

PHARMACY, MEDICINES & POISONS BOARD

Form CT 12

PHARMACY, MEDICINES AND POISONS BOARD MATERIAL TRANSFER AGREEMENT FORM ON SHIPPING OF SAMPLES

Shipment of samples outside the country is strictly discouraged.

Investigators are encouraged to develop capacity to do all tests required in the country. In special cases, where this may not be possible the investigators must justify in the proposal the reason for importation and exportation of samples.

In review process, the following have to be considered:-

- There must be a justification for importation and exportation of samples.
- PMPB shall make sure that there is material transfer agreement between relevant institution in the context of exportation and importation of samples. The material transfer agreement shall include the following:-
 - 1. The intention of the importation and exportation
 - 2. The duration of storage
 - 3. Location of storage
 - 4. The appropriate informed consent authorising the exportation and importation
 - 5. To whom it will be accessible
 - 6. Who will be the controlling officer of the samples.
 - 7. Ownership of samples
- For studies that require shipping of samples, investigators should fill the Material Transfer Agreement (MTA) form at PMPB. In case there are issues of Intellectual Property Rights (IPR), the committee shall advise the concerned parties to have prior agreement of IPR which has to be signed by all stakeholders before PMPB approval.
- Samples collected in Malawi may not be sold without prior permission from the collaborating or controlling institutions and the Clinical Trial Review committee in Malawi.

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Protocol Number:

Title of protocol:

(a) Intention and Justification of transfer:

(b) Duration of storage:

(c) Responsible Party:

(d) Location of stored samples:
(a) Transportation of complexit
(e) Transportation of samples:
(f) Ownership of samples:
(g) After all laboratory testing has been completed: Describe what will happen to the samples
(h) Appropriate informed consent authorising the exportation and importation of samples
(i) To whom will the samples be accessible
(i) To whom will the samples be accessible

(j) Who will be the controlling officers of the samples

Signed by:

Name of the PI:

Name of Institution:

Signature:

Date Signed:

PMPB APPROVAL

Name of the Chairperson: Secretary

Signature:

Date Signed:

PMPB STAMP OF APPROVAL:

Name of Co – PI

Name of Institution:

Signature:

Date Signed:

Name of

Signature:

Date Signed: