I-Introduction:

The basic pillars of the mission of a university are education, research and innovation. Due to immense opportunities in innovation and increasing technological progress, huge expectations arise. Research is described in The European Code of Conduct for Research Integrity [1] as “the quest for knowledge obtained through systematic study and thinking, observation and experimentation”. Hence, society and universities are dependent on the validity and reliability of the results of scientific work and academic scholarship. The outcome and interpretation of research can be verified by the scientific or academic community, but the research cannot be verified by the public for whom the new knowledge is intended. Therefore, in order to gain the confidence of society, the research of every institution needs to be valid and reliable. This expectation for reliable and valid research carries with it an ethical commitment to pursuing research in ways that ensure that this expectation is met. This code is intended to articulate the principles and standards of good research practice as a basis for a high standard of research quality at the university.

AURAK’S Research Code of Conduct provides guidelines for good practice in research, and guidance on avoiding misconduct in research. This code is based on codes and standards of a number of international organization [References 1,2,3,4,5,6].

AURAK is committed to maintaining the highest standards of rigor and integrity in the conduct of its research. Therefore, the University expects all those involved in research to be familiar with these standards and to embed good practice in all aspects of their work, including the training of new researchers.

II-Principles

As stated in the Netherlands Code of Conduct for Research Integrity [4], principles are the basis of integrity in research. These should guide individual researchers as well as other parties involved in research, such as the institutions where it is conducted, publishers, scientific editors, funding bodies and scientific and scholarly societies – all of which, given their role and interest in responsible research practices, may be expected to foster integrity.

This Code is based on the following five, widely supported principles.

1. Honesty

Honesty refers, among other things, to reporting the research process accurately, taking alternative opinions and counterarguments seriously, being open about margins of uncertainty, refraining from making unfounded claims, refraining from fabricating or falsifying data or sources and refraining from presenting results more favourably or unfavourably than they actually are.

2. Scrupulousness
Scrupulousness means, among other things, using methods that are scientific or scholarly and exercising the best possible care in designing, undertaking, reporting and disseminating research.

3. Transparency

Transparency refers, among other things, to ensuring that it is clear to others the data on which the research was based, how the data were obtained, what and how results were obtained, and the role played by external stakeholders. If parts of the research or data are not to be made public, the researcher must provide a clear account of why this is not possible. It must be evident, at least to peers, how the research was conducted and what the various phases of the research process were. At the very least, this means that the line of reasoning must be clear and that the steps in the research process must be verifiable or replicable.

4. Independence

Independence in the conduct of research means, among other things, not allowing the choice of method, the assessment of data, the weight attributed to alternative statements, or the assessment of others’ research or research proposals to be guided by non-scientific or non-scholarly considerations (e.g., those of a commercial or political nature). In this sense, independence also includes impartiality. Independence is required at all times in the design, conduct, and reporting of research, although not necessarily in the choice of research topic and research question.

5. Responsibility

Responsibility refers, among other things, to acknowledging the fact that a researcher does not operate in isolation. Therefore, the researcher is expected to take into consideration the legitimate interests of human and animal test subjects, as well as those of commissioning parties and funding bodies. Responsibility also entails conducting research that is scientifically and/or societally relevant and that is not harmful to the environment.

Principles can be regarded as ‘virtues’ of a good researcher, guiding them towards the right choices in all kinds of circumstances. The most important of these are specified in Section III, in the form of standards. By their very nature, however, principles are less subject to change than the standards they give rise to, which sometimes need to be adapted or extended as research practices change. All such revisions must remain true to the principles underlying them.

Principles are also guiding factors in cases not covered by the standards described in Section III. In such cases, even if an action is in conflict with a principle, as long as it violates none of the standards itemized in Section III nor any additional standard established by a discipline or institution, then sanctions as described in Section V will not be imposed.

III-Standards for good research practices

3.1 Design

In designing their research, researchers should:

1) Consider the interests of science and scholarship and/or society when determining the subject and structure of the research.
2) Conduct research that can be of scientific, scholarly and/or societal relevance.
3) Not make unsubstantiated claims about potential results.
4) Take into account the latest scientific and scholarly insights.
5) Make sure that the research design can answer the research question.
6) Ensure that the methods employed are well justified.
7) If the research is conducted on commission and/or funded by third parties, always specify who the commissioning party and/or funding body is.
8) Be open about the role of external stakeholders and possible conflicts of interest.
9) In research with external partners, make clear written agreements about research integrity and related matters such as intellectual property rights.
10) As necessary, describe how the collected research data are organized and classified so that they can be verified and reused.
11) As far as possible, make research findings and research data public subsequent to completion of the research. If this is not possible, establish and describe valid reasons for their non-disclosure.
12) In the event of an investigation into alleged research misconduct, make all relevant research and data available for verification subject to the confidentiality safeguards established by the institution. In highly exceptional cases, there may be compelling reasons for components of the research, including data, not to be disclosed to an investigation into alleged research misconduct. Such cases must be recorded and the consent of the institution must be obtained prior to using the components and/or data in question in the scientific or scholarly research.
13) Ensure that the required permissions are obtained and that, where necessary, an ethical review is conducted.
14) Accept only research assignments that can be undertaken in accordance with the standards in this Code.
15) Enter into joint research with a partner not affiliated with an institution which has adopted this or a comparable Code only if there is sufficient confidence that the research can be conducted in compliance with this Code and the joint research results will meet generally accepted principles of integrity in research.

3.2 Conduct
1) Conduct the research accurately and with precision.
2) Employ research methods that are scientific and/or scholarly.
3) Make sure that the choice of research methods, data analysis, assessment of results and consideration of possible explanations is not determined by non-scientific or non-scholarly (e.g., commercial or political) interests, arguments or preferences.
4) Do not fabricate data or research results and do not report fabricated material as if it were fact.
5) Do not remove or change results without explicit and proper justification.
6) Ensure that sources are verifiable.
7) Describe the data collected for and/or used in the research honestly, scrupulously and as transparently as possible.
8) Manage the collected data carefully and store both the raw and processed versions for a period appropriate for the discipline and methodology at issue.
9) Contribute, where appropriate, towards making data findable, accessible, interoperable and reusable in accordance with the FAIR Principles developed by the organization GO FAIR in collaboration with the Committee on Data (CODATA), Research Data Alliance (RDA), and World Data Systems [3].
10) Take into consideration the interests of any humans and animals involved, including test subjects, as well as any risks to the researchers and the environment, while always observing the relevant statutory regulations and codes of conduct (Please refer to Section 5.3 and 5.4).
11) Maintain a level of expertise appropriate to the research undertaken.
12) Take on only those tasks that fall within one’s area of expertise.

3.3 Reporting results
1) Ensure that everyone who contributed to the research, including obtaining and/or processing the data, is appropriately acknowledged.
2) Ensure a fair allocation and ordering of authorship, in line with the standards applicable within the discipline(s) concerned.
3) Ensure that all authors have made a genuine intellectual contribution to at least one of the following elements of the research: the design of the research, the acquisition and analysis of data, or the interpretation of findings.
4) Ensure that all authors have approved the final version of the research product, with the understanding that they are fully responsible for all contents of the research product, unless explicitly stated otherwise.
5) Present sources, data and arguments in a scrupulous way.
6) Be transparent about the method and procedures followed and record them where relevant in research protocols, logs, lab journals or reports. The line of reasoning must be clear and the steps in the research process must be verifiable. This usually means that the research must be described in sufficient detail for it to be possible to replicate the data collection and its analysis.
7) Be explicit about any relevant unreported data that has been collected in accordance with the research design and could support conclusions different from those reported.
8) Be clear about results and conclusions, as well as their scope.
9) Be explicit about uncertainties and contraindications, and do not draw unsubstantiated conclusions.
10) Be explicit about serious alternative insights that could be relevant to the interpretation of the data and the research results.
11) When making use of other people’s ideas, procedures, results and text, cite the research sources scrupulously and accurately.
12) Avoid unnecessary reuse of one’s previously published texts.
13) Be transparent about reuse by citing the original publication, unless the reuse is on a limited scale, such as the reuse of introductory passages or descriptions of the method employed.
14) Always provide references when reusing research material that can be used for meta-analysis or the analysis of pooled data.
15) Avoid unnecessary references and do not make the bibliography unnecessarily long.
16) Be open and complete about the role of external stakeholders, commissioning parties, funding bodies, possible conflicts of interest and relevant ancillary activities.
17) As far as possible, make research findings and research data public subsequent to completion of the research. If this is not possible, establish the valid reasons for this lack of public access.

3.4 Assessment and peer review
1) Be honest and scrupulous as an assessor or peer reviewer, and explain one’s assessment.
2) Do not use information acquired in the context of an assessment without explicit consent.
3) Do not use the system of peer review to generate additional citations for no apparent reason, with the aim of increasing one’s own or other people’s citation scores (‘citation pushing’).
4) Refrain from making an assessment if any doubts could arise regarding one’s independence (for example, because of possible commercial or financial interests).
5) Refrain from making an assessment outside one’s area of expertise.
6) Cooperate fully with internal and external reviews of one’s own research.
7) Associate only with journals and other sources of scholarly publications that adhere to the required standards of quality.

3.6 Communication
1) Be honest and clear in public communication about the limitations of the research and one’s own expertise.
2) Only communicate to the general public about the research results if there is sufficient certainty about them.
3) Be open and honest about one’s role in any public debate concerning published research.
4) Be open and honest about potential conflicts of interest.

3.7 Standards that are applicable to all phases of research
1) As a supervisor, principal investigator, research director or manager, provide for an open and inclusive culture in all phases of research.
2) As a supervisor, principal investigator, research director or manager, refrain from any action which might encourage a researcher to disregard any of the standards in this section of the code.
3) Do not delay or hinder the work of other researchers in an inappropriate manner.
4) Call attention to other researchers’ non-compliance with the standards as well as inadequate institutional responses to non-compliance, if there is sufficient reason for doing so.
5) In addressing research misconduct, make no accusation that one knows or should have known to be incorrect.
6) Use research funds only for approved and intended purposes.

IV-Research Misconduct and other Unacceptable Research Practices
The European Code of Conduct for Research Integrity [1] defines research misconduct as fabrication, falsification, or plagiarism (the so-called FFP categorization) in proposing, performing, or reviewing research, or in reporting research results:

- **Fabrication** is making up results and recording them as if they were real.
- **Falsification** is manipulating research materials, equipment or processes or changing, omitting or suppressing data or results without justification.
- **Plagiarism** is using other people’s work and ideas without giving proper credit to the original source, thus violating the rights of the original author(s) to their intellectual outputs.

These three forms of violation are considered particularly serious since they distort the research record.

4.1 Plagiarism
Authors who present the work of others; words, data, or ideas with the implication that they are their own, without proper acknowledgment of the source in a form appropriate for the medium of presentation, are committing theft of intellectual property and may be guilty of plagiarism and thus of research misconduct. This statement applies to all types of scientific communications including, unpublished data or findings, scholarly, peer-reviewed articles, review articles, news articles, magazine articles, books, preprints, dissertations, conference papers & proceedings. The same rules apply to privileged information taken from grant applications and proposals, clinical research protocols, and student papers submitted for academic credit.
Plagiarism violates the standard code of conduct governing all researchers; it could constitute an infraction of the law by infringing on a copyright held by the original author or publisher. The work of others should be cited or credited, whether published or unpublished and whether it was written work, an oral presentation, or material on a website. An author should cite the work of others even if he or she was a co-author or editor of the work to be cited or had been an adviser or student of the author of such work.

Members of a research group who contribute to work that is later incorporated into a proposal or protocol are entitled to be consulted and informed as to what their role will be if the proposal is funded or the protocol approved. A charge of plagiarism in the proposal or protocol on grounds that such members are not later included as part of the team that conducts the approved or funded research, however, can usually not be sustained. Such researchers who are excluded from subsequent research are entitled, however, to be considered for co-authorship in publications if their contributions merit it.

One particularly serious form of plagiarism is the misuse of privileged information taken from a grant application or manuscript received from a funding agency or journal editor for peer review. In such a case, the plagiarism is a serious matter of theft of intellectual property because it deprives the original author of appropriate credit by citation and pre-empts priority of first publication or use of the original idea to which the source author is entitled.

4.2 Fabrication, falsification and data-related misconduct

Fabrication and falsification of research results are serious forms of misconduct. It is a primary responsibility of a researcher to avoid either a false statement or an omission that distorts the research record. A researcher must not report anticipated research results that had not yet been observed at the time of submission of the report. In addition, a researcher must not report findings relying on data that has been manipulated to reflect positive or negative statements regarding research findings. In order to preserve accurate documentation of observed facts with which later reports or conclusions can be compared, every researcher has an obligation to maintain a clear and complete record of data acquired.

4.2.1 Integrity of Data

Meticulous record-keeping is a sound scientific and scholarly practice which provides an accurate contemporaneous account of observations that become a permanent reference for the researcher, who otherwise might not remember several weeks, months, or years later exactly what was observed or what methods were used. An accurate record also serves others who may want to replicate the observation or to apply a method to other situations. In addition, it is an aid in allowing the eventual sharing of information with others and as documentation that might disprove any subsequent allegation of fabrication or falsification of data.

In many fields of laboratory research, it is standard practice to record data in ink in an indexed permanently bound laboratory logbook with consecutively numbered pages. In the lab notebook, the researcher should document procedures, used reagents and their source, and all relevant notes to allow another researcher to reproduce similar results. Research methods, including statistical treatments, should be either described in the logbook or referenced by citation to some other primary or secondary source. Information on materials used, along with their sources, should be recorded. Entries should not be erased or whitened out.

If mistakes are to be corrected, a thin line should be drawn through the erroneous entry so as not to obscure it and an initialed dated correction written separately, along with an explanatory note, near the original entry
or in the margin. All entries or at least all pages of a logbook should be dated and initialed. Such records may also be important at a later date in establishing scientific priorities or intellectual property claims. All data should be recorded contemporaneously with the production or observation of the data. If some data are obtained as printouts from instruments or computers, these printouts should be appropriately labeled and pasted into the logbook or, if pasting is not possible, stored securely and referenced in the logbook as to storage location.

If unique critical materials, such as cell lines, archeological artifacts, or synthetic chemical intermediates, are prepared or discovered, they should be preserved and appropriately labeled, and explicit instructions should be written in the logbook as to where they are stored.

Extensive data sets may be stored either as hard copy or as electronic digital records. In such cases, carefully documented definitions for codes should be included, together with rules for applying them to the experimental, clinical, or field data and notes. The use of computers in research laboratories is a necessity, and managing the data generated and stored is becoming a challenge to the investigator. As more and more data are generated electronically, current documentation methods involve both the hand-written laboratory logbooks discussed above as well as electronic files pertaining to experiments. Establishing processes to organize, store and protect such electronic data is becoming crucial.

One way to manage the generated electronic data is to use electronic lab logbooks. Such logbooks allow the direct entry of laboratory observations, results from data analysis, and the seamless transfer of electronic data and images from a variety of laboratory instruments in a centralized fashion. In addition, background information on reference materials or protocol details can be entered from electronic sources. One advantage of using such a logbook is the ability to secure the data electronically so as to prevent subsequent data manipulations.

In addition, such systems will also provide the ability to add electronic signatures for further validation. Electronic logbooks can be developed in house or can be purchased from a commercial vendor. In establishing a process to protect the data and ensure that the data are formatted so that they could not be modified.

4.2.2 Use and Misuse of Data
Researchers should acquaint themselves with the relevant quantitative or qualitative methods available for processing data, including graphical and tabular methods of presentation, error analysis, and tests for reliability and validity. Research integrity requires not only that reported conclusions are based on accurately recorded data or observations but that all relevant observations are reported. It is considered a breach of research integrity to fail to report data that contradict or merely fail to support the reported conclusions, including the purposeful withholding of information about confounding factors. If some data should be disregarded for a stated reason, such as an approved statistical test for excluding outliers, the reason should be stated in the published accounts. All previous findings of negative results must be reported. Any intentional or reckless disregard for the truth in reporting observations may be considered to be an act of research misconduct. Special care must be taken in the use of photo-images not to misrepresent the underlying data. Expenditure of grant funds for fabricated or falsified research is a violation of research ethics, and those responsible may be subject to prosecution for fraud.

4.2.3 Ownership of and Access to Data
Research data obtained in studies performed at AURAK or by employees of the university are not the property of the researcher who generated or observed them or even of the principal investigator of the research group. They belong to AURAK, which can be held accountable for the integrity of the
data even if the researchers have left the university. Another reason for the university's claim to ownership of research data is that the university, not the individual researcher, is the grantee of sponsored research awards. Reasonable access to data, however, should normally not be denied to any member of the research group in which the data were collected. If there is any possibility that a copyright or patent application might emerge from the group project, a written agreement within the group should specify the rights, if any, of each member of the group to the intellectual property. A researcher who has made a finding which may be patentable should file an Invention Disclosure with the Office of Research and Community Service.

A principal investigator who leaves the university is entitled to make a copy of data to take to another institution so as to be able to continue the research or, in some cases, to take the original data, with a written agreement to make them available to the university on request within a stated time period. A formal Agreement on Disposition of Research Data should be negotiated in such cases through the Office of Research and Community Services (ORCS). Such an understanding should specify the extent to which a copy of research data may be taken. Co-investigators at another institution are entitled to access the data which they helped to obtain. For unique materials prepared in the course of the research, such as intermediates in a chemical synthesis, autoradiograms, cell lines, and reagents, items that can be proportioned should be divided among members of a research group at different locations under negotiated terms of material transfer agreements.

For non-divisible items, the allocation of the item should be clearly stipulated in the agreement. The ORCS facilitates the execution of such agreements. Since the scientific enterprise may be a cooperative endeavor encompassing many individuals who now or in the future might pursue related research interests, and since it is in the interest of all to rely on the contributions and findings of others, every investigator has an obligation to the general scientific community to cooperate by sharing of data. Other virtues of sharing data include the facilitation of independent confirmation or refutation of reported outcomes. It is generally accepted that the data underlying a research publication should be made available to other responsible investigators upon request after the research results have been published or accepted for publication.

4.2.4 Storage and Retention of Data
Data should be stored securely for at least five years after completion of the project, submission of the final report to a sponsoring agency, or publication of the research, whichever comes last. Some agencies that sponsor research may specify a longer period for which data must be retained.

4.2.5 Interference
Withholding data, and intentional removal of, interference with, or damage to any research-related property, including instruments and other equipment, is improper and can be considered to be research misconduct.

4.3 Other related violations and considerations
There are further violations of good research practice that damage the integrity of the research process or of the researchers. In addition to direct violations of the good research practices set out in this Code of Conduct above, examples of other unacceptable practices include, but are not confined to:

• Misrepresenting research achievements such as exaggerating the importance and practical applicability of findings.
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- Misusing seniority to encourage violations of research integrity. For example, a senior researcher or a Lab director pressuring junior researchers to cite his/her work or to use their funding to invite/accommodate him/her.
- Ignoring putative violations of research integrity by others or covering up inappropriate responses to misconduct or other violations by institutions.

4.3.1 Authorship and Other Publication Issues
Publication of research results is important as a mean of communicating to the scientific or scholarly community the results of the research results so that other researchers may build on the reported findings. In fact, it is an ethical obligation for an investigator at the university to make research findings accessible, in a manner consistent with the relevant standards of publication. The reported data and methods should be sufficiently detailed so that other researchers could attempt to replicate the results. Publication should be timely but should not be hastened unduly if premature publication involves a risk of not subjecting all results to adequate internal confirmation or of not considering adequately all possible interpretations. A commercial sponsor of a research project may not have a veto over a decision to publish, but a delay of publication for an agreed period, not to exceed six months, may be allowed in order to permit filing of a patent application.

a. Criteria for Authorship
Publication must give appropriate credit to all authors for their roles in the research. If more than one person contributes significantly, the decision of which names are to be listed as co-authors should reflect the relative contributions of various participants in the research. Manipulating authorship or denigrating the role of other researchers in publications is considered as a violation of good research practices.

Each author must have made substantial contribution in formulating the research problem, interpreting the results, or writing the research paper, and should be prepared to defend the publication as a whole against criticisms. A person's name must not be listed as author without his or her knowledge, permission, and review of the final version of the manuscript that includes the names of all co-authors. A person whose contribution merits co-authorship should be named even in oral presentations, especially when abstracts or transactions of the proceedings of a conference at which a paper is presented will be published. The entitlement to authorship should be the same whether or not a person is still at the original location of the research when a paper is submitted for publication. Just as one should include all those who have a right to be listed as co-authors, so one should avoid the listing of so-called honorary authors, who do not meet the criteria for authorship. It is suggested to use an alternative form of acknowledgment within the paper for contributions that do not merit co-authorship, e.g., for technical assistance, for providing research materials or facilities, or for meeting some but not all of the stated criteria for authorship. To avoid misunderstandings and even recriminations, the inclusion and exclusion of names of research participants as co-authors should be made clear to all participants in the research prior to submission of the manuscript.

b. Order of Authors
Customs regarding the order in which co-authors' names appear vary with the discipline. Whatever the discipline, it is important that all co-authors understand the basis for assigning an order of names and agree in advance to the assignments. A corresponding author should be designated for every paper that will be responsible for communicating with the publisher or editor, for informing all co-authors of the status of review and publication, and for ensuring that all listed authors have approved the submitted version of the manuscript. This person has a greater responsibility than other co-authors to vouch for the integrity of the
research report and should make every effort to understand and defend every element of the reported research.

e. Self-citations

Citing selectively to enhance own research profile or to please editors, reviewers or colleagues can be a very dangerous violation to good research practice. In citing one's own unpublished work, an author must be careful not to imply an unwarranted status of a manuscript. A paper must not be listed as submitted, in anticipation of expected submission. A paper must not be listed as accepted for publication or in press unless the author has received galley proof or page proof or has received a letter from an editor or publisher stating that publication has been approved, subject perhaps only to copy-editing.

d. Duplicate Publication

Researchers should not publish the same article in two different places without very good reason to do so, unless appropriate citation is made in the later publication to the earlier one, and unless the editor is explicitly informed. The same rule applies to abstracts. If there is unexplained duplication of publication without citation, sometimes referred to as self-plagiarism, a reader may be deceived as to the amount of original research data.

It is improper in most fields to follow the same manuscript to be under review by more than one journal at the same time. Very often journals specify that a submitted work should not have been published or submitted for publication elsewhere, and some journals require that a submitted manuscript be accompanied by a statement to that effect. An author must not divide a research paper that is a self-contained integral whole into a number of smaller papers merely for the sake of expanding the number of items in the author's bibliography.

e. Early release of information about to be published

It is unethical to release to the media scientific information contained in an accepted manuscript prior to the publication or to violate the embargo period noted by the respective publisher. An exception may be made if a public health issue is involved and the editor agrees to an advance release. This is of course different from sharing preprints in platforms such as arxiv, Research Gate or other academic social media platforms. A preprint is a full draft of a research paper that is shared publicly before it has been peer reviewed hence it does not generate any copyrights violations. It is fundamental to distinguish the two categories of publications and preprints when preparing a CV, grant proposal or even in a public personal webpage.

4.3.2 Conflict of Interest

There are some circumstances in which conflicts of interest could compromise the integrity of research or even lead to research misconduct. A faculty member must disclose to research students and members of the research staff the existence of his or her financial interests in activities related to the research. When asked to enter into peer review of a manuscript or proposal, a researcher must disclose any conflict of interest with respect to the matter under review. The principal investigator of a commercially sponsored study report must have access to all the data underlying a publication and must have full control over the decision to publish.

In the case of a multi-site study, the PI of the overall project must have access to data from all sites. Faculty are allowed to engage in outside professional activities such as consulting or service on a scientific advisory board, but approval of each such activity from the academic supervisor must be obtained in advance. In no
case are university facilities to be used in the conduct of an outside activity, and the university name and logo may be used by outside entities only with permission of designated university business officers.

Research performed for an external entity must be conducted by means of a sponsored research contract and not by way of consulting. A contract for consulting must be approved in advance, to ensure, among other things, that remuneration is related to specific services and that the university’s legitimate intellectual property rights are not compromised. Conflict of commitment must be avoided so as not to threaten a university researcher's primary professional allegiance and responsibility to the university. Faculty, but not staff, may spend up to one day a week in outside activities, and such activities must be approved in advance.

4.4 Disciplinary Procedures Related to Research Misconduct and Other Unacceptable Research Practices

Disciplinary procedures related to research misconduct and other unacceptable research practices are addressed in the university’s Disciplinary Procedure for Faculty.

V-Responsibilities and Obligations

5.1 Responsibilities of a Research Investigator

An investigator who leads a research group has leadership and supervisory responsibilities with respect to the research performed by members of the group. A principal investigator (PI) must not only put together the research group but also arrange for the assembly of an adequate financial and administrative structure to support the research. A supervisor not only provides guidance and advice to individual members of the group in the responsible conduct of the research but also has ultimate responsibility for the scientific integrity of the whole research project. He or she must thus take all reasonable steps to check the details of experimental procedures and the validity of the data or observations reported by members of the group, including periodic reviews of primary data in addition to summary tables, graphs, and oral reports prepared by members of the group. Written policies and procedures for collecting, maintaining and communicating experimental data within the research group are highly recommended. Close oversight is particularly important during the first few months of participation in the group of a student, junior researcher, or new member of the research group.

A principal investigator serves not only as a research manager with respect to members of the research group but also as a mentor responsible for the intellectual and professional development of students, postdoctoral fellows, research assistant, and junior faculty in the group, including awareness and sensitivity to issues in research ethics. Encouragement should be given to students and other junior researchers to report their research progress regularly both in oral and written modes and to present completed work at regional or national meetings. In order to fulfill all of the inherent role responsibilities, a supervisor should not have a research group larger than he or she can manage effectively and responsibly. Negotiation of sponsored research agreements is one of the responsibilities of the principal investigator with direct cooperation with the Office of Research Support Services. A researcher should be open to collaborative work with investigators having different but complementary skills, whether at AURAK or elsewhere. Early understandings should be reached in any collaboration about sharing of research resources and materials, authorship credit and responsibilities, and entitlement to any revenue from marketing of intellectual property through patents, copyrights, or licensing agreements.
5.2 Responsibilities to Funding Agencies

An investigator should be aware that the same standards of accuracy and integrity pertain to grant applications and proposals as to manuscripts submitted for publication. Reporting of results of experiments not yet performed as evidence in support of the proposed research funding, for example, is considered to be fabrication and is subject to a finding of research misconduct, even if the proposal is subsequently rejected for funding or is withdrawn before full consideration for funding is completed. The same definition of plagiarism applies to an application or proposal, including background and methodological sections, as to a publication. A PI must submit progress and final research reports to a sponsor at times specified in the award. He or she must authorize expenditures in a manner consistent with the approved budget and should review financial reports carefully. An investigator who has agreements with commercial sponsors of research, as negotiated with the help of the Office of Research Support Services, should familiarize themselves with the special terms of such agreements, such as those, for example, concerning reporting of results, disclosure of inventions, and confidentiality.

Failure to comply with the provisions might sometimes constitute a breach of contract or might compromise the university's claims to intellectual property.

It is also very important to keep a healthy interaction between the funders and the researchers. Allowing funders/sponsors to jeopardise independence in the research process or reporting of results so as to introduce or promulgate bias is not an acceptable practice.

5.3 Special Obligations in Human Subject Research

Research protocols involving human subjects must be approved in advance by the Institutional Review Board (IRB), which determines whether risks posed to subjects are acceptable and whether information describing risks and benefits of subject participation is conveyed to subjects in an accurate and intelligible manner. IRB review also ensures that all relevant university, and governmental regulations and policies are being followed.

The requirement for IRB review applies not only to biomedical research, but also to research projects in the social and behavioral sciences. Furthermore, regardless of where the research is being conducted, if the Principal Investigator or Co-Investigator is an AURAK faculty member, student or staff, that research project must be submitted to AURAK’s IRB (except institutional research conducted by OISE), even if it has been reviewed by another IRB. The IRB reviews both the protocol and the informed consent document (consent form) that potential subjects must sign before participating in the research study. Subjects must be informed that they may withdraw from a research program at any time. Research subjects already participating in a protocol by virtue of signing an approved consent document must be informed of any new information regarding risks and benefits of study participation when such data become available as the study progresses. If a consent document states that subjects will be informed of the research outcomes, the investigator must honor that commitment and so inform the subjects. Any proposed change in the research protocol or consent document must be approved by the IRB in advance of its implementation, and all co-investigators and study staff should be informed by the Principal Investigator of all relevant modifications. Every protocol submitted to the IRB must include a plan for data and safety monitoring. Protocols must also identify the research sponsor. If any investigator has a significant financial conflict of interest, the IRB protocol must include a plan for managing potential conflicts of interest, approved by ORCS. Such a plan may place limits on the role of an investigation who has a conflict. The existence of conflicts must also be disclosed to the research sponsor, to research subjects, and to members of the research team. AURAK has adopted the following eight guiding principles for research on human subjects to govern its research:

(1) Risks to subjects are minimized:
(i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
(ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB must consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB must take into account the purposes of the research and the setting in which the research will be conducted and must be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative.

(5) Informed consent will be appropriately documented and may be subject to audit.

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(8) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards are put in place.

Every research protocol involving human subjects should receive a formal scientific review, usually at the department or school level, prior to its review by the IRB. This review ordinarily addresses the scientific merit of the study and, depending on the nature of the research project, may also address availability of research subjects, resource utilization, and financial support. The IRB must be notified promptly of any significant adverse reactions or unanticipated problems involving risk to subjects or others. When large studies are organized as cooperative projects involving many different institutions, the institution that functions as a coordinating center has a special responsibility for developing a monitoring system to check the reliability of data reported from the various data-collecting centers.

5.4 Laboratory Animals in Research

Investigators who use laboratory animals are obliged to follow humane procedures so as to minimize animal pain, suffering, and distress and to use no more animals than absolutely necessary. Wherever possible, alternative protocols which do not require the use of animals should be considered, and if practicable, adopted. Written approval must be obtained from the IRB prior to the initiation of any research or teaching that requires the use of animals. The same requirements for disclosure of research sponsorship and conflicts of interest in the use of human subjects in research apply for vertebrate animal research. It is a requirement of this code that any teaching, testing, training or research endeavor involving the use of vertebrate animals be conducted in a manner compliant with the U.S. Animal Welfare Act [2].
5.4.1 U. S. Government Principles for the Care and Utilization of Vertebrate Animals Used in Testing, Research, and Education

The Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training [6] were prepared by the US Government Interagency Research Animal Committee, which was established in 1983. The committee's principal concerns are the conservation, use, care, and welfare of research animals. Its responsibilities include information exchange, program coordination, and contributions to policy development.

I. Procedures involving animals should be designed and performed with due consideration of their relevance to human or animal health, the advancement of knowledge or the good of society.

II. The animals selected for a procedure should be of an appropriate species and quality and the minimum number required to obtain valid results. Methods such as mathematical models, computer simulation, and in vitro biological systems should be considered.

III. Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, is imperative. Unless the contrary is established, investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals.

IV. Procedures with animals that may cause more than momentary or slight pain or distress should be performed with appropriate sedation, analgesia, or anesthesia. Surgical or other painful procedures should not be performed on un-anaesthetized animals paralyzed by chemical agents.

V. Animals that would otherwise suffer severe or chronic pain or distress that cannot be relieved should be painlessly killed at the end of the procedure or, if appropriate, during the procedure.

VI. The living conditions of animals should be appropriate for their species and contribute to their health and comfort. Normally, the housing, feeding, and care of all animals used for biomedical purposes must be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied. In any case, veterinary care shall be provided as indicated.

VII. Investigators and other personnel shall be appropriately qualified and experienced for conducting procedures on living animals. Adequate arrangements shall be made for their in-service training, including the proper and humane care and use of laboratory animals.

VIII. Where exceptions are required in relation to the provisions of these principles, the decisions should not rest with the investigators directly concerned but should be made, with due regard to Principle I, by an appropriate review group such as an Institutional Animal Research Committee. Such exceptions should not be made solely for the purposes of teaching or demonstration.

5.4.2 Compliance

In compliance with the above, the Principal Investigator (PI) has the following responsibilities:

He/she must:

- Have a working knowledge of the rules and regulations governing the care and use of laboratory animals.
- Be familiar with the factors that affect the selection, acquisition and maintenance of experimental animals and be aware of the ethical and social issues involved with the use of animals in biomedical research.

- Design the research protocol so as to utilize the least number of animals needed to provide reliable data.

- Ensure that all personnel involved in research projects using animals have:
  - Successfully completed animal care and use training
  - Enrolled in appropriate occupational health programs
  - Received proper training in techniques used for the experimental procedure.
  - Use animals that are lawfully acquired in compliance with an approved animal protocol
  - Not initiate any research, testing, or instructional project involving the use of vertebrate animals unless this protocol has IRB approval and training of the staff involved in the care and use of laboratory animals has been completed.

- Make certain that students using animals for training, testing or research do so under the direct supervision of an experienced teacher or investigator:
  - Animals are treated humanely, properly fed, and their surroundings are kept in a sanitary condition.
  - Anesthetics and analgesics, appropriate to the experimental design, are used to eliminate unnecessary pain during scientific procedures.
  - Postoperative care of animals in survival surgery is such as to minimize discomfort and pain as well as maintain health and well-being.

- Ensure that all animals are observed daily for signs of illness, injury or abnormal behavior and when found, the attending veterinarian is immediately contacted.

- Ensure that all applicable records and logs are properly documented.

VI-References


