

GSER-IEC-AF/01/04-SOP03/04

Study Submission Application Form

	(U)		nai c					
Protocol Number:		GS	ER –I	EC Track No).	GSER_		
		Da	te:					
Type of Submission:	Initial Review					Con	tinuing Review	
	Protocol Amendmer	its				Аррі	Approved Protocols	
	Resubmission of Pro	otoc	ols w	ith Correctio	ns		col Termination	
						J	oval extension	
Protocol Title:						- ippi		┺═┩
Principal								
Investigator:								
Telephone number		Fax	K:					
E-mail:		Pr	eferr	ed		Fax	e-mail	
		Co	ntact	:				
Site Address:								
Delivery route:	Pe	ost		E-su	ubmis	sion	in Person	
Documents	Complete					Incomple	ete	
submitted	will submit on							
Documents submitte	d with package		Che	ck what do	cume	nts will	be submit later	r
Study protocol				rmed consen				
Informed consent form	n		Case report forms (CRF)					
Case Report forms (CRF)			Product monograph					
Others	,		Oth		•			
Received by:		_						
		Da	te					

Note: Please bring this receipt with you when contacting the Good Society for Ethical Research -Independent Ethics Committee (GSER-IEC) office.



CDSCO Registration No. ECR/69/Indt/DL/2013/RR-19



IORG#: IORG0007542 OHRP: IRB00009053



T:

M:

NABH Accreditation No. EC-CT-2019-0115



E:

W:

ISO Certificate No. 0311Q5312006

Good Society for Ethical Research Regd. No- S/0010076/NE/2012 under Society Registration Act XXI of 1860 Regd. Office - D/129, St. No-13, Ashok Nagar, Shahdara, Delhi 110093

09015893925 09873329254 info@gser.org e 1 of www.gser.org



GSER-IEC-AF/01/04-SOP03/04 Document Receipt Form

un	ienu	. K	ece	īρι
((GSF	ER	Сот)v)

Ducto col		-	ED IEC Tread	Na	CCED		
Protocol			ER –IEC Track	NO.	GSER_		
Number:		Da	te:				
Type of	Initial Review				Conti	nuing Review	
Submission:	Protocol Amendmer	ıts				oved Protocols	
	Resubmission of Pro	otoc	ols with Correc	tions	Protoc	ol Termination	ı
					Appro	val extension	
Protocol Title:							
Principal							
Investigator:		-					
Telephone numbe	r:	Fa	x:				
E-mail:		Pr	eferred	F	ax	e-mail	
		Co	ntact:				
Site Address:							
			<u> </u>				
Delivery route:		ost	Ŀ	E-submissi		in Person	
Documents	Complete				ncomplet		
submitted:	will submit on						
Documents submi	tted with package		Check what	documen	ts will b	e submit late	r
Study protocol			Informed consent form				
Informed consent for	orm		Case report forms (CRF)				
Case Report forms	(CRF)		Product monograph				
Others			Other:				
Received by:		Da	te				

Note: Please bring this receipt with you when contacting the Good Society for Ethical Research -Independent Ethics Committee (GSER-IEC) office.



CDSCO Registration No. ECR/69/Indt/DL/2013/RR-19



IORG#: IORG0007542 OHRP: IRB00009053



T:

M:





E:

W:

ISO Certificate No. 0311Q5312006

e 2 of

Good Society for Ethical Research Regd. No- S/0010076/NE/2012 under Society Registration Act XXI of 1860

Regd. Office - D/129, St. No-13, Ashok Nagar, Shahdara, Delhi 110093

09873329254

09015893925

info@gser.org www.gser.org



GSER-IEC-AF/01/04-SOP03/04 Project Submission Application Form for Initial Review (BA/BE Studies)

GSER-IEC Track no-	GSER-						
Status of Review	Initial Rev			ng Review			
	Protocol /	Amendments		d Protocols			
		ssion of Protocols	Protocol	Termination			
	with						
Cbmiz	Correction		Арр	roval extension			
A. Summary of submis	sion Pack	tage					
 Proposal Title: 2. Investigator detai 	-		Vitae of all Investigato	ers with protocol packag	e. If		
additional collaborators PI Name	De	esignation &	Cont	act Address			
		ualifications					
			Tel No Fax No Email ID				
3. Sponsor Informat	ion:	Indian	l I Inte	rnational			
UI UNVINCE	1011.		International				
4. Contact Address o	f Sponsor	:					
	of Sponsor	•:					
4. Contact Address o		Non-		Non-			
 4. Contact Address o 5. Trial details 	Clinical	Non- Clinical	Interventional	Interventiona	al		
 4. Contact Address o 5. Trial details 	Clinical Phase-I	Non- Clinical Phase-II	Phase-III	Interventiona Phase-IV	al		
 4. Contact Address o 5. Trial details 5.1 Type of Study: 	Clinical Phase-I BE/BA	Non- Clinical	ļ	Interventiona	al		
 4. Contact Address o 5. Trial details 5.1 Type of Study: 	Clinical Phase-I BE/BA Single	Non- Clinical Phase-II	Phase-III	Interventiona Phase-IV	al		
 4. Contact Address o 5. Trial details 5.1 Type of Study: 	Clinical Phase-I BE/BA Single centric	Non- Clinical Phase-II Observationa Multi-centric	Phase-III PMS If other specify	Interventiona Phase-IV	al		
 4. Contact Address o 5. Trial details 5.1 Type of Study: 	Clinical Phase-I BE/BA Single centric	Non- Clinical Phase-II Observationa	Phase-III PMS If other specify	Interventiona Phase-IV	al		
 4. Contact Address of 5. Trial details 5.1 Type of Study: 5.2. Name and Add 	Clinical Phase-I BE/BA Single centric ress of the	Non- Clinical Phase-II Observationa Multi-centric e study centers/CRO	Phase-III PMS If other specify	Interventiona Phase-IV Other			
 4. Contact Address of 5. Trial details 5.1 Type of Study: 5.2. Name and Add 5.3. Is drug approv 	Clinical Phase-I BE/BA Single centric ress of the	Non- Clinical Phase-II Observationa Multi-centric e study centers/CRO	Phase-III PMS If other specify O :	Interventiona Phase-IV	al 		
 4. Contact Address of 5. Trial details 5.1 Type of Study: 5.2. Name and Add 5.3. Is drug approve <i>If yes please specify</i> CDSCO Registration No. ECR/69/Indt/DL/2013/RR-19 	Clinical Phase-I BE/BA Single centric ress of the	Non- Clinical Phase-II Observationa Multi-centric e study centers/CRO	Phase-III PMS If other specify O :	Interventiona Phase-IV Other Other	No		
 4. Contact Address o 5. Trial details 5.1 Type of Study: 5.2. Name and Add 5.3. Is drug approv If yes please specify CDSCO Registration No. 	Clinical Phase-I BE/BA Single centric ress of the red for many country rest country rest ress of the ress of the r	Non- Clinical Phase-II Observationa Multi-centric e study centers/CR arketing : name	Phase-III PMS If other specify O: NABH Accred	Interventiona Phase-IV Other Other Yes itation 19-0115 E: info@	No SO Certificate N		



5.4. Whether DCGI' obtained?	's /Any otł	ier Reg	ulatory authori	ty's P	ermission is	Yes	No	
If yes, Date of permis	sion:							
5.5. Is it an Investi	gational N	ew Dru	1g?			Yes	No	
If yes, IND No:			-					
•	-	oroposa	al – (Synopsis attac	ched)		Yes	No	
5.7. Subject selection								
		(N	IaleFemale	e _ Tr	ansgender_)		
ii. Duration of stu		torio di				Vee	No	
iii. Inclusion / exc					Patient	Yes	No	
iv. Type of subject			human volunteer	5	Patient		No	
v. Vulnerable sul If yes, Specify	bjects/ sp	ecial gr	oup subjects			Yes	No	
<i>ıj yes, specijy</i>								
6. Consent:	Written		Oral		Audio-vis	ual		
7. Will any advertisi	0		•			Yes	No	
(Posters, flyers, b	rochure, v	vebsite	es – if so, kindly a	attach	1 a copy)			
Data Monitoring						Yes		
I. Is there a data & safety monitoring committee/Board (DSMB)?							No	
II. Is there a plan for	II. Is there a plan for reporting of adverse events?							
If Yes, reporting is do	one to Sp	onsor	Ethics Committ	ee	DSMB			
III. Are there plans for storage and maintenance of all trial database?							No	
If Yes, for how long?								
IV. Is there compensation	ation for p	articip	ation					
If Yes, In kind Specify amount and type:								
8. Is there compensation for injury?						Yes	No	
9. Do you (or PI) have conflict of interest with study/sponsor? (financial/nonfinancial) <i>If Yes, specify:</i>						Yes	No	
B. Check list (please ti								
1. Protocol handling fee						Yes	No	
2. Clinical study protocol						Yes	No	
3. Informed consent	t documen	t in En	glish			Yes	No	
4. Informed consent document in Hindi / local language with translation certificate						Yes	No	
5. Back translated in certificate	nformed c	onsent	document with	trans	lation	Yes	No	



CDSCO Registration No. ECR/69/Indt/DL/2013/RR-19



IORG#: IORG0007542 OHRP: IRB00009053



T:

M:

NABH Accreditation No. EC-CT-2019-0115



E:

W:

ISO Certificate No. 0311Q5312006

Good Society for Ethical Research

Regd. No- S/0010076/NE/2012 under Society Registration Act XXI of 1860 Regd. Office - D/129, St. No-13, Ashok Nagar, Shahdara, Delhi 110093 09015893925 09873329254 info@gser.org e 4 of

www.gser.org



6. Case Report Form'	Yes	No			
7. Randomization schedule	Yes	No			
8. Product Monograph/ information Boucher / sheet	Yes	No			
9. Proposed methods for patient accrual including advertisement (s) etc. proposed to be used for the purpose.	Yes	No			
10.Principal Investigator's current CV	Yes	No			
11.Insurance Policy / Compensation for participation and for serious adverse events occurring during the study participation.	Yes	No			
12. Investigator's Agreement with the Sponsor.	Yes	No			
13. Investigator's Undertaking	Yes	No			
14.DCGI notification	Yes	No			
15.NOC from head of Institution / Clinical trial site	Yes	No			
16.NOC from head of Institution ethical community of clinical trial site (If applicable)	Yes	No			
Others					
Place:					
Date: Signature & Designation					



CDSCO Registration No. ECR/69/Indt/DL/2013/RR-19



IORG#: IORG0007542 OHRP: IRB00009053



T:

M:

NABH Accreditation No. EC-CT-2019-0115



ISO Certificate No. 0311Q5312006

Good Society for Ethical Research Regd. No- S/0010076/NE/2012 under Society Registration Act XXI of 1860 Regd. Office - D/129, St. No-13, Ashok Nagar, Shahdara, Delhi 110093

09015893925 E: 09873329254 W: info@gser.org e **5** of www.gser.org