BEST PRACTICES ON PATIENT CONSENTMENT

Source: extract from Best Practices Handbook, BiC project

When designing a new clinical study, the wording in the voluntary informed consent that the patients (or their legal representatives) sign should be formulated carefully as it dictates the future use of the specimens.

Best practices:

- Follow the format as suggested by the local ethics committee (each of which committees act in accordance with the Declaration of Helsinki for ethical principles for medical research involving human subjects), but also prepare for continuing research and utilization of the results obtained.
- Try to describe the scope and field of research at a level that is not too heavily bound on the ongoing project but rather allows use of the collected specimens in future projects involving other analysis techniques and/or targeting other molecules. The duration of storage of the specimens should be long enough to allow such continuing research.
- Also incorporate that the results obtained by using the specimens may be used for commercial purposes with the aim of producing new and more effective diagnostics and drugs for the diseases being investigated.
- Describe the anonymization process in the case that specimens are transferred between organizations. In the patient consent, include right for such transfer.
- Consult your legal department on which requirements of the EU General Data Protection Regulation (GDPR) need to be taken into account in your case.