Quality Medicines for Malawi

MATERIAL TRANSFER AGREEMENT FORM ON SHIPPING OF CLINICAL TRIAL SAMPLES

1 **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.

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

2.1 There must be a justification for importation and exportation of samples.

2.2 PMRA 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: -

2.2.1 The intention of the importation and exportation;
2.2.2 The duration of storage;
2.2.3 Location of storage;
2.2.4 The appropriate informed consent authorising the exportation and importation;
2.2.5 To whom it will be accessible;
2.2.6 Who will be the controlling officer of the samples;
2.2.7 Ownership of samples.

2.3 For studies that require shipping of samples, investigators should fill the Material Transfer Agreement (MTA) form at PMRA. 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 PMRA approval.

2.4 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.

PMRA MATERIAL TRANSFER AGREEMENT FORM
Protocol Number:
Title of protocol:
(a) Intention and Justification of transfer:
(b) Duration of storage:
(c) Responsible Party:

(d) Location of stored samples:
(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

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

SIGNED BY:

Name of the PI:…… Name of Co – PI:……..

Name of Institution:…….. Name of institution:……..

Signature:…… Signature:……

Date Signed:…….. Date Signed:……..

PMRA APPROVAL

Name of the Chairperson:…….. Name of Secretary:……..

Signature:…….. Signature:……..

Date Signed:…… Date Signed:……

PMRA STAMP OF APPROVAL: