CHECKLIST
SUBMISSION OF DISSERTATIONS TO THE ECARP SECRETARIAT

Date:

S.No.	Name of the Document	Enclosed? (Please tick the appropriate response)		
		Yes	**No**	**Not Applicable**
1	**Covering letter**			
A	Signed by Guide, Student & Head of Department with departmental stamp			
B	A declaration that "The project has been discussed in the Departmental Meeting held on (date/month/ year) and scientifically approved"			
C	Year & month of admission, Guide name & Protocol title with ECARP Number			
D	A declaration that this topic was not done in the Institute within the last 3 years			
2	**DRB certificate (Guide should NOT sign this document)**			
A	Departmental dispatch number and date			
B	Date of DRB review			
3	**ECARP application form:**			
A	Completely filled ECARP form with all details including email id and mobile number of the PG student, PG Guide, Co-Investigator/s (if any) & Head of Department including points like Assessment parameters, statistical analysis plan etc.			
4	**Protocol with pagination (pg 1 of --)**			
	➢ Protocol title, Version with date in the header section ➢ Name of Principal & Co-Investigator/s ➢ Clinical laboratories and collaborating departments ➢ List of abbreviations ➢ Introduction/ Background ➢ Research Question & Research Hypothesis ➢ Aim of the study ➢ Study Objectives ➢ Trial Design ➢ Study population ➢ Sample size with calculation and reference articles used for the calculation of the same. ➢ In case of retrospective & prospective studies separate sample size ➢ Study site ➢ Study Design ➢ Study period (years/months when the study data will be collected – eg. Retrospective study period & prospective study period) ➢ Study Duration (actual time period when study will be carried out & completed – 6/18 months) ➢ Ethical consideration: EC approval & written informed consent of the participants			

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	➢ Detailed Methodology: study related procedures with flow chart /sequence of events ➢ Data recording: assessment parameters relevant to the study ➢ Expected Outcomes: What is the Investigators assumption of the possible study results (alternate hypothesis) ➢ Data analysis: Statistical analysis plan that will achieve the study objectives ➢ Bibliography/References: ▪ at least 15 references relevant to the current topic in case of dissertations. ▪ All the references cited in the text ▪ Use Vancouver style of referencing for citing the references ▪ 75% of the references should be from the 5 years unless the medical condition under study is a rare condition and/or not studied previously			
5	**Informed Consent Document with pagination (pg 1 of --)**			
	➢ Version with date in the header section ➢ Participant/Patient Information Sheet & the Consent with signature page [English & translated version (Hindi & Marathi) once the English version is approved] ➢ Assent form & Parent Consent Document in case of studies conducted on study participants aged between 12 to 18 years of age.			
6	**Case Record Form (CRF) with pagination (pg 1 of --)**			
7	**GANTT chart (separate document)**			
8	**BCBR certificate of the PG student**			
9	**Other documents (if applicable)** MoU: in case of collaborative studies			
10	Investigator Undertaking for the management of research related injuries in case of interventional studies AND/OR new indication/route/dosage form of the drug under study or new procedure or Medical Device			
11	Copy of case files from the MRO in case of retrospective studies			

Guide's Name, Signature & Date **Student's Name, Signature & Date**

Head of Department (with stamp):

CHECKLIST
SUBMISSION OF ACADEMIC PROJECTS TO THE ECARP SECRETARIAT

Date:

S.No.	Name of the Document	Enclosed? (Please tick the appropriate response)		
		Yes	**No**	**Not Applicable**
1	**Covering letter**			
A	Signed by the Principal & Co-Investigators and forwarded by the Head of Department with departmental stamp			
2	**ECARP application form:**			
A	Completely filled ECARP form with all details including email id and mobile number of the Principal & Co-Investigators including points like Assessment parameters, statistical analysis plan etc.			
4	**Protocol with pagination (pg 1 of --)**			
	➢ Protocol title, Version with date in the header section ➢ Name of Principal & Co-Investigator/s ➢ Clinical laboratories and collaborating departments ➢ List of abbreviations ➢ Introduction/ Background ➢ Research Question & Research Hypothesis ➢ Aim of the study ➢ Study Objectives ➢ Trial Design ➢ Study population ➢ Sample size with calculation and reference articles used for the calculation of the same. ➢ In case of retrospective & prospective studies separate sample size ➢ Study site ➢ Study Design ➢ Study period (years/months when the study data will be collected – eg. Retrospective study period & prospective study period) ➢ Study Duration (actual time period when study will be carried out & completed – 6/18 months) ➢ Ethical consideration: EC approval & written informed consent of the participants ➢ Detailed Methodology: study related procedures with flow chart /sequence of events ➢ Data recording: assessment parameters relevant to the study ➢ Expected Outcomes: What is the Investigators assumption of the possible study results (alternate			

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SUBMISSION OF ACADEMIC PROJECTS TO THE ECARP SECRETARIAT

	hypothesis) ➢ Data analysis: Statistical analysis plan that will achieve the study objectives ➢ Bibliography/References: ➢ at least 15 references relevant to the current topic in ➢ case of dissertations. ➢ All the references cited in the text ➢ Use Vancouver style of referencing for citing the references ➢ 75% of the references should be from the 5 years unless the medical condition under study is a rare condition and/or not studied previously			
5	**Informed Consent Document with pagination (pg 1 of --)**			
	➢ Version with date in the header section ➢ Participant/Patient Information Sheet & the Consent with signature page [English & translated version (Hindi & Marathi) once the English version is approved] ➢ Assent form & Parent Consent Document in case of studies conducted on study participants aged between 12 to 18 years of age.			
6	**Case Record Form (CRF) with pagination (pg 1 of --)**			
7	**GCP certificates of all study team members**			
8	**CTRI number of the study**			
9	**Other documents (if applicable)** MoU: in case of collaborative studies			
10	Investigator Undertaking for the management of research related injuries in case of interventional studies AND/OR new indication/route/dosage form of the drug under study or new procedure or Medical Device			
11	Copy of case files from the MRO in case of retrospective studies			

Principal Investigator's Name, Signature & Date:

Co-Investigator I Name, Signature & Date:

Head of Department (with stamp):

GUIDELINES
SUBMISSION OF DISSERTATIONS TO THE ECARP SECRETARIAT

A. INITIAL SUBMISSION

1. Only a permanent Faculty member can be the Principal Investigator for the study
2. All documents [Application form, Protocol, ICDs (English & translated languages in pdf format), Case Record Form and all other relevant study specific documents] should be submitted (as separate documents) as soft copy *via* email to ecarpnairhospital@gmail.com and 3 hard copies [1 original + 2 photocopies] for ethical review to the ECARP Secretariat *via* dispatch.
3. The ECARP Checklist should also be submitted with the study documents with the details appropriately properly
4. The subject of the email should have the ECARP No./Project Title/Student Name/Dept & each document submitted *via* email should be labelled properly – ECARP No./Student Name/Dept & attached as separate documents
5. All emails should have details of what is being sent mentioned in the text of the mail with the properly **labelled documents** attached. The email needs to be sent either from PI/ Co-I's email Id. If this is not done, the mail will be ignored. Forwarded emails will not be entertained.
6. The protocol should have a Header & Footer which should mention the following details: **Header**: The Study title (running title will do) along with the Protocol Version & date & the Name of the Department. **Footer**: Pagination (Page numbers: Page – of--)
7. The Informed Consent Document (which includes the Participant/Patient Information Sheet & the Consent with signature page) also should have a Header & Footer with the same details as mentioned in the Protocol. i.e. Header: The Study title (running title will do) along with the ICD Version & date & the Name of the Department. Footer: Pagination (Page numbers - page – of--)
8. Page numbering should be separate for all documents viz. Protocol, Informed Consent Documents (English, Hindi, Marathi), Case Record Form
9. All the study documents will be accepted for further ethical review after technical scrutiny of the study documents. If there are any issues/clarifications in the study documents, it will be intimated to the PI and Co-I *via* email within the next 3-4 days.
10. Corrected documents should be submitted to the ECARP Office within the next 3 days after receiving intimation/email regarding the same.
11. After acceptance of the project for ethical review the ECARP fees need to be paid by the Study Investigators. (This will be intimated to the Investigators *via* email/telephonically)
12. Initial submission should be made within 6 months of joining the Course. All replies to ECARP queries should be submitted within 4-6 weeks of receipt of the same. A late fee will be applicable for queries that are replied to by the student after a period of 6 weeks. A further increase in the late fee will be applicable for queries that are replied to by the student between 6 weeks – 3 months.
13. If no reply is received up to 3 months after the Query letter is sent, the project will be considered as CLOSED and will not be considered for further review.

B. Replies to Queries raised at the ECARP meeting

1. Reply to EC queries to be submitted within 4-6 weeks of receiving the Query letter.
2. The revised documents should be submitted **10 days** before the next ECARP meeting if these are to be reviewed at the meeting (soft copy via email & 1 hard copy).
3. **All corrections made in the revised documents should be highlighted in both the soft & hard copies of the documents** and the details should be mentioned in the Query reply letter with the page numbers denoting where the changes have been made.
4. Please submit 2 hard copies (1 original + 1 photocopy) and one soft copy (via email of the Query reply
5. Please attach a copy of Decision/Query letter along with the Replies submission.
6. **All the documents should be labelled & paginated properly and submitted as separate documents (as mentioned above)**.

C. **Annexure-B** is to be submitted by the student to the ECARP Office **within 3 days** after intimation to submit the same along with a soft copy *via* email of all the final approved study documents in PDF format.

GUIDELINES
SUBMISSION OF ACADEMIC PROJECTS TO THE ECARP SECRETARIAT

A. INITIAL SUBMISSION

1. Only a permanent Faculty member can be the Principal Investigator for the study
2. All documents [Application form, Protocol, ICDs (English & translated languages in pdf format), Case Record Form and all other relevant study specific documents] should be submitted (as separate documents) as soft copy *via* email to ecarpnairhospital@gmail.com and 3 hard copies [1 original + 2 photocopies] for ethical review to the ECARP Secretariat *via* dispatch.
3. The ECARP Checklist should also be submitted with the study documents with the details appropriately properly
4. The subject of the email should have the ECARP No./Project Title/Student Name/Dept & each document submitted *via* email should be labelled properly – ECARP No./Student Name/Dept & attached as separate documents
5. All emails should have details of what is being sent mentioned in the text of the mail with the properly **labelled documents** attached. The email needs to be sent either from PI/ Co-I's email Id. If this is not done, the mail will be ignored. Forwarded emails will not be entertained.
6. All emails should have details of what is being sent mentioned in the text of the mail with the properly labelled documents attached. The email needs to be sent either from PI/ Co-I's email Id. If this is not done, the mail will be ignored. Forwarded emails will not be entertained.
7. The protocol should have a Header & Footer which should mention the following details: Header: The Study title (running title will do) along with the Protocol Version & date & the Name of the Department. Footer: Pagination (Page number: Page – of--)
8. The Informed consent Document (which includes the Participant/Patient Information Sheet & the Consent with signature page) also should have a Header & Footer with the same details as mentioned in the Protocol. i.e. Header: The Study title (running title will do) along with the ICD Version & date & the Name of the Department. Footer: Pagination (Page numbers - page – of--)
9. Page numbering should be separate for all documents viz. Protocol, Informed Consent Documents (English, Hindi, Marathi), Case Record Form
10. All the study documents will be accepted for further ethical review after technical scrutiny of the study documents. If there are any issues/clarifications in the study documents, it will be intimated to the PI and Co-I *via* email within the next 3-4 days.
11. Corrected documents should be submitted to the ECARP Office within the next 3 days after receiving intimation/email regarding the same.
12. After acceptance of the project for ethical review the ECARP fees need to be paid by the Study Investigators. (This will be intimated to the Investigators *via* email/telephonically)

13. Replies to ECARP queries should be submitted within 4-6 weeks of receipt of the same. A late fee will be applicable for queries that are replied to by the Study Investigators after a period of 6 weeks – 3 months.
14. If no reply is received up to 6 months after the Query letter is sent, the project will be considered as CLOSED and will not be considered for further review.

B. Replies to Queries raised at the ECARP meeting

1. Reply to EC queries to be submitted within **4-6 weeks** of receiving the Query letter.
2. The revised documents should be submitted **10 days before the next ECARP meeting** if these are to be reviewed at the meeting (soft copy via email & 1 hard copy).
3. All corrections made in the revised documents should be highlighted in both the soft & hard copies of the documents and the details should be mentioned in the Query reply letter with the page numbers denoting where the changes have been made.
4. Please submit 2 hard copies (1 original + 1 photocopy) and one soft copy (via email of the Query reply
5. Please attach a copy of Decision/Query letter along with the Replies submission.
6. **All the documents should be labelled & paginated properly and submitted as separate documents (as mentioned above)**.

ANNEXURE I: GUIDELINES ON PROTOCOL WRITING

The protocol should have the following details:

1. Protocol title, Version with date
2. Name of Principal & Co-Investigator/s
3. Amendment number(s) and date(s) (if applicable)
4. Clinical laboratories and collaborating departments
5. List of abbreviations used in the Protocol

The protocol should contain:

- Introduction/ Background:
  - Rationale for the current study
  - Lacunae in the previous studies and how the present study plans to address these lacunae
  - Summary of known and potential risks and benefits
  - Short description of the proposed study

- Research Question & Research Hypothesis.

- Study Objectives
  - Primary & Secondary
  - Keep the objectives simple, specific & straightforward
  - Should be S.M.A.R.T. – Specific, Measurable, Achievable, clinically relevant & time-based
  - Preferably 1-2 primary objectives

- Trial Design
  - Study participants selection
  - **Inclusion criteria should include:**
    - Patient characteristics (e.g. age, sex etc.)
    - Disease characteristics
    - Previous treatment administered
    - Environment & other factors
    - Screening results
    - Willingness of the participant
  - **Exclusion criteria**
    - Concurrent illness
    - Concomitant therapy
    - Contraindications to any of the therapies
    - Pregnancy/lactation
    - e/o organ damage
    - Noncompliant persons

  - Sample size with calculation and reference articles used for the calculation of the same.

- In case of retrospective & prospective studies, please mention how many retrospective cases & how many prospective cases will be enrolled
- Study site
- Study Design
- Study period (years/months when the study data will be collected – eg. Retrospective study period & prospective study period)
- Study Duration (actual time period when study will be carried out & completed – 6/18 months)

- Ethical issues – EC approval & written informed consent of the participants
- Detailed Methodology – study related procedures with flow chart /sequence of events
- Data recording - assessment parameters relevant to the study
- Expected Outcomes – what is the Investigators assumption of the possible study results (alternate hypothesis)
- Data analysis – statistical analysis plan that will achieve the study objectives
- Bibliography/References: There should be at least 15 references relevant to the current topic in case of dissertations. All the references need to be cited in the text. Also 75% of the references should be from the 5 years unless the medical condition under study is a rare condition and/or not studied previously

ANNEXURE II: INSTRUCTIONS FOR SUBMITTING ECARP PROJECTS FOR REVIEW

Please follow these guidelines for submitting hard & soft copies of the proposal for review and approval to ECARP.

TEMPLATE FOR INITIAL SUBMISSION OF THE PROJECT PROPOSAL

Respected Chairperson/Secretary,

I, (Name of Student), (Resident/ designation) department of (Name of the Department), am submitting the documents related to the Research Proposal entitled "(Title of the study)", under the guidance of (Name & designation of the guide). This is an (academic/dissertation) study. This project has been discussed in the departmental meeting held on (date) and scientifically approved.

We hereby submit the following documents for your review,

1. Covering letter
2. DRB Certificate
3. ECARP application form
4. Protocol
5. PIS and consent forms in English, Hindi and Marathi
6. Case record form
7. GANNT chart
8. Other documents (if applicable) like scales/ questionnaire, administrative approval, delegation of responsibilities, CV & GCP certificate of the investigators, BCBR certificate, MOU (applicable in case of multicentre studies) etc.

You are requested to kindly review the project and approve the same

Thanking you,
Yours sincerely,

Name & Sign of the PI

Name & Sign of the Co-I

TEMPLATE FOR SUBMISSION OF REPLY TO EC QUERIES WITH STUDY DOCUMENTS

Respected Chairperson/Secretary,

I, (Name of Student), (resident/ designation) department of (Name of the Department), am submitting the query reply for the project (Project Number) entitled "(Title of the study)", under the guidance of (Name & designation of the Guide). This is an (academic/dissertation) study.

We hereby submit the following documents for your review,

1. Covering letter
2. Query letter
3. Reply to queries
4. ECARP application form
5. Protocol
6. PIS and consent forms in English, Hindi and Marathi
7. Case record form
8. Other documents (whichever is applicable) like scales/ questionnaire, administrative approval, delegation of responsibilities, CV & GCP of the Investigators etc.

You are requested to kindly review the project and approve the same

Thanking you,
Yours sincerely,

Name & Sign of the PI Name & Sign of the Co-I

Forwarded by

Name & Sign of the HOD

- Kindly email the project documents to ecarpnairhospital@gmail.com & submit the same as 3 hard copies and one soft copy on a pen drive (Please note that templates for the letters has been provided above)
- Kindly attach all the supporting documents to your email with proper labelling (e.g. covering letter should be labelled as - 1. Covering letter.
- The email needs to be sent either from PI or Co-I's email Id
- Projects not complying to these guidelines will not be considered for further review of the project

ANNEXURE III: SUBMISSION OF COMPLETION REPORTS OF ACADEMIC PROJECTS APPROVED BY THE ECARP

1. A brief summary of all research projects that have been approved by the ECARP and have been completed, should be submitted to the ECARP Secretariat by the Guides/Principal Investigators within 2 months of completion of the study

2. **The completion report should in the Structured Abstract format –**

I. Study Title with ECARP project No.

II. Study Investigators with Department details

III. Date of approval from ECARP

IV. Background: This section should cover main rationale behind the study (**4-5 lines**)

V. Objectives: As per protocol approved by ECARP

VI. Methodology: **One paragraph** in which the following points should be covered:
   a. Study design
   b. Inclusion exclusion criteria
   c. Number of patients enrolled with randomization details if applicable. Please also give the numbers of screen failures, dropouts & withdrawals.
   d. Study period & duration
   e. Parameters used for assessment of study objectives with statistical details
   f. Results: (4-5 Lines). Please arrange the results as per your objectives

VII. Discussion & Conclusion: (**4-5 lines**)

If the Completion reports of projects approved over the previous 2 years are not submitted, then the ECARP has the discretion to withhold the review and approval of new projects submitted by the same Guide/Principal Investigator.