Leftover Sera Obtained during the Health Care Process Can Have a 2nd Usage in Research

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Background

Obtaining prospective samples is a Biobanks big challenge. They need very often collaboration of physicians or health care personnel that in general they are not interested in obtaining these samples if not involved in the project. So that, it would be very useful to find a simply way for obtaining these samples without Biobank external collaborations.

On the other hand, the Clinical Analysis Service and also Biotech companies need very often samples (mainly sera) from patients, to check new equipment or analyzers, or to test or validate new diagnostic kits.

This kind of proofs of concept, validations and tests using these leftover samples are not strictly research projects but they are neither for the patient particular benefit. The committees have doubts on how to proceed in these cases, so it is important to ensure that all ethical and legal requirements in handling these samples are met. Nobody knows if in the future, patents or scientific publications could be derived from these technical protocols.

Methods

Hospital leftover sera where infectious and/or tumor markers have been determined, are stored routinely at the Clinical Analysis Service for a security period of time of about 8 months, This time is reserved to reanalyze these samples that were obtained during the healthcare process if necessary for the patient care and follow-up.

Taking the advantage of this process, our MARBiobanc has established a protocol where the patient signs an informed consent and leftover samples are stored for a long period of time (about 5 years) for a potential use in research.

When these stored leftover samples linked to the clinical records are required for purposes other than those related to the health care process, a request must be submitted to the biobank. After being approved by the Biobank external Ethics and Scientific committees these samples can be transferred to research projects or to external companies for their tests or technical validations, and even for education purposes.

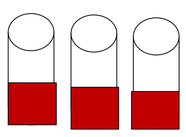
Objective

To facilitate a 2nd usage of leftover sera for research, education or for technical validations, fulfilling all the ethical and legal requirements

Biobank Informed Consent

Samples Request

- ***Prospective samples***
- ***Technical validations***
- ***Diagnostic kits***
- ***Education***



Scientific and Ethics Committees

HEALTH CARE PROCESS

Clinical Analysis Laboratory

Left over sera

8 month storage (security period)

Left over sera

BIOBANK (from 8 months to 5 years)

Criteria for long storage:
Only samples where infectious serologies and/or tumor markers have been analyzed

Conclusions

- We have established a useful strategy for obtaining prospective samples without external collaborations, based on a long storage and reusing leftover sera obtained at the hospital during the health care process.
- The Biobank takes responsibility of managing these residual samples if requested for research purposes.
- Clinical Analysis Departments and external Biotech Companies can apply a request to the Biobank in order to get samples for their technical tests and validations. Biobank and Committees are sure that all ethical and legal are met.
- This protocol opens the possibility of storing all types of residual samples obtained at the hospital (peritoneal, synovial or cerebrospinal fluids, sputum, feces, etc.) when necessary for research

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