 

**NorCog biobank and registry: data and biological material request form**

Norwegian Registry of Persons Assessed for Cognitive Symptoms (NorCog) is a national quality and research registry in Norway. Oslo University Hospital Trust (OUS) owns the NorCog registry while the Norwegian National Centre for Aging and Health is responsible for the management and operational aspect of this registry.

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| Please send the application form to: | Coordinator: Marit Nåvikmarit.naavik@sthf.no |
| Queries about the NorCog Registry: | Project lead/ principal investigator: Geir Selbækgeir.selbæk@aldringoghelse.no |

The NorCog steering committee will review this application. When the steering committee has approved the application, NorCog informs the Data Protection Officer at OUS. When this has been done, data can be released from the research server at OUS to the recipient. The recipient is responsible for ensuring that data and biological material are stored in a manner that ensures patient confidentiality and data protection, and that relevant approvals have been collected (REC, data protection agency, etc.).

**Project lead/ Principal investigator (PI)**

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| NameKlikk eller trykk her for å skrive inn tekst. | Research institutionKlikk eller trykk her for å skrive inn tekst. |
| Title Klikk eller trykk her for å skrive inn tekst. | Work AddressKlikk eller trykk her for å skrive inn tekst. |
| Telephone numberKlikk eller trykk her for å skrive inn tekst. | Mobile phone numberKlikk eller trykk her for å skrive inn tekst. |
| Email addressKlikk eller trykk her for å skrive inn tekst. |

**Recipient of data (team member responsible for carrying out the project)**

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| NameKlikk eller trykk her for å skrive inn tekst. | Research institutionKlikk eller trykk her for å skrive inn tekst. |
| Title Klikk eller trykk her for å skrive inn tekst. | Work AddressKlikk eller trykk her for å skrive inn tekst. |
| Telephone numberKlikk eller trykk her for å skrive inn tekst. | Mobile phone numberKlikk eller trykk her for å skrive inn tekst. |
| Email addressKlikk eller trykk her for å skrive inn tekst. |

**Please list any other project participants/collaborators and their institutions**

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| NameKlikk eller trykk her for å skrive inn tekst. | InstitutionKlikk eller trykk her for å skrive inn tekst. |
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Please note that the data in the NorCog database is classified as data containing personal information. Therefore registry data should only be used by the PI or the data recipient listed above. If it is envisaged that NorCog data will be used by another party such as a collaborator, a written data sharing agreement should be sought between the PI and the collaborator’s institution. The conditions for use of data must be stated clearly in this agreement.

**Project Overview**

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| Title of the projectKlikk eller trykk her for å skrive inn tekst. |
| Abstract (background, research questions, aims, study design, plan for analysis)Klikk eller trykk her for å skrive inn tekst. |
| A list of variables required from NorCog. Please not that the list of variables requested should be in keeping with the variables approved by the research ethics committee (REC).Klikk eller trykk her for å skrive inn tekst. |
| If applicable, please provide a description of biological material/samples required from the NorCog research biobank (type of sample, number of samples, sample volume etc): Klikk eller trykk her for å skrive inn tekst.Please note that when requesting biological samples, a Material Transfer Agreement (MTA) must be prepared between NorCog (Oslo University Hospital) and the recipient institution. |
| Please describe how the data will be stored. (This should be in keeping with the data storage methods approved by the research ethics committee/ data protection officer)Klikk eller trykk her for å skrive inn tekst. |
| Project timelineExpected start date: Klikk eller tt. Expected end date: Klikk eller tt.  |
| Is the study approved by a research ethics committee Yes [ ] No[ ] Please provide date of approval and REC reference number: Klikk eller tt. |

**Will the data be linked to other registries?** Yes [ ] No[ ]

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| If yes, please specifiy which registry/iesKlikk eller trykk her for å skrive inn tekst.Klikk eller trykk her for å skrive inn tekst. |
| Governing body and/or owning institution of registryKlikk eller trykk her for å skrive inn tekst. |

**Attachments**

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| Mandatory* Original REC application, REC approval letter and any subsequent amendments to REC application
* Any other approval for the project e.g. data protection officer from host institution
* Project protocol

Optional• Consent form for the sub-study• Written data sharing agreement with another party/institution• Material Transfer Agreement (MTA) (when delivering biological material))Suggestions for templates for data sharing agreements and MTA can be found here: <https://forskerstotte.no/home/avtaler-maler/Samarbeid>  |

**Terms and conditions for provision of NorCog registry data and biological samples**

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| The steering group approves the application provided the following terms and conditions are fulfilled:* Data provided by NorCog will be in accordance with the variables requested in this form and the variables approved by the REC.
* The data or biological material provided by NorCog will only be used for the purposes described in this application and should be approved by the REC. If the aims or research questions are changed at any stage, a new REC application and a new biological material and data request form must be submitted and approved.
* Data must be used in a way that ensures data confidentiality and in accordance with the legal and ethical framework within research governance.
* Data must be handled and stored securely ensuring that unauthorised persons cannot gain access.
* Data will be issued using serial numbers different to those stored in the NorCog database. The persons can be identified via a linked code list that will be stored and accessible only by the registry secretariat.
* The PI or the team member carrying out the study is responsible for securing a data sharing agreement in any collaborative projects. If NorCog data is to be processed by a party other than the PI or the team member carrying out the study, a written data sharing agreement must be drawn between the PI and the collaborating institution where the conditions for use of data should be clearly stated.
* Data can only be published provided that individuals in the registry are not identifiable.
* Submitted data or biological material may be used in accordance with the stated project schedule and as long as approval by the REC is applicable. Changes to the project schedule must be reported to the steering group.
* At the end of the project, the data file received from NorCog should be deleted or anonymised. Any remaining biological material should be returned to NorCog or destroyed if there is a negligible sample volume.
* The applicant must send a short presentation/ summary of the study for publication on the NorCog registry website within one month of approval by the steering group.
* The applicant must provide a progress report of the project describing the use of data from NorCog, within one year after the project has been approved. In instances where data has not been processed within one year after approval has been granted, the NorCog steering group reserves the right to re-examine the decision to provide NorCog data.
* At end of the project, a final report should be send to the registry secretariat. This report can, for example, be in form of a scientific article published in a peer-reviewed journal.
* The NorCog registry and biobank should be referred to in the method sections and acknowledgments in all scientific publications arising from the use of NorCog data or biological samples.
* The issuing institution stores the data file released to the applicant until the project is completed.
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**Declaration**

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| I confirm that I have read and accepted the terms and conditions governing the release of NorCog registry data and biobank biological samples. Signature: Klikk eller tryk. K lApplicant’s name: Klikk eller tryk. Date: Klikk eller tryk. |

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| Additional comments or conditions by steering groupKlikk eller trykk her for å skrive inn tekst. |
| Application approved: [ ]  |
| Application rejected: **[ ]** Reasons for rejection: Klikk eller trykk her for å skrive inn tekst.Klikk eller trykk her for å skrive inn tekst. |

This document was created in duplicate where each party receives their own copy.

 Date Klikk ell e When supplying biological material:

Electronic signature/ E-mail with confirmation of approval.

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Marit Nåvik Geir Selbæk

Coordinator Project leader/PI and head of biobank

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