18 Jul 2014

DSRB-022014: Changes to the Informed Consent Form Requirements for Studies Involving Prospective Collection of Biological Sample(s) and Re-Consenting Subjects for Ongoing Studies

(A) Changes to the Informed Consent Form Requirements for Studies Involving Prospective Collection of Biological Sample(s)

The NHG Domain Specific Review Board (DSRB) would like to inform investigators of studies involving the collection of biological sample(s) that they must now inform subjects that the collected biological sample(s) will not be returned to them. They must also inform subjects that they can request for their biological sample(s) to be discarded or destroyed (e.g. upon withdrawal) if it has not been anonymised (i.e. the sample can still be traced).

This change is being implemented to protect the interest of both the subjects and study teams. Biological sample(s) that are collected with the consent of the subjects are deemed to be gifted for research purposes and shall not be returned to them. Investigators must discard or destroy the collected biological sample(s) upon the request of the subjects, but will not be required to return it to the subjects.

With effect from 01 April 2014, studies that involve the prospective collection of biological materials must include a statement in the Informed Consent Form to seek consent from subjects that all biological samples collected for the study will be gifted to the institution/sponsor for the research purposes as described in the Informed Consent Form and will not be returned to them. However, subjects retain their rights to ask the Principal Investigator to discard or destroy any remaining sample(s) if it has not been anonymised.

(B) Re-consenting Subjects for Ongoing Studies that Involve the Prospective Collection of Biological Sample(s)

As this change is being implemented to protect the interest of both the subjects and study teams, investigators of ongoing studies where the subjects will be returning for study visits are also strongly encouraged to make the same changes to the ICF and re-consent returning subjects. Verbal consent may also be obtained from the returning subjects and documented in the subjects' case notes.

The Principal Investigator can submit a study amendment to DSRB to update the ICF(s) and re-consent returning subjects. A tracked change copy and a clean copy of the amended ICF(s) will have to be uploaded for the acknowledgement from DSRB prior to its use.

The DSRB Informed Consent Form Template (Document No. 207-001, Version 5, dated 3 Mar 14) has been updated to include this paragraph and can be downloaded here. Please refer to Section 11. Voluntary Participation.