



Royal Center for Disease Control

Framework of Technical Review Board

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Ministry of Health
Thimphu, BHUTAN

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1. Purpose

This framework outlines the composition, roles and responsibilities and authorities of the Technical Review Board (TRB) of the Royal Centre for Disease Control (RCDC).

2. Members

- 1) The Board will comprise of a maximum of five competent multidisciplinary technical officials with relevant qualifications;
- 2) The tenure of the members will be for a period of three years;
- 3) A member may be re-selected based on relevancy;
- 4) The chairmanship will be rotated among the members on a yearly basis;
- 5) A member secretary will be appointed on for a period of one year;
- 6) The quorum required for any decision making shall be at least three members, including the chairperson;
- 7) Co-opt members will be involved depending on relevancy.

3. Terms of References

The following shall be the roles and responsibilities of the Board:

- 1) Review and endorse research proposals and projects both from within and outside the RCDC;
- 2) Review suitability and justifications on applications requesting data from the RCDC;
- 3) Review and endorse the technical guidelines and protocols within the RCDC;
- 4) Review and analyze scientific and technical information related to RCDC.

4. Review and Amendment

- 1) The Terms of Reference will be subject to periodic review to ensure their relevance and effectiveness.
- 2) These may be amended with the consensus of the Board and approval from the RCDC Management.

5. Roles and Responsibilities of the Chairperson

The chairperson shall:

- 1) Decide on the duration required for review of proposals;
- 2) Distribute the proposals among the members for review;
- 3) Resolve any disagreements among the members;
- 4) Provide the final decision on any discussions.

6. Roles of the Member Secretary

The member secretary shall:

- 1) Coordinate and conduct the Board meetings depending on the agenda;
- 2) Keep minutes of the meetings and share it with the members for correction;
- 3) Share the final minutes with the RCDC management;
- 4) Communicate with applicants on the decisions of the Board;
- 5) Maintain records of all the decisions taken by the Board.

7. Procedure for Board meetings

The Board meetings shall be conducted in accordance with the following the key processes:

- 1) The member secretary proposes the meeting to the chairperson depending on the agenda;
- 2) The chairperson approves/rejects the meeting, with justifications in case of rejection;
- 3) In case of approval, the member secretary shares the agenda with the members;
- 4) The member secretary confirms the date of the meeting;
- 5) The members declare any conflict of interest in the respective agenda;
- 6) The members deliberate and provide the conclusions on the agenda;
- 7) The chairperson decides on the duration for review of the proposals by the members;
- 8) The member secretary records minutes of the meeting;
- 9) The member secretary shares the minutes for endorsement;
- 10) The minutes are finalized;
- 11) The applicant shall be informed of the decision of the Board within 10 working days.

Annexure A: Documents to be maintained

Sl. no.	Document
1	Appointment order of the Board members
2	Minutes of the meetings
3	Research site and Data request applications
4	Research and Data request approval letters
5	Rejection/Conditional approval letters
6	Declaration forms
7	CoI declaration form
8	Communication letters
9	Annual Board activity report

Annexure B: Research site request application form

Research Site Request Application Form

Project Title:

.....

Date of Request:

Duration of research: (days/weeks/months/years), from till

Is administrative clearance from the Ministry of Health obtained: Yes No

Principle Investigator/Coordinator:

Name:

Designation:

Organization:

Phone Number:

Email ID:

Co-investigators:

SN	Name	Designation	Organization	Phone No.	Email ID

Summary of Project (Maximum 300 words)

Briefly describe the significance of the planned research and the purpose for which it will be used (Maximum 300 words)

Is funding available for the project: Yes. Name of funding agency:
 No

Any additional information that may assist the review

Attachments

1. Complete protocol of the research
2. CV of investigators
3. Data collection template with the entire required variable list

Name & Signature of Applicant:

Date:

Annexure C: Data request application form

Data Request Application Form

Project Title:

.....

Date of Request:

Duration of data requested:

Purpose for which the data will be used:

Is administrative clearance from the Ministry of Health obtained: Yes No N/A

Principle Investigator/Coordinator:

Name:

Designation:

Organization:

Phone Number:

Email ID:

Co-investigators:

SN	Name	Designation	Organization	Phone No.	Email ID

Summary of Project (Maximum 300 words)

Briefly describe the significance of the planned research and the purpose for which it will be used (Maximum 300 words)

Where will the data be stored and accessed?

- On my affiliated organization's/institution's computer system
- On a stand-alone computer or laptop with password protection
- Others (describe) _____

Is funding available for the project: Yes. Name of funding agency:
 No

Any additional information that may assist the review

Attachments

1. CV of investigators
2. Data collection template with the entire required variable list

Terms & Conditions

I agree to the following terms and conditions:

- I ensure that the data will only be used for the above mentioned purpose
- I ensure that the data will only be accessed by I and the co-investigators listed in the application
- RCDC's data source will be acknowledged appropriately

Note: Failure to comply will result in withdrawal of data sharing for present and future purposes.

Name & Signature of Applicant:

Date:

Annexure D: Research site approval letter

Royal Centre for Disease Control

Technical Committee

RCDC/TC/.../2023/...

Date:

Research Site Approval Letter

The Technical Committee of the Royal Centre for Disease Control hereby approves the research site for the research titled “.....” submitted by (name), (position title) of (agency).

The applicant shall adhere to the following terms and conditions during the entire research period:

- 1) Conduct the research as per the approved protocol;
- 2) Ensure no interference with the routine works at the centre;
- 3) Seek permission from the head/in-charge of the division/unit prior to using laboratory facilities;
- 4) Undergo orientation/training on use of high-end equipment;
- 5) Not use resources of the centre (drugs, diagnostics & other consumables) for the purpose of the research;
- 6) Not give the preliminary findings/unpublished reports to the media without prior consultation with the committee;
- 7) Seek approval from the committee for any changes in the protocols before implementing them;
- 8) Submit a copy of the final results of the research to the committee;
- 9) Notify the committee after the research paper is published in a scientific journal.

RCDC reserves the right to **SUSPEND/WITHDRAW** the publication of the research findings if the applicant fails to abide by the terms and conditions.

(.....)
Chairperson,
Technical Committee,
Royal Centre for Disease Control.

Copy to:

1. Head, RCDC, for kind information;

2. Division/unit heads of RCDC, for kind information and necessary actions;
3. Official concerned;
4. Office copy.

Annexure E: Data request approval letter

Royal Centre for Disease Control

Technical Committee

RCDC/TC/.../2023/...

Date:

Data Request Approval Letter

The Technical Committee of the Royal Centre for Disease Control hereby approves the request for data on “.....” for the project titled “.....” submitted by (name), (position title) of (agency).

The data shall be used for a period of (days/weeks/months/years), from till

The applicant shall adhere to the following terms and conditions:

- 1) Use the data only for the above-mentioned purpose/project;
- 2) Ensure the data shall be accessed by only the principal investigator and the co-investigators;
- 3) Involve the relevant owner of the data from RCDC as a co-author;
- 4) Acknowledge the RCDC while publishing the research findings.

RCDC reserves the right to **SUSPEND/WITHDRAW** the publication of the research findings if the applicant fails to abide by the terms and conditions.

(.....)

Chairperson,
Technical Committee,
Royal Centre for Disease Control.

Copy to:

5. Head, RCDC, for kind information;
6. Division/unit heads of RCDC, for kind information and necessary actions;
7. Official concerned;
8. Office copy.

Annexure F: Research site declaration form

Royal Centre for Disease Control

Declaration for Research Site Approval

Subsequent to my request for research site approval to conduct the research titled “.....,” at the Royal Centre for Disease Control, I hereby declare to abide by the following terms and conditions:

- 1) Conduct the research as per the approved protocol;
- 2) Ensure no interference with the routine works at the centre;
- 3) Seek permission from the head/in-charge of the division/unit prior to using laboratory facilities;
- 4) Undergo orientation/training on use of high-end equipment;
- 5) Not use resources of the centre (drugs, diagnostics & other consumables) for the purpose of the research;
- 6) Not give the preliminary findings/unpublished reports to the media without prior consultation with the committee;
- 7) Seek approval from the committee for any changes in the protocols before implementing them;
- 8) Submit a copy of the final results of the research to the committee;
- 9) Notify the committee after the research paper is published in a scientific journal.

RCDC reserves the right to **SUSPEND/WITHDRAW** the publication of the research findings if the applicant fails to abide by the terms and conditions.

Signature:

Name:

Position title:

Date:

Place:

Annexure G: Data request declaration form

Royal Centre for Disease Control

Declaration for Data Request

Subsequent to my request for data on “.....” to conduct the research titled “.....” from the Royal Centre for Disease Control, I hereby declare to abide by the following terms and conditions:

- 1) Use the data only for the above mentioned purpose/project;
- 2) Ensure the data shall be accessed by only the principal investigator and the co-investigators;
- 3) Involve the relevant owner of the data from RCDC as a co-author;
- 4) Acknowledge the RCDC while publishing the research findings.

RCDC reserves the right to **SUSPEND/WITHDRAW** the publication of the research findings if the applicant fails to abide by the terms and conditions.

Signature:

Name:

Position title:

Date:

Place:

Annexure H: Rejection/Conditional approval letter

Royal Centre for Disease Control

Technical Committee

RCDC/TC/.../2023/...

Date:

Rejection/Conditional Approval Letter

The Technical Committee of the Royal Centre for Disease Control has taken the following decision with regard to the request for (research site/data) submitted by (name), (position title) of (agency).

Decision:

- Rejected. Reason for rejection:

- Approved with the following conditions:
 - i.
 - ii.

The proposal shall be re-submitted to the committee upon fulfilment of the above conditions.

(.....)
Chairperson,
Technical Committee,
Royal Centre for Disease Control.

Copy to:

1. Head, RCDC, for kind information;
2. Division/unit heads of RCDC, for kind information and necessary actions;
3. Official concerned;
4. Office copy.

Annexure I: Conflict of interest declaration form

Royal Centre for Disease Control

Declaration of conflict of interest

As a member of the Technical Committee of the Royal Centre for Disease Control, I declare the following with regard to potential conflict of interest in the current agenda under discussion:

- I do not have or anticipate any conflict of interest. I shall notify the committee immediately in the event such interests arise in the course of or before discharging my duty;
- I do have conflict of interest in view of the following:
 - Agenda:
.....
 - Reasons:
.....

I hereby confirm that the above information is true to the best of my knowledge. In the event the above declaration is found to be incorrect, I shall be liable for administrative/legal action.

Signature:
Name:
Position title:
Date:
Place:

The application & declaration forms can be downloaded from the “forms and download” section of the RCDC website and emailed to trbrcdc@gmail.com.

**Royal Centre for Disease Control,
Wangchutaba, Serbithang,
Thimphu.**

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**Email: trbrcdc@gmail.com,
rcdc@health.gov.bt**