Appendix 5: Exemption Procedure

INSTITUTIONAL ETHICS REVIEW COMMITTEE (IERC)
THE AGA KHAN UNIVERSITY - KENYA
PROCEDURE FOR ISSUE OF EXEMPTION LETTER BY IERC FOR SELECTED STUDIES

The studies in which human subjects are not involved directly, or no intervention is done are often exempted from full AKU- IERC review. Since majority of journals ask for approval by an Institutional Review Board or by AKU-IERC before accepting a manuscript for publication, it is necessary that the researchers get an approval or an exemption letter from IERC *before* starting the study, as it is unacceptable for IERC to review studies retrospectively. It is the responsibility of researchers to obtain such a letter before any study is started.

This point is again restated for emphasis: even if studies fall in the exemption category, they still need to be submitted to IERC for obtaining a letter of exemption prior to the commencement of the study as IERC does not allow retrospective review of studies, even for the purpose of publication. A system should be put in place in Unit/ departments whereby studies are signed-off by the Unit Head/ Departmental Chair prior to their commencement. This precautionary safeguard has been advised by the University Research Council to ensure that no controversial or sensitive studies are conducted even though they may have obtained clearance from relevant AKU subcommittees.

The following procedure has been developed for seeking an *exemption letter* from IERC for a study, if it is determined that the study falls in the exemption category based on the stated guidelines.

1. **Procedure For Submitting Applications:**
   1.1. Each department will set up a Departmental Research/ Review Committee (DRC).
   1.2. The researcher will submit his/ her proposal to the DRC.
   1.3. The DRC will review the proposal and send its recommendation to AKU-IERC on the prescribed form (attached).
   1.4. The proposal along with the DRC's recommendation will be submitted electronically to AKU-IERC secretariat along with one hardcopy.
   1.5. The recommendations will be reviewed by Chair of IERC. If no ethical issue is found, the Chair of IERC will issue a letter of exemption within seven days of receipt of the recommendation.
   1.6. In case Chair of IERC is not satisfied with recommendation, full proposal will be asked for review in the AKU-IERC committee.
   1.7. No study on human subjects will be done in any department (including students, residents or faculty) without obtaining exemption or approval from AKU-IERC.

2. Exempt Research Under The Revised 2018 Common Rule

(Adopted from Guidelines for Ethics Review Committee, Pakistan)

In line with the revised 2018 US guidelines of ethical review of research studies that are known as COMMON RULES, the Ethical Review Committees (ERCs) of FHS, AKU have updated their criteria for classifying research studies as exempt from review. These criteria are listed below. The Institutional Ethics Review Committee (IERC) Kenya has thus adopted these guidelines to be in compliant with the overall University guidelines.

Even when research is exempt from further requirements of review and reporting, basic ethical standards

still apply.

- Except in the case of chart reviews or database research, potential subjects must be provided enough information to be able to choose whether or not to participate. The information would typically include the voluntariness of their participation, the purpose of the research, the nature of the subject's involvement, time commitments, and contact information for the investigator.
- Research data must be handled and stored securely, in compliance with university policy.
- Access to research data must be limited to study team members and other authorized personnel.
- All members of the research team must be current on human subjects training and must have a current conflict of interest disclosure.

Please note that the researcher CANNOT himself or herself decide if the research project is exempt. The application for exemption still must be made via IERC chair who will decide if the project is exempt or not as per Procedure For Submitting Applications**:** stated in section one above.

Each exempt category is described below. The regulatory text is in blue, and clarifications follow.

2.1. **EXEMPT CATEGORY 1:**

Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

> Most educational research on regular and special educational instructional strategies, and research on the effectiveness of, or comparison among, instructional techniques, curricula, or classroom management methods may be exempt under this category.
>
> There must not be any impact of subject's opportunity to learn or any negative impact if the research involves an evaluation of the instructors. If the research involves significant time and attention away from the delivery of regular curriculum or withholding of standard educational content, this exemption would not apply. Also, there must be protection against negative impact on employment if instructors are being evaluated. Research involving randomization to a unproven educational technique, or research conducted by supervisors involved in employment decisions may not be approvable under this exemption.

Applicability to vulnerable populations:

- Pregnant women may be included in this type of research.
- Research that targets a prisoner population is not eligible for this exemption. The exemption is allowable if the research is aimed at a broader population and only incidentally includes prisoners.
- Research involving children is eligible for this exemption.

2.2. **EXEMPT CATEGORY 2:**

Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IERC conducts a limited IERC review.

This category involves interactions (verbal and written responses) and data collection only. The data collection can include audio or video recordings. Research involving "interventions" would not be approvable under this category. Interventions include manipulation of the environment or physical procedures to collection information, such as a cheek swab.

Applicability to vulnerable populations

- Pregnant women may be included in this type of research.
- Research that targets a prisoner population is not eligible for this exemption. The exemption is allowable if the research is aimed at a broader population and only incidentally includes prisoners.
- Research involving children is eligible for this exemption only when it related to educational tests or observations in which the investigators don't participate in the activities being observed. Additionally, children are not eligible for this exemption if the project requires limited IERC review.

2.3. **EXEMPT CATEGORY 3:**

Research involving benign behavioural interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audio-visual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IERC conducts a limited IERC review.

For the purpose of this provision, benign behavioural interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioural interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

Applicability to vulnerable populations:

- Pregnant women who are adults may be included in this type of research
- Research that targets a prisoner population is not eligible for this exemption.
    - Research that could include children is not eligible for this exemption. The exemption is allowable if the research is aimed at a broader population and only incidentally includes prisoners.
- Research involving decisionally impaired persons is not eligible for this exemption.

2.4. **EXEMPT CATEGORY 4**

Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable bio-specimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable bio-specimens are publicly available;

(ii) Information, which may include information about bio-specimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is for health care operations or for public health activities and purposes

- The requirement that all study data be existing at the time of IERC submission has been eliminated. Data under this exemption may be both retrospective and prospective.
- The requirement that the study involves data only has been eliminated. The research may also involve the use of specimens.

It is important to note the Exemption Category 4 only applies to the re-use of data and specimens that were or will be collected for non-research purposes or from research studies other than the proposed research study. The research materials typically will be publicly available materials, medical records or existing repositories of clinical specimens. No contact between investigator and

subject is allowed. If an investigator wants to collect information/specimens directly from research subjects, then another approval path would be required.

Applicability to vulnerable populations:

- Data/specimens from pregnant women would be allowed
- Data/specimens from prisoners could be allowed as long as the research wasn't designed to recruit prisoners and prisoners were only incidental subjects of the research.
- Data/specimens from children would be allowed
- Data/specimens from persons with decisional impairment would be allowed

2.5. **EXEMPT CATEGORY 5**

Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable bio-specimens for secondary research use, if the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable bio-specimens was obtained

(ii) Documentation of informed consent or waiver of documentation of consent was obtained

(iii) An IERC conducts a limited IERC review and makes the determination that the research to be conducted is within the scope of the broad consent

(iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from any legal requirements to return individual research results.

Research with vulnerable populations may be approvable with this exemption:

- Pregnant women may be included in this type of research.
- Research that targets a prisoner population is not eligible for this exemption. The exemption is allowable if the research is aimed at a broader population and only incidentally includes prisoners.
- Research involving children is eligible for this exemption.

Acknowledgement: ERC FHS Pakistan gratefully acknowledges the permission of University of Kansas Medical Center to use their following document as a resource used to draft this AKU FHS ERC document. http://www.kumc.edu/Documents/hrpp/Topical%20Guidance/KUMC%20Guidance%20Document%20for%20Exempt%20Research%202018%20Common%20Rule%20Changes.pdf

V. July 17, 2018

3. Composition of Departmental Review Committee:

3.1. The Departmental Review Committee (DRC) should consist of at least three members; each member should have

3.2. Obtained at least one grant from the Dean/ Director, URC or external sources. In case of an external grant he/ she must have written the research proposal himself/ herself.

3.3. Have published at least one paper in an international journal.

3.4. Obtained a certificate in on-line courses on research ethics. This could be AKU-IERC research ethics course or any international ethics research course.

4. Terms of Reference of a Department Review Committee

4.1. Review the proposal for its scientific content

4.2. The following points should specially be considered during scientific review:

4.3. Rationale/justification for the study is given.

4.4. Research question is clearly defined.

4.5. The objectives of the study are clear and achievable.

4.6. Clear analysis plan is given indicating what statistical tests will be applied for different variables of interest.

4.7. Other points/ criteria as may seem to be necessary.

5. Review of a proposal for ethical issues

The following points should specially be considered during ethical review:

5.1. The researcher is directly involved in the care of the patients if the data is collected from patient's charts. In case of students/ residents' research, his/ her supervisor is involved in the care of such patients.

5.2. In case the data is collected about a group of patients who are managed by more than one physicians, the other concerned physicians are also taken into confidence. They may or may not be a co-investigator in that research proposal.

5.3. In case of a multidisciplinary research proposal, all the stakeholders are taken into confidence.

5.4. The data to be collected does not contain any sensitive information of a financial, sexual nature etc. without the express permission of the patients.

5.5. Only data that is relevant to the study questions and objectives is to be collected. Collection of unnecessary data is to be avoided.

5.6. No photographs of patients are to be used without written permission of the patient/ guardian.

5.7. Informed-written or witnessed-verbal consent is obtained, if additional information other than that for routine clinical care is to be collected.

5.8. No intervention is planned in case of prospective review of patient data.

5.9. In case any intervention is planned, funding is available. Such proposals should be submitted for detailed ethical review to AKU-IERC.

5.10. Prospective epidemiological studies including KAP surveys, filling up of questionnaires and interviews must have a written/ witnessed informed consent form. In case of student/ residents' research as part of their curriculum (such as dissertations) such proposals should be reviewed by the Departmental Review Committee, and submitted to AKU-IERC with a recommendation for expedited approval. However, in case of faculty and other researchers, such proposals should be submitted to AKU-IERC for full ethical review and approval.

5.11. In case of analysis of laboratory/ radiological data, the data is not linked with the patient's profile.

5.12. No new tests are performed on stored laboratory samples especially genetic tests, without taking fresh consent from the donor of the samples.

5.13. In case of linking retrospective laboratory/ radiological data with clinical data, the relevant clinical departments/ physicians are taken into confidence.

5.14. In cases of linking prospective laboratory/ radiological data with clinical data, not only the relevant clinical departments/ physicians are taken into confidence but informed consent is obtained from the relevant patient/ guardian.

5.15. Researchers from laboratory/ radiology do not contact the patients directly for obtaining additional information for research purpose without taking the primary physician into confidence.