



Data Access Process

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1.0	31 st Aug 2021	Conan Donnelly	Legacy Document <i>DO2 INPDR Data Request Process Final 1.0</i> 311019SB entered into QMS



International Niemann-Pick Disease Registry

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INPDR is a registered charity in England and Wales: 1175311.

1. Background

The International Niemann-Pick Disease Registry (INPDR) is a global disease registry which collects clinical and patient reported data of Niemann-Pick Disease patients. Due to nature of the Registry, this provides opportunities to various stakeholders who may benefit from seeking access to data, maximising the impact of registry data. Indeed, one of the central aims of the INPDR is to foster collaboration with 3rd Parties to facilitate progress in NPD research and care through the use of Registry data via Data Access Requests (DAR).

Due to the sensitive nature of data held on the Registry, unrestricted 3rd Party access to data is forbidden. Therefore, this SOP defines the DAR process for 3rd parties for data held on the Registry.

Applicants submitting a DAR can be from any background, including (but not limited to) members of the INPDR, clinicians, researchers, patient advocates, members of industry and regulators.

The decision to approve or reject DARs is made by the INPDR Board of Trustees, with recommendations given by the INPDR Scientific Advisory Committee.

2. Process

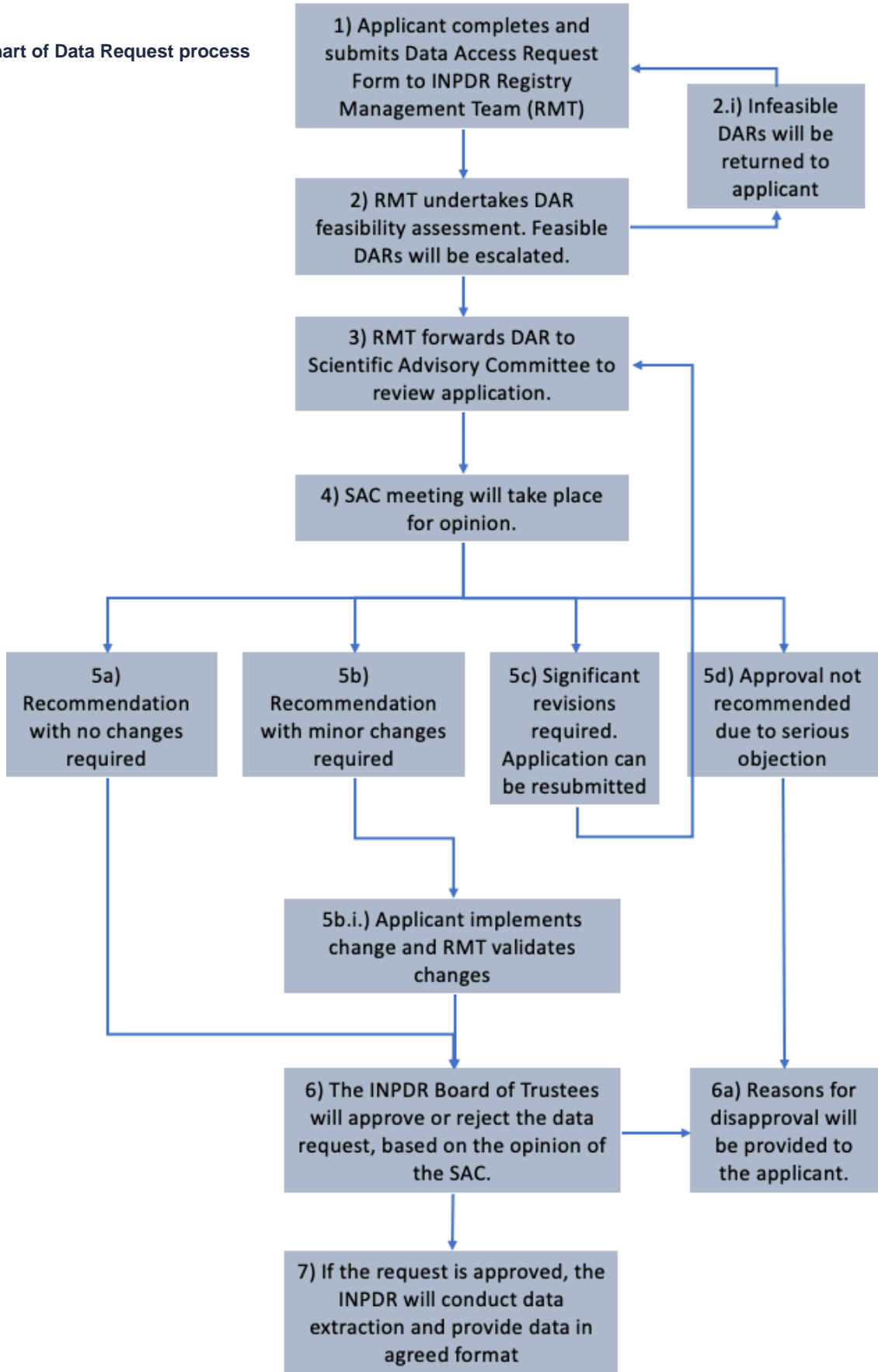
- 1) The Applicant will complete the 'INPDR Data Access Request Form', which is obtainable via email (eventually to be hosted online) from the Registry Management Team (RMT). The form contains detailed questions regarding the nature, scientific basis and other key aspects of the DAR.
- 2) The Applicant will submit the DAR form and any supporting documentation to the RMT. The RMT will undertake a preliminary review of the DAR for feasibility purposes. The RMT will inform the Applicant of the feasibility of the DAR.
 - a. If the DAR is judged to be feasible, the DAR will be accepted for review.
 - b. If the DAR is judged to be infeasible, the Applicant will be informed of the reason why the DAR is infeasible. The Applicant will be given the opportunity to revise the DAR and resubmit to the RMT.
- 3) The RMT will distribute the DAR Form and any supporting documents to the Scientific Advisory Committee (SAC). The RMT will advise the SAC on data protection implications of the request and methods to minimise and manage the risk of patient identification. A SAC review meeting is organised, typically via teleconference or via face-to-face where possible. The SAC meeting will take place up to 4 weeks after the DAR has been provided to the SAC.
- 4) SAC review meeting will take place, with the meeting minutes taken.
- 5) The SAC opinion will be one of the following:
 - a. Data request is recommended with no changes required.



- b. Data request is recommended with minor changes required that must be completed by the applicant and verified by the INPDR RMT prior to any approval given by the Board of Trustees. The minor changes will be provided to the applicant in writing. The RMT will confirm the implementation of the minor changes to the SAC.
 - i. The revised application must be submitted to the INPDR RMT within 15 working days of the applicant's receipt of the SAC opinion.
 - c. Data request is not recommended, with significant changes required if the applicant wishes to resubmit the request. The required changes will be provided to the applicant in writing. The applicant will have up to 30 working days to revise the request. Resubmitted requests will be subject to a further SAC review and will be reviewed within 4 weeks of resubmission either by teleconference, face-to-face meeting or email exchange, whichever is most convenient at the time.
 - d. Data request is not recommended due to serious objections. The objections will be submitted to the applicant in writing. If the applicant still wishes to appeal, they must write to the Board of Trustees with further clarification to re-open the application.
- 6) The SAC opinion will be communicated to INPDR Board of Trustees in writing (via email) by the RMT within 5 working days of the SAC review meeting. The Board of Trustees will communicate via teleconference and/or email during the decision-making process. The Board of Trustees will act on the SAC recommendation and issue their decision within 5 working days of receipt of the SAC recommendation.
 - a. Where requests are approved by the Board of Trustees, the applicant will be informed with 5 working days of the Board of Trustees decision.
 - b. Where requests are disapproved by the Board of Trustees, the reasons for disapproval will be provided to the applicant in writing with 21 working days of the Board of Trustee's decision.
- 7) Where approval is given, the INPDR will prepare a data use agreement (if applicable), undertake the data extraction exercise and provide the data in an agreed format to the applicant. The timeline of extracted data will be outlined in the notice of DAR approval decision.



Figure 1 - Flowchart of Data Request process



3. Expectations of the INPDR

- The INPDR, will be transparent in dealing with requests and all applicants will be treated with the same due care and process, regardless of the relationship the applicant may or may not have with the INPDR.
- The INPDR will work to all stated timelines, and where timelines cannot be followed due to circumstances out of the control of the INPDR, the applicant(s) will be informed of the delay and the expected resolution date.
- Members of Scientific Advisory Committee involved in DAR reviews will disclose any relationship they may have with the applicant. The SAC member may exclude themselves if required from the DAR review session and an alternative SAC member will take their place for the review.
- Where appropriate, the INPDR will prepare a Data Use Agreement with the requester in cases where such an agreement is required

4. Expectations of the Applicant(s)

- All applicants must ensure that the application form and any supporting documentation accurately reflects the purpose of the data request, and as such data procured through the request process must be used for only its INPDR approved purpose.
- All applicants must respond to comments, queries and questions the SAC may produce arising from the review.
- Applicants will be required to provide a copy of any produced literature that arises from INPDR data to the INPDR for their review and approval.

Validity and Approval

The owner of this document is the Chief Executive Officer, who shall check and if necessary update the document at least once a year.

The Chief Executive Officer is responsible for communicating the Data Access Process to all persons working for or on behalf of INPDR.

This process is valid from 31st August 2021.

Approved:

Conan Donnelly

Date:

31/08/2021

Conan Donnelly
Chief Executive Officer
INPDR

