#

# DATA REQUEST ASSESSMENT FORM

# *DAC DBG UMC Utrecht*

|  |  |
| --- | --- |
| **Date:** |       |
| **Unique identifier data request:** |       |
| **Applicant date:** |       |
| **Applicant institution:** |       |
| **Applicant name and position/title:** |       |
| **Department of applicant:** |       |

|  |
| --- |
| **Assessment by secretary of the Data Access Committee (DAC)** |
| 1. **Admissibility of the data request**
 |  |
|  | 1.1 ‘Data request form’ is completed  | Yes [ ]  / No [ ]  |
|  | 1.2 Information as stated in the ‘Data request form’ is not evidently incorrect | Yes [ ]  / No [ ]  |
|  | 1.3 The DTA is communicated to the applicant.  | Yes [ ]  / No [ ]  |
|  | 1.4 There are sufficient grounds to grant access to the applicant regarding the requested data set*\* The DAC will judge this based on privacy laws and consent permissions given in this context.* | Yes [ ]  / No [ ]  |
|  | 1.5 The data request is admissible*\* If parts 1.1, 1.2 and 1.3 are answered with ‘Yes’, the data request will be judged as admissible.* | Yes [ ]  / No [ ]  |
|  | 1.6 Remarks |       |
| 1. **Overview of requested data**
 |  |
|  | 2.1 The dataset that is requested:      . |  |
|  | 2.2 The requested format is:[ ]  BAM[ ]  VCF[ ]  Other:      . |  |
| 1. **Administrative procedure by secretary**
 |  |
|  | 3.1 The applicant was informed about the admissibility of the data request within five (5) workdays after application. Application of data request form on      .*\*The applicant will be informed within five (5) workdays after application regarding the admissibility of the data request.* | [ ]  |
|  | 3.2 The secretary schedules a Data Access Committee meeting for assessment of the Data Access Request | [ ]  |
|  | 3.3 The completed ‘Data Request Assessment Form’ and the ‘Data Request Form’ of the applicant will be uploaded in parallel to the secure UMC Utrecht environment on      . | [ ]  |

|  |
| --- |
| **Assessment by Data Access Committee (DAC)** |
| 1. **Scientific aspects of data request**

*\* If a data request is admissible, the DAC will judge on the medical and scientific aspects of the request. The DAC is always entitled to specify additional and/or more detailed criteria for scientific assessment of Data Requests. This ‘Data Request Assessment Form’ will be amended to reflect these changes.* |  |
|  | 4.1 The research question is valid. Clarification:     . | Yes [ ]  / No [ ]  |
|  | 4.2 The data request is compatible with the mission statement of the Department of Biomedical Genetics. Clarification:     . | Yes [ ]  / No [ ]  |
|  | 4.3 The research project has sufficient scientific value and relevance. Clarification:     . | Yes [ ]  / No [ ]  |
|  | 4.4 The requested data is relevant for the research project. Clarification:     . | Yes [ ]  / No [ ]  |
|  | 4.5 The research project seems feasible. Clarification:     . | Yes [ ]  / No [ ]  |
|  | 4.6 The capabilities of the applicant are adequate to carry out the research project. Clarification:     . | Yes [ ]  / No [ ]  |
|  | 4.7 Other (medical) scientific aspects that might be relevant for the Data Access Board in the judgement of the data request?      . | Yes [ ]  / No [ ]  |
|  | 4.8 Other (medical) scientific aspects that might be relevant for the applicant?      . | Yes [ ]  / No [ ]  |
| 1. **Required external scientific council**

*\* The DAC can, at its discretion, invite external experts to advise regarding the (medical) scientific aspects of a data request. In some cases the DAC is obligated to include external experts: if the requested data (partly) originates from a third party and if this party requests the judgement of an external expert on the Data Access Request.* |  |
|  | 5.1 The DAC is obligated to include external advice in its judgement of the data request.*\* If ‘Yes’, the scientific board has to include the opinion of an external expert and continue to 5.3. If ‘No’, continue to 5.2.* | Yes [ ]  / No [ ]  |
|  | 5.2 The DAC has sought council of an external expert at its discretion. Clarification:     .*\* If ‘No’, continue to 7.* | Yes [ ]  / No [ ]  |
|  | 5.3 The DAC has sought council of an external expert at      . Summary of the gained advice:     . |  |
|  | 5.4 The verdict of the DAC on the scientific aspects of the request deviates from the advice of the external expert. If yes, please specify reasoning:     . | Yes [ ]  / No [ ]  |
| 1. **Evaluation of data request after scientific aspects and external council**

*\* After steps 4 and 5, it is evaluated if the data request is still admissible for further evaluation or if it is rejected on lack of scientific grounds.* |  |
|  | 6.1 The evaluation of the scientific aspects (including potential advise by external council) resulted in the following intermediate result:     .*\* If data access request is rejected, please specify reason. Rejection should be communicated by the DAC directly to the applicant.* | [ ]  Rejected, do not continue completing this form.[ ]  Admissible, continue to next step. |
| 1. **Other (non-scientific) aspects of data request**

*\* If the scientific assessment of the data (5) does not result in rejection of the data access request, the non-scientific aspects of the data request are evaluated.*  |  |
|  | 7.1 For the data to be provided to the applicant, there will be a need for restrictions in the legal contract:* Collaboration agreement of clinical research between the UMC Utrecht and the institute of the applicant needed:
	+ Data request is submitted by an institute/party outside the EEA.
	+ Data request is submitted by a commercial institute/party.
 | Yes [ ]  / No [ ] Yes [ ]  / No [ ] Yes [ ]  / No [ ]  |
|  | 7.2 The informed consents are prohibiting the release of the data that is requested by the applicant. If yes, please specify reasoning:     .*\* In this section, the DAC checks if the specified research goals and methods are in line with the permissions granted by the patients when signing the informed consent (informed consents could be signed in the past). In this way, the DAC can decide if the patients’ interests are met.*  | Yes [ ]  / No [ ]  |
|  | 7.3 The legislation, rules and procedures applicable to the requested data are prohibiting the data release. If yes, please specify reasoning:     .*\* For example, if applicant is situated outside of the ERR and no further guarantees are agreed upon.* | Yes [ ]  / No [ ]  |
|  | 7.4 The UMC Utrecht policies and regulations prohibit the release of the requested data. If yes, please specify reasoning:     . | Yes [ ]  / No [ ]  |
|  | 7.5 The release of the requested data satisfies all conditions and fits within the purpose of the hospital. If yes, please specify reasoning:     . | Yes [ ]  / No [ ]  |
|  | 7.6 There are ethical or societal restrictions that prohibit the release of the requested data to the applicate. If yes, please specify reasoning:     .*\* For example, if there is a conflict of interest* | Yes [ ]  / No [ ]  |
| 1. **Required external council**

*\* The DAC can, at its discretion, invite external experts to advise regarding the other (non-scientific) aspects of a data request.* |  |
|  | 8.1 The Data Access Committee has sought council of an external expert at its discretion.*\* If ‘No’, continue to 9.* | Yes [ ]  / No [ ]  |
|  | 8.2 The Data Access Committee has sought council of an external expert at      . Summary of the gained advice:     . |  |
|  | 8.3 The verdict of the DAC on the other (non-scientific) aspects of the request deviates from the advice of the external expert. If yes, please specify reasoning:     . | Yes [ ]  / No [ ]  |
| 1. **Final verdict Data Access Committee**

*\* Based on the Data Access Request form, the Data Access Committee rules on the decision to make the requested data available to the applicant.*  |  |
|  | 9.1 The requested data can be made available to the applicant. Clarification:     . | Yes [ ]  / No [ ]  / In Part [ ]  |
|  | 9.2 The Data Access Boards verdict deviates from the advice given by the expert(s). Clarification:     .*\* If ‘No’, continue to 10. If yes, please provide reasoning and continue to 9.3 and 9.4.* | Yes [ ]  / No [ ]  |
|  | 9.3 Approval of ‘Management Team (MT)’ is needed. | Yes [ ]  / No [ ]  |
|  | 9.4 The Data Access Board has acquired approval of the ‘Management Team (MT)’ at      . | [ ]  |
| 1. **Required signature(s) for approval of Data Access Request**
 |  |
|  | Chairman of the Data Access Committee:Name:      Date:      Location:      Signature:DBG Authority (MT) to sign:Name:      Date:      Location:      Signature: | [ ]  |
| 1. **Administrative procedure to finalize Data Access Request by secretary**
 |  |
|  | 11.1 Applicant is informed about the final verdict on      .*\* Within 30 days.* | [ ]  |
|  | 11.2 Data Access Board informs MT about the verdict by email. | [ ]  |
|  | 11.3 The DTA is received by the DAC on       and are signed by the applicant. | [ ]  |
|  | 11.4 The completed and signed ‘Data Request Assessment Form’, ‘Data Request Form’ and ‘DTA’ of the applicant will be uploaded in parallel to the secure UMC Utrecht environment on      . | [ ]  |
|  | 11.5 Access to the requested dataset is granted by the secretary/data steward.Person that granted access:      Date that access is granted:       | [ ]  |