

Application to The Board of the Prostate Biobank and Registry at Oslo University Hospital (OUH) – Biological Samples and Registry Data

Send the signed form to the head of the board Professor Kristin Austlid Taskén (k.a.tasken@medisin.uio.no)

1 Ethical approval (REC/IRB)			
Approval reference number:		Approval date:	
2 Privacy officer approval (PVO)			
Approval reference number:		Approval date:	
3 Project title			
4 Project leader (group leader or senior scientist)			
Name:			
Institution:		Clinic/Institute:	
Phone:		E-mail:	
5 Applicant (the acting researcher)			
Name:			
Institution:		Clinic/Institute:	
Phone:		E-mail:	
6 Collaborators (including pathologist if TMA or tissue slides require microscopic examination and clinician if clinical data is used)			
<i>Name</i>	<i>Division</i>	<i>Clinic/Institute</i>	<i>Institution</i>
7 Goals and study design			

Application to The Prostate Biobank and Registry at OUH (28144)

8 Summary of project description to be published on our website (background, methods, results if relevant)(Max 250 words)

9 Specify the study population

10 Applies for access to biological samples or data derived from biological samples			
Sample type	Number of individuals or name of TMA	Amount (unit)	Comment
Fresh frozen tissue cores			
FFPE tissue			
Serum			
Plasma			
DNA			
TMA			

11 Protocol / Method to be used (for IHC assays, this section MUST include antibody validation data for specificity including by IHC). Append additional files as needed.

12 The following markers will be analyzed (genes/mRNA/proteins/lipids/glycoproteins/other)

13 Applies for clinical data		
Pre-, per- and/or post-operative data (yes/no)	Clinical follow-up data (yes/no)	Specify data storage location

14 Will the data from other sources be coupled to information from the Prostate Registry (specify the data source and the coupling process)

Application to The Prostate Biobank and Registry at OUH (28144)

15 Financial plan			
16 Publication plan			
17 Project periode			
Start of project (date):		End of project (end):	
18 Type of project (questions 20 – 27 have to be answered with YES or NO)			
Researcher initiated project (name):		Multi-centre project headed by OUS:	
Industry initiated Project (name):		Multi-centre project headed by external institution:	
19 The project will provide new knowledge about health and disease? If YES – an approval from the Regional Committees for Medical and Health Research Ethics and/or the Institutional Review Board (IRB) is needed			
20a The project includes genetic studies that might affect the diagnosis or treatment of the person involved? If YES - the project is affected by the law of biotechnology and question 20b has to be answered.			
b The project includes genetic studies that can predict disease or that the person involved is carrier of a genetic disease? If YES, genetic guidance will be considered (according to the law of biotechnology).			
21 In the publication(s) it should be written that the data comes from The Prostate Biobank and Registry at Oslo University Hospital.			
22 Information about the progress should be given upon request from the board.			
23 The results obtained will be presented for The Board of The Prostate Cancer Biobank and Registry and Department of Urology at Oslo University Hospital and made accessible after publication.			
24 Expenses related to data extraction and to sampling and processing of the biological samples have to be covered by the project leader.			
Applicant		The board of the Prostate Biobank and Registry at OUH	
Date:		Date of approval:	
Signature by applicant		Signature by board of The Prostate Biobank and Registry at OUH	

The Board of The Prostate Biobank and Registry consider:

- *Is the project of medical interest?*
- *Is the project of academic interest?*

Application to The Prostate Biobank and Registry at OUH (28144)

- *Is the financial plan satisfactory?*
- *Has the research environment competence in the methodology to be used?*

The data has to be deleted or anonymized at the end of the project period.

Biological left-over samples are returned for destruction at the end of the project period.