

National Committee of Bioethics (NCBE)

Controls for Sending Genetic Substance to Institutions Outside Saudi Arabia

It is known that biological specimens (blood, tissue and others) are sent for investigation outside Saudi Arabia either for diagnostic purpose due to the lack of such investigations in the Kingdom or for purposes of participation in research studies particularly those related to detection of certain diseases that are common in Saudi Arabia. Therefore, the following controls have been developed:

First: Specimen Sent Outside Saudi Arabia for Research Purposes:

When it becomes necessary to send biological specimens or participation in a research study conducted outside Saudi Arabia, the following must be observed:

1. Research study must be conducted with a world-renowned research institution that has well-known experience in the field of research.
2. An agreement must be made which should secure the rights of the Saudi patient and investigator as well as the national rights. It must be presented in the form of participation in a research study which must be approved by the National Committee of Bioethics (NCBE) and the local committee at the reporting institution of the investigator who is interested in sending patient specimens for participation in an

out-of-Kingdom research. This must be approved by the official in-charge at the reporting institution of the investigator.

3. Ensure that the research study has not been previously conducted or registered in the Kingdom, to avoid duplication of research activities.
4. If it appears that another Saudi investigator or institution conducts the same study with the support of Saudi institutions or hospitals, no biological specimens should be sent outside the Kingdom. Cooperation must be made with the progressing research inside the Kingdom, ensuring that research terms, conditions and ethics are guaranteed for participating patients.
5. Biological specimens must carry numbers and codes only with no personal information of the patient from whom specimen is taken.
6. NCBME must be notified in writing of the contents and the parties conducting the research study to verify that such study cannot be conducted in the Kingdom neither is there another research dealing with the same subject. The Committee will also ensure that international institutions and/or investigators cooperating with the study are known for that type of research. Moreover, it will review the national rights and determine the extent of benefit, the in-Kingdom medical institution can gain from the results of such research. The NCBME may reject the initiation or completion of the study if it appears to the Committee that it is of no benefit for the Saudi Community, or if it is directly or indirectly proven to be detrimental to the community. This right of the Committee must be clearly defined in the agreement concluded between the local

institution, which will be sending the specimens, and the overseas institutions.

Second: Specimens sent outside Saudi Arabia for Laboratory and Diagnostic Procedures.

When it becomes necessary to send biological specimens outside Saudi Arabia for laboratory and diagnostic procedures, the following must be observed:

1. Ensure that the required procedure is not available in Saudi Arabia.
2. Specimens must be sent to well recognized referral centers in the country of origin such as diagnostic centers for that particular disease. This is in order to secure an acceptable level of quality, control and ethical standards.
3. Sign a codified agreement, which should preserve rights of the two parties, as well as patient and community. It must encompass preventive measures to protect patient's confidentiality as well as the method of specimen disposal after the procedure.
4. Biological specimens must carry numbers and codes only with no personal information of patient from whom the specimen is taken.
