Code of conduct for information security
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Agreements and authorizations relating to research

Supporting document
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Target group This fact sheet is particularly relevant for:	☐ Supplier ☐ IT manager ☐ Researcher ☒ Manager	☒ Head of security/Security coordinator ☐ Organization manager/management ☒ Person or body responsible for research	☐ Staff/employee ☒ Data processor ☒ Privacy protection ombudsman
Responsibility	The project manager is responsible for the daily operation of the research project, and the project manager will thus have a particular responsibility for ensuring that necessary agreements and authorizations are in place.		
Execution	Executed during the formation of each research project and throughout the duration of the project in order to ensure continuing compliance with the agreements and authorizations.		
Purpose	The purpose of the fact sheet is, amongst other things, to: • Make project managers aware of relevant agreements and authorizations • Ensure that the research project has the necessary authorizations from the Regional Committees for Medical and Health Research Ethics (REK) and, as the case may be, from any other authorities (the Norwegian Medicines Agency) prior to the commencement of the research • Raise awareness concerning the formal responsibility for information security in research projects • Contribute to compliance with the relevant provisions of the Code, acts, and regulations		
Scope	• Agreement here refers to a written contract between the research project and other parties, e.g.: o Institution/organization/group making research data available to the research project o Any data processor, if used o The commissioner, in relation to commissioned research o The research subject (individuals whose data form the basis for the research) • Authorization means here approvals received by the research project from competent authorities, e.g.: o Prior approval from REK, in accordance with section 33 of the Health Research Act o Approval received from the ministry to transfer a biobank abroad in accordance with section 29 of the Health Research Act		
Authority	Agreements and authorizations in connection with research are anchored in, *inter alia*,: • The Health Research Act • The Biobank Act		
References	• Code of conduct for information security, Chapter 1.5 • The Regional Committees for Medical and Health Research Ethics (REK): www.etikkom.no/REK (in Norwegian only). • Guidelines for information security in research projects in the healthcare and care sector (in Norwegian only)		

Action/Execution

The extent of agreements and authorizations needed may vary between health research projects, and will depend on, amongst other things, the source of the data, whether data will be transferred abroad, whether the research project is independent or commissioned, etc. The below list provides an indication of the agreements and authorizations that usually must be present prior to the commencement of the project and prior to the collection of health and personal data:

No	Action/Execution
1	**REK** - The research project requires advance approval from REK, obtained through an application with attachments. Advance approval is both a necessary and a sufficient basis on which the project can process health data - The form is available at REK's website (www.etikkom.no/REK) and shall be submitted to the REK in the region in which the person or body responsible for the research has his/its work address
2	**Disclosing organization** - The research project will often depend on gathering data from groups outside the organization in which the health research is taking place. The research project must then arrange for an agreement to be made with the institution/organization that is making the data available (e.g. the Norwegian Institute of Public Health, a university hospital, a foreign medical research foundation, etc.) - The different groups will most often impose different criteria concerning the use of the data, etc., and the research project must take care to ensure that the data can be used in accordance with the research objectives
3	**Research subject** - Prior to the registration of health and personal data informed consent must be obtained. Consent shall be obtained through the consent language approved by REK in connection with the application - The National Committee for Medical and Health Research Ethics (NEM), the Norwegian Medicines Agency, and the Data Inspectorate have collaborated in producing templates for informing and obtaining consent for research projects. The templates are available at: www.etikkom.no/REK/02012008/view (in Norwegian only)
4	**Commissioner (for commissioned research)** - If the project is performing commissioned research a written agreement must have been made (in which the publication of results and the rights to these are key topics) - The Ministry of Education and Research has developed a standard contract which may form the basis for the agreement (http://www.regjeringen.no/nb/dep/kd/aktuelt/nyheter/2006/ny-standardkontrakt-for-oppdragsforsknin.html?id=10064) (in Norwegian only)
5	**Data processor** - If the research project makes use of a data processor a data processing agreement must be made - Please refer to Fact sheet 10 – Use of data processor (external business unit) for the recommended procedure
6	**Agreements concerning the transfer of health and personal data to countries outside the EEC** - When transferring data to countries outside the EEC the EU's standard contract can be used, or informed consent obtained from the data subject. See http://www.datatilsynet.no/templates/article____2626.aspx (in Norwegian only) for standard contracts
7	**The agreement should take into consideration whether the research makes use of** - Anonymized health and personal data - De-identified health and personal data - Pseudonymized health and personal data - Fully identifiable health and personal data