

### China Specimen-sharing policy, December 2004

The following information has been derived from the American Embassy in China policy report and confirmed by the Embassy's Environment, Science, Technology and Health counselor and the DHHS health attaché currently posted to the Embassy. Embassy staff have confirmed with Fogarty International Center counterparts that the procedures work well.

It should be noted that different procedures exist depending on whether the human specimen contains genetic content.

**If specimens contain genetic content**, then the researcher must apply to the Human Genetic Resources Administration of China (HGRAC), a small, specialized agency jointly established by the Ministry of Science and Technology (MOST) and the Ministry of Health (MOH). These exports are subject to the "Interim Measures for the Administration of Human Genetic Resources", promulgated by the State Council on June 10, 1998. IN the case of an international collaborative project, the Chinese partner to the project is to apply to the HGRAC. Principal criteria in determining whether to approve the export include:

- Whether proper informed consent procedures have been followed
- Whether apportioning of ownership and IP deriving from the samples is "fair"
- Whether the research-related purpose is clear and
- Whether the recipient organization has the capability to conduct the intended research

Significant paper work is involved in documenting compliance with these criteria. Export of human genetic material without a permit can be punished by confiscation of the material and a fine. The agent can also be held legally responsible as an individual. Reviewing officials at HGRAC can also be punished for violating confidentiality.

**If specimens do not contain genetic material** (cannot be derived), then the researcher must get approval from the Ministry of Health (MOH). The Chinese collaborating party of the joint project should apply to the Division of Health Technology Management in the Department of Science Technology and Education of the MOH with the following documents:

- A formal application letter including purpose, name of specimens, place and time of export and destination
- Detailed information on the specimen including name, quantity, unit, package, safety and notice of opening for inspection
- A copy of the project approval document or the certificate for the project or work unit
- A copy of the contract (in Chinese and English) between the applicant and the overseas collaborating institute or laboratory
- A copy of the contract between the applicant and domestic collaborating research institutes
- A copy of the approval letter from the Ethics Committee of the domestic collaborating research institute
- The formal research plan
- Informed consent forms and copies of signatures of the individuals being tested and
- Other documents required by the approving authority

The MOH contacts note that the applications should be made 30 days in advance of shipment of samples. The Department of Science Technology and Education should reply within 15 days after receiving the application. The MOH point of contact is:

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