PI Online submission steps for IEC I & IEC II for faculty, PhD Scholars and PGS conducting studies involving drugs & devices

PI registration first

- https://iecmanager.org/institution/63

Gmail

COMPOSE

Inbox (28,051)

Starred

Important

Chats

Sent Mail

e-EC - You have been Registered as PI

Inbox   x

CREATE4 <eec.noreply@gmail.com>

to me

Hello Pankaj Shah

Thank you for registering. You account is awaiting approval.
On approval by Admin you will receive an approval email and will be

Yours sincerely,
e-EC Admin

Click here to Reply or Forward

14.51 GB (96%) of 15 GB used
Manage

Terms - Priva

After iec approves account

Gmail

COMPOSE

Inbox (28,050)

Starred

Important

Chats

Sent Mail

Pankaj

krishnan Balaji

e-EC - Approved Existing User's Request to Register as

CREATE4 <eec.noreply@gmail.com>

to me

Hello Pankaj Shah,

Your request to register as a Principle Investigator has been approve

Please click on the link provided below and login into the application
details.
https://iecmanager.org/institution/63

Yours Sincerely,
e-EC Admin

After iec approval of account as PI login as PI - Dashboard

← → C | 🔒 Secure | https://iecmanager.org/dashboard

▦ Apps | Y Dea | G Google | G ear | ⊡ Import citations into y | S 1st Grade Reading Co | ℓ best for pan correction | NIH pubmed submission N | M best

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Sri Ramachandra University (SRU), Chennai

| Dashboard | My Projects | Project Notifications | Reminders | My IEC | My Account |

Pankaj Shah
Principal Investigator
⏻ Logout

🏠 **Dashboard**

⊕ **Submit New Project**

Project Summary

Submissions Initiated(Draft)	0
Submission under IEC Review	0
Project with Queries	0
Ongoing Projects	0
Submission Returned	0

Project Notificatio

Project Number

Announcements

ENG

22:48
09-06-2017

Submit new project

← → ⟳ 🔒 Secure | https://iecmanager.org/createproject

Submit Documents   Projects Documents/Project Review

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⊕ **Submit New Project**

Project Summary

Project Type *   Select Project Type ▼   Review Type *

Project Full Title *   [   ]   Project Short Title *

                       Please Provide Complete Title

                                                       Sponsor

PI Name *   Pankaj Shah

Submit Document(s)

Document Type *   Select Project Type First   Document Title *

Version *   [   ]

Document date *   [   ] 📅

ENG

22:49
09-06-2017

Select

- Faculty- Investigator initiated (no drug or device study)

- PhD PGs only- thesis/disseration

- Faculty, PGs- Pharma Industry if (drug or device study)

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Submit Documents   Projects Documents/Project Review

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⊕ **Submit New Project**

Project Summary

Project Type *

Select Project Type ▼

| Select Project Type |
| Investigator Initiated |
| NGO/Govt |
| Other |
| Pharma/Industry |
| Thesis / Dissertation |

Review Type *

Project Full Title *

Project Short Title *

Sponsor

PI Name *

Submit Document(s)

Document Type * Select Project Type First

Document Title *

Version *

Document date *

ENG

22:52
09-06-2017

Select

- Review type: Full board review
- Fill other details in upper section and save

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⊕ **Submit New Project**

Submit Documents   Projects Documents/Project Review

Project Summary

Project Type *   Investigator Initiated ▾

Review Type *

Project Full Title *   assnnaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaa

Please Provide Complete Title

Project Short Title *   a

PI Name *   Pankaj Shah

Sponsor

Submit Document(s)

Document Type *   Select Document Type ▴

Document Title *

Version *

Document date *

ENG

22:53
09-06-2017

Submit documents

- Red are mandatory

- Others are optional

- Please start the document name with your name for easy identification and name of the project

- Also please start document type name with your name for easy identification

- Red colour indicates mandatory documents

Secure | https://iecmanager.org/createproject

Apps   Dea   Google   ear   Import citations into y   1st Grade Reading Co   best for pan correction   pubmed submission   best

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Submit Documents | Projects Documents/Project Review

⊕ **Submit New Project**

Project Summary

Project Type *

Project Full Title *

PI Name *

Review Type *

Project Short Title *

Sponsor

Select Document Type

Select Document Type

Informed consent document in English *

Informed consent documents in Regional languages (Total No:- Hindi, Marathi, Gujarati) *

Letter to Member Secretary/ Chairperson *

Protocol *

Research participants recruitment procedures: advertisement, notices (If applicable) *

Administrative sanction from the Head of the Institution for the samples to be sent to outside host institution (one copy)

Administrative sanction from the Head of the Institution in case of collaborative studies with other institutions / foreign agencies (one copy)

Submit Document(s)

Document Type *

Select Document Type

Document Title *

Version *

Document date *

ENG

22:54
09-06-2017

Upload documents

- Upload all mandatory documents one by one and save each time
- No possibility of multiple upload at one point of time.
- Version and date is important for identification
- Once document is uploaded it will show in the list of uploaded documents
- CV to be included every time as per format included with this email only- attach is as any other document or CV

Secure | https://iecmanager.org/createproject

Pankaj Shah
Principal Investigator
⏻ Logout

⊕ **Submit New Project**

Submit Documents | Projects Documents/Project Review

Project Summary

Project Type *   Investigator Initiated ▼   Review Type *

Project Full Title *   assnnaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaa   Project Short Title *   a
Please Provide Complete Title

PI Name *   Pankaj Shah   Sponsor   N

Submit Document(s)

Document Type *   Letter to Member Secretary/ Chairperson * ▲   Document Title *

Version *   1

Document date *   09/06/2017   🗓

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⊞ Apps | Y Dea | G Google | G ear | Import citations into y | 1st Grade Reading Co | best for pan correctio | pubmed submission | best

PI Name *   Pankaj Shah

Sponsor

Submit Document(s)

Document Type *   Select Document Type ▼   Document Title *

Version *

Document date *   [   ] 📅

Documents List

Document Type	Document Title	Ve
Letter to Member Secretary/ Chairperson	letter to MS	1

ENG

22:57
09-06-2017

Submit Document(s)

Document Type *   [Select Document Type ▼]   Document Title *
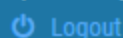
Version *   [   ]

Document date *   [   ]   [📅]

Documents List

Document Type	Document Title	Ve
Research participants recruitment procedures: advertisement, notices (If applicable)	recruitment	4
Protocol	protocol	2
Informed consent document in English	ICF eng	1
Informed consent documents in Regional languages(Total No:- Hindi, Marathi, Gujarati)	ICF	1
Letter to Member Secretary/ Chairperson	letter to MS	1

Click next- submission check list

- Will show all mandatory documents and optional documents with document version date
- Actions- view and download
- Save as draft till you are sure for submission
- Go to view option- projects-add study team members
- Submit to iec
- If any IEC member is part of the team, say yes to the question and select the IEC and search the name.
- IEC admin will refer to respective IEC i.e IEC I or IEC or refer back to you if documents are not complete.
- Auto generated email will be sent

e-EC

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Dashboard | **My Projects** | Project Notifications | Reminders | My IEC | My Account

> My Projects > Submit New Project

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Principal Investigator
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➕ **Submit New Project**

Submit Documents | **Projects Documents/Project Review**

Submission Checklist / Document Receipt Form

Document Type	Document Version
Informed consent document in English	1
Informed consent documents in Regional languages(Total No:- Hindi, Marathi, Gujarati)	1
Letter to Member Secretary/ Chairperson	1
Protocol	2
Research participants recruitment procedures: advertisement, notices (If applicable)	4
Administrative sanction from the Head of the Institution for the samples to be sent to outside host institution (one copy)	
Administrative sanction from the Head of the Institution in case of collaborative studies with other institutions / foreign agencies (one copy)	
Any other Documents submitted	

ENG

23:03
09-06-2017

investigator (information may be submitted separately)

DCG (I) approval letter [if the study falls in new drug category.]

Documentation of CTRI registration/ any other WHO platform registry (whenever applicable)

Ethics Committee clearance of other centers (Total No _____)

if DCGI approval letter is awaited, upload the application letter to DCGI[If the study falls in new drug category.]

Investigator's undertaking to DCG (I) [if the study falls in new drug category.]

Log of delegation of responsibility of the study team members

Memorandum Of Understanding, as applicable, for collaborator (draft if final not ready)

Project submission application form for initial review for all academic (non-sponsored) studies duly filled

Questionnaire

Scales

Summary of protocol (in not more than 500 words)

Vulnerable participants for Research Involving Children

Vulnerable participants for Research Involving Cognitively Impaired Adults

Vulnerable participants for Research Involving Pregnant Women & Fetuses

Vulnerable participants for Research Involving Students, Employees or Residents

Create4 ✕

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Apps 🅨 Dea G Google G ear Import citations into y 1st Grade Reading Co best for pan correctio pubmed submission best

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🏠 > My Projects

My Projects

Pankaj Shah
Principal Investigator
⏻ Logout

⚙ My Projects

➕ Submit New Project

➕ Archived Projects

Project saved as draft successfully.

Search Projects by: 🔍

▲ Project Number	▲ Project Title	▲ Project Status	▲ Latest Submission	Late
20323	abc	Pending Submission	Project Initial Submission	10-06-2
1	asn	Under IEC Review	Project Initial Submission	09-06-2

ENG

08:52
10-06-2017

Secure | https://www.iecmanager.org/projects/projectoverview/354/485

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🏠 > My Projects > abc

Project Summary | Submissions List | Project Documents | Queries

Pankaj Shah
Principal Investigator
⏻ Logout

⚙ **20323** ▼

Overview

Study Team Member

Project History

➕ Submit New Project

Project Summary ❓

Project Title:	abc
Project Status:	Pending Submission
Review Type:	Full Board Review
Latest Submission Status:	Pending Submission
PI:	Pankaj Shah
Date of submission:	10-06-2017
Insurance Expiry:	-
Continuation submission Date:	-
Sponsor:	-

IEC

No Le

ENG

08:53
10-06-2017

Question will be asked

Secure | https://iecmanager.org/documentsreceipt/545/1605

investigator (information may be submitted separately)

Conflict of Interest

Is any of the study team members is an IEC member of the institute ? * ● Yes ○ No

Specify the Ethics Committee *

Select Ethics Committee ▼

| Select Ethics Committee |
| INSTITUTIONAL ETHICS COMMITTEE (Clinical Evaluation of Drugs / Procedures / Devices / Diagnostics / Vaccine / Herbal Remedies) |
| INSTITUTIONAL ETHICS COMMITTEE (Other than Clinical Evaluation of Drugs / Procedures / Devices / Diagnostics / Vaccine / Herbal Remedies) |

Scales

Summary of protocol (in not more than 500 words)

Vulnerable participants for Research Involving Children

Vulnerable participants for Research Involving Cognitively Impaired Adults
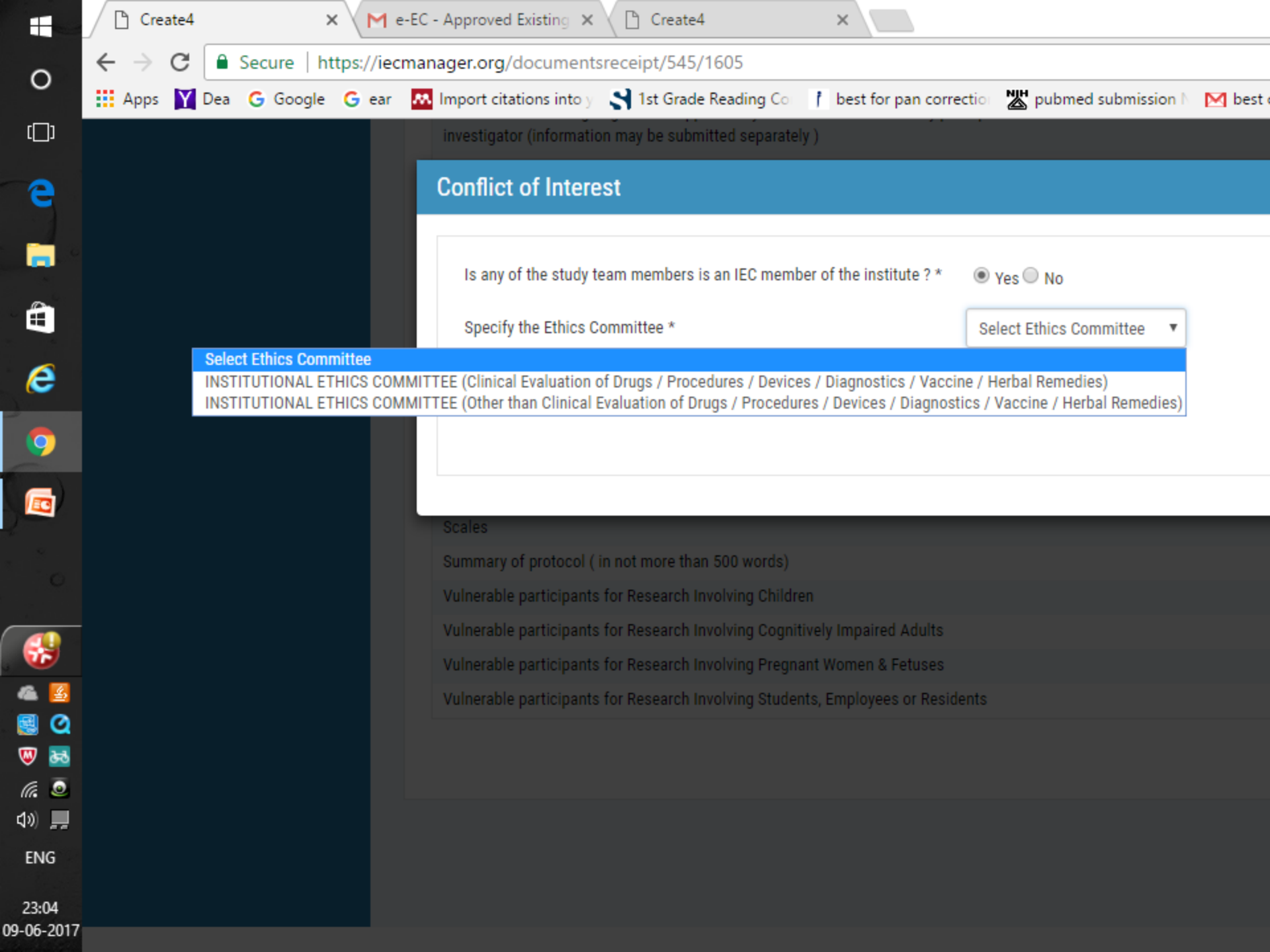
Vulnerable participants for Research Involving Pregnant Women & Fetuses

Vulnerable participants for Research Involving Students, Employees or Residents

ENG

23:04
09-06-2017

investigator (information may be submitted separately)

Conflict of Interest

Is any of the study team members is an IEC member of the institute ? * ○ Yes ● No

Project submission application form for initial review for all academic (non-sponsored) studies duly filled

Questionnaire

Scales

Summary of protocol (in not more than 500 words)

Vulnerable participants for Research Involving Children

Vulnerable participants for Research Involving Cognitively Impaired Adults

Vulnerable participants for Research Involving Pregnant Women & Fetuses

Vulnerable participants for Research Involving Students, Employees or Residents

Secure | https://iecmanager.org/documentsreceipt/545/1605

iecmanager.org says:

Are you sure you are ready to submit for IEC review ?

OK   Cancel

investigator (information may b

Conflict of Interest

Is any of the study team members is an IEC member of the institute ? *   Yes   ● No

Project submission application form for initial review for all academic (non-sponsored) studies duly filled

Questionnaire

Scales

Summary of protocol (in not more than 500 words)

Vulnerable participants for Research Involving Children

Vulnerable participants for Research Involving Cognitively Impaired Adults

Vulnerable participants for Research Involving Pregnant Women & Fetuses

Vulnerable participants for Research Involving Students, Employees or Residents

Submit the proposal

- Once submitted it can not be changed unless IEC admin refers back to you.

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🏠 > My Projects

My Projects

Pankaj Shah
Principal Investigator
⏻ Logout

⚙ My Projects
➕ Submit New Project
➕ Archived Projects

Project submitted to IEC successfully.

Search Projects by: 🔍

▲ Project Number	▲ Project Title	▲ Project Status	▲ Latest Submission	▲ Lates
41295	asn	Submitted to IEC	Project Initial Submission	09-06-20

Return to PI

IEC admin forwarded to MS

- Click link to see further details

← → C   🔒 Secure | https://mail.google.com/mail/u/0/#inbox/15c8df509acbb637

Apps   Dea   G Google   G ear   Import citations into y   1st Grade Reading Co   best for pan correctio   pubmed submission   best

Google

Gmail ▾

COMPOSE

Inbox (28,050)
Starred
Important
Chats
Sent Mail
Drafts (189)
All Mail

P Pankaj ▾   +

krishnan Balaji

e-EC - IEC Admin forwarded A Project for IEC Review Consideration   🏷   Inbox   x

CREATE4 <eec.noreply@gmail.com>   11:10 PM (10 minutes

to me ▾

Hello Pankaj Shah,

The project titled asn has been forwarded by the IEC Admin for your consideration and further course of action.

Please click on the link provide below to login and review the details.

https://iecmanager.org/projects/projectoverview/353/484

Yours Sincerely,
e-EC Admin

👤 | Click here to Reply or Forward

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Manage

ENG

23:20
09-06-2017

Meeting

- Post meeting letter will be issued as PDF
- Download

Provisional Permission issued by Ethics Committee

Inbox   x

e-EC <eec.noreply@gmail.com>

11:16 PM (16 minutes

to me

Hello Pankaj Shah,

The **asn** has been reviewed and Provisional Permission issued by Ethics Committee .
Please click on the link provided below to login with the necessary details.

https://iecmanager.org/institution/63
Yours Sincerely,
Create4 Admin,

Click here to Reply or Forward

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Secure | https://iecmanager.org/projects/projectoverview/353/484

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Dashboard   **My Projects**   Project Notifications   Reminders   My IEC   My Account

🏠 > My Projects > asn

Pankaj Shah
Principal Investigator
⏻ Logout

⚙ 1 ▾

Overview
Study Team Member
Project History

⊕ Submit New Project

Project Summary | Submissions List | Project Documents | Queries

Project Summary   ❓

Project Title:	asn
Project Status:	Under IEC Review
Review Type:	Full Board Review
Latest Submission Status:	Provisional Permission
PI:	Pankaj Shah
Date of submission:	09-06-2017
Insurance Expiry:	-
Continuation submission Date:	-
Sponsor:	-
Ethics committee:	INSTITUTIONAL ETHICS COMMITTEE (Other than Clinical Evaluation of Drugs / Procedures / Devices / Diagnostics / Vaccine / Herbal Remedies)

IEC
09-06

ENG
23:26
09-06-2017

Submission of clarification

Submission of amendments

- Resubmission request to be as new investigator initiated project

- PhD students have to follow the same steps as shown in earlier slides except that they have to select project type as Thesis/dissertation.
- At this point, the online facility is not applicable to UG or PG medical and paramedical students.

- Projects submitted earlier than online submission has to be continued in offline paper format for all clarifications, amendments, completion etc.

- Projects only submitted online have facility of submitting of clarification, amendments and completion etc.

- Along with online submission, you need to submit 2 copies for IEC office for record purpose.

- If need arises, more copy may be requested.