# User Manual Biobank Registry PeopleSoft

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## 1. SCOPE

The purpose of this SOP is to give assistance to people using the Biobank Registry in PeopleSoft. The Biobank Registry is intended to be used by Biobank and non-Biobank personnel to register data of incoming and outgoing samples in order to comply with the requirements of the Law on human bodily material of 19 December 2008 and its corresponding Royal Decree of 09 January 2018. The dataset as defined in the Registry is based on legal requirements, operational requirements (e.g. volume etc.), biobank quality standards/guidelines (e.g. MIABIS, FAIR data), the minimal dataset of the Flemish Biobank Network and the items required to construct the Standard PRE-analytical Code (SPREC).

## 2. DEFINITIONS AND TERMINOLOGY

- FAMHP: Federal Agency of Medicinal Health Products
- FFPE: Formalin Fixed/ Paraffin Embedded
- HBM: Human Bodily Material
- PI: Principal Investigator
- PS: PeopleSoft
- RM: Residuary Material
- SOP: Standard Operating Procedure
- SPREC: Standard PRE-analytical Code - an indicator of the sample pre-analytical phase, mapping the 7 most important parameters that impact the downstream analytical result

- Primary use of HBM: any use as consented to by the donor at the time of procurement (INFORMED CONSENT)
- Secondary use of HBM: any other use than specifically consented to by the donor at the time of procurement (requires additional consent, Biobank approval and ethical committee approval)
- Residuary material or RM: HBM procured for diagnostic or treatment purposes that is no longer necessary and therefore can be destroyed, provided a sufficient sample is kept for setting, fine-tuning or finalizing the diagnosis or treatment (PRESUMED CONSENT)

- Primary samples: specimens directly collected from the donor at the time of procurement (e.g., whole blood, urine, and solid tissue)
- Simple derivatives: the samples prepared through a simple laboratory manipulation (e.g., after centrifugation of collection tubes or mechanical disruption of tissues) without the addition of chemical substances by the laboratory technician and without cell disruption or cell selection as part of a multistep process; a list of simple derivatives can be found in document BB-TEC002-AN01 “Biobank Registry Content and Description”

- Complex derivatives: those sample derivatives whose isolation requires usage of multiple steps and/or addition of chemical substances by the lab technician (e.g., nucleic acids, proteins, lipids, sorted cells, cultured cells, immortalized cells); a list of complex derivatives can be found in document BB-TEC002-AN01 “Biobank Registry Content and Description”

## 3. ROLES, RESPONSIBILITIES AND AUTHORITIES

Every PI and/or members of his/her research team and every Staff Member of the AC Biobanking, who is working with the Biobank Registry in PeopleSoft is responsible for following the methods described in SOP BB-TEC002-PR.

Any person entering sample data is responsible for the correctness and completeness of the data entered.

The Principal Investigator of the study/project/collection for which the sample data is entered, is responsible for the correctness and completeness of the data and its correspondence to reality.

## 4. PROCEDURE

### 4.1 General information

The following rules apply:

- Every container holding HBM (e.g. tube, vial, slide, block, …), irrespective of the amount of pieces inside, has a unique (alphanumerical) identification (ID) to guarantee traceability:
  - e.g. 5 tubes of 500 µl serum each = 5 IDs
  - e.g. 1 tube with 5 biopsy pieces = 1 ID
- Sample IDs shall be unique within one study.
- Fields marked with an asterisk (*) are mandatory.
- Given the amount of HBM generated by collection and processing procedures, a delay of up to 2 weeks will be allowed for data entry into the Registry. However, the data should be readily available at the collection/processing department upon simple request by the Biobank Coordinator in the event of a FAMHP inspection, or in the case of internal and external audits.
- Sample data can be registered in the Registry either directly through the application as described in 4.2 and 4.3, or by an upload using Microsoft Excel .xlsx template files as described in 4.5.
- Registration of historical data (i.e. the existing samples, collected prior to 01NOV2018) can be done either directly through the application as described in 4.2 and 4.3, or by an upload using Microsoft Excel .xlsx template files as described in 4.5. These historical samples have to be registered IN prior to being used (with subsequently being registered OUT).

4.2 Access to the application:

- Access to the application can be requested through the Biobank Registry Access Request Form BB-GEN022-FO01 (available on request). This request contains the name of the person(s), PI of the project(s), S-number(s) of the study/project/collection for which access is needed. The completed and signed form should be submitted to the Biobank (wbb@uzleuven.be).
- Access can only be granted when the study/studies have prior approval from the ethical committee and the Biobank Board. Upon approval, the Staff Member of the AC Biobanking will forward the request to the IT department, who will enable the necessary rights within the application.
- Users only have access to data from studies to which they are linked by the Staff Member of the AC Biobanking, as indicated in the Registry Access Request Form (BB-GEN022-FO01).

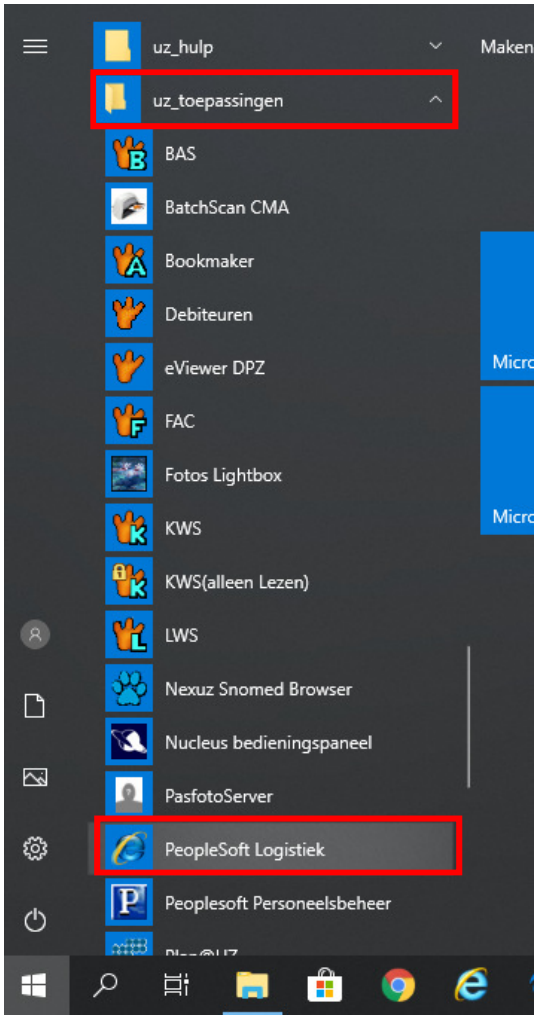
4.3 Registry IN, application based registration

*4.3.1 Following general rules apply :*

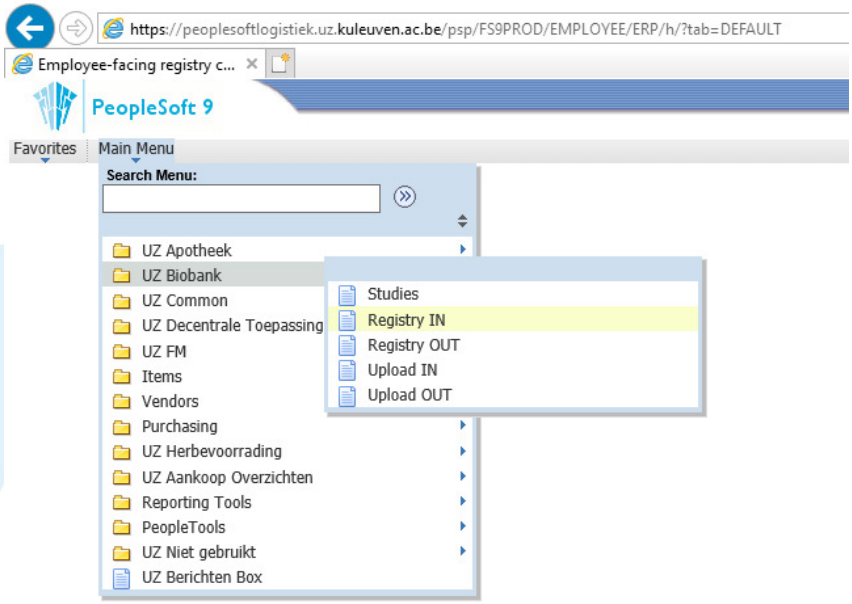
- All collected samples and processed samples shall be registered. When the primary sample (i.e. the sample collected from the donor e.g. blood) is different from the sample stored (e.g. serum), then both the parent sample (i.e. blood) and child sample(s) (i.e. serum) have to be registered in the application.
- If actual times are unknown, the value “00:00” has to be entered. Actual times are important as they form the basis for the calculation of the SPREC, an indicator of the main pre-analytical factors that may have impact on the integrity of sampled clinical fluids and solid biospecimens and their derivatives during collection, processing and storage.

*4.3.2 Procedure:*

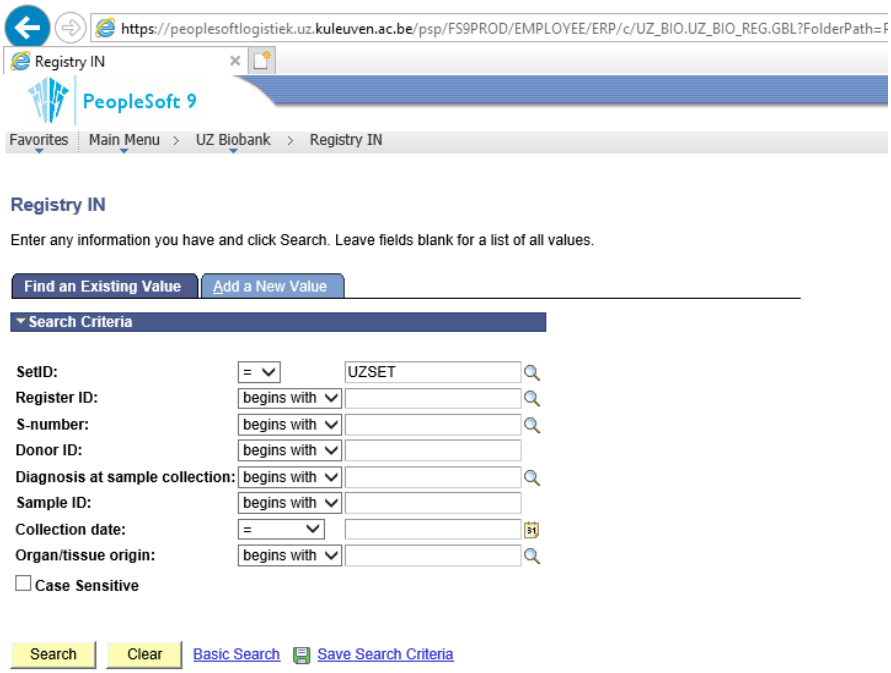
- Open the PeopleSoft Logistiek application by selecting it via the start screen and uz_toepassingen. Log in using your UZ Leuven account and password. It is recommended to log in into the Registry via the PeopleSoft Logistiek desktop application. When using a different browser, please check the regional settings since these could affect formatting of locale-sensitive data (“.” or “,” as decimal separator).




- From “Main Menu” select “UZ Biobank” and click on “Registry IN”

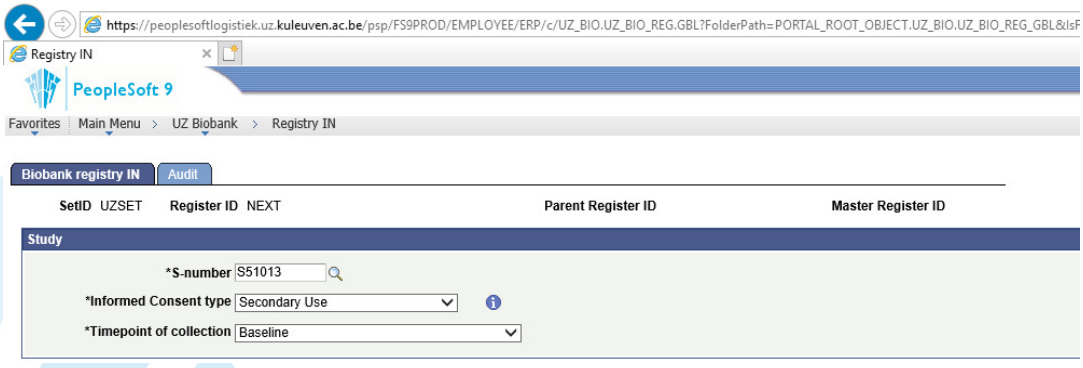


- The tab “Find an Existing Value” allows to search for already registered samples based on different attributes (S-number, Donor ID, Diagnosis at sample collection, Sample ID, Collection date or Organ/tissue origin)

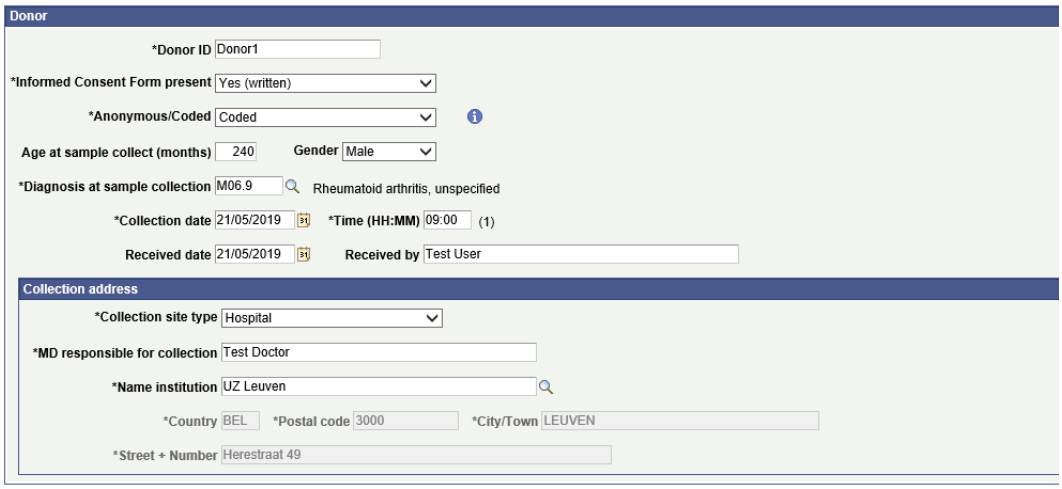



- Click on the tab “Add a New Value” to enter a new sample: it is intended to register every individual sample that is collected and/or stored for research use. Fill in all fields (see section 4.6 below for detailed explanation of each field)

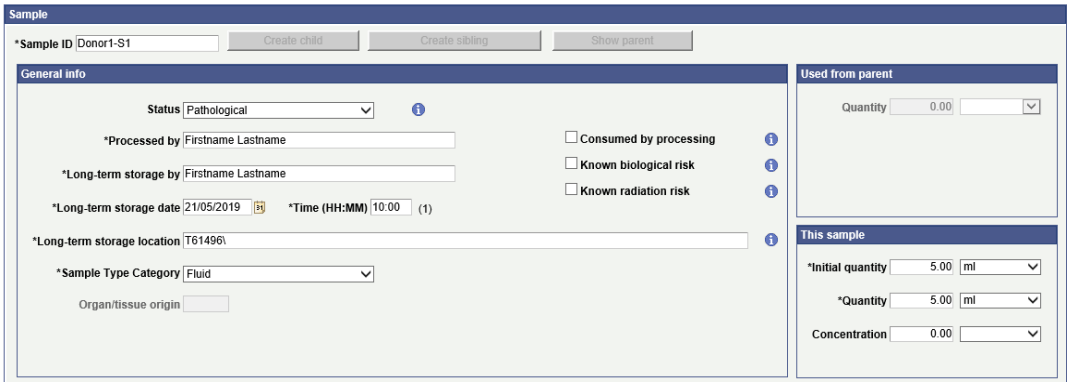
  - Study information



- Donor information




- Sample information



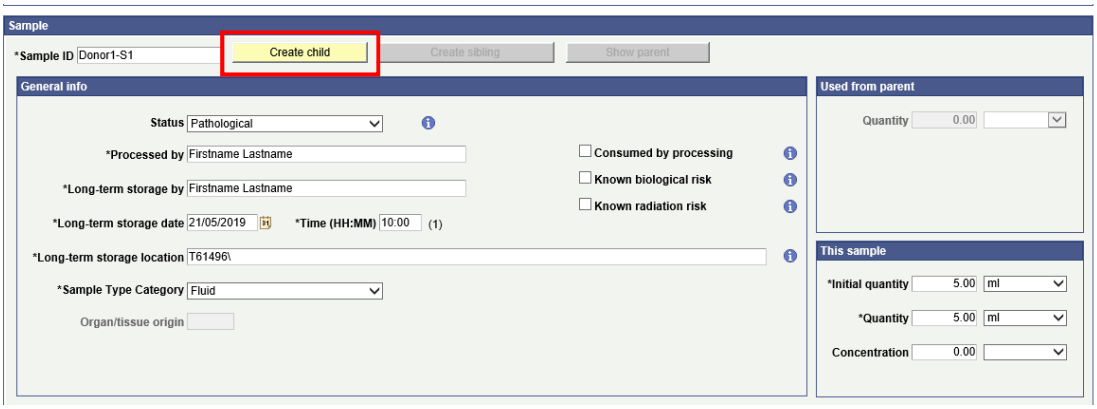

  - Remark for the Long-term storage location: Please register the storage location of the sample to the highest level of detail. Start with the unique ID of the storage unit (“T-number” for UZ equipment) and separate the individual levels with a “\”. E.g. T61496\shelf_1\rack_1\box_1\pos_A1. The field must contain at least one “\” to be accepted upon saving.

  - Remark for the quantity fields: Dependent on the regional settings of the browser used for data entry, decimals should be entered with “,” or “.”
    - When using the PeopleSoft desktop application (Internet Explorer) a point “.” will be the default decimal separator.
    - When using a different browser (e.g. Google Chrome) or a different version of Internet Explorer, decimals should be entered either with a point “.” or a comma “,” dependent on the regional settings of the browser. Please check the initial value (e.g. 0,00) for reference and correct if necessary.

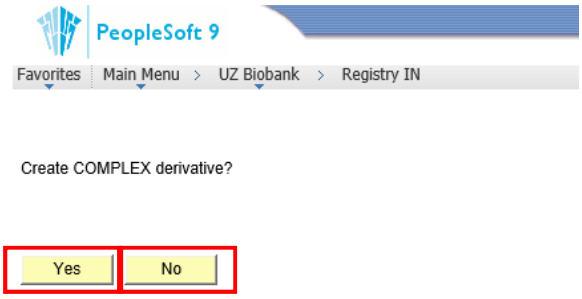
- Upon choosing a Sample Type Category (fluid, solid, complex with fluid parent or complex with solid parent), additional fields are displayed, relevant for the selected sample type category. These fields allow to build the SPREC code (see section 4.6 below).

- Upon completion of the data, click the “Save” button at the bottom left of the page.

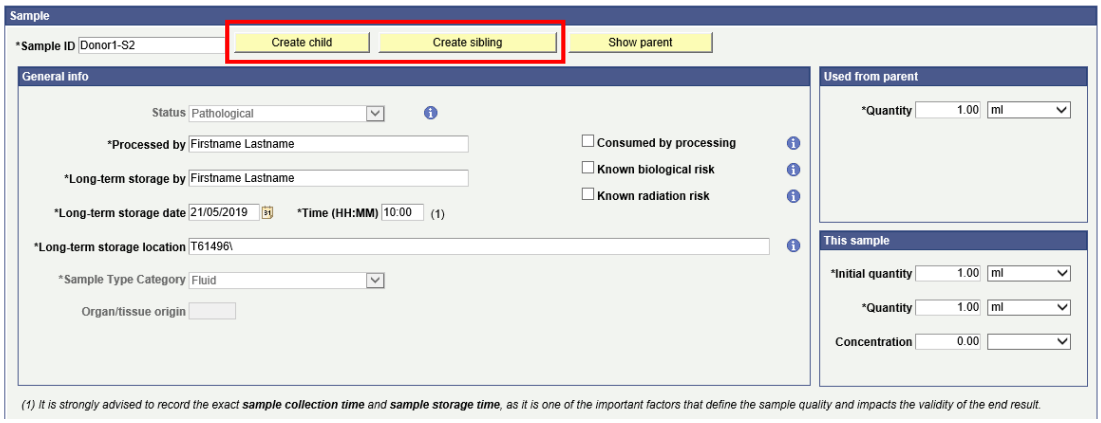
- If applicable, it is now possible to create child samples (e.g. serum sample from blood sample) by clicking the button “Create child”. Shared data is copied from the parent sample to the new sample to minimize input time and reduce errors.



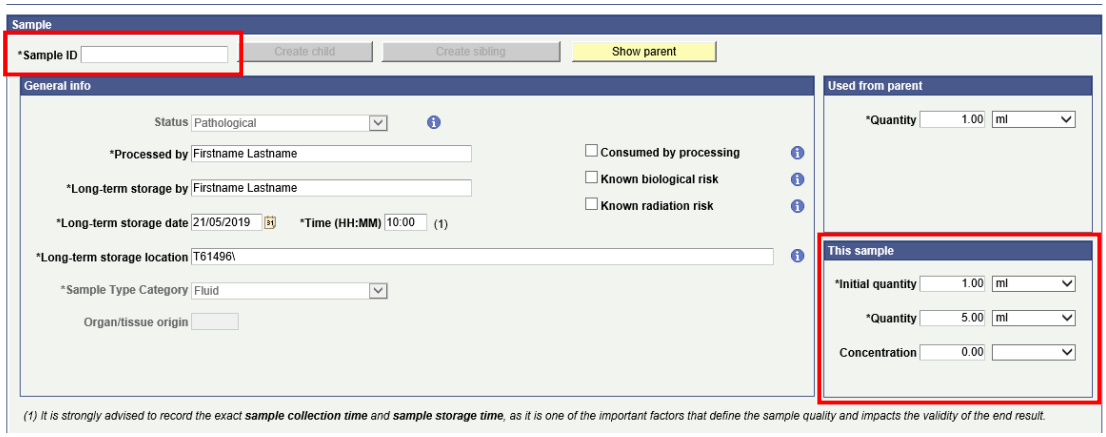

- The application will pose the question whether the child sample is a complex derivative or not. A list of complex derivatives (e.g. nucleic acids, proteins, lipids, sorted cells, cultured cells, immortalized cells) and simple derivatives (e.g. serum, plasma, snap frozen tissue, formalin fixed/ paraffin embedded tissue) can be found in document BB-TEC002-AN01 Biobank Registry Content and Description. When creating simple derivatives, click the “No” button, when creating complex derivatives, click the “Yes” button. Since it is not possible to create a simple derivative from a complex sample, this question will not pop-up when creating a child from a complex parent.



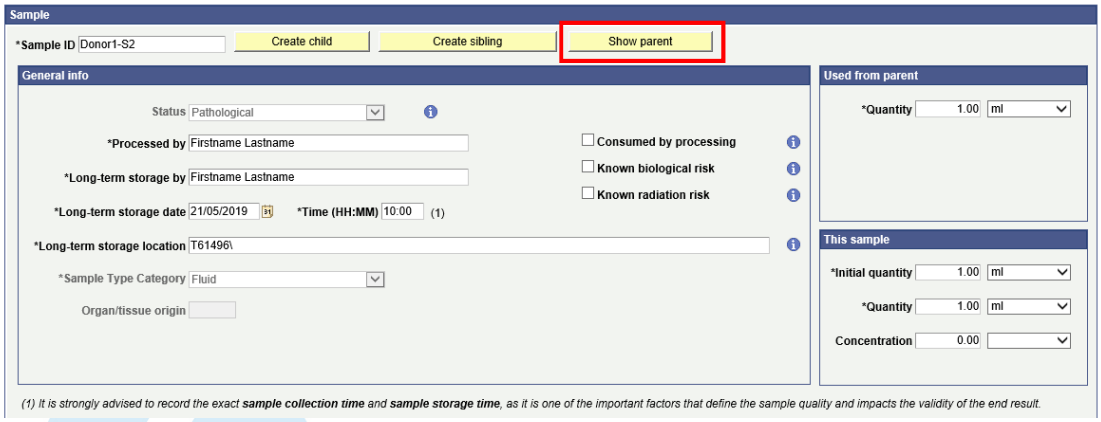

- The common study and donor data will be copied to the child sample. The other sample data needs to be completed for the newly created child as described above.
- Upon completion of the data, click the “Save” button at the bottom left of the page.
- If applicable, it is now possible to create child samples (e.g.a cDNA sample obtained from a previously created RNA sample that was derived from a blood sample) or sibling samples (e.g. additional aliquot of same the sample type) by respectively clicking the buttons “Create child” or “Create sibling”. Shared data are copied from the parent or sibling sample to the new sample to minimize input time and reduce errors.




- When creating a sibling sample, the common study, donor AND sample data will be copied to the sibling. The only fields required to be completed and revised for a sibling sample are the Sample ID and quantity fields (as all other info is shared between the siblings and therefore only modifiable through the initial child from which the siblings were created).




- If required, it is always possible to easily view the parent sample by clicking the “Show parent” button.




- Examples of registrations IN can be found in document BB-TEC002-AN02.

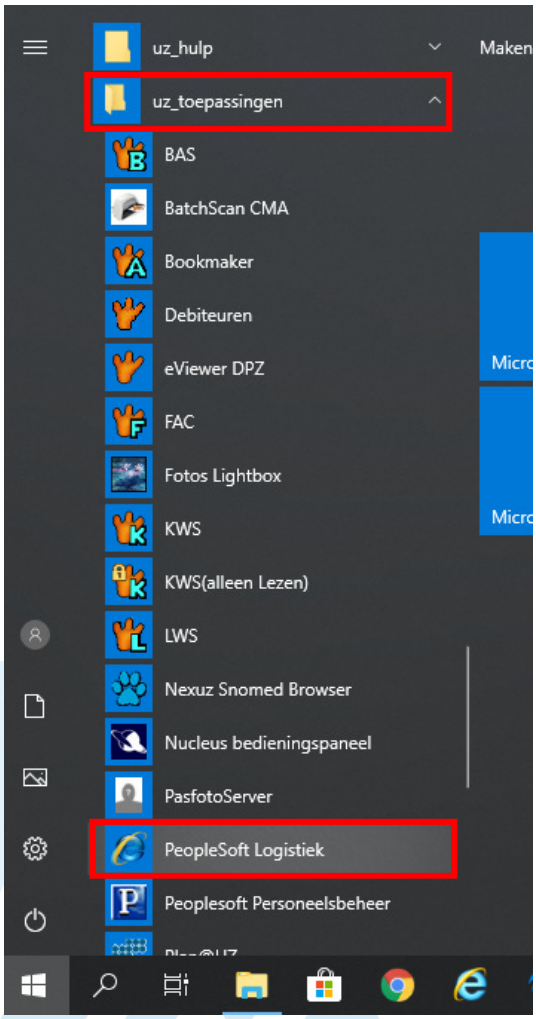
4.4 Registry OUT, application based registration

*4.4.1 Following general rules apply :*

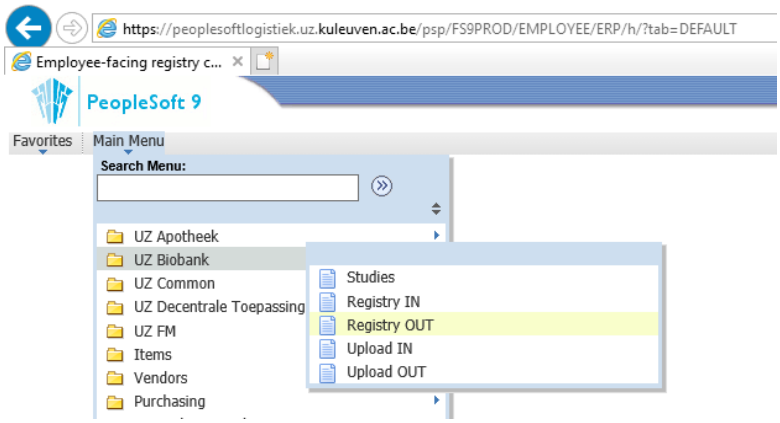
- All samples used for scientific research (also internally) shall be registered
- Registration OUT is only possible for registered samples; if a new aliquot (i.e. new sample container with unique ID) is created from an already existing and registered sample before actual use, the newly created aliquot should be registered IN first (traceability)
- It is accepted to take the “remainder” of a sample back in (“Return” section)

*4.4.2 Procedure:*

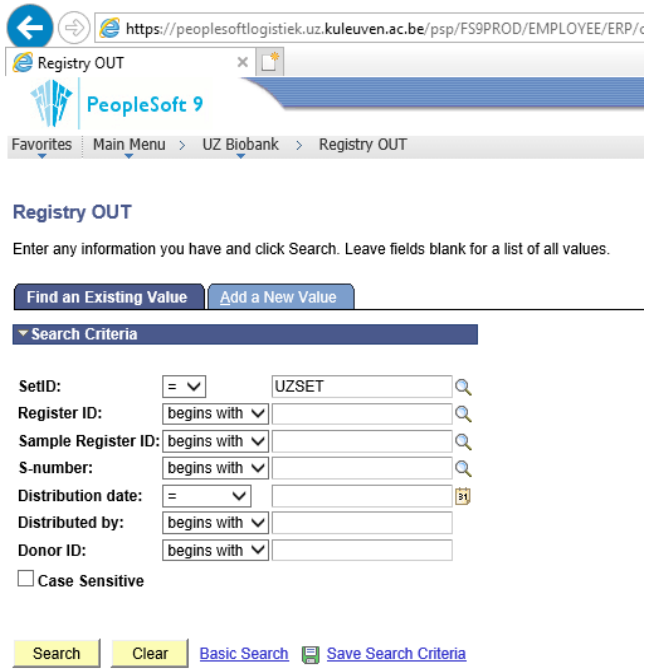
- Open the PeopleSoft Logistiek application by selecting it via the start screen and uz_toepassingen. Log in using your UZ Leuven account and password. It is recommended to log in into the Registry via the PeopleSoft Logistiek desktop application. When using a different browser, please check the regional settings since these could affect formatting of locale-sensitive data (“.” or “,” as decimal separator).



- From “Main Menu” select “UZ Biobank” and “Registry OUT”

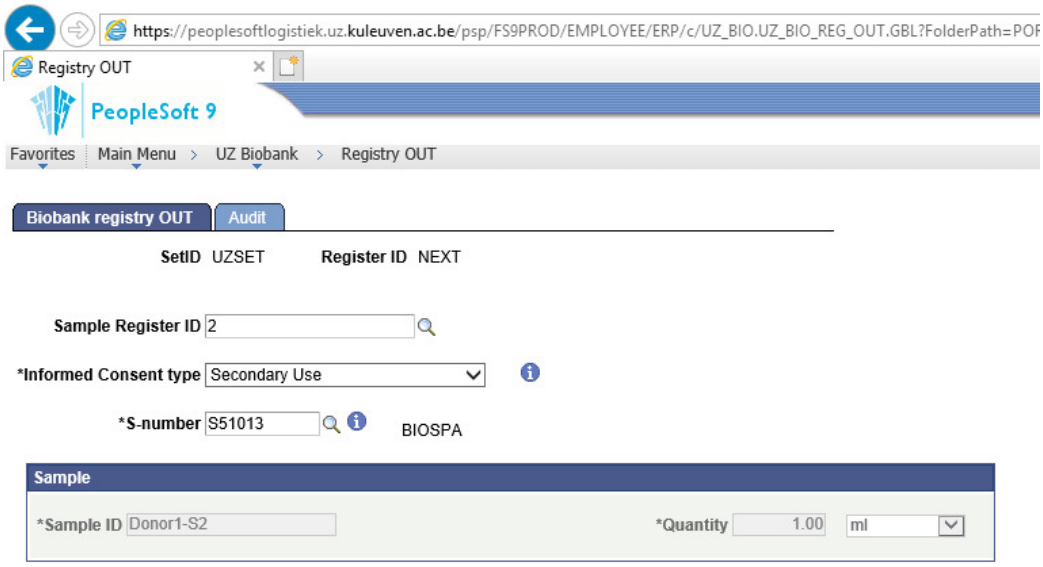



- The tab “Find an Existing Value” allows to search for already registered data based on different attributes (S-number, Donor ID, Distribution date, Distributed by)




- Use the tab “Add a New Value” to register an outgoing sample movement (“distribution for use”) of a sample that is already registered within the PeopleSoft database (Registry IN): it is mandatory to register every individual sample that is “distributed” from storage, either for research use (i.e. has been taken from storage to be used for scientific research, both internal and external by third parties) or for diagnostic purposes (under construction).

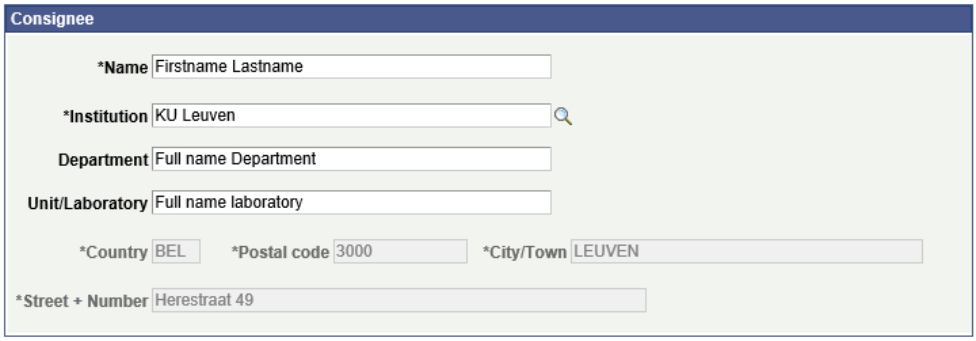
- Select the sample to be registered OUT and fill in all fields (see section 4.6 below for detailed explanation of each field)
    - Sample information: the majority of the data originates from the data input during registration IN. It is mandatory to indicate the study number (S-number) for which the sample will be used. This can differ from the study number for which the sample was collected.
        - For primary use of samples: enter the S-number of the study within which the sample was collected
        - For secondary use of samples: enter the S-number of the study for which the samples will be used and are taken out of storage



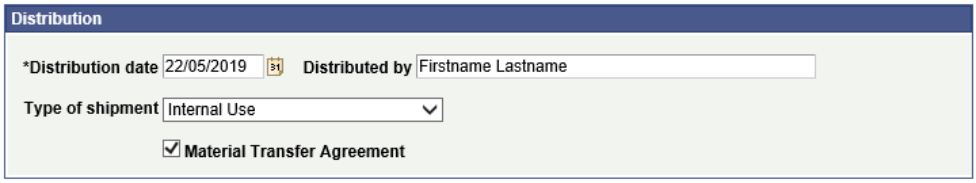

    - Donor information

        - Art 11 applicable: Does the Informed Consent Form (ICF) mention that the donor has the right to receive meaningful information if that information has been generated by the use of the sample?

- Consignee information (applicable when registering samples for research use)




- Distribution information (applicable when registering samples for research use)




- Return information (only applicable when registering samples that have been previously registered OUT and the remainder is being put back into storage for future use)

- Destruction information (applicable when registering samples that are destroyed e.g. at the end of a study and are no longer needed for research)

- Upon completion of the data, click the “Save” button at the end of the page
- Examples of registrations OUT can be found in document BB-TEC002-AN02

## 4.5 Import file based registrations

Sample data can also be entered indirectly into the Registry through upload of files formatted to a fixed template. This approach can be a preferred option when sample data is already present in (existing) databases/inventory systems.

- The same general rules apply as described in section 4.3 and 4.4. Additionally, one row in the template corresponds to one sample, i.e. for registration of 1 (consumed) blood sample

processed into 2 serum samples, 3 rows should be completed with the necessary data in the import file.

- File BB-TEC002-FO01 Template biobank_reg_in is to be used to enter data regarding incoming samples (Registry IN).
- File BB-TEC002-FO02 Template biobank_reg_out is to be used to enter data regarding samples used/distributed for research or destroyed (Registry OUT).
- The data in these files is to be provided in a pre-defined format, as described in columns L, M and N in document BB-TEC002-AN01 “Biobank Registry Content and Description”.
- Both template files contain representative examples of different sample types and situations and are colour coded corresponding to the different sample type categories as described in section 4.6.
- When a certain field is not applicable for the sample to be registered, it should be left **empty**.
- When compiling a Registry IN file, make sure that all rows containing information regarding the parent samples are placed prior to the rows containing information regarding their child samples. This is essential to avoid errors during the upload. E.g. for registration of one blood sample processed into two serum samples, the first row will contain the information regarding the blood sample and the subsequent rows will contain the information regarding the serum samples.
- When a parent sample is already present in the Registry IN (through a previous upload/registration) and a new child sample is created afterwards, only this newly created child sample needs to be provided in a new import template. The parent sample does not need to be present again in that second import file.
- The upload files are prepared by the PI and his/her research team, the actual upload of data into the Registry is performed by Staff Members of the AC Biobanking, unless otherwise agreed and upon prior training by the Biobank.
- Before actual import of data can start, a draft/test file is created by the PI and his/her research team reflecting each sample type collected, processed and used in their facilities. This file is used by the Staff Members of the AC Biobanking to verify that the file provided to the Biobank can be uploaded successfully into the PeopleSoft database.
- This draft/test file is evaluated and uploaded by the Biobank into the Registry to correct any occurring inconsistencies, which are then communicated by the Biobank to the PI and his/her research team.

- Upon approval of the draft/test file by the Biobank, actual data can be sent to the Biobank by emailing the Excel template file format to wbb@uzleuven.be. Files will be checked for consistency per default protocol, and any inconsistencies will be cleared with the PI and his/her team before proceeding.

- Whenever an adaptation is made to the existing sample types, processing procedures or use or when new sample types, processing procedure or use are added, a new test file reflecting these changes/additions has to be provided by the PI and his/her research team in order to verify that these adaptations can be uploaded successfully to the PeopleSoft database by the Biobank.

4.6 Biobank Registry content

Document BB-TEC002-AN01 “Biobank Registry Content and Description” contains a list of all data fields in the Registry and can be used as an explanatory guide to complete the Registry:

- Column A shows whether the field is required for incoming samples (blue) or outgoing samples (grey)
- Column B shows the data fields as present in the Registry
- Column E and F show whether data are mandatory for Historical Collections and New/Active Collections respectively
- Column G gives an explanation of the field content
- Column H shows the type of data that can be entered
- Column I shows the data that can be selected in case of a drop down list
- Column K provides additional background information
- Column L lists whether the field is displayed in a search result
- Column M contains the name of the corresponding field in the import file template. ATTENTION: two separate import file templates exist, one for incoming samples (BB-TEC002-FO01 Template biobank_reg_in) and one for outgoing samples (BB-TEC002-FO02 Template biobank_reg_out)
- Column N contains the allowed values for fields where data validation applies for the import file template
- Column O shows in which column of the import file template the corresponding data needs to be presented

The rows in document BB-TEC002-AN01 are colour coded per sample movement and per sample type category

- Registry IN
  - Blue rows: data to be registered for all incoming samples
  - Green rows: data to be registered for fluid samples, simple derivatives (e.g. serum, plasma, …)
  - Yellow rows: data to be registered for solid samples, simple derivatives (e.g. tissue, FFPE blocks, …)
  - Orange rows: data to be registered for complex derivatives from fluid parents (DNA, RNA, … e.g. from blood)
  - Lilac rows: data to be registered for complex derivatives from solid parents (DNA, RNA, … e.g. from tissue)
- Registry OUT
  - Grey rows: data to be registered for all outgoing samples (i.e. used for scientific research or destroyed)

4.7 Troubleshooting

In the event of issues during data entry, please consult this manual, the examples provided in annex BB-TEC002-AN02 or the description of the fields provided in annex BB-TEC002-AN01 for initial support. In case the issue remains, contact wbb@uzleuven.be with a clear description of the problem encountered (and a print screen of the issue if applicable/possible).

## 5. REFERENCES


- Standard PREanalytical Code version 3.0., Betsou F et al. Biopreserv Biobank. 2018 Jan 29. doi: 10.1089/bio.2017.0109.
- Standard preanalytical coding for biospecimens: defining the sample PREanalytical code. Betsou F et al. Cancer Epidemiol Biomarkers Prev. 2010 Apr;19(4):1004-11. doi: 10.1158/1055-9965.
- Toward Global Biobank Integration by Implementation of the Minimum Information About Blobank Data Sharing (MIABIS 2.0 Core). Merino-Martinez R et al. Biopreserv Biobank. 2016 Aug;14(4):298-306. doi: 10.1089/bio.2015.0070.
- A Minimum Data Set for Sharing Biobank Samples, Information, and Data: MIABIS. Norlin L et al. Biopreserv Biobank. 2012 Aug;10(4):343-8. doi: 10.1089/bio.2012.0003.
- Enhancing Reuse of Data and Biological Material in Medical Research: From FAIR to FAIR-Health. Holub P et al. Biopreserv Biobank. 2018 Apr;16(2):97-105. doi: 10.1089/bio.2017.0110.

## 6. LIST OF ANNEXES AND WORKSHEETS

- BB-TEC002-AN01 Biobank Registry Content and Description
- BB-TEC002-AN02 Examples of Sample Registrations
- BB-TEC002-AN03 List of Simple and Complex Sample Types and Derivatives
- BB-TEC002-FO01 Import template Biobank Registry IN
- BB-TEC002-FO02 Import template Biobank Registry OUT
- BB-GEN022-FO01 Biobank Registry Access Request Form