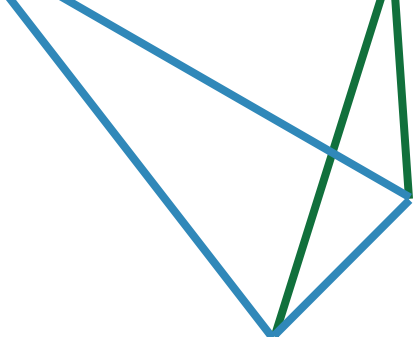


Guidelines for Research on Living Creatures in Epidemics/Pandemics and Emergencies

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The National Committee of Bioethics
King Abdulaziz City for Science and Technology



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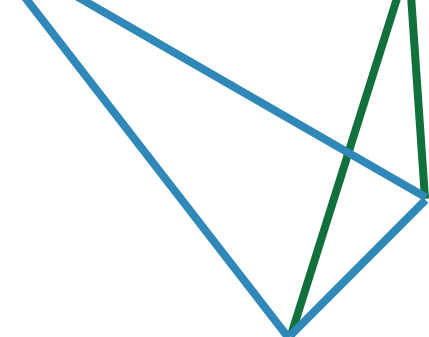
Preamble:

Research in epidemics/pandemics and emergencies is conducted in situations that are marked by uncertainty, time constraint, and remarkable pressure for addressing health care needs. The implications are magnified in cases where the impact has global dimensions. Hence, effective research in epidemics/pandemics and emergency becomes a necessity that requires rapid response from all relevant stakeholders.

Ethical issues in such circumstances require careful review of the overall research activities by all the stakeholders (researchers, research institutions, institutional review boards/local ethics committees (IRB/LECs), healthcare organizations, funding agencies, and policy makers) to conduct effective research on ethical grounds while carefully managing the delicate balance between the community good and the personal rights of participants.

In general, the approved regulations of the NCBE (second version) should be strictly followed.

At all levels, relevant biosafety standards should be rigorously applied and monitored.



1. Health Care System:

1.1.In case of epidemics/pandemics and emergencies, it is strongly recommended that the Saudi Center for Disease Prevention and Control (Weqaya) assumes the responsibility of a national repository for data storage and samples collection.

1.2.The Saudi Center for Disease Prevention and Control (Weqaya) should work by a system of how data and samples can be stored and shared (Follow the Policy on Sharing Data/Biological Samples to Facilitate Their Access for Research Purposes, Center for Health Research Studies, Saudi Health Council)

1.3.Weqaya Center should:

A.serve as a controller for data and samples that encourages, supports, and facilitates collaboration with relevant national and international organizations, research institutions, and researchers by the FAIR principles (i.e. making the data and samples Findable, Accessible, Interoperable, and Reusable).

B.establish and maintain an online registry where all approved research proposals and ongoing studies addressing the epidemics/pandemics in Saudi Arabia are registered. The registry should have a web-based resource with all the needed information about the studies for all stakeholders including patients, family members, and the public.

C.ensure that:

1.Privacy and confidentiality of participants are protected unless there is a threat to the public health.



2.The risks of conflict of interest are eliminated.

3.The rights of vulnerable individuals/groups are protected.

4.The enrollment of participants is just and the access to their data and samples is fair.

5.Unnecessary multiple samples collection from the participants is avoided.

6.The research institutions conducting such studies have the essential infrastructure and competency requirements.

1.4.When there is a need to have access to pertinent clinical information, coding of data may be adopted instead of anonymization provided that all measures of protecting the individuals' privacy are strictly adhered to.

1.5.Research on humans that does not carry heavy ethical load (e.g. nonexperimental, psychosocial studies) should be left to the IRB/LECs to approve and monitor.



2. Research Institutions:

2.1. Research institutions should develop a preparedness system where research activities in emergencies and epidemics are:

- A.** Planned.
- B.** Prioritized.
- C.** Coordinated.
- D.** Facilitated in an efficient and responsive manner.

2.2. The preparedness system should include Standard Operating Procedures (SOPs) that can be efficiently adopted in current and future epidemics/pandemics and emergencies.

2.3. The SOPs should encourage, facilitate, and support collaboration at the national level (MOH, Weqaya, Saudi FDA, Research Centers, Hospitals, Universities) taking into consideration:

- A.** avoidance of unnecessary duplication;
- B.** exploring nationwide capacities;
- C.** efficient utilization of resources.

2.4. Procedures for communication between research institutions (and their respective IRB/LECs) and relevant national authorities (MOH, Weqaya or other organizations in health care) should be specified in the SOPs.

2.5. As pandemics inherently have global impact and repercussions, research institutions should foster and support collaboration with relevant international organizations and research centers.



3. Institutional Review Boards/Local Ethics Committees (IRB/LECs):

3.1. Each IRB/LEC should develop an SOPs model for emergency ethical review that efficiently adapts to the expected large number of submitted projects.

3.2. The SOPs should specify the requirement for submission of plans for sharing:

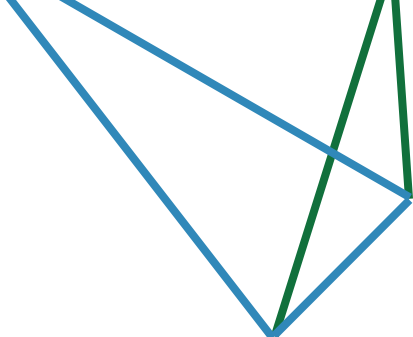
- A.** Preliminary and final data; and
- B.** Biological samples.

3.3. For fast processing, the IRB/LEC may consider developing pre-review standards to be included in pre-approval phase. Alternatively, the IRB/LEC may draft generic protocols to be adopted by the investigators to model their proposals.

3.4. For proposals that require full board review (e.g. interventional, collection of biological samples), IRB/LEC may consider:

- 1.** Distributing the assignment of reviewing the proposals to small expert groups that can review then present their recommendations to the full committee.
- 2.** Convening more frequently for full committee review by utilizing electronic means.
- 3.** Utilizing online deliberations.

3.5. The expedited review process as specified in the regulations can be used for observational, non-interventional, and low risk studies.



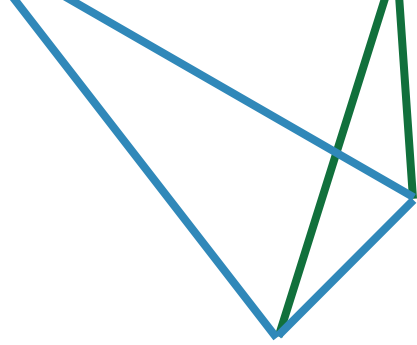
3.6.The IRB/LEC should ensure that:

- 1.**The inclusion/exclusion criteria are designed in a way that respects: (i) fairness among participants; and (ii) protection of the rights of vulnerable subjects, organizations and research centers.
- 2.**The enrollment process ensures voluntary participation. The process should be carefully reviewed when inviting individuals in quarantine.
- 3.**The rights and benefits of individual participants do not infringe the rights of or harbor risks to the public.
- 4.**The privacy and confidentiality are respected by either anonymization or coding of data.

3.7.Decoding of the participants' identifiers and their clinical data will only be granted by the IRB/LEC when needed.

3.8.In addition to adhering to the approved regulations of the NCBE in relation to the informed consent process, the following procedures are recommended:

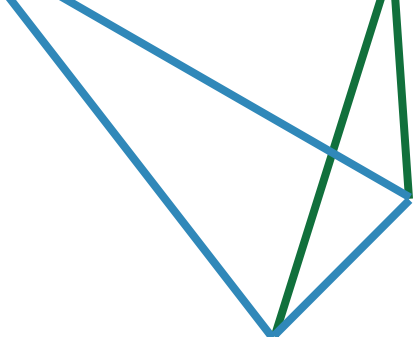
- 1.**Waiver of informed consent will only be granted by the IRB/LEC upon reviewing of the proposal in accordance with the regulations.
- 2.**For proposals involving highly contagious diseases, consent can be obtained verbally provided that the consenting process is:
 - A.**documented in the consent form; and
 - B.**witnessed and cosigned by an independent individual.
- 3.**For studies involving large-scale surveillance, waiver of informed consent can be granted.



4. Institutions of Health Care Delivery:

4.1. If a healthcare delivery institution has a process for approving compassionate administration of medications, such mechanism should be judiciously applied and in a very limited scope, in a way that does not negatively affect ongoing clinical trials, if present.

4.2. Such institution may appoint a panel of experts to determine the situations in which a drug is repurposed or used off-label, in addition to limiting the number of such exceptions to a particular level which, if exceeded, a research protocol should be presented to the IRB/LEC.



5. Researchers:

5.1. Researchers should be encouraged and supported to initiate research proposals that:

- 1.** seek substantial scientific value;
- 2.** adopt valid scientific methods;
- 3.** address national priorities; and
- 4.** establish partnership nationally and internationally.

5.2. In proposals requiring large data collection, the research protocols should include the possibility of:

- 1.** collaboration with other investigators;
- 2.** sharing data and samples concurrently or in the future.

The protocols should devise a clear plan for the management of collaboration, data/ samples sharing, and the fair utilization of the possible products of the study.

End,,