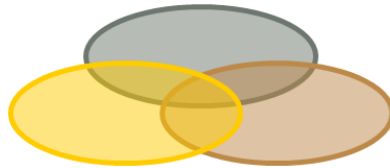


POLICY AND PROCEDURES FOR RESEARCH ETHICS APPROVAL AND PLAGIARISM POLICY

Without ethical culture, there is no salvation for humanity.

-Albert Einstein



A/2, Jahurul Islam Avenue | Jahurul Islam City | Aftabnagar | Dhaka-1212 | Bangladesh

[The following documents and appendices have been composed from various sources. Professor M. M. Shahidul Hassan contributed the introductory section. The Appendices were contributed by other members of the committee; they include, Professor Chowdhury Faiz Hossain, Dr. Farhana Ferdousi, Dr. Md. Mahatab Uddin, Dr. Reatul Karim and Dr. Suraia Nusrin. Professor Fakrul Alam coordinated the work of the committee and edited the document.]

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1. Introduction: Research Integrity and Preventing Academic Misconduct

The objective of East West University (EWU) is not only to provide high quality comprehensive educational and career enhancing training that are compatible with the changing times and the demands of the marketplace, but also to make use of, and to encourage a wide range of research with which staff members and students can engage. Research integrity and preventing misconduct must be at the core of high quality research and good science. All research work at EWU should adhere to the highest ethical standards; any research work carried out at EWU which has significant ethical implications will have to be submitted for independent ethical review. In any research study involving people, their data, or tissue, the dignity, rights, safety and well-being of participants must also be significant considerations. Research involving animals, pathogens and genetically engineered microorganisms should also go through a sustained and intensive review process.

Ethical scrutiny in all such cases will be essential. Such scrutiny is intended to assist in protecting research participants from harm, but a further important consideration is that the researcher is facilitated and supported in carrying out research which has the potential to be of benefit for society. In other words, the scrutiny must be carried out efficiently, and according to the highest possible professional and ethical standards.

Another and related ethical concern is to ensure originality and to prevent plagiarism in academic work. To these end, faculty members as well as students will have to familiarize themselves with the plagiarism policy of the university and learn how not to get involved in any kind of practice that makes them vulnerable to charges of academic dishonesty and misconduct.

The guidelines given in this document describe the overall principles and procedures by which the University will make ethical judgments on research investigations that involve human beings as participants or animals, pathogens and genetically engineered microorganisms, and judge cases brought before it of plagiarism and academic dishonesty. In applying these principles, a balance has to be found. On the one hand, the University requires that appropriate safeguards are in place, but on the other, and of course, it does not want to impose unnecessary regulatory barriers that would prevent research from taking place.

Finally, this document comes with appendices and templates that can be used by faculty members and students when research work is to be carried out or writing produced that need to conform to the highest ethical standards.

2. EWUREC and Forms of Ethical Review

2.1 Research projects that will need the approval of the East West Research Ethics Committee (EWUREC) include the following:

- i) Research involving human participants, their personal data and tissues collected,
- ii) Research that poses a reputation risk to the University or its researchers,
- iii) Externally funded research that need to meet the standards expected of funding agencies,
- iv) Evaluation studies involving human participants,
- v) Research which does not involve human participants but which is high risk, or which has the potential for negative effects on the environment or on society,

- vi) Research that involves experimentation on animals,
- vii) Research involving tissues from protected animals obtained from a third party who must ensure that the material was obtained legally and ethically before transferring any materials to EWU.
- viii) Research involving pathogens and other microbes that may severely impact on nature or could be harmful for individuals.
- ix) Research involving genetically engineered microorganisms that may affect the environment.

2:2 Ethical Review and Documentation in Cases of Plagiarism

Research projects will need to have requisite documentation and acknowledgement when they involve;

- i) Use of published or unpublished sources that need to be acknowledged,
- ii) Use of copyright materials,
- iii) Interaction with human participants from outside the university who have been interviewed and quoted, and whose ideas have been sought and used in the writing

2: 3 Ethics of Student Research

Student research is expected to meet the same ethical standards as research conducted by staff members but is proportionate to the level of risk of the project.

2:4 Light Touch Reviews

- i. “Light touch” reviews may be conducted when the potential of the research to cause harm to participants and others and to the environment are not deemed significant or high risk.
- ii. Researches that do not involve direct participation of living human persons may also be eligible for light touch reviews, unless they significantly affect living persons or the environment.

2:5 Exclusion of Ethics Review

Ethics review is generally not required for projects/researchers that do not involve human or living animal subjects or handle sensitive materials, and for those that draw on published and unpublished material already in the public domain and out of copyright. Such review is also not necessary where the people involved do not contribute to the actual findings. Nevertheless, acknowledgement is an act of courtesy even in such cases.

3. Principles and Procedures for Obtaining Ethical Approval

For all research projects covered by this guideline, approval must be given by the EWU Ethics Committee before work commence. The primary task of the Research Ethics Committee lies in the ethical review of research proposals and their supporting documents, with special attention given to the nature of any intervention and its safety and protection for participants and researchers, to informed consent processes and documentations, and to the suitability and feasibility of the proposal.

A decision by the EWUREC to give ethical approval to a research project does not imply an expert assessment of all possible ethical issues, or of all possible dangers or risks involved; nor does it detract in any way from the ultimate responsibility which researchers must themselves have for all research which they carry out, and for its effects on human participants.

The committee will address ethical matters information supplied by the researcher. Any Information submitted is expected to be properly researched, full, truthful and accurate.

Any decision to change the University's policies or procedures for ethical review of research does not imply that previous policies or procedures were inappropriate and any such changes do not invalidate ethical approval that has been given.

The following is a step-by-step guide to the procedures to be followed:

- i. Submission of Ethical Application Form and other application paper work (e.g. consent form and participant information sheet, consent of chair of department) to Member Secretary. (see appendices)
- ii. The EWUREC shall make decisions at scheduled meetings at which a quorum is present (see 5.0); regularly scheduled meeting dates shall be announced in advance.
- iii. In order to respond to applications within 8 weeks, applications can be considered between meetings but the Chair is responsible for ensuring that an appropriate level of scrutiny informs the decision.
- iv. Any decision made by the Chair should be on the basis of detailed scrutiny by at least two members of the Committee. The decision will be reported to the next available meeting of the Committee for ratification.
- v. In certain circumstances a 'light touch review' of ethics applications may be appropriate; this means that the EWUREC Chair may approve the project without sending the application for further scrutiny. The Chair's decision will require ratification by the EWUREC at its next meeting.
- vi. In respect of a proposal being put forward by a member of the Reviewing Committee, those involved in the research submission should withdraw from the meeting while the submission is being considered.
- vii. Observers, who should play no part in the Committee's deliberations, may be invited, subject to the prior agreement of members. Observers should be allowed only if they accept in writing the same duty of confidentiality as the Committee members.
- viii. Meetings shall be minuted and there shall be an approval procedure for the minutes.
- ix. EWUREC members shall keep a register of all proposals that come before them. The registers shall form the basis of EWUREC's annual report.
- x. EWUREC should always be able to demonstrate that they have acted responsibly in reaching a particular decision. When EWUREC rejects research proposals, the reasons for that decision shall be made available to the applicants and, where appropriate, opportunities for resubmission provided. Where approved, the basis for that decision should be recorded.
- xi. The EWUREC shall consider valid applications in a timely manner. A decision should be reached and communicated to the applicant, wherever possible, within 8 weeks of the submission of a valid application.
- xii. Once an application is approved, the investigators must not deviate from it as approved. The Chief Investigator must notify the committee of any proposed amendments and allow the committee time to consider and approve them beforehand. Similarly, if there is any change to

- the personnel involved in the investigation, the committee should be asked to approve this amendment and should be provided with details of the qualifications and experience of the new investigator(s).
- xiii. Where the application is not approved, this decision, and the reasons for reaching that decision, will be communicated to the Chief Investigator in writing. The Committee may give guidance as to modifications that the applicant may wish to consider with a view to making a new application.
- xiv. Where significant amendments are made to the research protocol, the researcher is responsible for notifying the EWUREC of these amendments for approval.
- xv. If further information or amendments are sought for a particular application from the relevant investigators, the member secretary may be delegated authority by the committee to consider the additional information or changes made, and either to approve it on behalf of the committee, or to return it to the committee for further consideration. The information and amendments must be provided before ethical approval can be given. Any decisions will be reported to the next meeting of the Committee for endorsement.
- xvi. Any adverse events which occur as a result of the research should be notified to EWUREC.
- xvii. Review by Chair's action may be undertaken in the case of staff project proposals which are being submitted for funding from major funding bodies, where ethical approval is a prerequisite. In such cases, full review will be postponed until the outcome of the funding bid is known, but must then be carried out in line with the requirements of both the University and the funding body.
- xviii. Where the research is terminated prematurely, a report shall be provided to the relevant committee within 15 days, indicating reasons for early termination.

4. Obligations of Research Teams

There is an obligation on all investigators to protect participants, and potential participants, from possible harm and to preserve their dignity and rights.

- i. Investigations should not involve any significant risk to the physical or mental well-being of the participants.
- ii. Confidentiality and privacy of participants must be maintained.
- iii. An appropriate person (the Chief Investigator or equivalent) must take responsibility for the investigation; in particular, in the case of student investigations, the student's supervisor is responsible for the investigation, and must act as the Chief Investigator.
- iv. Transparency and openness, including accurate reporting of data.
- v. Investigations which duplicate other work unnecessarily, or which are not of sufficient standard to make a useful contribution to existing knowledge, are in themselves unethical.
- vi. Investigators should justify the number of participants chosen for each study.
- vii. Consent by or on behalf of participants in an investigation.
- viii. Protecting a person's right to autonomy and dignity, including, but not confined to, bodily integrity, privacy and confidentiality.

5. Complaints

No appeal can be made against the decision of the Research Ethics Committee. Complaints on procedural grounds should be sent to the Vice Chancellor. The Vice Chancellor will place it to syndicate.



APPENDIX I: PLAGIARISM DECLARATION

THIS FORM MUST BE COMPLETED, SIGNED, DATED AND ATTACHED TO EACH RESEARCH WORK/ THESIS/DISSERTATION TASK THAT YOU CONDUCT AS PART OF ACADEMIC ACTIVITIES OR AN INDIVIDUAL RESEARCH ACTIVITY

1. ADMINISTRATIVE DETAILS

Title of the Research:

Name of the Student/Researcher:

Student ID number [If applicable]:

Department:

Faculty:

Date due:

Date submitted:

Course Instructor /Research Guide/ Dissertation supervisor:

2. COMPULSORY STUDENT /RESEARCHER DECLARATION

Plagiarism refers to using another person's intellectual work and presenting it (without apposite acknowledgement of the author or source) as one's own work. Plagiarism is an academic misconduct. If any reasonable ground is found for believing that plagiarism has taken place, disciplinary procedures as outlined in the East West University Core Policy for Academic Honesty and Preventing Plagiarism will be instituted.

PLEASE TICK TO INDICATE THAT YOU HAVE SATISFIED THESE REQUIREMENTS

- I have read the East West University Core Policy for Academic Honesty and Preventing Plagiarism and the relevant referencing guides.
- I understand the consequences of committing academic misconduct as outlined in the abovementioned policy.
- This academic work /thesis/ dissertation/ assignment is my own work.
- I have not previously submitted this or a version of it for assessment in any other unit of study at the University or any other institution without having obtained proper approval of the concerned guide/authority/teacher.
- I have taken proper and reasonable care to prevent this academic work /thesis/ dissertation/ assignment from being copied by others for the purpose of academic uses.
- For the purpose of proper assessment of my work, I give permission to act according to University policy and practice to reproduce this academic work and provide a copy to another member of staff for the purpose of cross-checking and moderation, and to take steps to authenticate the assessment, which includes submitting a copy to a checking/detection system that in turn may retain a copy of this work on a database for future checking.

Signature of the Student/Researcher:

Date:



APPENDIX II: INTELLECTUAL PROPERTY DECLARATION

THIS FORM MUST BE COMPLETED, SIGNED, DATED AND ATTACHED TO EACH RESEARCH WORK/ THESIS/DISSERTATION TASK THAT YOU CONDUCT AS PART OF ACADEMIC ACTIVITIES OR AN INDIVIDUAL RESEARCH ACTIVITY

1. ADMINISTRATIVE DETAILS

Title of the Research:

Name of the Student/Researcher:

Student ID number [If applicable]:

Department:

Faculty:

Date due:

Date submitted:

Course Instructor /Research Guide/ Dissertation supervisor:

2. COMPULSORY STUDENT /RESEARCHER DECLARATION

Intellectual property refers to intangible properties, which are creation of 'intellect' or 'mind' of the creators. Such creations can be literary or artistic works, scientific product or process, or symbols, names and images used in commerce. The just-mentioned intellectual creations are protected by laws, namely copyright, patent, trademark or trade name etc. respectively. Management and licensing of intellectual creation of the students/researchers/staff of the East West University is regulated by the Core Policy for ownership and management of Intellectual Property adopted by the University.

PLEASE TICK TO INDICATE THAT YOU HAVE SATISFIED THESE REQUIREMENTS

- I have read and fully understood the East West University Core Policy for ownership and management of Intellectual Property.
- I am fully aware of the fact that rights of any intellectual creation, which has been supported by university grants or university resources, shall be owned by university.
- I am fully aware of the fact that if intellectual property right over any intellectual creation is owned by the university further decisions concerning licensing and management of that intellectual property shall be made by the University.
- I am aware of the fact that copyright and moral right over dissertation/thesis that I wrote as part of my academic programme shall be owned by me.
- I am fully aware of the fact that any of my scientific creation or innovation, which has resulted from research funded jointly by University, and any other third party, the ownership of intellectual property over the innovation will be governed as per agreement amongst the university, me , and the concerned third party .
- I am fully aware of the fact that during my research activities, if I need to use other people's intellectual creation, I must acknowledge the source and receive prior permission of the original intellectual property rights owner, if required.

Signature of the Student/Researcher:

Date:



Appendix III: Intellectual Property and Stand of East West University

Intellectual property [hereinafter also referred to as IP] refers to intangible properties, which are creation of the 'intellect' or the 'mind' of the creators. Such creations can be literary or artistic works, scientific products or processes, or symbols, names and images used in commerce. The above-mentioned intellectual creations are protected by laws, namely copyright, patent, trademark or trade name etc. respectively.

As a knowledge-producing hub, the higher education institutes or universities or research organizations are supposed to be concerned with specific policies regarding copyright, patent, and in some cases trademarks or trade-names. East West University also takes seriously its concern in adoption and compliance with IP policies. In this regard, the university shows its commitment to respect and observe the existing intellectual property laws of Bangladesh as well as the 'IP Policy for University Manual for IP Management at University' prepared by the Higher Education Quality Enhancement Project (HEQEP) of the University Grants Commission of Bangladesh.

University Core Policy for Ownership and Management of Intellectual Property:

1. Rights over intellectual property created by any student, university personnel, researchers, staff, project staff, visitors and others, using grants or funds or using the university's resources or facilities, or created pursuant to a written agreement with the university, shall be owned and managed by it, if no contrary cataract or agreement exists between the university and the concerned creator or inventor. However, the above mentioned university ownership of the intellectual creations supported by the University shall not hinder the concerned inventor / creator /scientist/researcher :
 - i. to use their 'moral rights' over the creations.
 - ii. to use their intellectual creations for their research or academic activities in the University .
2. In cases of creations or inventions supported partially by university resources, the IP rights over the creation will be partially and proportionately owned by the university.
3. In cases of collaborative innovation funded by the university and research conducted by any individual researcher, whether as a part of the academic program or any individual research activity, the cost of patent filing will be borne by university. In cases of collaborative innovation funded by university and any other third party, the cost of patent filing will be covered as per the concerned agreement.

4. In cases of any creation or invention of any student, university personnel, researchers, staff, project staff which came into existence not as a result of using any resource or fund or official assistance of the university, the IP rights over the creation will not be owned or claimed to be owned by the university.
5. In case of any creation or invention of any student, university personnel, researchers, staff, project staff supported jointly by the university and any third party, the IP rights over the creation will be governed as per the agreement between the university, the inventor/creator[s], and the concerned third party [ies].
6. Copyright on thesis/ dissertation created as a part of academic programs of the students/researchers/creators will be owned by the concerned student/researcher/creator. In this connection, the owner of the Copyright shall grant royalty-free permission to the university to reproduce and distribute copies of the concerned creation for teaching and research purposes both within and outside the university.
7. Any decision concerning licensing and management of the intellectual property owned by the university or any decision concerning dispute as to ownership of any intellectual creations of any student, university personnel, researcher, staff, project staff, and visitor, shall be made or resolved by the University IP Cell, which will be guided by the Vice Chancellor of the university.
8. The University IP Cell shall make decisions in line with the existing intellectual property laws of Bangladesh, University core IP policy and the 'IP Policy for University Manual for IP Management at University' prepared by the Higher Education Quality Enhancement Project (HEQEP) of the University Grants Commission of Bangladesh.
9. The University IP Cell shall work for building awareness among students, university personnel, researchers, staffs, project staffs, visitors and others regarding University core IP policy and other relevant rules, laws, or policy documents.



**Appendix IV- No Objection Certificate for Publication of Dissertation/ Thesis/
University Publications**

1. Name of the Applicant:

2. Age (in Years): _____

3. Permanent Postal Address:

—

4. Postal Mailing Address:

—

5. Email Address: _____

Phone: _____ Mobile: _____

6. Title of the Dissertation (In Capital

Letters): _____

—

7. Name of the Department: _____

9. Month & Year in which the Degree was awarded: _____

10. Name of the

Instructor: _____

11. Other Information: (if any):

—

—

Department/IP Cell has no objections in regards to the publication of the work mentioned above.

Signature of the Applicant Signature of Head of Department

Signature of Secretary IP Cell



Appendix V- Deed of Assignment

Recital: Students/inventor/creator/university personnel enrolled/ appointed by the University are bound by the university's rules and regulations, especially those framed under the IP Policy of university. Pursuant to the IP Policy, Students/ Inventor/ creator/ university personnel involved in the research and development, will assign ownership and transfer all the rights and privileges subsisting in the Intellectual Property (IP) or potential Intellectual Property generated and created by the use of resources / facilities of the university and affiliates of the university and its affiliates. If and when the Intellectual Property under this deed of assignment is commercialized, the net revenue generated from the licensing and technology transfer of IP owned by the university would be shared as per the IP Policy of the university.

This Deed of Assignment is entered into on this ___ day of _____.

BETWEEN

Mr. / Mrs. / Ms. _____ (Name) aged about _____ years (age) _____ (nationality), _____ (designation) having permanent address at _____ and currently residing at _____ (hereinafter referred to as Assignor), which expression shall, unless repugnant in the context, include its successors and assigns, of the first part.

AND

East West University, an Institution declared under the UGC Act, and having its main campus at _____, Bangladesh (hereinafter referred to as 'Assignee'), which expression shall, unless repugnant the context, include its successors and assigns, of the other part.

NOW THEREFORE, IN CONSIDERATION OF THE MUTUAL PROMISES, COVENTS AND TRANSACTIONS HEREIN CONTAINED, THE PARTIES DO HEREBY AGREE AS FOLLOWS:

1. "ASSIGNMENT"

- a) The Assignor hereby irrevocably assigns and transfers to the Assignee _____ the right with respect to Patent /Design Application No. _____ dated _____ filed by the Assignor.
- b) This assignment is further supported by the terms and conditions laid out in the IP Policy of university.
- c) By this Assignment the complete ownership of the Inventions covered under aforementioned Patent /Design Application rests with the university for Bangladesh and overseas jurisdictions. However, this assignment is subject to further modifications and amendments as may be agreed between the parties.

2. COVENANTS

The Assignor and the Assignee both hereby covenant as follows:

- a) The Assignor has full right and absolute authority to assign the said Patent /Design Application in the manner aforesaid.
- b) The inventions above-mentioned are made during the course of research done in university, in the Department of _____.
- c) The said Patent /Design Application is free and clear from all encumbrances and claims.
- d) The Assignee shall be entitled to hold and use the said Patent /Design Application exclusively so long as the said Patent /Design Application exists, and earn and enjoy the profit or income there from and without any objection or interruption on the part of the Assignor or persons claiming under them, for the overseas jurisdictions.
- e) The Assignor will execute any further agreements as may be required for further and more perfectly assuring the said Patent /Design Application unto the Assignee.

IN WITNESS WHEREOF the Parties hereof have put their hands the day and year first herein written.

Assignor:

Assignee:

Signature

Signature

Name:

Name:

Designation:

Designation:

Date:

Date:

Witness:

Witness:

Signature

Signature

Name:

Name:

Date:

Date:



Appendix VI- Prior Art Search Report Format

Prior Art Search Report Format Date on which search performed: _____

Searcher's Name, affiliations: _____

1. Summary of Invention: _____

More Detailed Description of the Invention: _____

2. Search Strategy: _____

Tabulate the search queries and number of hits is given in the table below

#	Search String	Number of Hits

3. Results of Search Results

#	Reference	Relevant Passage from the Reference	Relevancy	Comments
Patent Search				
Non-Patent Search				

Relevancy

- Possibly/clearly affects novelty of the invention
- Possibly/clearly affects inventive step of the invention

4. Observations and Conclusions: _____



Appendix IX (Part B)- Research Involving Microbiological Samples

Ethics are of vital importance in microbiology. No new scientific or technological development can claim immunity from ethical scrutiny. More specifically, moral and ethical concerns are of considerable importance in influencing public attitudes towards microbiological research. Therefore, EWU Research Ethics Committee (EWUREC) sets a guideline to secure the biosafety and biosecurity according to the national and international standards relating to research involving microorganisms. A summarized version of the policies and guidelines has been mention below-

1. All microbiological samples collected from environment must be obtained with proper care so that the natural landscape and natural habitats are not displaced or damaged.
2. Microbiological samples collected from humans should be obtained by maintaining EWUREC policy regarding Human Samples (Appendix IXA).
3. Genetically modified microorganisms should be handled with highest possible precautions.
4. A high level of ascetic techniques and transparency must be maintained at all times in all areas whenever dealing with microbiological samples.
5. Researchers involved in isolating microorganisms should refrain in engaging any activity or research that would be intended or likely to cause harm to plants, animals, humans, or environment.
6. Microbiological researchers should recognize the duty to the public to propagate a true understanding of science. They should avoid making statements known to be premature, false, misleading, or exaggerated and discourage any use of microbiology contrary to the welfare of human kind.
7. Researchers should work for proper and beneficent application of scientific discoveries and call to the attention of the public or the appropriate authority's misuses of information derived from microbial research.
8. The ethical issues of microbiological characterization techniques in controlling the infectious diseases and avoiding the spreading should include both individuals and public at large since professional ethics is the moral bond that links a profession, the people it serves, and society.
9. It is important for researchers to have a set of standard operating procedures that should be followed, and any deviation from these procedures would require ethical and scientific justification where the choice of test systems should be based on valid scientific procedures. If an alternative, inexpensive test, with the same performance indicators, is available, the researchers are ethically mandated to provide information about that test as

- well to both working individuals related to the project and EWUREC. Procurement of equipment and consumables dealings with suppliers necessarily need to be transparent.
- 10. At the end of the experiments, suitable methods must be used to kill microorganism in samples and other disposable consumables before discarding them in appropriate waste containers. Reusable glasswares must be sterilized and instruments used must be disinfected at their use.
- 11. Ethical issues in the documentation of tests and environmental variables should include a definition of what test is carried out, when, how, and by whom. In addition, it is ethically wrong to allow unqualified personnel to carry out tests without supervision of principal investigator. Raw and derived data from the tests need to be documented carefully, and any tampering with this data is unethical.
- 12. Researchers are ethically mandated to provide information about interpretation and limitations of the test. Confidentiality of every result needs to be maintained.
- 13. The researchers are encouraged to communicate knowledge obtained in their research through discussions with their peers and the relevant experts.

*** Please fill up Appendix X .**



Appendix X: - Application Form for Ethical Clearance of Research Proposals Involving Samples Collected from Humans and/or Microbial Samples

Section I: General Information about Research/Project Details

1. **Title of the Research/Study:**

2. **Objective of the Research/Study:**

3. **Detailed Methodology:**

4. **Required Number of Human Participants/Samples and Justification of this Estimated Number:**

5. **Place of the Study/Institution(s):**

6. **Type of Study:**

7. **Duration of Study:**
 Research Start Date (Tentative):
 Expected Completion Date:

8. **Is the Research/Study Funded?** YES / NO

9. **If yes, mention the source of funding:**

10. **Type of the Research:** MPhil-PhD Research / MS Thesis Research / Undergraduate Research / University Funded Research / Govt. Funded Research / Contract Research /Others
 If others please specify:

11. Will students work in this project? YES / NO

12. How will students be selected?

13. Will consent be obtained from students?

14. Will students be provided incentives/payments?

15. If yes, what is the source of funds?

16. What are the possible benefits/risks to students?

17. Have arrangements been made to report results to students?

18. Will students be fully informed and trained of everything that will be required of them prior to the start of the research?

Section II: General Information about the Investigator(s)

1. Principal Investigator(s):

Name:

Qualification:

Detail Address:

Mobile:

Telephone (Off/Res):

E-mail:

2. Co-Investigator(s):

Name:

Qualification:

Detail Address:

Mobile:

Telephone (Off/Res):

E-mail:

3. Persons(s) Conducting the Project/Study:

Name:

Qualification:

Detail Address:

Mobile:

Telephone (Off/Res):

E-mail:

Section III: Checklist for Working with Human Samples

Circle the appropriate answer to each of the following (If not applicable write NA)

- | | | | |
|----|---|-----|----|
| 1. | Are the subjects going to be informed clearly about the objective and procedure of the study? | Yes | No |
| 2. | Does the study involve participants who are particularly incapacitated/vulnerable to give informed consent? (e.g. minor, people with learning disabilities, patients, etc.) | Yes | No |
| 3. | Will the study involve the following risks to the subjects? | | |
| | a. Physical risks | Yes | No |
| | b. Psychological risks | Yes | No |
| | c. Social risk | Yes | No |
| | d. Discomfort to subjects | Yes | No |
| | e. Invasion of the body | Yes | No |
| | f. Invasion of Privacy | Yes | No |

If yes, please specify the measures that are proposed to manage these risks.

--

- | | | | |
|-----|--|-----|----|
| 4. | Will the study involve collection or disclosure of information on sensitive topics? (e.g., sexual activity, drug use, mental health etc.)
If yes, please also fill up Appendix XV. | Yes | No |
| 5. | Will the study use records (Hospital, Medical, Death, Birth or Other)? | Yes | No |
| 6. | Will blood/body fluid, tissue samples, abortus or organs be obtained from participants? | Yes | No |
| 7. | Will the samples be stored in appropriate conditions (especially temperature)? | Yes | No |
| 8. | Will the participants be informed about the procedures to be followed during sample collection, including alternatives used? | Yes | No |
| 9. | Is pain/severe discomfort likely to result from the study?
If yes, state how to minimize unnecessary pain and/or distress. | Yes | No |
| 10. | Will drugs, placebos, or other substances (e.g., drinks, foods, dietary supplements) be administered to the study participants?
If yes, name each substance with its amount. | Yes | No |

- | | | | |
|-----|--|-----|----|
| 11. | Will the study use a Participant Information and Informed Consent Form?
If yes, please attach a copy of the form along with this application. | Yes | No |
| 12. | Will measures be taken to ensure confidentiality, privacy and data protection
where appropriate? | Yes | No |
| 13. | Will the participants have right to refuse to participate or to withdraw from the
study? | Yes | No |
| 14. | Will compensation be given to participants where there are risks or loss of
working time, or where privacy is involved in any particular procedure? | Yes | No |
| 15. | Will the study involve experiments involving microbes?* | Yes | No |

*** If answer of number 15 is yes, please fill up section IV.**

Section IV: Information on Study Involving Microorganisms

1. Methods of data collection: _____

2. Locations of Samples Collection: _____

3. Will the study involve the following risks?

Displaced or damaged natural landscape?

Displaced or damaged natural habitats?

If yes, please justify the appropriateness of the study.

4. Will the study cause harm to-

Plants?

Animal?

Human?

Environment ?

If yes, please justify the appropriateness of the study.

5. Will the study involve genetical modification of any microorganism or use any genetically modified microbe?

If yes, please mention the purpose of the genetic modification, or the altered characteristics of the genetically modified microbe (in case of using already genetically modified microbe) and the precautions that will be taken to ensure biosafety.

6. Describe the possible benefits to science and/or humans from this study.

7. Will the experiments be conducted in a well equipped laboratory with bio-safety and biosecurity precautions?

8. Are the personnel involved are properly trained for maintaining bio-safety?

9. Describe the methods that will be used to kill the microbes present in the samples and consumables at the end of experiments.

10. Describe the method that will be used to sterilize or disinfect the reusable glasswares and instruments at the end of experiments.

11. Describe the information about interpretation and limitation of the test.

12. How the confidentiality of result at each stage will be maintained/ensured?

Approval from the EWUREC is valid for a period of three (3) years

Co-Investigator's signature

Date signed

Principal Investigator's signature and stamp

Date signed

**Dean of Faculty/Head of Department' signature
and stamp**

Date signed

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Decision of East West University Research Ethics Committee (EWUREC)

- Approved
- Approved Pending Minor Modification
- Withhold Approval Pending Justification and Clarification
- Rejected

This form has been reviewed by the EWUREC and the decision has been made based on the information provided.

Signature of EWUREC Chair

Date

Date of Approval: