VITILIGO BIOBANK GUIDELINES
for data collection

1 OVERVIEW

This document describes data collection (without collecting biosamples) within Vitiligo Biobank initiative hosted by the VR Foundation, which aims to collect detailed description of disease course and treatments outcomes.

Data are collected at the time of the primary visit of the patient and (preferably) additional data are collected during the course of vitiligo treatment(s) and/or after its (their) completion to document results of particular treatment(s). For data collection, specific Patient Biobank Profile forms are used. Collected data should to be transferred to a central database hosted by the VR Foundation to enable data search and analysis.

This document describes procedures for data collection.

2 DEFINITIONS

Terms described below are used in this document.

Biobank code – a unique digital identifier to be assigned to each combination of patient's data.

Dataset – collection of data describing patient, its vitiligo course, treatments received and their outcomes.

Local biobank – remote facility operating according to a standard Vitiligo Biobank protocols where datasets and biosamples are collected.

Central database – centralized database of patient and biosample associated data derived from all local biobanks.

Primary visit – a first visit of patient not enrolled previously in Vitiligo Biobank project.

Follow-up visit – any consecutive visit of patient after the primary visit.

3 GENERAL DESCRIPTION OF THE PROCEDURE

Basic procedure of biobank dataset collection includes 2 basic steps at primary or follow-up visit(s), and is strictly associated with the visit(s) of patient to a professional dermatologist.

3.1 Primary visit

Step 1. Professional dermatologist (or his assistant) familiarizes a patient with basic aims of Vitiligo Biobank and answer his questions. If the patients voluntary agrees to participate in the Vitiligo Biobank (agrees with using his de-identified medical information in research purposes), and only under this condition, get the Informed consent form signed by the patient followed by the signature of a person who is taking the Informed consent form.

Step 2. Professional dermatologist, based on information provided by the patient and results of patient's examination fills out the Patient Biobank Record form and assigns unique Biobank code to the record. The same code should be entered into dedicated field on the last page of the Informed consent form signed by the patient.

3.2 Secondary visit

Step 1. Professional dermatologist (or his assistant) confirms with the patient that he (she) remains voluntary agreed to participate in the Vitiligo Biobank and agrees with using his de-identified medical information in research purposes.

Step 2. Professional dermatologist, based on information provided by the patient and results of patient's examination fills out the Patient Biobank Record Follow-up form which should be labeled with assigned to patient earlier unique biobank code.

4 ETHICAL ASPECTS

VRF follows existing ethical aspects in Vitiligo Biobank projects. Therefore datasets could be collected only if patient voluntary agrees to contribute to the Vitiligo Biobank project which has to be confirmed be signing him the Informed consent form. Adopted be VRF Informed consent form could be used, or it might be adjusted to meet specific local requirements.

5 CRITERIA DATA COLLECTION

5.1 Primary visit

At primary visit, the Patient Biobank Record form should be filled out in full (see Data collection section), including data on previous vitiligo treatments and their outcomes. If patient is prescribed new vitiligo treatment, description of prescribed treatment should also be documented, leaving respective Treatment outcome section of the Patient Biobank Record form blank.

5.2 Secondary visits

At secondary visits, the Patient Biobank Record Follow-up form should be filled out in full (see Data collection section), which is designed to record information on the current treatment efficiency and outcome.

We recommend that follow-up data are collected not earlier than three month after previous visit to avoid overloading database with intermediate data.

6 BIOBANK CODE

6.1 Biobank code description

Data collected from a single patient and his Patient Biobank Record should have unique identifier. This identifier should be of the same type used in other local biobanks to enable data incorporation into a single database.

Vitiligo Biobank uses 8-digit code to uniquely identify biosamples and datasets.

The biobank code has a format XX-YYYY-ZZ. Barcoding of biobank code might also be implemented if desired.

The first two-digit block of the code, XX, is assigned by VRF and identifies particular local biobank.

The middle four-digit block YYYY is used to consequently enumerate unique patients whose biosamples and data are collected, starting from 0001.

NOTE: *it is responsibility of personnel at each local biobank to develop and implement suitable procedure of record-keeping for already used biobank codes to assure their consecutive and non-redundant use.*

The last two-digit block of the code, ZZ, is used to indentify type of labeled item derived from one patient.

When blood and serum are collected, following values of this block should be used:

20 - for labeling dataset (i.e. filled out patient profile) and blood sample(s). Also is used to identify items derived from a particular patient (for example, during blood processing for serum production, etc).

22 - for labeling serum samples collected at the primary visit.

23, 24, ..., 29 - for labeling each consecutively collected serum sample, if any (for example, collected after completing treatment, etc), collected at follow-up visits.

21 - is reserved for labeling DNA samples isolated from blood, if any.

6.2 Items labeled by biobank code

1. Patient Biobank Record and Patient Biobank Record Follow-up forms
2. Patient's medical record
3. Informed consent form

6.3 Patient's personal information and biobank code

VRF will not store patient's personal information allowing his identification such as name and postal address. However we would advise physicians at local collection points to confidentially keep a record where biobank codes assigned to patient's personal information such as name, etc., and listed in an ordered manner are juxtaposed with patient's personal details allowing contacting them in case such a need would arise (for example, when recruiting for clinical trails).

7 ENTERING DATA INTO PATIENT'S MEDICAL RECORD

We strongly recommend labeling patient's routinely used medical record with assigned to his biosamples and datasets biobank code at a time of completing Patient Biobank Record. This would simplify updating Patient Biobank Record during patient's follow-up visits to record treatment results.

8 DATA COLLECTION

Data collection comprises from filling out Patient Biobank Record which is contained in PBR_xx-xxxx-xx.docx file. This should be done by a professional dermatologist during patient visit to assure the most accurate data are entered.

Filling this form by a patient alone is not allowed.

Based on the existing experience, we found that physicians generally prefer to enter data into hard (paper) copy of the form, with data converted into digital format later using hard copy filled out during the visit by a physician. At the moment, the most appropriate way is entering data into MS Word file PBR_xx-xxxx-xx.docx file by typing in text fields and selecting appropriate options by changing color of the appropriate selection(s) from black to red. File than is saved under the name PBR_xx-xxxx-xx.docx, where xx-xxxx-xx is a unique biobank code.

Filling Patient Biobank Record Follow-up form which is contained in PBR_FU_xx-xxxx-xx_dd-mm-yy.docx file, is done in a similar way, and the file is saved under the name PBR_FU_xx-xxxx-xx_dd-mm-yy.docx, where xx-xxxx-xx is a unique biobank code assigned previously to a patient, and dd-mm-yy is a current date which would allowing unique identification of each follow-up record.

If standard protocols are used for treatment, in order to save time on treatment description, they could be entered under specific codes in a designated field on Treatment description section in Patient Biobank Profile, with only patient-specific deviations from a standard protocol entered in detailed protocol description section. To use this option, standard protocols should be send to central database (please use e-mail address i.korobko@vrfoundation.org) for assignment of a

special code. Based on this code, protocols details in full will be entered into central database by VRF staff.

10 DATA MANAGEMENT

Collected data should be transferred to VRF to be included in the central database. Currently this should be done by sending MS Word files with patient's data to e-mail address i.korobko@vrfoundation.org. Sending files should be done periodically (beweekly or monthly).