not be used or interpreted as a “Regulatory Approval” for commercialization of any product developed from the proposed study, without further approval from the UWU-REC.

16. Acknowledgement for Ethical Clearance

Publications facilitated by Ethical Clearance granted by Uva Wellassa University should acknowledge the Research Ethics Committee of Uva Wellassa University and accordingly, following statement shall be suggested to be included in the acknowledgement by adapting the changes, as appropriate, (i.e. year and the Ethical Clearance number). The second sentence should be included, only if it is appropriate to the study specified.

"**Ethical clearance for the present research was granted by Uva Wellassa University of Sri Lanka under UWU/REC/2021/001 and the authors acknowledge the Research Ethics Committee of Uva Wellassa University for the service provided. The participants gave informed consent before taking part in the research**".

References

1. Ethics Review Committee Guidelines (2007). A guide for developing standard operating procedures for committees that review biomedical research proposals. Forum of Ethics Review Commitees, Sri Lanka. p78.
2. Guidelines for Ethics Review of Research Proposals Involving Animals in Sri Lanka (2009). Forum of Ethics Review Committees, Sri Lanka. p.49.
3. Research Policy, Uva Wellassa University of Sri Lanka. p75.