Investigator Initiated Studies (IIS)
Concept and Full Proposal Form

For consideration, please submit an IIS Concept to the UroGen Medical Affairs Department and include the following:

- Completed concept proposal form for preliminary review
- Please note, if the study concept is preliminarily accepted, a full proposal will be required for review and approval. Full Proposals include detailed information regarding enrollment and budget (See Appendix A on page 3 for more information)
- Current Principal Investigator's Curriculum Vitae (CV) and Medical Licensure (ML)

Date of Application:	Submit completed concept proposal/full proposal to: UroGen Pharma Medical Affairs at research@urogen.com	
Study/Protocol Title:		
Principal Investigator Information (Please attach CV and ML)		
Principal Investigator Name: List any sub-investigator(s):	Institution/Organization:	
Address:		
Phone:	FAX:	E-mail:
Concept Design Information		
Please include briefly each of the following elements identified below:		
Hypothesis /Rationale:		
Study Design:		
Budget Estimation ***Values must be directly related to study cost, equipment, and product needed for study.***		
Budget Requested		

Enrollment Expectations ***Please include for full proposal if applicable***		
Planned Sample Size	Expected Patient Accrual Per Month	Duration of Study
Trial Timelines (Estimate Quarter and Year)		
Activation Date	First Patient Enrolled	Last Patient Enrolled
Statistical Plan ***Please include for full proposal if applicable***		
Sample Size Justification:		
Power Calculation:		
Statistical Analysis Plan:		

Proposed Study Budget Summary
Please include for full proposal if applicable. Values must be directly related to study cost, equipment, and product needed for study.

Sponsor-Investigator:	**Date:**
Protocol Title:	**Protocol #:**

Item	**Cost ($/Item)**	**Number of Items**	**Total Cost for Item**
Per Patient Costs			
Clinical/Procedural			
Physical Exam			
Blood Draw, etc.			
Number of Patients			
Total Patient Costs (total per patient x n)			
Site Costs			
Site start up costs			
Coordination fee			
IRB submission			
Total Site Costs			
Institution Overhead			

Appendix A

Full Proposal Submission Package

A Full Proposal Submission must contain the Principal Investigator's Curriculum Vitae and a detailed budget (if funding is requested) and include at a minimum the information outlined below to enable a final decision to be made for support:

- Primary Investigator contact information.
- Complete Study protocol, including study plan and design, study endpoint(s), study objective(s), inclusion/exclusion criteria, treatment plan (dosing, etc.).
- Duration of study.
- Statistical section including sample size justification and power calculation, and proposal for analysis.
- Specific drug supply requirements, including special needs (e.g., placebo, comparator, or supply to multiple sites or countries).
- Details of other funding or support being requested.
- Publication/presentation plan
- Safety reporting capabilities and processes

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signatures.

Signatory Table

Action Name	User Name	Title	Signature Date
Send for Review (Written By)	Victoria Tsurutis	Director, Medical Affairs & Ops	31-Oct-2023 22:57 (GMT+2)
Review	Orit Moshe	QA Manager, Supplier Quality and Compliance	31-Oct-2023 23:57 (GMT+2)
Review	Jim Ottinger	EVP, Regulatory and Quality Assurance	02-Nov-2023 17:47 (GMT+2)
Review	Adi Raz	QA Associate Manager, Compliance	07-Nov-2023 13:15 (GMT+2)
Review	Michael Toohey	Director, Compliance	13-Nov-2023 23:43 (GMT+2)
Review	John O'Reilly	Associate General Counsel	17-Nov-2023 22:17 (GMT+2)
Review	Michael J. Louie	SVP, Med Affairs & Clin Dev	29-Nov-2023 00:48 (GMT+2)
Send for Approval	Victoria Tsurutis	Director, Medical Affairs & Ops	05-Dec-2023 23:58 (GMT+2)
Approve	Michael J. Louie	SVP, Med Affairs & Clin Dev	06-Dec-2023 00:04 (GMT+2)
Approve	Orit Moshe	QA Manager, Supplier Quality and Compliance	06-Dec-2023 00:06 (GMT+2)
Approve	John O'Reilly	Associate General Counsel	06-Dec-2023 04:38 (GMT+2)
Approve	Jim Ottinger	EVP, Regulatory and Quality Assurance	10-Dec-2023 15:32 (GMT+2)
Approve	Michael Toohey	Director, Compliance	11-Dec-2023 22:22 (GMT+2)
Approve	Adi Raz	QA Associate Manager, Compliance	12-Dec-2023 07:19 (GMT+2)
QA Approval	Keren Shmushkevich	QA Manager, Quality Operations	12-Dec-2023 08:26 (GMT+2)