Ahus - Checklist for quality and research projects

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As a project manager, you will find an overview of points relevant to the start-up, implementation, and completion of quality and research projects. The document is set up as a checklist you can fill out. Information and guidance on the items in the checklist can be found here.

For clinical trials of medicinal products, it is recommended to supplement with checklists developed specifically for this type of study. The checklists are available on NorCRIN.no.

Project information

Project title	
Manager	
P360 Case No.	

NOTE! Project documentation (consent, protocols, etc.) must be archived on the applicable case in P360.

Before start-up

The following must be assessed/executed before the start of the project:	Responsible	Done	Not Applicable
Read Responsibility in quality and research projects			
Anchor the project in your own department			
Literature search/literature review			
Designing research protocol			
Creation of a biobank:			
- Designing biobank protocols			
- Creating a biobank budget			
- Establish use of eBiobank (electronic tracking solution)			
- Purchase of Services			
Prepare consent and information letters			
Clarify project staff			
Set up a total research budget			
Apply for funding			
Letter of award/signing of contract			
Creation of project number (external funding)			
Collaboration agreements with external parties (reviewed with a lawyer before signing)			
Internal cooperation and purchase of services			
Prior approval from the Regional Committee for Medical and Health Research Ethics (REK) – application and decision			
For clinical trials or trials of medical devices: Pre-approval from the Norwegian Medicines Agency (SLV) – application and decision			
Assess the need for exemption from the duty of confidentiality			

Create a separate case for the project in Public360			
Notification to the Data Protection Officer via eSkjema			
- The head of department has approved in eSkjema			
- Assess the need for a data protection impact assessment (DPIA); the assessment is stored in P360.			
If external parties are to process personal data on behalf of the project: Enter into a Data Processing Agreement. Assessing data management plan			
Carry out risk assessment of information security using digital tools:			
Create storage area for project data			
Clarifying intellectual property rights (innovation)			
For clinical trials: publish the study on helsenorge.no/ahus.no and clinicaltrials.gov			

On completion

The following shall be assessed/executed during implementation:	**Responsible**	**Done**	**Not Applicable**
Obtain informed consent and document			
Ensure secure storage and handling of research data			
Safeguard secure storage and handling of biobank:			
- Update biobank protocol			
- Update biobank budget			
- Using eBiobank (electronic tracking solution)			
- Purchase of Services			
When disclosing biological material and/or data to external parties: enter into relevant agreements			
Revision of total research budget			
In the event of changes to the consent form, protocol and/or DPIA, send a change notification to:			
- Data Protection Officer via eSkjema			
- Regional Committee for Medical and Health Research Ethics (REK)			
- Norwegian Medicines Agency (SLV)			
Progress reporting to funding sources			
Statistical analyses of research data			
Publication of results			
Register publications in Cristin			

Ending

The following should be assessed/executed at closing:	**Responsible**	**Done**	**Not Applicable**
Overspending/repayment of funds			
Consider discontinuing or continuing a research biobank – application to the Regional Committee for Medical and Health Research Ethics (REK)			

Send final report to:			
- Funding sources			
- Regional Committee for Medical and Health Research Ethics (REK)			
- Data Protection Officer via eSkjema			
Long-term storage of research documents on paper after project completion (at Skytta)			
Delete link keys and declarations of consent			

For a more complete checklist for completion of projects, see the appendix to this EQS procedure.