Coding of trial subject accepted by swissethics

Generally and preferentially, swissethics accepts CRFs that contain the year of birth (YYYY) with a coding number. In contrast, a coding number with the date of birth or coding with initials and date of birth are not accepted.

If the CRF in international clinical trials foresees the recording of both initials and date of birth, the field foreseen for the initials must, for Switzerland, be completed with a combination of letter ('dummy initials') that have no relation to the true initials of the trial subject (e.g. 'AAA', 'BBB'). Regarding the date of birth it must be noted that that only the field for the *year* can be completed. The fields *day* and *month* must be either crossed out (' --.--. YYYY ') or filled out with '01 .01.YYYY'.

In justified exceptional cases (e.g. pediatric oncology studies), swissethics also accept the use of:

- the month and the year of birth (MM/YYYY)

or

- the use of the full date of birth (DD/MM/YYYY), together with a code

Secure storage of subject identification list

The investigator, resp. the project leader is responsible for the secure storage of the subject identification list of the coded data for the clinical trial, resp. the research project.

According to art. 8.3.21 GCP E6(R2), the subject identification list must be kept in the Investigator Site File during the course of a clinical trial. In addition, according to art. 8.4.3, the subject identification list must be kept in a confidential manner after completion or termination of the clinical trial.

If coded data and/or samples are further used for a research project, the subject identification list must be kept by an external person responsible for the coding (e.g. at the databank and/or at the biobank). In this case, the researchers that use the coded data and/or samples for their research project, must not have access to the subject identification list (art. 26 HRO).