Target group	Supplier	☐ Head of security/Securityy	Staff/employee
		coordinator	□ Data processor
This fact sheet is	Researcher	□ Organization	☐ Privacy protection
particularly relevant	□ Project	manager/management	ombudsman
for:	manager	Person or body responsible for	
		research	
Responsibility	The data controller is responsible for incident registration, but daily tasks are normally		
	delegated to the person responsible for the individual information system.		
		er has a special responsibility in conne	
Execution	Planned prior to the use of a new information system, and executed while it is being		
	used.		
Purpose	The purpose of incident registration and follow-up of incident registers is to:		
	provide an overview of authorized use of health and personal data in the		
	organization		
		inization to uncover unauthorized use,	or attempts at unauthorized
		and personal data	
	_ · ·	er, and counter repeats of security brea	aches in the information
	systems		
		atient/user's right of access to incident	registers, in order that he may
	be able to atter		
		byees' right of access to information st	tored about them in the
	incident registe		
Scope	All sector organizations processing health and personal data electronically must keep		
	and control inciden		
Authority		Regulations sections 2-14, 2-16, and 7	
References		onduct for information security, Chapt	ers 5.2, 5.3, 5.4, 5.5 and 5.7,
	6.5, (<u>www.nor</u>		1.2
		Iealth Data Filing System Act section	13a
		rsonnel Act section 21a.	022
		www.kith.no/templates/kith_WebPag	
		remote access for maintenance and up	dates between supplier and
		ation, (<u>www.normen.no</u>)	1
		protection and information security in a	
		care sector, (<u>www.normen.no</u>) (in No	orwegian only)
	• Fact sheet 47 –	Register of authorizations	

The requirements found in this fact sheet will become legal requirements with the adoption of the Statutory Instrument 'Regulations concerning information security, access control, and access to personal health data in personal health data filing systems established for therapeutic purposes'.

No	Action		
1.	Incident registration procedure		
	a) The data controller shall ensure that procedures are implemented that ensure that incident		
	registration is implemented		
	b) The procedures shall		
	take into consideration that incident registration may entail a new processing of		
	personal data that may be subject to a duty of reporting. The reporting duty does not		
	apply if the processing is for the purpose of		
	o administering the system, or		
	o uncover/clear up security breaches in the computer system		
	attend to the requirement that it shall be possible to compare incident registers to the		
	register of authorizations and the presence register		

No Action attend to the requirement that incident registers be analysed in such a manner that incidents are detected before they may have any serious consequences, and preferably within 1 week attend to the requirement that the Data Inspectorate is to be notified if health and personal data have been disclosed or accessed without authorization 2. Incident registration shall be implemented for a) Access to personal health data filing systems established for therapeutic purposes and specialized systems All access to personal health data filing systems established for therapeutic purposes and specialized systems All attempts at unauthorized use of personal health data filing systems established for therapeutic purposes and specialized systems All principle of necessity access with the reason for such access b) Infrastructure Incidents relevant to security in security barrier (e.g. firewall and router), such as: All attempts at illegal access, both internal and external All violations of rules prohibiting traffic All violations of rules that allow legal traffic from external connections All attempts at unauthorized use of network operating systems 3. Incident registration in research projects shall be implemented for a) All research access, registration, correction, and deletion, authorized and unauthorized attempts to use and copy/duplicate research data the research file b) All authorized and unauthorized attempts to use and copy/duplicate the re-identification key file containing re-identification keys Both manual and electronic incident registration may be utilized. 4. The incident register must, at minimum, contain a) For authorized use: The unique identifier of the authorized user (see Fact sheet 47 – Register of authorizations) The role of the authorized user when accessing Organizational affiliation of the authorized user (usually organization or data processor) The internal organizational (departmental) affiliation of the authorized user (department name or department code is usually sufficient). May be the same as the organizational affiliation if the organization is not structured into separate departments The kind of information to which access has been granted The reason for access (e.g. medical care, principle of necessity access, administrative Time and duration of the access (date and time) The reason for the use of principle of necessity access For remote access from supplier: traffic initiated to IP address and port number which actions have been executed (commands, transactions, etc.). If possible the time of execution for any commands shall be noted in the incident register the data/data files that have been downloaded by the supplier (data files) or uploaded to the organization (program files and patches) Name and unique identifier of the person(s) having utilized the remote access in auestion b) For attempts at unauthorized use: The user identity utilized

No	Action			
	IP address or other identification of PC/work station used (e.g. MAC address or NAT			
	address)			
5.	Incident register security and storage			
	a) The incident registers shall be secured against access, editing, and deletion by unauthorized			
	personnel			
	b) Incident registers must be stored for a minimum of 2 years			
6.	The incident register as evidence			
	a) An incident register that is to be used as evidence should be mirrored to a separate storage			
	medium prior to analysis			
	b) The mirroring should take place under the supervision of 2 or more persons			
	c) A written record of the mirroring should be created, indicating the actions undertaken. The			
	record must be signed by all persons present and stored together with the registered			
	nonconformity			
7.	Use of the incident register			
	a) Electronic incident registers shall be easily analysed with analysis tools with a view to			
	uncovering violations of the rules (see also the Personal Health Data Filing System Act			
	section 13a and the Health Personnel Act section 21a.)			
	b) For manual incident registers the organization shall create procedures for satisfactory analysis of the registers			
	c) If violations are uncovered sanctions against employees must be imposedd) If sanctions do not have the necessary effect, i.e. there is repeated access by several			
	unauthorized persons, necessary technical measures must be implemented			
	e) All use of principle of necessity access must be documented and each incident must be			
	followed up as a nonconformity in order to ensure that the reason for the use of such access			
	was relevant			
	f) When rules concerning connection to a network outside the organization are violated, the			
	channel must be closed until a new secure solution has been implemented			
	g) When rules concerning the logical separation of the Internet and a network in which health			
	and personal data are being processed are violated the violation shall be handled as a			
	nonconformity and employee sanctions considered			
	h) When rules forbidding the disclosure of sensitive personal data via e-mail are violated the			
	violation shall be handled as a nonconformity and employee sanctions considered			
8.	Deletion of incident registers			
	a) If records in the incident register may be connected to an individual the incident register			
	must be deleted when its security-related purposes have been fulfilled but only after the			
	passage of 2 years			