Function/ role:	Institution responsible for research	Clinic manager / Head of department	Person in charge of biobank	Project manager	Project team member	Student
Condition	The institution, in other words the senior most manager. Tasks may be delegated, but not responsibility.	The line manager with management responsibility for the project manager and/or responsibility for all or parts of the research project that is implemented at the department/clinic	The person in charge of a biobank with medical or biological qualifications at Master's degree level or higher, appointed by the institution responsible for research	Necessary academic and scientific competence, and as a main rule a PhD is required	Necessary competence to carry out the tasks, as defined by the project manager	Necessary competence to carry out the tasks, as defined by the project manager / manager
Areas of responsibility	- Superior responsibility for research projects and biobanks - Local responsibility in multi-centre studies - Sponsor responsibility in clinical trials	- Responsibility for ensuring that: - research participants are looked after, personal health data, research data and/or biological material in his/her own department/clinic is managed pursuant to legislation, regulations and routines	The person in charge of the biobank, the institution responsible for research and the board (if one exists) shall ensure that the research biobank is set up and managed pursuant to the legislation	Responsible for: - the day-to-day operation of the research project - inform the person or body responsible for the research (or for multi-centre studies also the local person or institution responsible for research)	- Responsible for following legislation, rules and routines for the research project - inform the project manager - extended responsibility to coordinate multi-centre studies with the project manager	- Responsible for following legislation, rules and routines for the research project or quality assurance project - Comply with the project manager / manager
Tasks	Ensure that: - adaptations are made for the research to be implemented in a manner that attends to ethical, medical, health, academic, protection of personal information and data security conditions - arrangements are made for sound organisation, start-up, implementation, dissemination, termination and after management of the research project - research data is treated securely - adequate insurance cover is in place for the research participants - internal controls are carried out	Ensure that: - training of staff with respect to research and ICT security - approve use and distribution of data and biological material for research - clarify and enter into necessary operational agreements and agreements for the use of students/research fellows and the like and for student projects - carry out any delegated tasks from the person or body responsible for research	Ensure that: - material in research biobanks is stored and processed properly - legislation, permits and routines are followed - the system for right of reservation against the use of biological material in research for patients is attended to	Take care of: - necessary prior approval from REK and any other approval bodies - ensuring the research project is implemented in accordance with the approved research protocol - ensuring that ethical, medical, health, academic, protection of personal information and data security conditions are taken care of in the day-to-day operation - informing the person or institution responsible for the research project (or for multi-centre studies also the local person or institution responsible for research)	Be familiar with and follow: - ethical, medical, health, academic, protection of personal information and data security conditions - internal control systems for research - Coordinate multi-centre studies at one's own institution together with the project manager	Be familiar with and follow: - ethical, medical, health, academic, protection of personal information and data security conditions - internal control systems for research

	- the person in charge of the biobank is appointed - external parties gain access to biobank material on certain conditions					

Organ:	**Regional Committee for Medical and Health Research Ethics (REK)**	**The National Committee for Medical and Health Research Ethics (NEM)**	**Norwegian Medicines Agency (SLV)**	**Norwegian Directorate of Health (HDIR)**	**Ministry of Health and Care Services (HOD)**	**Norwegian Board of Health Supervision (HTIL) / Data Inspectorate (DTIL)**
Areas of responsibility	- Approval body - Assess and approve that research projects are ethically sound and pursuant to the prevailing legislation and regulations - Approve research biobanks - Approve routines for destruction - Appeals body in cases relating to the refusal to surrender biobank material - Provide advice about matters relating to research ethics	- Appeals body	- Approval body - Assess and approve clinical trials - Supervision for clinical trials	- Approval body - Assess clinical trials of medical devices - Assess gene research projects pursuant to the Biotechnology Act - Assess projects which involve the use of genetically modified organisms pursuant to the Gene Technology Act	- Appeal body	- Regulatory authority
Tasks	- Approve research projects - Grant dispensation from confidentiality requirements - Consider complaints about the surrendering of biobank material	- Assess and determine appeals against decisions made by REK	- Approve clinical trials - Supervision and inspections	- Approve clinical trials of medical devices - Approve gene research projects	- Assess and determine appeals relating to clinical trials of medical devices	- Supervision - Provide instructions - Give coercive penalties, where necessary - Inform the other regulatory authority about instructions that are issued