NCGC data access contract

Agreement on access, sharing and publication of data generated in research projects under the umbrella of the Norwegian Cancer Genomics Consortium (NGCG).

1. The NCGC is a consortium of organisations that have signed an agreement to collaborate on research, evaluation, and implementation of genome-based personalization of cancer medicine in Norway. The members are defined in the collaboration agreement for the specific project.
2. Individual research projects that are funded or supported by grants obtained by NCGC are required to comply with the provisions stated below. This also includes collaborations with separate funding, but using NCGC personnel and/or infrastructure.
3. Data access rights, purpose of analyses, and publication, presentation or dissemination of data will be determined by the NCGC leadership group[1], in agreement with ethical approvals and data security provisions. All research projects must be within the approvals by the relevant Regional Ethical Committee to the providing group (provided there is a collaboration) or to the group gaining access to data.
4. Each individual needing access to NCGC data, also within the project, needs to fill in and sign this agreement and have it approved both by the project leadership and the research leader owning the subproject (leader of the research group disposing of the biobank and having the REK approval for the studies).
5. Access to project data for purposes not defined in the project description, or by groups not part of the consortium, requires also completing this agreement and written approval by the same parties.
6. The genome data acquired by the project will be deposited in a national thematic research registry governed by a scientific steering group as defined in the concession by the Data Protection Authority.
7. Studies across biobanks decided by the NCGC leadership group will always have access to all data, but project owners may request delayed publication for completion of research to be published in parallel or for patenting purposes. Such requests are decided on by the NCGC leadership group, and may be appealed to the Project Board.
8. If the subproject owner rejects access to NCGC-generated data but does not sufficiently pursue their own investigation of the data, or has had privileged access to the data for an unreasonable long period, the NCGC leadership group may overrule this decision by brining it to the Project Board.
9. Coauthorship will be given for at least one scientist from each subproject group who has provided samples included in studies by NCGC or other collaborating groups.

[1] As of february 2013 this group consists of Tom Dønnem, Bjørn Tore Gjertsen, Harald Holte, Eivind Hovig, Ragnhild A Lothe, Per Eystein Lønning, Leonardo Meza-Zepeda, Ola Myklebost, Ole Morten Seternes, Jan Helge Solbakk, Giske Ursin, and Anders Waage.

As a general rule, the personal (germ line) genome data are considered very sensitive, and protection of privacy must be absolute. This implies that such data are properly coded, and should never be stored together with keys that can be used to identify the patient. Such data can only be stored and analysed on systems approved for this purpose by NCGC.

For non-heritable, derived data, *i.e.* somatic mutations in tumours, access rules and coding requirements are maintained, but such data are considered less sensitive, and may be analysed outside the closed maximum security system designed for highly sensitive data. However, the data confidentiality is to be maintained, and accessibility by, or disclosure to non-approved individuals is not permitted.

Data users are responsible for ensuring that all uses of the data are consistent with laws and any relevant institutional policies, and that the data are always securely maintained. No unauthorized data movement or duplication may be performed.

The undersigned party agrees to treat the provided human genome data confidentially, and to not investigate the personal identity of any research participant or their relation to other individuals.

Which data will be accessed

Purpose of investigation

What analysis infrastructure will be used

REK approval no | Given to project leader:

…… Date ……..

Signature if "project leader" responsible to REK is different from requesting "group leader"

Signatures Date ……..

…… Date ……..

Person requesting access | Responsible group leader

…… Date ……..

Institutional approval (*Name, Signature, Function*)

If affiliated with institution that is not partner of the project generating the data

…… Date ……..

Approved by the partner owning the project from which the data is obtained.

…… Date ……..

Approved by the NCGC leadership group
Notification to the Data security officer is sent
Ola Myklebost, Project leader