

Research Guidelines Involving the Sharing of Human Materials /Data with Commercial / Industrial Entity

The Gambia Government/ Medical Research Council The Gambia – Joint Ethics Committee (GG/MRCG-JEC) has decided that applicants submitting proposals for the purposes of research that involve the sharing of human materials/data with commercial or industrial interests shall be required to comply with the following guidelines:

- i. That the researcher is advised to re-consent all participants who were involved in the original study research in all cases where there is need to engage a commercial or industrial entity for further research or use of the data/samples.
- ii. That a scientific justification for collaborating with the commercial or industrial entity must be provided to the GG/MRCG-JEC for approval, and that it is NOT merely a case to meet the interest of the commercial or industrial company.
- iii. That the Information Sheet should indicate the aim and objective(s) of sharing the original research data and/or samples with the industrial or commercial entity.
- iv. That the Ethics applications shall include an explanation of any risk to the study population and shall indicate how the populations' data will be protected.
- v. That a binding agreement between the researcher and the commercial entity should be submitted to the GG/MRCG-JEC which should include (1) Material and Data Transfer Agreement (MDTA); (2) consistent and regular notification of the progress and outcome of the commercial research/innovation; and (3) proposal(s) on potential benefit sharing with the study population.
- vi. That the commercial entity shall not share data/samples with a third party without prior consent of the primary provider and researcher.
- vii. That the informed re-consent document shall outline that the intended sharing of data/samples is with an organization that markets products of value in health-care landscape.
- viii. That a blanket consenting statement (*such as "genetic or other samples we obtain from you can be used and shared in future for any form of research"*) is **not acceptable** when it comes to collaboration with commercial and Industrial entity.
- ix. The GG/MRCG JEC directs the inclusion of the following statement in the re-consenting document:

- a. ***We are seeking your permission to share your samples/data with a specific company called-----
----- who are seeking to develop drugs, or reagents (laboratory work materials) or vaccines.***
- b. ***This company is interested in its research to get an outcome from such samples/data of a final product that may be put into the market for sale if they are successful in the research with your sample.***
- c. ***We cannot, at this stage, commit any future benefit for you or to the community because these kinds of research are not simple and straightforward. It may fail, and may take a long time to know if there will be a beneficial outcome.***
- d. ***The sample/data you provide may also be passed on to a third party during the research process. However, you are assured that your sample/data will be anonymized and protected."***
- e. ***Do you have any concerns or questions?"***