|  |
| --- |
| **General instructions for completing and submitting this request form for the use of human biological material (release review)**   * This form is to serve a wide variety of research types using human biological material from the following sources: sub-biobanks, residual material (fresh or otherwise) from diagnostic procedures or treatment, leftover human biological material from research (WMO or non-WMO), and human biological material from collections that are not yet registered with the Central Biobank UMC Utrecht (CBB). * All questions included in this form are based on current legislation and regulations, UMC Utrecht policy and other scientific and ethical standards that are relevant for the Biobank Research Ethics Committee (in Dutch: Toetsingscommissie Biobanken, TCBio) to arrive at an accurate assessment. Hence, all questions in this form are required for a proper release review. * TCBio will review this release protocol according to the criteria laid down in Article 10a of the UMC Utrecht Biobank Regulations (in Dutch: Kaderreglement Biobanking UMC Utrecht). The review will be primarily based on the information provided in this protocol, including the mandatory annexes. Please fill in this form as completely as possible and in accordance with the instructions given with each question. * Enter your answers to the questions in the appropriate text boxes. These text boxes will automatically expand as you insert text, there will be sufficient room for your answer. * Some answers may be (partly) derived from another research document (e.g. the data management plan). In that case, copy the relevant information from the other document, so that the content of this release protocol will be stand-alone. * Template text may not be changed or removed. * Remember to enter the study title, version number and date in the footer of this form. The version number and date should match the number and date in your file name. * Fully signed requests, including all associated annexes, should be submitted in PDF format and in line with all other instructions posted on the TCBio website via [TCBio@umcutrecht.nl](mailto:TCBio@umcutrecht.nl). * For more information, please visit the TCBio website: [Use of Human Biological Material (Release Review) - TCBio](https://tcbio.umcutrecht.nl/en/use-of-human-biological-material-release-review). |



**Release protocol[[1]](#footnote-1) for use of human biological material**

|  |
| --- |
| **TCBio number:**  *Note:*  *This concerns the TCBio release protocol number (not the TCBio biobank number from which the human biological material is requested). The TCBio release protocol number is assigned by the TCBio secretariat. If already known, please mention it here.* |

1. **Origin of the human biological material:**

*Note:*

*Are you requesting human biological material from multiple sources? Please tick all applicable sources below and ensure that the questions in this form are answered for each of the marked sources.*

WMO study: use for WMO research question → no request required

WMO study: leftover material from WMO research question → proceed to A [see also (ii)]

Non-WMO study: leftover material from non-WMO research question → proceed to A [see also (ii)]

Sub-biobank → proceed to A [see also (ii)]

(Fresh) residual material from diagnosis or treatment → proceed to A [see also (ii)]

Researcher’s collection → please contact the Central Biobank and proceed to A

[see also (ii)]

1. **Purpose of the use of human biological material:**

Scientific study → proceed to A

Scientific activity → proceed to F (see instructions there)

**Table of Contents**

*Note:*

*To complete the release protocol, the table of contents must be updated. Move the mouse to anywhere in the table of contents, right-click, select “Update Field” and then “Update Entire Table”, and click “OK”.*

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# Definition of Terms

The following definitions apply in the context of this release protocol:

| **Term** | **Definition** | **Derived from** |
| --- | --- | --- |

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| --- | --- | --- |
| Incidental finding | Unforeseen research finding (or diagnostic result) not related to the underlying study protocol and  - in the case of residual material - not noticed upon the initial use of the human biological material | UMC Utrecht Biobank Regulations 2013 |

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| Consent |  |  |
| * Broad consent | Written consent from the donor for the use of his/her biological material and (clinical) personal data for the purpose of future, not yet specific but not unrestricted, medical scientific research | CIOMS Guidelines 2016 |
| * Informed consent | Written consent from the donor for the use of his/her biological material and (clinical) personal data for the purpose of specific future medical scientific research | CIOMS Guidelines 2016 |

|  |  |  |
| --- | --- | --- |
| Data |  |  |
| * Anonymous | Information which does not relate to an identified or identifiable natural person (the donor)  Or:  Personal data rendered anonymous in such a manner that the donor is not or no longer identifiable | EU General Data Protection Regulation (GDPR) (in Dutch: AVG) |
| * Coded | Data that have been processed in such a manner as to exclude any data that may be used, either directly or indirectly, to establish the identity of the donor, and to which a code has been added that can only be traced back to an identified or identifiable donor by the intervention of one or more independent third parties using one or more encryption keys, in accordance with the provisions of the GDPR and the Code of Conduct for Health Research 2022 of the Dutch Committee on Regulation of Health Research (COREON) | UMC Utrecht Biobank Regulations 2013 |
| * Directly identifying | Personal data that can be attributed to a specific natural person without the use of additional information | EU General Data Protection Regulation (GDPR) (in Dutch: AVG) |
| * Genetic | Personal data relating to the inherited or acquired genetic characteristics of a natural person which result from the analysis of a biological sample from the natural person in question, in particular chromosomal, deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) analysis, or from the analysis of another element enabling equivalent information to be obtained. | EU General Data Protection Regulation (GDPR) (in Dutch: AVG) |
| * Indirectly identifying | Personal data that can no longer be attributed to a specific natural person without the use of additional information | EU General Data Protection Regulation (GDPR) (in Dutch: AVG) |
| * Personal data | Any information relating to an identified or identifiable natural person. When data can be qualified as personal data, the GDPR applies and (among other things) a legal basis is required for the processing of that data. | EU General Data Protection Regulation (GDPR) (in Dutch: AVG) |
| * Pseudonymous | See: Coded |  |

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| --- | --- | --- |
| Data minimization | Data processing where the personal data are adequate, relevant and limited to what is necessary for the purposes for which they are processed | EU General Data Protection Regulation (GDPR) (in Dutch: AVG) |

|  |  |  |
| --- | --- | --- |
| Donor | A patient or (healthy) volunteer who donates or has donated biological material and/or (clinical) data  An identifiable donor is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, or one or more factors specific to the physical, physiological, genetic or mental identity of that donor | UMC Utrecht Biobank Regulations 2013  EU General Data Protection Regulation (GDPR) (in Dutch: AVG) |

|  |  |  |
| --- | --- | --- |
| Further use | Further processing for scientific research of human biological material and personal data that have primarily been collected or processed for another purpose. | EU General Data Protection Regulation (GDPR) (in Dutch: AVG) |

|  |  |  |
| --- | --- | --- |
| Human biological material | All material separated from the human body not covered by another legislation (e.g. Embryo Act; in Dutch: Embryowet) | UMC Utrecht Biobank Regulations 2013 |

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| Residual material from standard care | Human biological material that has been obtained in the context of diagnostic procedures and/or treatment and is no longer required for the purpose of quality assurance and/or additional individual diagnostic procedures | UMC Utrecht Biobank Regulations 2013 |

|  |  |  |
| --- | --- | --- |
| Sub-biobank | Collection of human biological material and associated (clinical) data that is being compiled or has been compiled with a view to future medical research, the nature of which was not specifically defined at the time of sample collection  Or:  Collection of human biological material and associated (clinical) data that have been obtained in the context of diagnostic procedures and/or treatment and is no longer required for the purpose of quality assurance and/or additional individual diagnostic procedures (also referred to as ‘residual material’; see above). This definition also covers residual material that can be amplified, for instance by growing stem cells or creating cell lines from residual material.  Or:  Collection of human biological material and associated (clinical) data that have been obtained for a specific study (WMO or non-WMO) and that was not used (completely) for that study. | UMC Utrecht Biobank Regulations 2013 |

|  |  |  |
| --- | --- | --- |
| Treatment relationship | Healthcare providers directly involved in the implementation of the treatment agreement | Dutch Medical Treatment Contracts Act (in Dutch: WGBO) |

# A. Registration details scientific study

|  |  |
| --- | --- |
| **Study title:** | |
| **Protocol number sub-biobank(s)** or **WMO/non-WMO study/ies** from which the material is being requested or, in case of (fresh) residual material from diagnosis or treatment, the **name of the department(s)** responsible for the donors who provided the material |  |
| **Contact details:** | |
| **Name responsible investigator**  (employee appointed by UMC Utrecht as having final responsibility for this study proposal)  See also section G, part 1. |  |
| Division: |  |
| Department: |  |
| E-mail: | @umcutrecht.nl |
| **Name** **contact person**  (only to be provided if this is not the responsible investigator)  *Note: Correspondence is only sent to the responsible investigator and contact person.* |  |
| Division: |  |
| Department: |  |
| E-mail: | @umcutrecht.nl |
| **Name of person with final responsibility for the sub-biobank(s) from which the material is being requested/the (fresh) residual material** (head of the UMC Utrecht department(s) with final responsibility for the sub-biobank/the (fresh) residual material)  (only to be provided if this is not the responsible investigator)  See also section G, part 2. |  |
| Division: |  |
| Department: |  |
| E-mail: | @umcutrecht.nl |

**Are there any collaborations with parties outside UMC Utrecht?**

*Note:*

*In case of research collaborations with non-UMC Utrecht employees, the human biological material and/or associated sub-biobank data will only be made available by the Central Biobank (CBB) under the standard UMC Utrecht 'Material Transfer Agreement' (MTA). A copy of the MTA concluded with the partner must be provided. For sample MTAs, refer to* [Modelcontracten](https://team.mijnumc.nl/connect/RvB/juridischbestuurlijkezaken/Paginas/Modelcontracten.aspx)*.*

*Note that research collaborations with non-UMC Utrecht employees also include: the deployment of service providers who receive human biological material and/or data (e.g. human biological material from patients at UMC Utrecht that is provided to a third party for laboratory assessments).*

*In case of a commercial partner review costs will be charged. Please add a billing sheet, which can be requested from the TCBio secretariat (*[TCBio@umcutrecht.nl](mailto:TCBio@umcutrecht.nl)*).*

Not applicable

Non-commercial partner (please add MTA)

Commercial partner (please add MTA and billing sheet)

|  |  |
| --- | --- |
| Name of Institute / Organization / Company / Industry: |  |
| Contact person: |  |
| Postal address: |  |
| Postal code: |  |
| City/Town: |  |
| Country: |  |
| Telephone number: |  |
| E-mail: |  |

# B. Study

## **B1. From which sub-biobank(s) or source(s) is the human biological material being requested?**

*Note:*

*The information provided here must correspond to all sources of origin marked in section (i) Origin of the human biological material (page 2).*

|  |
| --- |
| Protocol number:  Title:  Other: |

## **B2. Rationale and study purpose**

*Note:*

*What is the importance of the research described in* ***this*** *release protocol? Which knowledge gap will this research address? Describe in no more than 250 words, similar in structure to the introduction of a scientific publication.*

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## **B3. Research question(s)**

*Note:*

*Which research question(s) does this study intend to answer? Describe as accurately as possible and in accordance with section B4.*

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| --- |
|  |

## **B4. Research methods**

1. Type of research and design

*Note:*

* + *Name the* ***type*** *of research, for example: fundamental (molecular) research, epidemiological research, technical pilot, proof-of-concept or preparatory scientific activities for a preliminary research plan to be worked out in more detail.*
  + *Also name any research in which, for example, the result of one experiment leads to another. In such a case, a detailed description (or assessment) of the research methods and any new scientific insights may not yet be feasible; the release protocol will then be approved for a limited period. Extension may be granted later based on reporting of the results.*
  + *Describe the* ***study design****, for example: in vitro experimental, cross-sectional, longitudinal.*

|  |
| --- |
|  |

1. Study population, including the in- and exclusion criteria

*Note:*

*From which population will biological material being used in this study?*

|  |
| --- |
|  |

1. Primary and secondary outcome measures

*Note:*

*Indicate for each research question described in section B3 which outcome measure or measures will be used to present the results of the study. Alternative terms for outcome measure include:*

* + *dependent variable (general statistics)*
  + *endpoint (primary, secondary, exploratory) (epidemiology, biostatistics)*
  + *target variable, label attribute (machine learning)*
  + *response variable*
  + *“y” in y=a+bx*

|  |
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1. Methodological/statistical substantiation of the number of donors whose biological material and/or data are being requested

*Note:*

*If a sample size calculation is not possible, you should substantiate the number of samples requested in a different way. Indicate clearly why it is not possible to perform the study with fewer samples as well as why it is not necessary to perform the study with more samples.*

|  |
| --- |
|  |

1. Data analysis plan

*Note:*

* + *Describe which statistical analysis methods will be used to analyze the data. If applicable, describe this separately for each research question and indicate why the particular statistical methods are selected.*
  + *If no statistical methods will be used, describe how (based on which measure or outcome) the success of the study will be determined.*

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## **B5. What is the potential relevance of the study results?**

|  |
| --- |
|  |

## **B6. Study duration**

|  |  |
| --- | --- |
| Start date of the study: |  |
| End date of the study: |  |

*Note:*

*Provide a realistic start date that also takes into account the assessment period of the TCBio.*

*The investigator will send a final report of the results to the TCBio within 1 year after the end of this study.*

# C. Human biological material

## **C1. Quantity of human biological material (volume/weight) per type/category**

*Note: The Pathology Tissue Facility (in Dutch: Weefselfaciliteit Pathologie) only releases blank sections (not whole paraffin blocks). Selection of the most informative blocks is done by the investigator as much as possible, in consultation with an employee of the Tissue Facility.*

|  |
| --- |
| Type/Category human biological material:  Number of tubes:  Volume/Weight:  Type/Category human biological material:  Number of tubes:  Volume/Weight: |

## **C2. Will the human biological material be (or has it been) cultivated and/or amplified?**

No

Yes

If yes, for how long will the cultures be retained?

… months

Indefinitely

If yes, will the material be amplified to immortal (stem)cells or cell lines?

No

Yes (donor consent is required)

*Note: When amplifying to immortal (stem) cells or cell lines always verify*

*whether the required information about these procedures is present in the*

*consent letter and consent form.*

## **C3. Has consent been granted for the use of the human biological material defined in section C1? If yes, in what way?**

*Note:*

*Please tick the appropriate box(es) below: informed consent and/or broad consent and/or no consent. Only if you tick more than one option, you must indicate in the text box for each option which part of the donors or human biological material (as defined in section C1) it concerns.*

Consent has been granted via informed consent for a specific study (WMO or non-WMO).

*Note:*

*This concerns human biological material that has been collected for a specific study (irrespective of whether that study was subject to the WMO) but had not been (fully) used for that study. Note that re-use in a new scientific project must always be within the scope of the previously obtained informed consent. If the planned research falls outside the scope of the previously obtained informed consent, a request for re-use of the human biological material may be submitted to the TCBio, provided that reasonable efforts have been made to obtain the donor’s consent.*

Informed consent applies to the following group of donors/human biological material:

|  |
| --- |
|  |

***NOTE:Provide the original informedconsentletter and consent form!***

Consent has been granted via broad consent.

Broad consent applies to the following group of donors/human biological material:

|  |
| --- |
|  |

***NOTE:Provide the original broadconsentletter and consent form!***

No consent has been requested (i.e. the donor has not objected to the processing or use of his/her biological material through the UMC Utrecht no-objection/opt-out arrangement for further use of residual material/medical data).

No consent applies to the following group of donors/human biological material:

|  |
| --- |
|  |

## **C4. Describe in your own words why the proposed study with the requested human biological material falls within the scope of the consent previously granted by the donors or within the scope of the ‘no-objection’/‘opt-out’ arrangement.**

|  |
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|  |

## **C5. Describe in your own words how the anticipated amount of human biological material to be used in this study is justifiable in relation to the scientific relevance of the study.**

*Note:*

*Possible considerations may be: Will any material from these donors remain after these experiments? Are there many similar donors whose material will be available in the future for further or other research questions in this population? Does it concern rare material and is the importance of this study such that the material should be used specifically for this study?*

|  |
| --- |
|  |

# D. Data

## **D1. Which personal data from donors will be used in and/or will result from this scientific study with human biological material?**

*Note:*

*“Personal data” not only refers to personal data that are collected from other sources (e.g. HiX) and used in your study, but also personal data resulting from your study (e.g. DNA or RNA sequences).*

None. Proceed to section D7.

Residence

Postal code and/or address

Sex

Date of birth

Age

Race or ethnicity

Medical data, namely (please see the explanation in blue below the box):

|  |
| --- |
|  |

*Note:*

*Specify which medical data will be used in and/or will result from this study. Will these data include images? Will these data include patient numbers or pathology numbers (T-numbers)?*

Genetic data, namely (please see the explanation in blue below the box):

|  |
| --- |
|  |

*Note:*

*Specify which genetic or epigenetic data will be used in and/or will result from an analysis of a biological sample. Explain whether the data concern, for example, a partial profile, a complete profile or single mutations/single nucleotide polymorphisms (SNPs). Also indicate the technique(s) used to generate the data (e.g. karyotyping, PCR, Sanger, array or NGS).*

## **D2. In case you will be using existing data in your study: which data source(s) will you be using?**

CBB (UMC Utrecht Central Biobank)

RDP (Research Data Platform)

UPOD (Utrecht Patient Oriented Database)

DP2.0 (Data Platform 2.0)

HiX (Healthcare Information eXchange)

Other (e.g. previous research of another database), namely:

|  |
| --- |
|  |

## **D3. Can the donor’s identity potentially be derived (either directly or indirectly) from the personal data defined in section D1?**

*Note:*

*In determining whether a donor is potentially identifiable (either directly or indirectly), consideration should be given to all resources that could reasonably be expected to be used, regardless by whom (a researcher or anyone else).*

*In other words: in terms of identifiability, no distinction is made between those involved, e.g. the treating physician (coder) versus the researcher or the principal investigator versus another researcher. Data are either identifying or not identifying.*

*If the donor can potentially be identified (either directly or indirectly), regardless by whom (a researcher or anyone else), data are considered “personal data” under the General Data Protection Regulation (GDPR) (in Dutch: Algemene Verordening Gegevensbescherming, AVG), and processing of such data in principle requires the donor’s consent (see section D4).*

*A donor can be identified based on data that you collect from another source or based on data resulting from your research. This may concern identification based on a single, unique characteristic (e.g. a DNA profile), but also identification based on a combination of data from the human biological material and/or personal data. Such combinations also make a donor unique and are more often than not identifying.*

*A donor can also be identified in case of, for example:*

* *a limited number of cases (such as in very rare diseases or genetic abnormalities) or*
* *a specific geographical area (such as a small or sparsely populated postal code area).*

*Note that when patient numbers or pathology numbers (T-numbers) are used, data are not anonymous, but potentially identifying and therefore considered personal data under the GDPR.*

Yes

No

If no, please explain why the donor’s identity cannot be derived (either directly or indirectly) from the personal data:

*Note:*

*Describe why you think that the set of personal data is not directly or indirectly identifying, thereby allowing accurate determination of whether or not the data should be considered “personal data” under the GDPR and processing of the data, in principle, requires donor consent. Keep in mind that the TCBio may come to a different conclusion than you. You will therefore be asked further on in this form (D4.B) to always provide an explanation why the donor is not asked for consent, even if you indicate here that you do not think that the data are identifying.*

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## **D4.A Has consent been granted for the use of the personal data defined in section D1? If yes, in what way?**

*Note:*

*Please tick the appropriate box below: informed consent and/or broad consent and/or no consent. Only if you tick more than one option, you must indicate for each option in the text boxes which part of the donors or personal data (as defined in section D1) it concerns.*

Consent has been granted via informed consent for a specific study (WMO or non-WMO).

Informed consent applies to the following group of donors/personal data:

|  |
| --- |
|  |

***NOTE:Provide the original informedconsentletter and consent form!***

Consent has been granted via broad consent.

Broad consent applies to the following group of donors/personal data:

|  |
| --- |
|  |

***NOTE:Provide the original broadconsentletter and consent form!***

No consent has been requested (i.e. the donor has not objected to the processing or use of his/her personal data through the UMC Utrecht no-objection/opt-out arrangement for further use of residual material/medical data).

No consent applies to the following group of donors/personal data:

|  |
| --- |
|  |

***NOTE:***

* ***If your answer in section D4.A indicates “No consent has been requested” for some or all donors/personal data: please complete section D4.B below and then proceed to section D5.***
* ***If your answer in section D4.A indicates that consent has been granted in all cases (via informed consent and/or broad consent): please skip section D4.B and proceed directly to section D5.***

## **D4.B Your answer in section D4.A includes “No consent has been requested” for some or all donors/personal data. What is your rationale for this?**

*If your answer in section D3 is “Yes”:*

*As stated in section D3, the donor’s consent is required for the processing of identifying personal data. Deviation from this rule is only allowed if the grounds for exception as laid down in the Dutch Medical Treatment Contracts Act (in Dutch: WGBO), GDPR (in Dutch: AVG) and Dutch GDPR Implementation Act (in Dutch: Uitvoeringswet AVG, UAVG) have been met:*

* *asking consent is reasonably not possible or cannot reasonably be required;*
* *the study serves the general interest;*
* *the study cannot be performed without the personal data;*
* *safeguards (such as coding/pseudonymization and data minimization) are in place during the study conduct in a way that a donor’s privacy is not disproportionately harmed;*
* *the donor has not explicitly objected.*

*See also:* [*Decision tree (U)AVG-WGBO.pdf (kc-usercontent.com)*](https://preview-assets-eu-01.kc-usercontent.com/25b20d25-d13c-01de-3f74-7ca92fec5e2f/72565c1f-8bf7-47fc-ab34-31c7643666f8/Decision%20tree%20(U)AVG-WGBO.pdf)*.*

*The aim of the series of questions below is to determine whether all grounds for exception of the Dutch Medical Treatment Contracts Act (WGBO), GDPR (AVG) and the Dutch GDPR Implementation Act (UAVG) have been met. First you describe why consent has not been requested: is it reasonably not possible or can it reasonably not be required? Then answer all additional questions (1 through 5).*

*If your answer in section D3 is “No”:*

*As stated in section D3, the TCBio may come to a different conclusion than you when it comes to the identifiability of the data. You are therefore asked to always provide an explanation why the donor is not asked for consent. First you describe why consent is not requested: is it reasonably not possible or can it reasonably not be required? Then answer all additional questions (1 through 5).*

Asking donor consent is reasonably not possible, given the circumstances of the donor (e.g. donors have died or current contact details are unknown or probably no longer accurate and it is not possible to update them).

Explain here why it is reasonably not possible to ask for consent. If possible and reasonable, make a distinction between donor groups to whom the exception applies and donor groups who can be asked for consent:

|  |
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|  |

Or:

Asking donor consent cannot reasonably be required, given the nature of the study (e.g. asking for consent would require a disproportionate effort or there is a reasonable chance that approaching donors for consent would be too much of a burden for them).

Explain here why it cannot reasonably be required to ask for consent:

*Note:*

*A mere reliance on selection/response bias is not sufficient to demonstrate that asking consent cannot reasonably be required. You must also argue that there are no options available other than use of the data without consent. In addition, the sample size of the study population (“large numbers”) is not in itself sufficient grounds for not asking consent.*

|  |
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**Additional questions**

*Note: Please answer all questions (1 through 5) below if you indicated in section D4.A that in some or all cases no donor consent has been requested. If consent has been requested from all donors, you can skip the questions below and proceed to section D5.*

1. Why does the study serve the general (public health) interest?

|  |
| --- |
|  |

1. Explain why all personal data defined in section D1 are required for the conduct of the study.

|  |
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1. How will either direct or indirect identification of the donor reasonably be prevented?

|  |
| --- |
|  |

1. It is important that you ensure that the donor has not objected to the processing or use of his/her personal data. How will this be taken care of?

|  |
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|  |

**Risk of clinically relevant incidental findings**

*Note:*

*If there is a real risk of individual clinically relevant incidental findings in your research, these must be reported to the donor on the basis of the UMC Utrecht duty of care. This may concern clinically relevant incidental findings that may or may not be related to the research question(s) in this release protocol. To ensure that a donor will not be overwhelmed by the reported finding, the donor’s consent is required for using his/her biological material and data for this release protocol; the no-objection/opt-out arrangement does not suffice as consent. You are therefore asked to describe and substantiate the risk of individual clinically relevant incidental findings in your research.*

*Of note: the question below is therefore not about the clinical relevance of the research itself.*

*For more information on the reporting of incidental findings, refer to the SOP* [*Review - Reporting of Findings.*](https://assets-eu-01.kc-usercontent.com/25b20d25-d13c-01de-3f74-7ca92fec5e2f/3fcdb503-37c5-45c2-bbfb-74c6598d1537/SOP04-%20Melding%20bevindingen%20v002_EN.pdf)

1. Substantiate for this study the risk of clinically relevant findings.

|  |
| --- |
|  |

## **D5. How will the personal data for this study be collected and processed?**

*Note:*

*Coding (or pseudonymization) is not the same as anonymization. Coding (pseudonymization) of personal data means that the identity of the donor can still be traced, because the coding is reversible with the use of the code list ('key'). Thus coding (pseudonymization) as such does not lead to anonymous data, it only limits the extent to which the data can be identifying. In the case of coding (pseudonymization), the principles of data processing laid down in the GDPR therefore still apply, regardless of who has access to the code list at any time during the conduct of the study.*

*Anonymization is a form of coding in which the code list (‘key’) is destroyed. The identity of the donor can no longer be traced. Once anonymization has been completed, the principles of data processing laid down in the GDPR therefore no longer apply.*

*Anonymization of personal data is not always justifiable. For example: if there is a real risk of clinically relevant incidental findings (see section D4.B, question 5), you should be able to recontact the donor.*

By using a code and code list (coding/pseudonymization)

*Code and code list means that the donor-identifying data are replaced by a code and a code list ('key') is used, so that a donor can only be identified by the person who has access to the code list.*

By using a code without code list (anonymization)

*Code without code list means that neither the researcher nor the provider of the code number can identify the donor based on the code number.*

By using directly identifying personal data

*Examples of directly identifying personal data are a name or a date of birth. It should be emphasized that coding personal data (with or without a code list; see the two options above) is the basic principle. The processing of directly identifying data will only be allowed in highly exceptional cases and only if it can be thoroughly substantiated.*

Explain in the text box below why only directly identifying personal data can be used (i.e. why coding/pseudonymization or anonymization of the personal data is not possible). Then proceed to section D7.

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## **D6. Who will code the personal data?**

*Note:*

*Because of doctor-patient confidentiality, it is in principle not allowed that someone without a treatment relationship with the donor codes personal data. If there is no treatment relationship, an independent party can be engaged to code or anonymize the data. In UMC Utrecht you can contact Data Management. See:* [Data Management UMC Utrecht](https://intranet.umcutrecht.nl/connect/onderzoek/QualityofResearch/Paginas/Datamanagement.aspx).

*In exceptional cases, for research reasons, researchers may also need access to the code list. In that case, you must clearly substantiate below why this is necessary.*

Name:

Position:

Division/Department:

Treatment relationship with the donor:

Yes

No; please explain here why in this exceptional case it is not possible that someone with a treatment relationship codes the data:

## **D7. What measures have you taken against unauthorized access to and loss of the personal data, study results, and/or the code list?**

*Note:*

*To protect data, technical as well as organizational measures must be in place as laid down in the GDPR.*

*Examples of technical measures are:*

* *coding (pseudonymization) of personal data*
* *encryption of data (e-mail, files, folders)*
* *two-factor-authentication (i.e. there should be two steps to access the data, e.g. a password and fingerprint on a mobile phone)*
* *back-ups*
* *virus scan*

*Organizational measures must particularly prevent unauthorized persons from having access to certain data. Examples of organizational measures are:*

* *location where data are stored (e.g. secure drives in UMC Utrecht)*
* *limiting the number of users who can access the data*
* *authorization and authentication to restrict access*
* *strong passwords*
* *no sharing of login details with others*

*The aim of the four questions below is to determine whether the above measures are adequately taken. Some of the answers may be (partly) derived from the study’s data management plan (DMP). In that case, copy the relevant information from the DMP, so that the content of this release protocol is stand-alone (see also the Instruction box on page 1).*

1. Where are the code list (if applicable in accordance with section D5), the personal data and the study results stored?

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1. Who has access to the code list (if applicable in accordance with section D5), the personal data and the study results?

*Note:*

*Similar to section D6: In exceptional cases, for research reasons, researchers may also need access to the code list. In that case, you must clearly substantiate why this is necessary.*

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1. How will unlawful access to the code list (if applicable in accordance with section D5), the personal data and the study results be prevented?

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1. How will loss of the code list (if applicable in accordance with section D5), the personal data and the study results be prevented?

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# E. Summary for the general public (in Dutch, max. word count 500)

*Note:*

*This summary is essential for the review process. In addition, it may be published by UMC Utrecht internally and externally as part of transparency regarding the use of human biological material and data.*

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**> Proceed to section G**

# F. Registration details scientific activity

***(Not applicable to a scientific study)***

A scientific activity using human biological material (contrary to Article 10a.3 of the UMC Utrecht biobank regulations):

* concerns a limited amount of material (no amplification to immortal stem cells and cell lines).
* occurs structurally within the department.
* occurs without the use of clinical data.
* does not occur in collaboration with any third parties (i.e. use within UMC Utrecht only).

|  |  |
| --- | --- |
| **Description of the activity** (e.g. equipment testing, testing of tissue staining): | |
| **Quantity of human biological material (volume/weight) per type/category** | Type/Category human biological material:  Number of tubes:  Volume/Weight:  Type/Category human biological material:  Number of tubes:  Volume/Weight: |
| **Has consent been granted for the use of the human biological material? If yes, in what way?**  *In case of informed consent for a specific study (WMO or non-WMO):*  *This concerns human biological material that has been collected for a specific study (irrespective of whether that study was subject to the WMO) but had not been (fully) used for that study. Note that re-use in a new scientific project must always be within the scope of the previously obtained informed consent.* | Consent has been granted via informed consent for a specific study (WMO or non-WMO)  ***NOTE: Provide the original informed consent letter and consent form!***  Consent has been granted via broad consent  ***NOTE:Provide the original broadconsentletter and consent form!***  No consent has been requested (i.e. the donor has not objected to the processing or use of his/her biological material through the UMC Utrecht no-objection/opt-out arrangement for further use of residual material/medical data) |
| **Annual frequency activity:** |  |
| **Start date activity:** |  |
| **End date activity:**  Note: reporting of the amount of biological material used takes place at the end of this period. |  |
| **Name of person with final responsibility for the scientific activity:**  (head of the UMC Utrecht department where the scientific activity takes place)  See also section G, part 1. |  |
| Division: |  |
| Department: |  |
| E-mail: | @umcutrecht.nl |
| **From which sub-biobank(s) or source(s) is the human biological material being requested?** | Protocol number:  Title:  Other: |
| **Name of person with final responsibility for the sub-biobank(s) from which the material is being requested/the residual material**  (head of the UMC Utrecht department(s) with final responsibility for the sub‑biobank(s)/the residual material)  See also section G, part 2. |  |
| Division: |  |
| Department: |  |
| E-mail: | @umcutrecht.nl |

# G. Signature

1. **The undersigned (investigator with final responsibility/person with final responsibility for scientific activity)**

hereby declares that:

* he/she has taken note of the procedures, requirements and guidelines laid down in the UMC Utrecht biobank regulations with regard to the inclusion, release and use of human biological material and associated (clinical) data.
* in case of any response to questions from the TCBio, the other signatories under G2 and G3 will be informed about the modifications and these will be presented to them for their approval. In this case, this release protocol will not need to be re-signed by the responsible persons G2 and G3 when resubmitted.

Name: …………………………………………………………………………

Signature: …………………………………………………………………………

Place: …………………………………………………………………………

Date: …………………………………………………………………………

1. **The undersigned (department head with final responsibility for the sub-biobank/the (fresh) residual material)**

hereby declares\* that he/she has taken note of the request submitted for the (fresh) human biological material that has been collected by them and/or is becoming available, and provides his/her permission for the use of the material by the above-named requesting party.

Division: …………………………………………………………………………

Name: …………………………………………………………………………

Signature: …………………………………………………………………………

Place: …………………………………………………………………………

Date: …………………………………………………………………………

**\* signature required at first submission**

1. **The undersigned (medical division manager)**

hereby declares\*\* on behalf of the division management of the division:

…………………………………………………………..………………

* that the request submitted for the use of human biological material and/or associated (clinical) data meets the scientific requirements.
* that the scientific study/scientific activity as described above is in line with the division’s and UMC Utrecht’s scientific policy.
* that the costs for this request may be charged by the provider of the material and by signing this release protocol the division management accepts these costs.

Name: …………………………………………………………………………

Signature: …………………………………………………………………………

Place: …………………………………………………………………………

Date: …………………………………………………………………………

**\*\* signature required at first submission**

**Note: Protocols with missing signature of the division management will not be processed.**

# H. General remarks

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# I. Annexes (if applicable)

Original broad consent and/or informed consent letter(s) and consent form(s) for the collection of the human biological material. If multiple versions have been used over time, please provide all relevant versions.

**This Annex is mandatory, except in cases where the material was obtained via the no‑objection/opt-out arrangement.**

MTA/contract(s) with research partner(s).

**This Annex is mandatory in case of collaborations with parties outside UMC Utrecht.**

Quotation/price arrangements with the provider of the material.

Other: ………………………………………………………

1. Release protocol form, version dated 1 February 2023. Author: UMC Utrecht. Dutch copyright law applies to this document. [↑](#footnote-ref-1)