

Type of project	Approval/reporting authority	Exemption from confidentiality (if necessary)
Medical and healthcare research	Regional Ethics Committee (REK) (Health Research Act [helseforskningsloven]§ 9)	<p><u>As a general rule:</u> REK (hpl. § 29 or helseregisterloven §19, cf. FOR-2021-05-27-1725)</p> <p><u>Exception:</u> Helsedataservice is the dispensation authority for access to data from health registers that are under the Directorate for e-health.</p>
Research that uses health information but falls outside medical and healthcare research	Data protection officer	<p><u>As a general rule:</u> REK (hpl. § 29 or helseregisterloven §19, cf. FOR-2021-05-27-1725)</p> <p><u>Exception:</u> Helsedataservice is the dispensation authority for access to data from health registers that are under the Directorate for e-health.</p>
Clinical research involving medicinal products (or preparation to be used as a medicinal product) that is not CE-marked or used outside of its intended purpose	REK (FOR-2009-10-30-1321 § 3-1) and the Norwegian Medicines Agency (SLV) (FOR-2009-10-30-1321 § 4-1)	When a dispensation is needed, the same applies as in the box above.
Clinical research involving testing of medical equipment, including algorithms, software, etc	REK and SLV (FOR-2021-05-09-1476 § 18, cf. MDR art. 62)	When a dispensation is needed, the same applies as in the box above.
<p>Research involving the use of fetal tissue</p> <p>Research involving the use of supernumerary fertilized eggs and cells derived from supernumerary fertilized eggs</p>	<p>REK (helseforskningsloven § 9) and the Directorate of Health [Helsedirektoratet] (bioteknologiloven § 4A-3)</p> <p>REK (Biotechnology [bioteknologiloven] Act § 3-3)</p>	When a dispensation is needed, the same applies as in the box above.
Internal quality assurance	Data protection officer	
Quality improvement/assurance	The Directorate of Health [Helsedirektoratet]	<p><u>As a general rule:</u> REK (hpl. § 29 or helseregisterloven §19, cf. FOR-2021-05-27-1725)</p> <p><u>Exception:</u> Helsedataservice is the dispensation authority for access to data from health registers that are under the Directorate for e-health.</p>
Establish a quality register	<p>Local register: data protection officer</p> <p>National register: Directorate of Health.</p> <p>Sender for klinisk dokumentasjon og evaluering (SKDE) is used for advice.</p>	The Norwegian Directorate of Health [Helsedirektoratet] (FOR-2019-06-21-789 § 2-3)
Statistics and health analyses that are not research or quality work	Data protection officer	<p><u>As a general rule:</u> REK (hpl. § 29 or helseregisterloven §19, cf. FOR-2021-05-27-1725)</p> <p><u>Exception:</u> Helsedataservice is the dispensation authority for access to data from health registers that are under the Directorate for e-health.</p>
Planning, management or preparedness	Data protection officer	<p><u>As a general rule:</u> REK (hpl. § 29 or helseregisterloven §19, cf. FOR-2021-05-27-1725)</p> <p><u>Exception:</u> Helsedataservice is the dispensation authority for access to</p>

		data from health registers that are under the Directorate for e-health.
Product development	The Directorate of Health	The Norwegian Directorate of Health [Helsedirektoratet] (hpl. § 29) or REK if it concerns the development of clinical decision support tools that takes place within the framework of a research project (FOR-2021-05-27-1725)