RETENTION OF ORIGINAL CONSENT FORMS

December 20, 2019

1. TOPIC

Our recommendation addresses the question of whether the signed consent forms for participation in a study/biobank must be kept in the original (paper) version, or whether it is sufficient to keep the scanned version of the consent form.

2. OUR RECOMMENDATION

SBP encourages researchers/clinicians to retain the original signed consent forms in their records, even if electronic copies are archived on local servers.
Some may argue that if the server is secure and complies with all applicable security standards, any falsification of the electronic copies is efficiently prevented, and therefore the originals can be destroyed.
From a legal standpoint, though, Article 180 of the Civil Procedure Code states, about production of physical records:
"A copy of the physical record may be produced in place of the original. The court or a party may request that the original or an officially certified copy be produced if there is justified doubt as to the authenticity of the physical record."
It therefore requires an "officially certified copy", and such a copy can only be obtained from a Notary or from the institution that had delivered the original, which does not suit this context. Therefore, the question is: Would a judge decide that an electronic copy, archived on a secure server providing all the necessary metadata to assess whether the copy was falsified, is sufficient and/or considered as equivalent to an "officially certified copy"?
To the best of our knowledge, this question has not been clearly addressed in this context so far. Hence, SBP recommends researchers to retain all the original signed consent forms.

SWISS BIOBANKING PLATFORM
Avenue d'Echallens 9, 1004 Lausanne - Switzerland
+41 21 314 52 84 - info@swissbiobanking.ch - www.swissbiobanking.ch

3. LEGAL ANALYSIS

Neither the ***Human Research Act***[1] nor the ***Ordinance***[2] mentions specifically the obligation to keep original informed consent forms. They only request to have such consents given in writing (with exceptions):

"HRA - Art. 16 Informed consent
1 *Persons may only be involved in a research project if they have given their informed consent. Consent must be given in writing. (...)"*

"HRO, Art. 9 Exceptions to written form
1 *Information and consent may be provided and documented in a non-written form if:*
   a. *the research project in question comes under Category A, as defined in this Ordinance, and involves adults with capacity;*
   b. *provision of written information and consent would be disproportionate, given the project design; and*
   c. *reference is made to the departure from written form in the application to the responsible research ethics committee (ethics committee).*

2 *In individual cases, information may be provided and consent granted in a non-written form if:*
   a. *the person concerned, for physical or cognitive reasons, cannot read or cannot write; and*
   b. *the project leader furnishes proof of the provision of information and consent, specifically by means of written confirmation by witnesses, or by a recording of verbal consent.*
   (...)"

Therefore, a copy of the informed consent form should be sufficient to establish a fact, whether the copy is in paper or in electronic form

Nevertheless, and according to Article 180 of the ***Civil Procedure Code***:
If the production of a copy of a document as evidence is admitted, yet the judge or the opposing party is entitled to require the production of the original or an officially certified copy if there are justified reasons to doubt the authenticity of the document.

CPC, Art. 180 al.1:
"A copy of the physical record may be produced in place of the original. The court or a party may request that the original or an officially certified copy be produced if there is justified doubt as to the authenticity of the physical record".

One of the relevant questions one may ask is whether an electronic copy could be considered as an "officially certified copy"? According to Swiss law, an officially certified copy is a copy obtained from a Notary, or from the institution that had delivered the original document.

In this context, if you have only kept an electronic copy of the informed consent form, you may not be able to establish its authenticity, which may work against you when assessing the evidence.

Furthermore, it has to be highlighted that in case of research on embryonic stem cells, Article 27 of the ***Stem Cell Research Ordinance*** applies. It provides "*It [The clinic performing the IVF procedure] shall retain the data of the couple concerned, the information sheet, the original signed consent form and the code key for ten (10) years. The data security measures must conform to the current technical standards".*

4. IN PRACTICE

Some institutions only keep the original signed consent forms for clinical trials (those forms are stored together with all other trial documents for the duration specified by the HRA).

Regarding general consent (including biobank related consent), the original signed documents are destroyed after having been scanned and archived, presumably on a secure server. Furthermore, some institutions mentioned the words "authenticated documents", and underlined that their archiving prevents the falsification of documents.

Such decisions appear to be made after having weighed the benefits and risks of destroying the originals, i.e. the potential authenticity issue mentioned here above.

1 Federal Act on Research involving Human Beings (HRA) – 2011
2 Ordinance on Human Research with the Exception of Clinical Trials (HRO) – 2013