ApplicationFormforInitialReview

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ECRef.No.*EC/NEW/INST/2024/4277*

GeneralInstructions:a)Tickoneormoreasapplicable.MarkNAifnotapplicable
b) Attachadditionalsheetsifrequired
c) Mayselectmorethanoneoption

SECTIONA-BASICINFORMATION

1. ADMINISTRATIVEDETAILS

(a)NameofOrganization:.....

(b)NameofEthicsCommittee:.....

(c)NameofPrincipalInvestigator:.....

(d)Department/Division: .....(e)Dateofsubmission: dd mm yy

(f)Typeofreviewrequested[1]:

Exemptionfromreview☐ Expeditedreview☐ Fullcommitteereview☐

(g)Titleofthestudy:.....

.....

.....

(i) DetailsofInvestigators:

Name	Designation andQualification	Department andInstitution	Addressforcommunication[2]
PrincipalInvestigator/Guide			
Co-investigator/student/fellow			

(k)Durationofthestudy:.....

[1]*RefertoNationalEthicalGuidelinesforBiomedical&HealthResearchInvolvingHumanParticipants2017onPage36Table4.2.fortypesofreview*
[2]*Includetelephone/mobile,faxnumbersandemailid*

2. FUNDINGDETAILSANDBUDGET

(a)Totalestimatedbudgetforsite:.....

(b) Self-funding ☐ Institutionalfunding ☐ Fundingagency*(Specify)* ☐

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SECTIONB-RESEARCHRELATEDINFORMATION

3. OVERVIEWOFRESEARCH

(a) Laysummary[3](within300words):.....

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(b)Typeofstudy:

BasicSciences	☐	Clinical	☐	CrossSectional	☐
Retrospective	☐	Epidemiological/	☐	CaseControl	☐
Prospective	☐	PublicHealth		Cohort	☐
Qualitative	☐	Socio-behavioral	☐	SystematicReview	☐
Quantitative	☐	Biologicalsamples	☐		
MixedMethod	☐	Anyothers*(Specify)*	☐		

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4. METHODOLOGY

(a) Samplesize/numberofparticipants*(asapplicable)*

Atsite.....At other sites (If applicable) .....

Control group ..... Study group ... .

Justification for the sample size chosen (100 words); In case of qualitative study, mention the criteria used forsaturation .....

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[3]*Summarizeinthesimplestpossiblewaysuchthatapersonwithnopriorknowledgeofthesubjectcaneasilyunderstandit.*

(b) Isthereanexternal laboratory/outsourcinginvolvedforinvestigations?[4] Yes☐No☐NA☐

(c) Has the proposal been reviewed for thescientificquality?

Yes☐No☐
If Yes then,

Dateofreview: dd mm yy

Comments of Research AdvisoryCommittee,if any (100words)

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……

SECTIONC:PARTICIPANTRELATEDINFORMATION

5. RECRUITMENTANDRESEARCHPARTICIPANTS

(a) Typeofparticipantsinthestudy:

Healthyvolunteer☐ Patient ☐ Vulnerablepersons/Specialgroups☐

Others ☐ *(Specify)*……

Whowilldotherecruitment?……

Participant recruitment methods used:

Posters/ leaflets/Letters ☐ TV/Radio ads/ ☐ Social media/Institutionwebsite Patients/Family/Friends visitinghospitals ☐ Telephone ☐

Others ☐ *(Specify)* ……

(b) i.Will there be vulnerable persons /special groups involved? Yes☐No☐NA☐

ii.Ifyes,typeofvulnerablepersons/specialgroups

Childrenunder18yrs ☐ Pregnantorlactatingwomen

☐Differentlyabled(Mental/Physical)

☐ Employees/Students/Nurses/Staff☐Elderly

☐ Institutionalized

☐Economicallyandsociallydisadvantaged ☐ Refugees/Migrants/Homeless

☐Terminallyill(stigmatizedorrarediseases)☐

Anyother*(Specify)*: ☐… ……

iii. Providejustificationforinclusion/exclusion……

……

…… iv.

Arethereanyadditionalsafeguardstoprotectresearchparticipants?……

……

……

[4] *Ifparticipantsamplesaresentoutsideforinvestigations,providedetailsofthesameandattachrelevantdocumentationsuchasanMTA/MoU*

(c) Isthereanyreimbursementtotheparticipants? Yes☐No ☐

Ifyes, Monetary ☐ Non-monetary ☐ *Providedetails*

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.....

(d) Arethereanyincentivestotheparticipants? Yes ☐No☐

Ifyes, Monetary ☐ Non-monetary ☐ *Providedetails*

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(e) Arethereanyparticipantrecruitmentfees/incentivesforthestudyprovidedtothePI/Institution?

Ifyes, Monetary ☐ Non-monetary ☐ *Providedetails* Yes☐No☐

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6. BENEFITSANDRISKS

(a) i. Arethereanyanticipatedphysical/social/psychologicaldiscomforts/risktoparticipants? Yes☐No ☐

Ifyes,categorizethelevelofrisk[5]:

LessthanMinimalrisk ☐ Minimalrisk ☐

Minorincreaseoverminimalriskorlowrisk ☐ Morethanminimalriskorhighrisk ☐

ii. Describe the risk management strategy:.....

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(b) WhatarethepotentialbenefitsfromthestudyFort	Yes	No	Ifyes,	Direct	Indirect
heparticipant	☐	☐		☐	☐
For the	☐	☐		☐	☐
society/communityForimpr	☐	☐		☐	☐
ovementinscience					

Please describe how the benefits justify the risks .....

.....

.....

.....

(c) Areadverseeventsexpectedinthestudy[6]? Yes ☐No ☐NA

☐Arereportingproceduresandmanagementstrategiesdescribedinthestudy? Yes ☐No ☐If

Yes, Specify .....

.....

.....

7. INFORMEDCONSENT

(a) VersionnumberanddateofParticipantInformationSheet(PIS):.....

VersionnumberanddateofInformedConsentForm(ICF):.....

[5] *ForcategoriesofriskrefertoNationalEthicalGuidelinesforBiomedical&HealthResearchInvolvingHumanParticipants2017,Page6Table2.1*

[6] *Thetermadverseeventsinthisregardencompassbothseriousandnon-seriousadverseevents.*

(b) Typeofconsentplannedfor:

Signedconsent ☐ Verbal/Oralconsent ☐ Waiverofconsent ☐ Witnessedconsent ☐

ConsentfromLAR (Ifso,specifyfromwhom) ☐ Forchildren<7yrs parental/LARconsent ☐ Verbalassentfrom minor (7-12 yrs) alongwithparental consent ☐ Written assentfrom minor (13-18 yrs) alongwithparental consent ☐

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Audio-Video(AV) consent ☐ Other *(specify)*..... ☐

(c) Whowillobtaintheinformedconsent?

PI/Co-PI☐ Nurse/Counselor ☐ ResearchStaff☐ Other☐(*Specify*) .....

Anytoolstobeused.....

(d) ParticipantInformationSheet(PIS)andInformedConsentForm(ICF)

English☐ Locallanguage ☐ Other ☐*(Specify)*.....

Listthelanguagesinwhichtranslationsweredone.....

Iftranslationhasnotbeendone,pleasejustify.....

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(e) Areyouseekingwaiverofconsent?Ifyes,whatarethereasons. Yes ☐No☐

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(f) Providedetailsofconsentrequirementsforpreviouslystoredsamplesifusedinthestudy[7]

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(g) ElementscontainedintheParticipantInformationSheet(PIS)andInformedConsentForm(ICF)

Simplelanguage ☐
Risksanddiscomforts ☐
Alternatives to participation ☐
Righttowithdraw ☐
Benefits ☐
Purposeandprocedure ☐
Others(Specify) ☐

Data/Samplesharing ☐
Needtorecontact ☐
Confidentiality ☐
Storageofsamples ☐
Return of research results ☐
Paymentforparticipation ☐

Compensationforstudyrelatedinjury ☐
Statementthatconsentisvoluntary ☐
Commercialization/Benefitsharing ☐
Statementthatstudyinvolvesresearch ☐
Useofphotographs/Identifyingdata ☐
Sponsorcontactinformation ☐

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8. PAYMENT/COMPENSATION

(a) Who willbear thecosts relatedtoparticipation andprocedures[8]?

PI ☐ Institution ☐ Sponsor ☐ Otheragencies ☐ *(specify)*

.....

(b) Isthereaprovisionforfreetreatmentofresearchrelatedinjuries? Yes ☐No☐

Ifyes,thenwhowillprovidethetreatment?.....

(c)Isthereaprovisionforcompensationofresearchrelated SAE? Ifyes,specify. Yes☐No☐

Sponsor ☐ Institutional/Corpusfund ☐ Projectgrant ☐ Insurance ☐

(d)Isthereanyprovisionformedicaltreatmentormanagementtilltherelatednessisdeterminedforinjurytotheparticipants duringthestudyperiod?If yes,specify. Yes☐No☐

.....

[7] *Informationonre-consentrequirementscanbefoundatNationalEthicalGuidelinesforBiomedical&HealthResearchInvolvingHumanParticipants2017,Page54inSection5.8.*

[8] *EncloseundertakingfromPIconfirmingthesame*

9. STORAGEANDCONFIDENTIALITY

(a) IdentifyingInformation:StudyInvolvessamples/data*(specify)*:

Anonymous/Unidentified ☐Anonymized: Reversibly coded ☐Irreversibly coded ☐Identifiable ☐If identifiers must be retained, what additional precautions will be taken to ensure that access is limited /data issafeguarded?(e.g.datastoredinacabinet,passwordprotectedcomputeretc.).....

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(b)Whowillbemaintainingthedatapertainingtothestudy?.....(c)Where willthedatabeanalyzed[9]andbywhom?.....

(d)Forhowlongwillthedatabestored? .....

(e)Doyouproposetousestoredsamples/datainfuturestudies? Yes☐No☐Maybe☐

Ifyes,explainhowyoumightusestoredmaterial/datainthefuture?.....

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SECTIOND:OTHERISSUES

10. PUBLICATION,BENEFITSHARINGANDIPRISSUES

(a) Willtheresultsofthestudybereportedanddisseminated?Ifyes,specify. Yes☐No ☐

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.....

(b) Willyouinformparticipantsabouttheresultsofthestudy? Yes☐No☐

(c) Arethereanyarrangementsforcontinuedprovisionoftheinterventionforparticipants,ifeffective,oncethestudyhasfinished?Ifyesdescribeinbrief(Max50words) Yes ☐No ☐NA ☐

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(d) Isthereanyplanforpostresearchbenefitsharingwithparticipants?Ifyes,*specify* Yes☐No ☐

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(e) Isthereanycommercialvalueoraplantopatent/IPRissues?Ifyes,pleaseprovidedetails Yes ☐No ☐

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(f) Doyouhaveanyadditionalinformationtoaddinsupportoftheapplication,whichisnotincludedelsewhereintheform?If yes,providedetails. Yes☐No☐

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[9]*Forexample,adataentryroom,aprotectedcomputeretc.*

SECTIONE:DECLARATIONANDCHECKLIST[10]

11.DECLARATION(Pleasetickasapplicable)	
☐	I/Wecertifythattheinformationprovidedinthisapplicationiscompleteandcorrect.
☐	I/Weconfirmthatallinvestigatorshaveapprovedthesubmittedversionofproposal/relateddocuments.
☐	I/WeconfirmthatthisstudywillbeconductedinaccordancewiththelatestICMRNationalEthicalGuidelinesforBiomedicalandHealthResearchinvolvingHumanParticipantsandotherapplicableregulationsandguide-lines.
☐	I/WeconfirmthatthisstudywillbeconductedinaccordancewiththeDrugsandCosmeticsAct1940anditsRules1945asamendedfromtimetotime,GCPguidelinesandotherapplicableregulationsandguidelines.
☐	I/Wewillcomplywithallpoliciesandguidelinesoftheinstituteandaffiliated/collaboratinginstitutionswherethisstudywillbeconducted.
☐	I/Wewillensurethatpersonnelperformingthisstudyarequalified,appropriatelytrainedandwilladheretotheprovisionsoftheECapprovedprotocol.
☐	I/Wedeclarethattheexpenditureincaseofinjuryrelatedtothestudywillbetakencareof.
☐	I/Weconfirmthatanundertakingofwhatwillbedonewiththeleftoversamplesisprovided,ifapplicable.
☐	I/We confirm that we shall submit any protocol amendments, adverse events report, significant deviationsfromprotocols,progressreports(ifrequired)andafinalreportandalsoparticipateinanyauditofthestudyifneeded.
☐	I/We confirm thatwe willmaintain accurateand completerecords ofall aspects ofthe study.
☐	I/Wewillprotecttheprivacyofparticipantsandassureconfidentialityofdataandbiologicalsamples.
☐	I/Weherebydeclarethat I/anyoftheinvestigators,researchersand/orcloserelative(s),havenoconflictofinterest(Financial/Non-Financial)withthesponsor(s)andoutcome ofstudy.
☐	I/Wehavethefollowingconflictofinterest(PI/Co-PI): 1..... .... 2..... ....

Name of PI: .....

Signature:..... dd mm yy

NameofCo-PI:..... .....

Signature:..... dd mm yy

NameofCo-PI:..... .....

Signature:..... dd mm yy

[10]*TheseformatsareadaptableandcanbemodifiedbytheEthicsCommitteemembersdependingontheirneedsandrequirementsAcknowledgementforReceiptofApplication(CopytobeprovidedtoPI)*

12.CHECKLIST

S.No	Items	Yes	No	NA	Enclosure No	EC Remarks(Ifapplicable)
ADMINISTRATIVEREQUIREMENTS						
1	Coverletter	☐	☐	☐		
2	BriefCVofallInvestigators	☐	☐	☐		
3	GoodClinicalPractice(GCP)trainingofinvestigatorsinlast3years	☐	☐	☐		
4	Approvalofscientificcommittee	☐	☐	☐		
5	ECclearanceofothercenters*	☐	☐	☐		
6	Agreementbetweencollaboratingpartners*	☐	☐	☐		
7	MTAbetweencollaboratingpartners*	☐	☐	☐		
8	Insurancepolicy/certificate	☐	☐	☐		
9	Evidenceofexternallaboratorycredentialsincaseofanexternallyoutsourcedlaboratorystudy QA/QCcertification	☐	☐	☐		
10	Copyofcontractoragreementsignedwiththesponsorordonoragency	☐	☐	☐		
11	Provide all significant previous decisions (e.g. those leading to anegative decision or modified protocol) by other ECs/Regulatoryauthoritiesforproposedstudy(whetherinsamelocation orelsewhere)andmodification(s)toprotocol	☐	☐	☐		
PROPOSALRELATED						
12	Copyof the detailedprotocol[11]	☐	☐	☐		
13	Investigators Brochure(Ifapplicablefordrug/biologicals/devicetrials)	☐	☐	☐		
14	ParticipantInformationSheet(PIS)andParticipantInformedConsentForm(ICF)(Englishandtranslated)	☐	☐	☐		
15	Assentformforminors(12-18years)(EnglishandTranslated)	☐	☐	☐		
16	Proforma/Questionnaire/CaseReportForms(CRF)/Interviewguides/GuidesforFocusedGroupDiscussions(FGDs)(Englishandtranslated)	☐	☐	☐		
17	Advertisement/materialtorecruitparticipants(fliers,postersetc)	☐	☐	☐		

PERMISSIONFROM GOVERNING AUTHORITIES

	Otherpermissions	Required	Notrequired	Received	Applied dd/mm/yy	ECRemarks
18	CTRI	☐	☐	☐		
19	DCGI	☐	☐	☐		
20	HMSC	☐	☐	☐		
21	NAC-SCRT	☐	☐	☐		
22	ICSCR	☐	☐	☐		
23	RCGM	☐	☐	☐		
24	GEAC	☐	☐	☐		
25	BARC	☐	☐	☐		
26	TribalBoard	☐	☐	☐		
27	Others (Specify)	☐	☐	☐		

ANYOTHERRELEVANTINFORMATION/DOCUMENTSRELATEDTOTHESTUDY

	Item	YES	NO	NA	Enclosureno.	ECremarks
28						
29						

**Formulticentricresearch.*
MTA-Materialtransferagreement;CTRI-ClinicalTrialRegistry-India;DCGI-DrugControllerGeneralofIndia;HMSC-HealthMinistry'sScreeningCommittee;NAC-SCRT-NationalApexCommitteeforStemCellResearchandTherapy;IC-SCR-InstitutionalcommitteeforStemCellResearch;RCGM-ReviewCommitteeonGeneticManipulation;GEAC-GeneticEngineeringApprovalCommittee;BARC-BhabhaAtomicResearchCentre
[11]RefertoNationalEthicalGuidelinesforBiomedical&HealthResearchInvolvingHumanParticipants2017,section4Pageno.35Box4.4(b)