Comments CIOMS (Rieke van der Graaf PhD) on WMA Expert Meeting on the draft to WMA Declaration on Ethical Considerations regarding Health Databases and Biobanks, Copenhagen on 15-16 September 2015

CIOMS would like to make 5 comments, which have been submitted in more detail earlier:

1. The type and purposes of the biobank could be further specified. For instance, there are population-based biobanks consisting of a large collection of biological tissue donated by thousands of individuals from the general population who might or might not have a specific disease, disease-specific biobanks, databanks, with health related data, but also biobanks for clinical purposes (such as stem cell transplantation). Each of these biobanks call for different governance structures.

2. It is important to differentiate between known and unknown research aims and between the different types of material that are stored in biobanks.

   If the research aims are clear: specific informed consent should be asked. If not depending on the type of material different forms of informed consent may be applied:

   1. New material, specifically collected for research purposes; usually this type of material is associated with broad consent. Broad consent describes the range of future uses in research for which consent is given, among others conditions and duration of storage, who will manage access to the material, etc.
   2. Left over material from diagnostics and treatment, which is now stored for research purposes; in some countries, and also according to the current CIOMS draft, it is sufficient to use an opt out procedure for this type of research. In the WMA draft however, neither left over material, nor the opt out procedure is mentioned. Opt out procedure: material is stored and used unless the person objects. Conditions: people need to be aware, they have to be informed about the opt out and that they can withdraw, and there should be a genuine possibility to object
   3. Archived material for which there is no consent for future research purposes, consent for materials collected in the past may be waived:
      a. If the research would not be feasible or practicable to carry out without the waiver
      b. The research has important social value
      c. The research poses no more than minimal risk when there are no benefits to be expected

3. We propose that the draft includes some guidance on return of individual, and aggregate, results (e.g. genetic results), because some results may bear a health impact on the participant.

4. Guidance on re-contacting participants to ask for re-consent should be included in the draft. A reason for re-contacting, for instance, may be asking consent to adults whose data or biological material was stored when they were a child and not able to consent. Or in case of registries in which data are stored people should be aware that they might be contacted after several years to ask consent for obtaining new data

5. Sections on governance should be further clarified. Broad consent is not so much consent to an unspecified range of future research, but consent to a governance structure. The following issues should be part of the governance structure of a biobank:

- Ethical oversight
- Property rights and commercial interests, who manages the biobank, material transfer agreements, property rights of the donor
- Data and sample management: which personal information is linked, who will have access, quality control
- Communication with donors: broad consent, return of results and also engagement of participants, and also benefit sharing
- Aim of the biobank: disease specific or population-based

References

Boers S.N., van Delden J.J.M., and Bredenoord A.L. Broad consent is consent for governance. *American Journal of Bioethics* 2015 (in print).

Boers S.N., van Delden J.J.M., Bredenoord A.L. Organoid technology: identifying the ethics (under review)

Bredenoord A.L., Onland-Moret N.C., van Delden J.J.M. Feedback of individual genetic results to research participants: in favor of a qualified disclosure policy. *Human Mutation* 2012, **32**, 861-867.

Giesbertz N.N.A., Bredenoord A.L., van Delden J.J.M. Inclusion of residual tissue in biobanks: opt-in or opt-out? PLoS Biology 2012, 10(8): e1001373. Doi:10.1371/journal.pbio.1001373.