



## THE AGA KHAN UNIVERSITY

### Research Policy

<i>Policy No. ORGS/007-2020</i>	
<b>POLICY FOR SUBMITTING EXTRAMURAL GRANT APPLICATIONS</b>	
<i>Last updated :</i>	May 11, 2020 <sup>1</sup>
<i>Contact Office:</i>	Office of Research & Graduate Studies
<i>Approving Authority:</i>	University Research Council

*The Aga Khan University, in this document means all its schools, colleges, institutions, departments, research centres and hospitals across all campuses around the globe.*

#### 1.0 RATIONALE

- 1.1. Research and other externally sponsored activities including but not limited to capacity building, trainings, and consultancies at the Aga Khan University (AKU) have expanded significantly over the years, and continue to grow. Consequently, the number and scope of applications for extramural grants is also escalating. For purposes of integrity and consistency, it is important to ensure that grant applications intended for submission to external agencies, conform to University policies and comply with all the legal requirements. Ultimately the Office of Sponsored Research (OSR) with assistance from other departments of the University is required to safeguard the University interest and ensure that the grant proposal has undergone an institutional review before its final submission to a funding agency. On behalf of the University, the OSR will not endorse any agreements that have not gone through the University's internal approval process. This document is a policy statement on the Extramural Grant Application.
- 1.2. It is intended that this policy will assist applicants in:
  - 1.2.1 preparing better proposals for extramural sponsored grants.
  - 1.2.2 seeking required internal approvals before a research proposal is to be submitted to a funding agency.
  - 1.2.3 Will help AKU in establishing requirements for sponsors of research to ensure their commitment to the conduct of ethical research in accordance with the applicable laws and regulations
- 1.3. The applicant or the lead person for the project for which funding is sought (Principal Investigator (PI) in case of research grants, or Project Lead or Director in case of other activities) can have preliminary discussions about a proposed project including exchange of emails with the funding agency, however no written proposal (paper or electronic), which binds the University to a legal or moral responsibility can be submitted until an internal approval is obtained in writing.

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<sup>1</sup> Previous revisions: December 14, 2017; July 12, 2018

## **2.0 ROLE OF THE OFFICE OF SPONSORED RESEARCH (OSR)**

2.1 The OSR was set up as a global office to facilitate researchers across all campuses of the University in promoting, applying and availing of funding both from external sources. Potential applicants should keep the OSR informed in matters pertaining to extramural funding submissions beforehand, for example, in matters related to completeness of applications, taking into consideration the requirements/conditions of the funding agency, and conformity with University policies and the law prior to submission to the funding agency. The primary objective of the OSR is to assess the level of compliance of the proposal to university policies and funder requirements and not to primarily review the science of the proposal.

2.2 With respect to extramural funding opportunities, the OSR:

2.2.1 Periodically disseminate information on grant funding opportunities across the University;

2.2.2 Maintain a list of funding agencies relevant to the University and its regions of operation, and make available the same to researchers upon request and through the periodic bulletin *viz.* Research and Grants Funding Opportunities (RGFO). The OSR may subscribe to lists of funding options available and assist faculty in accessing the same as and when possible;

2.2.3 Make any and all internal guidelines and policies available to researchers, both general and specific, as well as forms and FAQs related to research and grants, as available and get policies endorsed by the AKU governance bodies as appropriate.

2.2.4 Gives advice, where sought, on completing the pre-award checklist and other documents, including but not limited to advice on all aspects of a proposal in consultation with the other approving departments, and the submission of applications to funding agencies;

2.2.5 Assist applicants or their representatives in completing administrative requirements related to the grant, including centralised electronic submissions if required, and any documentation for submission with the grant proposals to extramural funding agencies;

2.2.6 Log applications for the record and enter information of approved and funded applications into the Funded Projects Database maintained by OSR;

2.2.7 Advise, review and confirm availability of bench space and equipment and other physical resources under the supervision of the Research Office.

## **3.0 ELIGIBILITY**

3.1. All full-time, faculty members and research staff<sup>2</sup> are eligible to apply for research grants but it is important for PIs to have the necessary expertise/ qualification, experience and commitment to take the project to a successful completion. This is subject to approval from the Department/Entity Head certifying that there is no other reason for ineligibility, including, but not limited to other committed responsibilities, long leave, approaching end of contract, resignation, and disciplinary action. In exceptional circumstances, contract faculty, part time faculty or a non-faculty can be the lead person of a project, but will require prior approval of the Provost or the Provosts' designate. The same criteria of eligibility strictly apply to Co-Principal Investigators (Co-PIs) as they will be held equally responsible for everything that the PI does.

3.2. All faculty, and in exceptional cases staff, are eligible to be Co-Investigators (Co-I). This is subject to approval from the Department/Entity Heads certifying that there is no other reason for

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<sup>2</sup> Research Fellows or equivalent in AKU Research Institutes and entities.

ineligibility, including, but not limited to other responsibilities, leave, resignation, disciplinary action, etc. To qualify as Co-Is, they must provide significant demonstrable intellectual input to the research project.

- 3.3. In addition to the clause 3.2 above, researchers external to AKU, such as members of other institutions can be Co-Is, subject to written approval by competent authority of their parent institution.
- 3.4. Graduate students, postdoctoral fellows and research staff hired on a specific project cannot apply for extramural funding as PI. However, students can become a Co-I with their supervisor's approval in the project(s).
- 3.5. In all the cases except 3.3, the head of the department/ Chair certifies that they will provide the PIs and Co-Is sufficient time to participate in the project. The supervisor takes responsibility for Graduate students conduct while working in a project led by them.

#### **4.0 CONFLICT OF INTEREST**

- 4.1 Conflicts of interest, (COI) or perceptions of conflicts may occur when there is a convergence of an investigator's personal interests with his or her research interests, such that an independent observer might reasonably question whether the investigator's professional actions or decisions are inappropriately influenced by considerations of personal financial gain. Such conflicts are common in universities and do not question the character or actions of any individual. Such conflicts of interest can also arise in non-research grants including consultancies.
- 4.2 It is required that any member of the research team, including the investigator (that is, any AKU employee responsible for the design, conduct, or reporting of a sponsored project at AKU) may be required to disclose significant personal financial interests related to his/her institutional responsibilities pursuant to circumstances specified by AKU's COI policy. Increasingly many granting agencies including but not limited to the National Institutes of Health (NIH) ask the university to provide undertaking about ensuring that the COI will be managed.
  - 4.2.1 This disclosure must be done through a section entitled 'Conflict of Interest' in the "Checklist".
  - 4.2.2 When AKU reasonably determines that the significant financial or other interest could directly and significantly affect the design, conduct, or reporting of the research, AKU will take steps either to manage or to eliminate any COI from the project. The PI agrees to fully cooperate with the university in this regard.

#### **5.0 SUBMISSION OF CHECKLIST TO THE ORGS**

- 5.1 The lead person will develop a proposal as per the requirements of the Funding Agency. He/she or a person authorized by him/her will then fill out the OSR Checklist and after due approvals from all relevant departments, submit the same to the OSR for processing.

During submission of concept notes or letter of intents, there are two types. Type 1 - This usually consists of a project outline, more of a concept note and does not include any financial, personnel or other details. This can be submitted directly to the funding agency. But, you must send a copy to OSR. Type 2 - This is much more than a concept note/ LOI. While names as such by a funder, it is close to a full proposal and includes detailed budget such as personnel, equipment costs, etc. This cannot be submitted directly. It would follow the same process as a full grant proposal.

To protect the PI and the university's reputation as well as any legal liability that may ensue, identical or similar proposals must not be made to different sponsors nor should duplicate funding be solicited from any institution. To avail funding opportunity, a PI can apply an identical or similar proposal to different sponsors; provided that sponsors are made aware in writing of submissions to the other agency(ies).

5.2 Responsibilities of the applicant regarding the grant proposal and Checklist:

5.2.1 It is the responsibility of the lead person to submit the duly filled proposal, Checklist, and supporting documents to the approving departments, satisfy their queries, and seek their approval.

5.2.2 He/she will submit the proposal well ahead of the deadline to allow the respective departments adequate time to make changes, they deem necessary. In circumstances when the deadlines are genuinely short, the OSR in cooperation with other reviewing departments will do a quick review and give a conditional approval for submission during the deadline. In such a situation the PI undertakes to have detailed completed review within 30 working days of submission. If there is any significant issue found with the proposal the PI agrees to withdraw the proposal from the sponsor.

5.2.3 Further to the above it is the responsibility of the PI to especially keep in mind unanticipated social, political, and technical, challenges that may delay the submission of the grant application, as well as the chance of resubmission due to errors arising from the funding agency end related to the technical/compliance aspects of the grant application itself. While the OSR and other support offices will do their utmost to facilitate under these circumstances, adequate time will alleviate pressures on all involved.

5.3 The Grants & Contracts Office (G&C), Finance Division Pakistan or the Finance Offices in East Africa or UK, upon request, will assist in preparing a financial budget in the case of PIs from departments which do not, or have limited capacity within their departments to prepare the budget.

5.4 In addition to direct expenses, the budget should aim to recover indirect costs of the University, as approved from time to time (the current figure may be requested from the Finance). This recovery may be done either through a straight charge to the grant (up to the extent allowed by the funding agency's policy), or by charging allowable core University costs as direct expenses to the grant. Naturally, either of the above options should be chosen and executed in a transparent manner, and based on guidelines/policies of the respective Funding Agency. Examples of core costs can be:

5.4.1 *Cost of rent and utilities of existing office space.* This includes charges for rent of space, electricity, gas, water and sewage services;

5.4.2 *Reprography services.* These include photocopying, copy-printing, and other similar document services;

5.4.3 *Communication costs.* These include costs of telephone calls, postage, courier, fax, email and Internet;

5.4.4 *IT Services including procurement of software or its license.* The cost of IT services support includes expected routine software provision, hardware and software maintenance/trouble-shooting, etc.

5.4.5 *Space and technical assistance*

5.4.6 *Statistical consultation.* Cost for data analysis and interpretation of results by means of advanced statistical analysis generally done by a statistician.

5.4.7 *Core facilities, utilization and maintenance.*

## 5.5 REVIEW AND ENDORSEMENTS

The following departments/individuals review and approve the proposals. The extent of their responsibility and their endorsements are in Annexure 2.

- 5.5.1 The head of department/ Chair must approve the relevant sections of the Checklist,
- 5.5.2 Estate/Housing Department (only if there is an off-campus component in the proposal);
- 5.5.3 Human Resources (if personnel are to be hired or there are core personnel being utilised);
- 5.5.4 Finance (to ensure that Institutional financial policies are adhered to and project budgets are reasonably accurate and adequate. PI is responsible for the scientific basis of the budget);
- 5.5.5 Legal Department (to minimise the exposure of AKU to anything mentioned in the proposal);
- 5.5.6 Registrar (only in case of student sponsorships, and/or funding of academic programmes); to ensure that fees are accurately depicted.
- 5.5.7 CTU (only in case of clinical trials).
- 5.5.8 Safety and security of off-campus research sites (only if project activities are to be performed anywhere outside the AKU campus).

In addition to the above approvals, the Checklist must be accompanied by the following documents:

- 5.5.9 A profile of External Collaborators (if any);
- 5.5.10 Individual support letters from any and all Collaborators/External Co-Investigators indicating their willingness to participate and that they are authorised to do so in the project, along with the extent of their involvement in the proposed study, as well as their budget (if any);
- 5.5.11 Copy of the proposal that is to be submitted to the Funding Agency. If any changes are required to the proposal after submission, it would require explicit approval of the OSR.
- 5.5.12 Copy of the financial budget with justification.
- 5.5.13 The following information for records and data analysis.
  - Brief objectives of the project
  - Anticipated impact
  - Research Design
  - Laboratory space needs.
  - Animal requirements. (PI to take advise from the ECACU regarding availability of capacity at AKU to complete the planned deliverables in the grant).
- 5.5.14 To ensure biosafety, all projects involving activity in the research lab or handling biological or hazardous materials have to be reviewed by the Institutional Biosafety Committee. The process flowchart for biosafety approval as well as bench space need in the juma building laboratory is at [https://www.aku.edu/research/facilities/Documents/Implementation Process for Juma Lab Bench Needs and Biosafety Aspects.pdf](https://www.aku.edu/research/facilities/Documents/Implementation%20Process%20for%20Juma%20Lab%20Bench%20Needs%20and%20Biosafety%20Aspects.pdf)
- 5.5.15 In case human subjects are related to AKU/ AKUH an undertaking is required from the PI that all JCIA compliance requirements will be followed.
- 5.5.16 Any other document required for this purpose, including, but not limited to informing the OSR of any change requested by the funding agency or the PI as the case may be.

- 5.6 Further to the clauses above, in case after submission, the funding agency recommends changes to the application it is the responsibility of the lead person to ensure that entity/departments whose endorsement is affected by the said change must re-endorse the changes in the application (for example, in case of personnel changes, HR must re-endorse changes). OSR can advise if the lead investigator has any queries in this regard.

## **6.0 SUB-RECIPIENT SELECTION**

- 6.1 The need for a sub-award is normally made at the proposal stage. The lead person writes the scope of work for the potential sub-recipient. The scope of work describes exactly the work the sub-recipient must do to meet the terms of the sub-award. The scope of work is also used to justify sub-recipient selection in cases where a sole-source justification is required.
- 6.2 The PI is required to complete section entitled ‘Multicentre /Collaborative Grants’ in the Checklist in order to ensure that the relationship between AKU and the sub-recipient is clear and the selection of the sub-recipient can be justified. For all subcontracts greater than US\$5,000 in a grant, AKU will ensure that due diligence of the sub-recipient is undertaken. This would require the sub-recipient filling in the form and providing supporting documents. The OSR, Finance and Legal will review the documents to decide if there are any reasons the organization should not be taken up as a sub-recipient. Finance may at its discretion, further review the financial system of the sub-recipient.

## **7.0 CHANGE IN PRINCIPAL INVESTIGATOR**

- 7.1 The PI is expected to complete the project to its logical conclusion. Periodically situations may arise when a project lead, including a PI or project director, is unable to continue the project due to any reason. In these case, please refer to the policy on “Mechanism for Change of Principal Investigator”.

This policy can be downloaded from <https://www.aku.edu/research/policies/Pages/home.aspx>.

- 7.2 Certain granting agencies e.g. the Higher Education Commission of Pakistan (HEC) now require in their agreements that the PI must complete the project (which cannot be terminated midway), or a Co-I must complete it. In such cases having a Co-I willing to take over the project is mandatory and the PI and Co-I(s) must undertake jointly or severally to complete the project.

## **8.0 INTELLECTUAL PROPERTY, PUBLICATIONS AND CONFIDENTIALITY**

- 8.1 As a general rule, the University will follow the university policy of Intellectual property rights (IPR) which allow intellectual property to be owned or shared by the University subject to agreements with appropriate funding sources, which do not impose restrictions on publication, and which do not impose other unusual restrictions on the basis of confidentiality on faculty, staff and students. The University is cognisant, however, that in certain circumstances, confidentiality clauses may be necessary, such as in the case of patent development, etc. This will be decided and dealt with on a case-by-case basis.

- 8.2 Data will be retained by AKU for further research, with due permission from relevant parties, including, and when necessary, not limited to the survey population, the funding agency, and any other party that may be directly affected. This is subject to the initial agreement with the funding agency. University personnel (existing or former) can have access to data based on Annexure B of the IPR policy.

This policy can be downloaded from <https://www.aku.edu/research/policies/Pages/home.aspx>

- 8.3 For the purpose of record keeping and protecting the intellectual property of the University, all PIs would be required to keep all data of their project in a secure place, in the custody of their respective department administration, and a centralised repository. Electronic or softcopy is preferable.
- 8.4 Materials, especially coming from human subjects have to be kept secure and can only be shared with other collaborators after a material transfer agreement (MTA) is signed. This transfer must have the approval of the AKU's Ethics Review Committee and the Institutional Biosafety Committee (IBC). The process of getting an MTA signed is at [https://www.aku.edu/research/downloads/Documents/MTA Approval Process.pdf](https://www.aku.edu/research/downloads/Documents/MTA%20Approval%20Process.pdf)
- 8.5 Data (whether having an IP value or not) especially containing information extracted from human subjects has to be kept confidential and secure (whether physical or electronic form) and can only be shared with other collaborators after a data transfer agreement (DTA) is signed. This transfer must have the approval of the AKU's Ethics Review Committee. The process of getting a DTA signed is at [https://www.aku.edu/research/downloads/Documents/DTA Approval Process.pdf](https://www.aku.edu/research/downloads/Documents/DTA%20Approval%20Process.pdf)

## **9.0 FINAL AGREEMENT, RELEASE OF FUNDS AND ETHICAL APPROVAL**

- 9.1 The funding agency usually prepares the final agreement. Once the final agreement, or its draft, is received from the funding agency, it is reviewed by Finance, the Legal Office, and the OSR (and other department, if and as relevant) to ensure that the terms and conditions mentioned in the agreement are acceptable to AKU. Furthermore, the budget and other requirements are checked to see if they concur to what was approved during the initial proposal submission stage. Difference if any are reviewed and if adequate approved. The authorised signatories from the Research office and Finance subsequently sign the agreement/MoU/Sub-contracts/MTA/DTA and any other arrangements on behalf of the University.
- 9.2 After the agreement is signed by both the funding agency and the University, the grant is considered as an approved project. However, in case of projects involving interaction/study on human subjects or human tissues, the PI must obtain an approval from the University's Ethics Review Committee (ERC). See section 9.4
- 9.3 It should be especially noted that the internal approval process is mandatory in all cases, prior to final submission of proposal even where funding agencies require only the PI and/or the concerned head of department to sign the proposal form. Agreements are between institutions and not individuals hence all agreements/contracts will be signed for AKU by the relevant authorized signatories. Should you receive any agreement in your own name, you must immediately contact the OSR for further guidance.
- 9.4 In addition to the requirements of AKU and the funding agency, ethics reviews must be carried out by the AKU-ERC:
- 9.4.1 Prior to activation of a grant, PIs are required to state whether all clearances (approval or exemption) for matters, such as human subject protection have been obtained from the relevant AKU-ERC; or the AKU-Ethical Committee for Animal Care & Use (ECACU) in case of animals. All relevant national and provincial regulations must also be complied at all times during the conduct of the research.
- 9.4.2 If AKU-ERC is pending at the signing of the agreement, the PI and Departmental Chair will have to provide a written undertaking that no human subject / animal related work/interaction will be undertaken prior to the respective AKU-ERC and/or ECACU approval.
- 9.4.3 In case ethical approval is pending, the budget code can be activated on a case to case basis, and preliminary expenses, if any, will be allowed for recruitments, setting up the project, prepare for submission of ethics application etc. PI (with the help of Finance) will develop a preliminary

expense sheet for such fees/costs/expenses. However, PI must ensure and will be responsible that no human subject/ animal related work can be initiated without the necessary and applicable regulatory approval(s).

- 9.4.4 The provision for who will be paying for the expenses if the ethical approvals are denied can be built in the grant applications, and the Department would be responsible for paying any expenses that are not reimbursed by the funders if the project is prematurely terminated due to non-approval by regulatory bodies.
- 9.5 Providing proof of AKU-ERC/ECACU/national and provincial regulatory body/authority approvals as well as complying with ethics guidelines of the funding agency is the responsibility of the PI.

## **10.0 REQUIREMENTS FOR SPONSORS AND CONTRACT RESEARCH ORGANIZATIONS (CRO)**

10.1 In compliance with the university and hospital's policies and processes for monitoring and evaluating the quality, safety, and ethics of research, the investigator will work with the sponsors, in case the sponsors are a commercial organization or a CRO involved in the clinical research, to ensure:

- Research teams used by the sponsor are trained and qualified to conduct the research.
- Privacy and confidentiality of subject data is maintained
- Research data are reliable and valid and the results and reporting are statistically accurate, ethical, and unbiased.
- Patient or researcher incentives do not compromise the integrity of the research.

10.2 In case the sponsor is transferring its duties, functions and responsibilities to the CRO, the investigator will ensure that the following requirements are met:

- A written contract clearly delineating this transfer of responsibilities.
- The contract should specify that the CRO or sponsor is also responsible for compliance with University and Hospital's policies and process for monitoring and evaluating the quality, safety, and ethics of the research per item 10.1.

**11.0** This policy will be reviewed on an annual basis (or more frequently, if required)

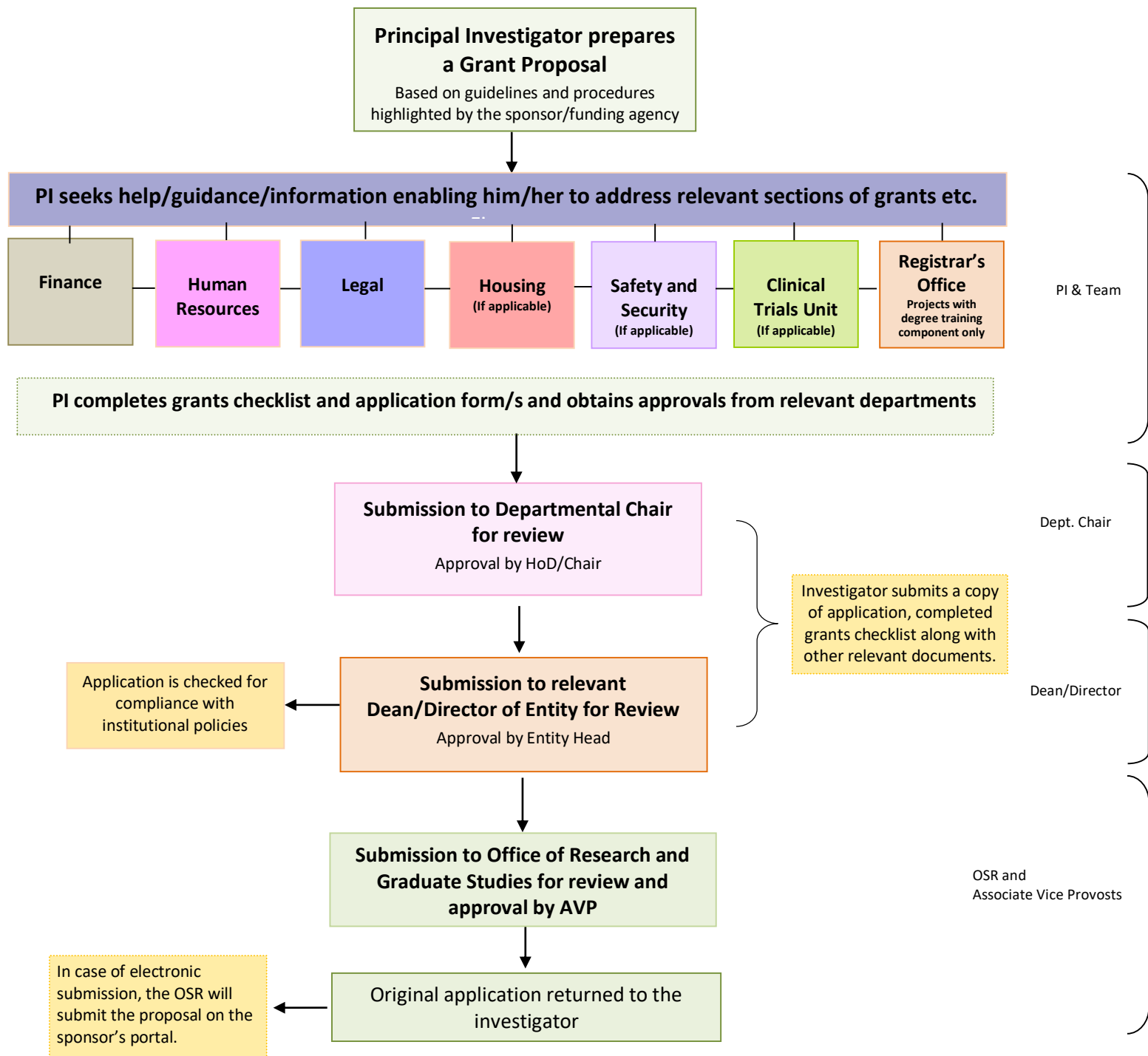
**12.0** The following annexures are to support the policy

- a) Flow chart (Procedure for applying to extramural funding).
- b) Endorsement (Responsibilities of endorsing departments).



**Annexure I**

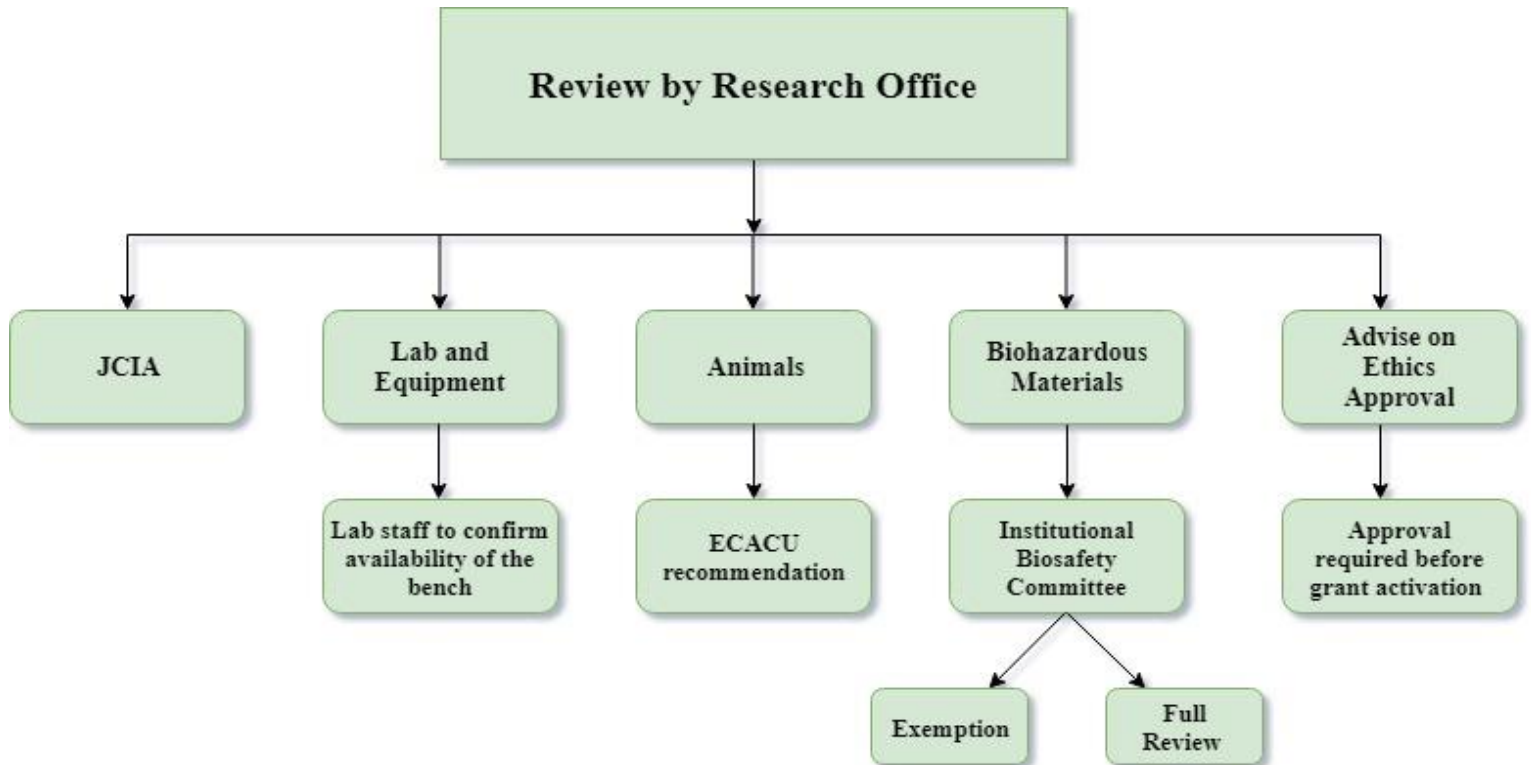
**PROCEDURE FOR APPLYING FOR EXTRAMURAL FUNDING**



///End of Annexure I

**Annexure I.I**

**SUBMISSION TO OFFICE OF RESEARCH AND GRADUATE STUDIES FOR  
REVIEW AND APPROVAL BY ASSOCIATE VICE PROVOST (RESEARCH)**



///End of Annexure I.I

## Annexure II

### ENDORSEMENTS

Endorsements by the applicant and associates,

1. Undertake that the information provided by them is to the best of their knowledge correct and free from any errors.
2. They are capable of undertaking this activity in the time allocated by AKU to them, and confirm the percent time contribution attributed to the individuals listed in this proposal closely reflect their contribution to this project
3. Certify that the resources requested by them from the granting agency are adequate and will only be utilized for this project in line with the policies of AKU and the granting agency.
4. They will jointly and severally maintain the highest standards of integrity and ethical standards and will not do anything that compromises the good standing and resources of AKU or violate ERC approval.
5. Undertake to report any major change in this proposal to the OSR and the relevant unit whose review parameters are changed by it.
6. Have not submitted this or a similar grant to any other funder.
7. The proposal is an original effort and all references are cited with due acknowledgements.
8. Use their best efforts to ensure that the deliverables, reports and data requested by the funding agency will be submitted on time and will bring the project to its logical conclusion as mentioned in the proposal, or subsequent amendments.

The **Chairs of Departments** must approve on the relevant sections of the Checklist, thereby certifying availability of facilities necessary for execution of the grant, releasing the Researchers for the time necessary for the duration of the project. The Department Chair also use their influence to ensure their faculty comply with the terms and conditions of the grant including, but not limited to, timely submission of reports, maintaining records, and achieving the required milestones.

The following administrative departments endorse the following:

**Estate/Housing Department** (if there is an off-campus component in the proposal);

They will confirm that they have examined the off-campus premises/facilities to undertake this project activity (e.g. rent, utilities, refurbishment etc.) including the budget and certify that these are adequately covered.

Certify that to the best of their knowledge the lease and other documents executed for this purpose are as per AKU policy requirements and the contracted party is acceptable.

OR

They will ensure that the lease documents are executed appropriately and are involved in short listing parties for this purpose.

**Human Resources** (if personnel are to be hired or there are core personnel being utilised);

Confirm that the designations of personnel comply with AKU's staffing and grading policy and the amounts budgeted for personnel for this project are adequately covered.

Confirm that the PI and Co-I's have not tendered their resignation, are not retiring or their contract ending before the expected end date of the grant.

**Grants and Contracts** (to ensure all the Institutional policies are adhered to and project budgets are adequate); G&C certifies that;

- The budget is mathematically correct.
- The budget numerically reflects all requirements of the project, as specified by the PI or their representatives.
- To the best of their knowledge, the budget has been prepared based on the relevant policies of AKU and those of the granting agency.
- Financial feedback, if any, provided by HR, Housing or other departments has been incorporated.
- The amount of core recoveries of existing personnel (based on percentages provide by the PI) are correct.
- Have informed about the deficit AKU would incur if the proposal is successful.

**Legal Department** (to minimise the exposure of AKU to anything mentioned in the proposal, and on receipt of agreement, review the legal ramifications in case of non-compliance or other disagreements based on contracts/agreements with the Funding Agency);

**Registrar** to ensure that fees are accurately depicted (in case of student sponsorships, and/or funding of academic programmes);

**Clinical Trial Unit** in case of clinical trials to ensure that proper procedure is followed;

**Safety and security** will approve and advice if visiting areas outside the main AKU campus as specified in the proposal are safe to operate in.

**Institutional Biosafety Committee (IBC)** to review the project proposal to determine if protocols of laboratory operations or handling biohazardous materials are being appropriately planned and followed.