Instructions

If you are interested in submitting an application for ethical review for research purposes, please complete the relevant documents and email at iec@tech4health.org.in. Kindly review the purpose of each document and submit only those that are applicable.
Where applicable, guidance has been provided to assist in completing certain forms (refer to pages 8-12).
Templates are available for documents marked with an asterisk (*).

S. No.	Document name	Purpose	Page no.
Mandatory documents			
1	Cover letter* (should be submitted using the applicant's organization letterhead)	To provide an overview of the study, introducing the research and to outline the purpose of the submission and highlight any specific points that the IEC should focus on.	3
2	IEC application*	To inform key details of the study, such as the study design, and participant information. This form ensures the study aligns with ethical standards and guidelines.	4-7
3	Study protocol* (should be submitted using the applicant's organization letterhead)	To outline the entire research plan, including objectives, methodology, participant recruitment, and data analysis strategies.	8-9
4	Informed consent*	To ensure that participants are provided with clear, understandable information about the study, including its purpose, risks, benefits, and their rights.	10-12
5	Conflict of interest (COI) declaration (if there isn't any conflict, it should be stated so in the COI) *	To ensure transparency regarding any potential conflicts of interest that could influence the study's outcomes.	13-14
6	Undertaking* (should be submitted using the applicant's organization letterhead)	This document is a formal commitment by the investigators to conduct the study in accordance with ethical guidelines, ensuring accountability and adherence to the approved protocol.	15- 17
7	Survey tools	Questionnaires or similar instruments that will be used to gather data from participants along with upholding the confidentiality and privacy of the participants.	
8	Data collection tools (e.g., questionnaires, case record form, case report forms, follow-up cards, patient instruction card, diary, etc., as applicable)	Questionnaires or similar instruments that will be used to gather data from participants along with upholding the confidentiality and privacy of the participants.	
9	Approval letters from funders/sponsors	To demonstrate that the study has received appropriate funding and support.	
10	Curriculum vitae of principal investigator and co-investigators and study team members with relevant publications in the last five years	To confirm that the research team members have qualifications, expertise, and experience in conducting research, especially in the study's area of focus.	
11	Good clinical practice training certificates	To demonstrate that the research team has undergone training in ethical standards.	

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12	List of all ongoing research studies under the PI supervision	To confirm that the research team members have relevant experience in conducting research, especially in the study's area of focus.	
13	Translation certificate	To ensure that any translated research materials are accurate and culturally appropriate, ensuring that non-native speakers understand the study.	
Additional documents (include as applicable)			
14	HIV testing pre-test and post-test counselling forms (if applicable) *	To ensure that participants are properly informed and supported before and after sensitive tests such as HIV or genetic screening.	18-19
15	Investigator's brochure (applicable to clinical trials)	A compilation of the clinical and non-clinical data on the investigational medicinal product or products which are relevant to the study of the product(s) in humans.	
16	Permission of using copyrighted proforma/questionnaire	To ensure that the investigator has obtained legal rights to use copyrighted materials such as proformas or questionnaires.	
17	Recruitment procedures: advertisement, notices, etc.	To help the IEC review whether the methods for recruiting participants are ethical, non-coercive, and transparent, ensuring that potential participants are fully informed about the study and their participation rights.	
18	Regulatory permissions	To demonstrate compliance with government and institutional regulations.	
19	Relevant administrative approval(s)	To confirm that the research study has been sanctioned by the appropriate administrative bodies within the institution or relevant organizations.	
20	MoU in cases of studies involving collaborations with other institutions	To ensures that all collaborative arrangements are transparent and agreed upon by all involved institutions.	
21	Clinical trial agreement between the investigator and sponsors of the study	To formalize the responsibilities and expectations between the investigator and the study sponsors.	
22	Insurance policy	To provide a proof that participants are protected in case of injury or adverse effects during the research.	
23	Any other documents relevant for research ethics	To provide any additional documents that pertain to the ethical conduct of the research.	

For any queries, please contact:	
Admin Email: iec@tech4health.org.in. Phone no.: 9962533491	Seshadri Dutta/Abhishek Shah Email: seshadri@tech4health.org.in Phone no.: 9874077415/9886482205

Cover Letter – Version 1.0

The Member Secretary,
Institutional Ethics Committee of the Tech4Health Foundation
Bengaluru, Karnataka

Date:

Subject: Submission of application for ethical review of research protocol - [Study title]

Dear Sir/Madam,

I, on behalf of the [name of organization], am writing to you regarding the submission of a study proposal "[Title of the study]" for approval by your Ethics Committee. The study is expected to commence on [proposed start date] and end on [proposed end date] and will be conducted at [study site(s)].

This study aims to [briefly describe the main objective of the study]. The protocol has been designed to ensure compliance with ethical guidelines and to safeguard the rights and well-being of all participants.

The study is funded by [name of the sponsor], an [international/national organization]. [Specify if it is a for clinical trial projects sponsored by pharma companies]

We would request an [expedited review/full committee review/exemption from review] for this study. [Please justify your request].

Enclosed with this letter, please find included the documents listed in the checklist for your perusal.

Sincerely,
[Name of Principal Investigator]
[Designation (or student)]
[Department name]
[Institution/Organization name]
[Address]
[City, State, Zip Code]
[Email address]
[Phone number]

[Name of Co-Principal Investigator]
[Email address]
[Phone number]

IEC Application – Version 1.0

To,
The Member Secretary,
IEC, Tech4Health Foundation,
Bengaluru

1.	Title of the Project			
2.	Type of Application	a. Fresh study b. Amendment of an existing study c. Extension of an existing study		
3.	Principal Investigator's (PI) details			
	Investigator type	Name	Designation (if student, please mention)	Department & Institute
	a. PI			
	b. Co-PI			
	c. Guide (if applicable)			
4.	Duration of the study	a. Duration (in months): b. Study start date (month, year): c. Study completion date (month, year):		
5.	Location of the study			
6.	Sponsorship details of the study	a. Non-sponsored b. Sponsored		
7.	If non-sponsored study **(go to question 11)**	a. Thesis/dissertation b. ICMR studentship c. Other research, please mention_____		
8.	If sponsored study, select the correct option	Indian	a. Government b. Academic Institute c. Healthcare industry (such as pharma, biotech, medtech, etc.) d. Non-healthcare industry e. Corporate Social Responsibility (CSR) f. Non-Government Organisation (NGO) g. Other, please mention_____	
		International	a. Government b. Academic Institute c. Healthcare industry (such as pharma, biotech, medtech, etc.) d. Non-healthcare industry e. Corporate Social Responsibility (CSR) f. Non-Government Organisation (NGO) g. Other, please mention_____	
9.	Name and full address of the Sponsor/Funder			
10.	Total Budget	Rs. _____ Please give details of allocation of the budget in attachment.		
11.	Type of study (select all the options that apply)	a. Observational b. Experimental c. Invasive d. Non-invasive e. Clinical trial		

		f. Pilot g. Randomized h. Blinded i. Other, please mention the type _____ j. Multicentric, how many centers:_____
12.	Does the study involve use of (select all the options that apply)	a. Drug/vaccine b. Device c. Alernative medicine d. If any other intervention, please specify _____ **e. Not applicable, go to question 18**
13.	Is the product marketed in India?	- Yes, please attach package details - No, please attach permission from Drug Controller General (India) [DCG(i)]
14.	Is the product marketed in other countries?	- Yes, please specifiy _____ - No
15.	Is the test drug an Investigation New Drug (IND)?	- Yes, please submit Investigator's brochure which contains data of pre-clinical studies and permission from DCG(I) - No
16.	Does the test drug involve a change in use, doage, route of administration?	- Yes, please attach a copy of permission from DCG(I) - No
17.	In case of clinical trial, please specify	a. Phase I b. Phase II c. Phase III d. Phase IV e. Not applicable
18.	Subject selection	a. Number of subjects enrolled at this center: b. If multicentric, total number of subjects enrolled: c. Vulnerable subjects: - Yes, if yes please select the relevant options • Pregnant women • Children • Elderly • Fetus • Illiterate • Handicapped • Terminall ill • Mentally challenged • Economical/ socially backward • Any other, please specify_____ - No d. Special group subjects: - Yes, please select the relevant options • Employees • Students • Nurses/dependant staff • Any other, please specify_____ - No
19.	Does the study invove the	a. Fetal tissues or abortus

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	use of the following:	- Yes - No b. Organs or body fluids - Yes - No c. Recombinant/gene therapy - Yes, please submit a copy of Genetic Engineering Advisory Committee (GEAC) permission - No d. Ionising radiation/radioisotopes - Yes, please submit a copy of Bhaba Atomic Research Centre (BARC) permission - No e. Infectious biohazardous specimens - Yes - No f. Will pre-exisitng/stored/left over samples be used? - Yes - No g. Will samples be collected for biobanking/furture research? - Yes - No h. Will any sample collected from patient be sent abroad? - Yes, please submit a copy of Director General of Foreign Trade (DGFT) permssion - No i. Is there a collaboration with any foreign lab, clinic, hospital or any other foreign instituion - Yes, please submit a copy of Health Ministry Screening Committee (HMSC) approval - No
20.	Risk stratification for the participants: - Less than minimal risk - Minimal risk - Minor increase over minimal risk or Low risk - More than minimal risk or High risk **Please refer to Table 2.1 of the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, ICMR 2017 for detailed risk categories**	
21.	Will any advertising be done for recrutiment of subjects? (Posters, flyers, brochures, etc.) - Yes, kindly attach a copy for IEC review - No - Not applicable	
22.	Data monitoring: a. Is there a Data & Safety Monitoring Board/Committee (DSMB)? - Yes - No - Not applicable b. Is there a plan for interim analysis of data? - Yes - No	

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	- Not applicable c. For how long will the trial data be stored? _____ years
23.	Is there a compensation for participation? - Monetary, specify amount_____ - In kind, specify type_____ - No - Not applicable
24.	Are there any arrangements for compensations for trial related injury? - Yes, please submit a copy of the insurance policy if it is available - No - Not applicable

We hereby declare the information given above is true and that we do not have any financial or non-financial conflict of interest.

Signature of Principal Investigator/ with date

Signatures of Co-investigators

Forwarded by Heads of Department(s)
(Stamp/Seal of the Department(s) with date)

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Study Protocol – Version 1.0

a) The first page carries the title of the proposal with signatures of the investigators, along with
   I. Name of the applicant with designation.
   II. Name of the institute/ hospital / field area where the research will be conducted.

b) Brief summary/lay summary of the study.

c) Background with rationale of why a human study as well as inclusion/exclusion of vulnerable populations is needed to answer the research question, if applicable.

d) Clear research objectives and endpoints/ outcome.

e) Eligibility/ inclusion criteria and participant recruitment procedures.

f) Detailed description of the methodology of the proposed research, including sample size (with justification), type of study design (observational, experimental, pilot, randomized, blinded, etc.), types of data collection, intended intervention, dosages of drugs, route of administration, duration of treatment and details of invasive procedures, if any.

g) Duration of the study.

h) Justification for use of placebo, benefit-risk assessment, plans to withdraw and rescue medication, if applicable.

i) Procedure for seeking and obtaining written informed consent with a sample of the participant information sheet and participant informed consent forms in English and local languages.

j) Informed consent for storage of samples, assent, re-consent.

k) Plan for statistical analysis of the study.

l) Plan to maintain the confidentiality of information related to the study participants.

m) List of ethical issues in the study and plans to address these issues.

n) An account of management of risk or injury to study participants, especially for research involving more than minimal risk.

o) Proposed compensation, reimbursement of incidental expenses and management of research related injury/illness during and after research period and insurance policy.

p) Providing ancillary care to study participants for unrelated illness during research.
q) An account of storage and maintenance of all data collected during the study.

r) Plans for publication of results – positive or negative – while maintaining confidentiality of personal information/ identity.

s) Ethical considerations and safeguards for protection of participants.

t) Depending on the type of study (particularly the ones involving stigma, for e.g., HIV and genetic diseases), provide information on pre-test and post-test counselling procedures along with the relevant documents.

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The informed consent form has two parts:

- Information Sheet (to share information about the research with the participants)
- Certificate of Consent (for signatures if the participant agrees to take part)

Part I: Information Sheet

Introduction
Briefly sate who you are and explain that you are inviting them to participate in the research you are doing.

Purpose
Explain in lay terms why you are doing the research.

Type of research intervention
Briefly state the type of intervention that will be undertaken.

Participant selection
State why this participant has been chosen for this research.

Voluntary participation
Indicate clearly whether the participant can choose to participate or not. State, only if it is applicable, that the participant will still receive all the services they usually do whether they choose to participate or not.

Information on the Trial Drug [Name of the Drug]

Include this section only if the protocol is for a clinical trial

1) Give information on the phase of the trial and explain what that means. Explain to the participant why you are comparing or testing the drugs.
2) Provide as much information as is appropriate and understandable about the drug such as its manufacturer or location of manufacture and the reason for its development.
3) Explain the known experience and outcomes associated with this drug based on prior research or trials.
4) Explain comprehensively all the known side-effects/toxicity of this drug, as well as the adverse effects of all the other medicines that are being used in the trial.

Procedure and Protocol
Describe or explain the exact procedures that will be followed on a step-by-step basis, the tests that will be done, and any drugs that will be given. From the beginning, clarify any procedures that may be unfamiliar, such as placebo use, randomization, or biopsies. Clearly indicate which procedures are standard practice and which are part of experimental or research activities.

Firstly, explain that there are standards/guidelines that will be followed for the treatment of their condition. Secondly, if as part of the research a biopsy will be taken, or surgery carried out, then explain whether it will be under local anesthesia, sedation or general anesthesia, and what sort of symptoms and side effects the participant should expect under each category.

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For any clinical study (if relevant)

If blood samples are to be taken, explain how many times and how much, in a language that the participant understands. It may, for example, be inappropriate to tell a tribal villager that blood equal to a wineglass full will be taken but it may be very appropriate to use pictures or other props to illustrate the procedure if it is unfamiliar.
If the samples are to be used only for this research, then explicitly mention here that the biological samples obtained during this research procedure will be used only for this research and will be destroyed after _____ years, when the research is completed.

Description of the Process
Describe to the participant what will happen during the study on a step-by-step basis.

Duration
Include a statement about the time commitments of the research for the participant including both the duration of the research and follow-up, if relevant.

Side Effects
Potential participants should be told if there are any known or anticipated side effects and what will happen in case of a side effect or an unexpected event.

Risks
Explain and describe any possible or anticipated risks. Describe the level of care that will be available if harm does occur, who will provide it, and who will pay for it.

Discomforts
Explain and describe the type and source of any anticipated discomforts that are in addition to the side effects and risks discussed above.

Benefits
Mention only those activities that will be actual benefits and not those to which they are entitled regardless of participation.

Incentives
State clearly what you will provide the participants with because of their participation. WHO does not encourage incentives. However, it recommends that reimbursements for expenses incurred because of participation in the research be provided.

Confidentiality
Explain how the research team will maintain the confidentiality of data, especially with respect to the information about the participant which would otherwise be known only to the physician but would now be available to the entire research team.

Sharing the Results
Where it is relevant, your plan for sharing the information with the participants should be provided.

Right to Refuse or Withdraw
This is a reconfirmation to the participant that participation is voluntary and includes the right to withdraw.

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Alternatives to Participating
Include this section only if the study involves administration of investigational drugs or use of new therapeutic procedures. It is important to explain and describe the established standard treatment to the participant.

Who to Contact
Provide the name and contact information of someone who is involved, informed and accessible (a local person who can be contacted) to the participant. Also state to the participant how the proposal has been approved.

Part II: Certificate of Consent

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I had have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research and understand that I have the right to withdraw from the research at any time without in any way affecting my medical care.

Name of the Participant:_____

Signature of the Participant: _____

Date: _____

If illiterate,

A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team).

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of the Witness: _____

Thumb print of the Participant: _____

Signature of the Witness: _____

Date: _____

I have accurately read or witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of the Researcher: _____

Signature of the Researcher: _____

Date _____

A copy of this Informed Consent Form has been provided to participants (initiated by the researcher/assistant).

Conflict of Interest Declaration – Version 1.0

Study Title:

Principal Investigator (Full Name):

Co-Investigator(s) (Full name):

Leading Institution/Organization:

Partnering Institutions/Organizations:

1. _____
2. _____
3. _____

As a Principal Investigator, and on behalf of all co-investigator(s) and study team members for the above-mentioned study, I declare the following regarding any potential conflicts of interest:

- Financial Interests:

  [ ] Yes [ ] No

  If yes, specify (e.g., grants, stock, consulting, etc. with study sponsors):

- Non-Financial Interests:

  [ ] Yes [ ] No

  If yes, specify (e.g., relationships or affiliations affecting the study):

- Other Conflicts:

  [ ] Yes [ ] No

  If yes, specify (any other potential conflicts of interest):

I declare that the information provided above is complete and accurate to the best of my knowledge.

Should any conflict of interest arise during the course of the study, I will promptly notify the Institutional Ethics Committee (IEC) of the Tech4Health Foundation and provide relevant updates.

I understand that the declaration, once signed, will be kept on file and in the custody of the IEC.

Signature of Principal Investigator: _____

Date: _____

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Undertaking by the Investigator – Version 1.0

1. Full name, address and title of the Principal Investigator (PI) (or Investigators when there is no Principal Investigator)

   Name: _____

   Title: _____

   Designation: _____

   MCR No. (if applicable): _____

   Address: _____

   Phone number: _____

   Email: _____

2. Name and address of the medical college, hospital or other facilities where the research will be conducted:

3. Is the proof of education, training and experience that qualifies the Investigator for the research study/clinical trial attached with this undertaking?
   [ ] Yes [ ] No

4. If applicable, name and address of all the clinical laboratory facilities to be used in the study.

5. Name and address of the Ethics Committee that is responsible for approval and continuing review of the study.

6. Names of the other members of the research team (Co- or Sub-Investigators) who will be assisting the Principal Investigator in conducting the investigations.

7. Protocol Title and Study number (if any) of the research to be conducted by the Investigator.

   a. Protocol Title:
   b. Protocol No. (if applicable):

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I agree:

i. I have reviewed the study protocol and agree that it contains all the necessary information to conduct the study. I will not begin the study until all necessary ethics committee and regulatory approvals have been obtained.

ii. I agree to conduct the study in accordance with the current protocol. I will not implement any deviation from or changes to the protocol without agreement with the sponsor and prior review and documented approval or favourable opinion from the ethics committee on the amendment, except where necessary to eliminate an immediate hazard to the trial subject or when the changes involved are only logistical or administrative in nature.

iii. I agree to personally conduct or supervise the study at my site.

iv. In case of a clinical trial,
   a. I agree to inform all the trial subjects, that the drugs are being used only for investigational purposes.
   b. I will ensure that the requirements that are specified in the New Drugs and Clinical Trials Rules, 2019 and Good Clinical Practices guidelines to obtain informed consent and ethics committee approval are met.

v. I agree to report to the sponsor and the ethics committee all the adverse experiences that occur in the course of the investigation(s) in accordance with the regulatory requirements and Good Clinical Practices guidelines.

vi. If applicable, I have read and understood the information in the Investigator's brochure, including the potential risks and side effects of the drug.

vii. I agree to ensure that all the associates, colleagues and employees assisting in the conduct of the study are suitably qualified and experienced and they have been informed about their obligations in meeting their commitments in the study.

viii. I agree to maintain adequate and accurate records and to make those records available for audit or inspection by the sponsor, ethics committee, Central Licensing Authority or their authorized representatives, in accordance with regulatory provisions and the Good Clinical Practices guidelines. I will fully cooperate with any study related audit conducted by regulatory officials or authorized representatives of the sponsor.

ix. I agree to promptly report to the ethics committee all the changes in the study activities and all unanticipated problems involving risks to human subjects or others.

x. I agree to inform all serious adverse events to the Central Licensing Authority, sponsor as well as the ethics committee within twenty-four hours of their occurrence. In case of failure to do so, I shall furnish the reason for the delay to the satisfaction of the Central Licensing Authority along with the report of the serious adverse event.

xi. The report of the serious adverse event, after due analysis, shall also be forwarded by me to the Central Licensing Authority, the Chairperson of the ethics committee and the Head of the

Institution where the study has been conducted within fourteen days in accordance with the regulatory requirements.

xii. I will maintain confidentiality of the identification of all participating subjects and assure security and confidentiality of study data.

xiii. I agree to comply with all other requirements, guidelines and statutory obligations as applicable to clinical Investigators participating in clinical trials.

Principal Investigator's Name: _____

Signature: _____

Date: _____

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Consent Form for Human Immunodeficiency Virus (HIV) Testing & Pre-Test Counselling – Version 1.0

Date: _____

Patient Information:

Name: _____ Age: _____ Gender: ☐ Male ☐ Female ☐ Others

Physician Name: _____

Reporting Centre/Lab: _____

Mobile: _____

Address: _____

Consent:

I, the undersigned, provide my consent* to get my blood tested for HIV. The significance, relevant information, and pre-test counselling have been provided to me. Post-test counselling shall be done by the lab on prior appointment, or I can choose to be counselled by my referring doctor. I am aware that I can reach out to the concerned lab for my HIV test reports.

I understand that my result shall be kept confidential. I authorize the following person/agency to collect the report on my behalf.

☐ Self ☐ Referring Doctor ☐ Referring Agency ☐ Next of kin

Signature of the Patient: _____

Name of the Counselor: _____

Signature of the Counselor: _____

License/Identification number: _____

Mobile: _____

Address: _____

* In case of minors, the consent form must be signed by either of the Parents / Legal Guardian.
* In adoption of minor cases, the consent form must be signed by Orphanage / NGO / Adopting Parents.
* In case of incapacitated or hospitalized patients, consent must be signed by the next of kin or doctor.

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General Information on HIV

AIDS (Acquired Immune Deficiency Syndrome) is caused by infection with HIV (Human Immunodeficiency Virus), either HIV-1 or HIV-2. Initial primary infection, over time, becomes chronic and persistent, which may lead to advanced HIV disease if untreated.

Modes of transmission:

- Sexual contact – heterosexual or homosexual
- Transfusion of contaminated blood/blood products
- Sharing of contaminated needles & syringes among injection drug users
- Intrapartum / perinatally from mother to infant
- Transmission from lactating mother to infant via breast milk
- Transmission from HIV-infected specimens to healthcare / laboratory workers (occupational risk)

HIV cannot be transmitted by:

- Insects like mosquitoes
- Holding hands
- Sharing drinking or eating utensils
- Toilet seats
- Living in a house with an HIV-infected person

Diagnosis:
Laboratory diagnosis of HIV infection depends on demonstrating anti-HIV antibodies and/or detection of the virus.

Tests for diagnosing HIV:

- HIV screening tests – Enzyme Immunoassay (EIA) / Rapid Immunochromatography / Chemiluminescence Microparticle Immunoassay (CMIA) / Electrochemiluminescence Immunoassay (ECLIA)
- Western blot test
- p24 antigen test

Tests for monitoring HIV:

- HIV RNA test
- CD4+ T cell count

Window period:
Antibodies to HIV begin to appear after 2 weeks of infection, but detectable antibodies typically appear within 3 months of exposure to the virus. This interval between exposure and appearance of detectable antibodies is called the *window period*.

Results:
All positive results are retested by 3 different methods using different antigens or different principles.

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