Secondary use of data and samples: Ethics guidance on consent

1. **General guidance regarding consent and secondary use of data and samples**

With respect to secondary use of stored data or samples, the steps regarding consent are outlined in the Department of Health (DoH) (2015) ethics guidelines (pp. 43-44, 3.3.7) as follows:

1. **Request for proof of original consent** to store and use the data/samples for future research.

2. If this consent **covers the objectives of the current research project**, then no new consent is required.

3. If this original / future use consent **does not cover the scope of the current research, then new consent may be required.**

4. **Failing being able to demonstrate consent** as in the above three steps, and with justification as to why new consent cannot be obtained, **UREC may consider a strongly motivated waiver of consent request** which demonstrates not just our conditions of anonymised data at the point of collection and aggregated findings, but also justification as to why this research is believed to not pose the risks outlined in 3.7.7. iii) (p. 44) in the DoH guidelines, and highlighting the social value of the research. We have previously given feedback to this effect as follows:

UREC will consider whether granting a waiver of informed consent for use of these samples is ethically appropriate given the unique circumstances and potential social value argued for by the applicant. If UREC were to grant a waiver of informed consent, it would be based on consideration of whether the requirement for informed consent (respect for autonomy) could in this case be trumped by the potential social value (anticipated benefit to society) of the research and any potential benefits to patient management/care that are anticipated. The researcher is encouraged to submit convincing evidence of these anticipated benefits and social value in the revised protocol.

2. **Guidance on use of donated samples / cadavers for research purposes**

According to the National Health Act, the consent processes for use of such materials that are donated for "teaching/research" purposes is:
1) **donor consent**;
2) **proxy consent by next of kin** and
3), failing (1) and (2), the **Director General can give, through his/her representative (e.g. the Inspector of Anatomy), proxy consent,** provided that **steps have been taken to try and obtain next of kin consent.**

UREC will consider ethics applications to use donated cadavers/samples in research that demonstrate/detail the following:
Provided that:

1. All steps as outlined in the National Health Act regarding consent for use of donated samples / cadavers have been followed – that is, i) original donor consent; ii) next of kin consent failing (i), and iii) authorised proxy consent given by the Director General and his/her representative – in this case, the Inspector of Anatomy, as stipulated in the legislation;
2. The proxy consent provided by the Inspector of Anatomy is made on the basis of his/her satisfaction that all steps have been taken to locate next of kin;
3. Policy is implemented to trace next of kin as required by the Inspector of Anatomy; and
4. **Proxy consent is demonstrated for each donated sample / cadaver that will be used in the study.** This can be in the form of a standardised letter from the division/department concerned which states that the requisite documentation from the Inspector of Anatomy has been obtained for each individual cadaver listing dates of the proxy consent approvals for the included samples/ cadavers.

…it should be possible for UREC to approve student projects on this basis, although each application will be considered on a case by case basis.