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SOP: Biosample handling

Basel, 14. Mai 2013

Note *This version of the SOP was approved by the semi-annual meeting of the Council of the Swiss Hepatitis C Cohort Study Foundation 14. May 2013 in Bern.*

1 PURPOSE

This SOP defines procedures for requesting biosamples from the Swiss HCV Cohort Study. The biosamples from the Swiss HCV Cohort Study are physically stored in the laboratories of each center (see website http://www.swisshcv.ch).

2 DEFINITIONS

Biosample List A complete biosample list needs one row for every sample and the following columns:

patID HCV-ID of the patient

labDate Date when the sample arrived in the laboratory

center name of the center

sampleType "plasma", "cell pellet", or "viable cells"

sampleID Identifier for the samples of a patient taken at one timepoint

sampleNoInStock Number of samples in stock

sampleSize Size of the samples (available only for sampleType "plasma")

retriveNo Number of samples that need to be retrieved

Investigator The role of an Investigator as described in this SOP refers to all persons that are able to apply a biosample request to the Scientific Board. This may be an Investigator of the Swiss HCV Cohort or a mandated person as well as other scientists.

3 PROCEDURE

1 Preparation of the list of available samples

To be able to plan projects, investigators need to know how many biosamples of a specific type and size are available within the entire cohort. This will possibly need complex requests on the database needing a detailed understanding of the database and the information therein. Therefore a Statistician/Datamanager can be contacted for preparing a list of samples. This will often inclose an interaction with the investigators.

Responsibility:

1.1. The Investigator sends an email to `hcvBiosampleRequest@clinicaltrialunit.ch` with the following information: — Investigator

- name of the project,
- description of patients for whom the samples are required,
- description of the sample type required ("plasma", "cell pellets", "viable cells") and minimal amount required (currently available for sample type "plasma" only),
- name and phone number to contact the Investigator in case of questions.

1.2. In straight forward cases the responsible Statistician/ Datamanager (CTU) will prepare a *Biosample List* within five working days. In all other cases the Statistician/ Datamanager (CTU) will contact the Investigator within five working days and discuss with him the exact definition. *The CTU Basel will have one statistician and one datamanager in charge. They will be able to replace each others during holidays but nevertheless it will be possible that both are on holidays together.* — Statistician/ Datamanager (CTU)

1.3. If any changes in the definition of the *Biosample List* are required (e.g. because not enough samples were available) Investigator will recontact the Statistician/ Datamanager (CTU). — Investigator

1.4. The Investigator prepares the project and asks the Scientific Board for approval. — Scientific Board

2 Biosample Request

Biosamples can only be requested if a project has been approved by the Scientific Board. In order to be able to ensure up-to-date information on available biosamples in the HCV database, laboratories will only provide samples if the request has passed the central process described in this SOP.

Responsibility:

2.1. The Scientific Board approves a biosample request of an Investigator by an email. — Scientific Board

2.2. In order to request the biosamples from the laboratories the Investigator forwards the approval email from the Scientific Board to `hcvBiosampleRequest@clinicaltrialunit.ch`. The request needs to contain the following information: — Investigator

- *Biosample List*
- invoicing details for the laboratory work
- shipping address for sending the samples
- special notes for the laboratories concerning the handling of the samples.

2.3. The responsible Technician (CTU) splits the *Biosample List* for the laboratories involved and sends the request to the HCV-responsible Person in the Laboratories together with the additional information supplied. — Technician (CTU)

2.4. Samples are sent directly by the HCV-responsible Person in the Laboratories to the shipping address in the request. If not all samples could be provided e.g. because the list of available samples was not correct, the clinical trial unit Basel will be informed by an email to `hcvBiosampleRequest@clinicaltrialunit.ch` within one month. — HCV-responsible Person in the Laboratories

2.5. The work in the laboratories is individually invoiced using the details in the request. — HCV-responsible Person in the Laboratories

2.6. The database is updated by the number of samples that were requested taking into account the feedback by the HCV-responsible Person in the Laboratories in cases where not all samples could be delivered as requested. — Statistician/ Datamanager (CTU)

3 Misc

Responsibility:

3.1. An up to date list of HCV-responsible Person in the Laboratories is maintained on the website http://www.swisshcv.ch in case of changes the CTU is informed at `hcvBiosampleRequest@clinicaltrialunit.ch`. — Scientific Board