

## **FREQUENTLY ASKED QUESTIONS (FAQs)**

### **Q 1. Who can register on Naitik portal?**

**Ans.** All ethics committees reviewing biomedical, social and behavioural science research for health conducted in India involving human participants, their biological material and data, are required to submit application for registration of Ethics Committees on Naitik portal (<https://naitik.gov.in/DHR/Homepage>).

### **Q 2. How do I create my login credentials on Naitik portal?**

**Ans.** To create login credentials on the Naitik portal proceed as follows: -

1. Click on the "Register" button available on the homepage of the portal (available at: <https://naitik.gov.in/DHR/Homepage>)

2. Fill the applicant registration form with the required details and upload the essential documents and submit the form.

(It is recommended to use an official email id of the ethics committee as the username. All correspondence w.r.t. Naitik portal should be done on this registered email id.)

3. After successful submission of login credentials an email with a link will be sent to the registered email id for confirmation of registration

(If you cannot visit this link directly, kindly copy and paste the above URL in your browser window.)

4. Proceed for authentication of user through Aadhar based E-sign.

5. Mention your Aadhar no. or virtual ID no. and OTP received in the registered mobile number to complete the registration process.

6. Once your registration is complete you will receive an auto-generated acknowledgement e-mail on the registered e-mail ID.

### **Q 3. How to proceed if the login request is rejected?**

**Ans.** Kindly refer to the response with reason for rejection received in registered email ID during preliminary login registration attempt and repeat the login registration process accordingly.

### **Q 4. I am not able to receive any confirmation mail from Naitik Portal?**

**Ans.** Check your Junk/Spam folder for emails from NECRBHR. If you are receiving our emails in Junk/Spam, then you can save "noreply@naitik.gov.in" in your contacts.

### **Q 5. How to proceed if I forget my password?**

**Ans.** Proceed as follows: -

1. Go to Login page on Naitik Portal.

2. Click on 'Forgot Password' available just below the Login button.

3. Enter your registered email ID and click 'Submit'.

4. An email will be sent to your registered mail ID from <noreply@naitik.gov.in> in which a link will be available to create a new password.

5. Click the link in the email and create the new password from that page by entering the password in both the fields and click on submit.

(Please make sure you have followed the requirements mentioned below the password field for creating a strong password. The password may be verified by logging into the Naitik portal.)

### **Q 6. How do I submit an application for Ethics Committee registration on Naitik portal?**

**Ans.** After your login credentials are approved, to submit an application for Ethics Committee registration on Naitik portal, follow below steps:

1. Login with your credentials.

2. Go to the 'Submit Form' link available on the dashboard.

3. Start filling the application.

4. Please ensure that you read the mandatory guidelines displayed on this webpage before filling the form.

**Q 7: How do I fill the correspondence address while submitting the application?**

**Ans.** To fill the correspondence address proceed as follows: -

1. After logging in with your registered email ID click on the submit form tab.
2. The option for filling up the correspondence address can be found on the first page and it can be done in the 'click here' section present in the second checkbox that allows you to fill the correspondence address.

**Q 8. Why am I getting 'Contact to Administrator' error while uploading the document?**

**Ans.** For rectifying this error: -

1. Please check your document's file extension. The file extension should not be in Capital letters (i.e. .PDF). In that case please save the document with file extension in small letters (i.e. .pdf)
2. The file size should not be more than 10 MB.

**Q 9. Where can I find applications which were saved and not submitted?**

**Ans.** All saved applications are visible in the 'Saved as Draft' tab on the dashboard. Each Application has different Actions and Status based on the stage of Application submission. For further processing of the application, go to the action column and select View/Modify form option.

**Q 10. How do I locate my submitted applications?**

**Ans.** All submitted proposals are visible in the 'Submitted' tab option on the dashboard.

**Q 11. How will I know when a query is raised on my application?**

**Ans.** You will receive an email intimation on the registered email ID regarding the query raised. You may login to the portal, and find the application in 'Query Raised' tab on the dashboard.

**Q 12. How do I respond to a query raised?**

**Ans.** Open 'Query Raised' tab on the dashboard and Go to action column > click 'View/Modify checklist' link. You will be able to upload the revised document /provide justification against the checklist item for which query has been raised. After successfully responding to all the queries please submit the application by clicking on the 'Submit' button on the bottom of the page.

**Q 13. How do I track the status on my submitted application?**

**Ans.** You can view the status of your submitted applications online. View submitted applications, in the displayed web page check the 'Status' column to view status of submitted application.

**Q 14. When the Hospital is a part of a trust or a corporate organization, Should the Ethics Committee be registered under the name of hospital or the trust?**

**Ans.** The Ethics Committee should be registered in the name of the hospital for which it is constituted.

**Q 15. Is there a recommended affiliation ratio for members in the EC of any institute/organization?**

**Ans.** According to ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Participants, 2017, preferably 50% or more members should be non-affiliated in any EC and there should be a balance between medical and non-medical members/ technical and non-technical members, depending upon the needs of the institution.

**Q 16. What is meant by address of the organization? What can be provided for address proof?**

**Ans.** Address of the organization refers to the address of the hospital/organization under which the EC is constituted and the meeting are held. Any document displaying complete address of your organization issued by a Government authority may be submitted and should be attested by Head of the Institution/Applicant. The address proof should match with the address provided in the portal.

**Q 17. How to get the auto-generated EC undertaking and CT-01 form when submitting a fresh application?**

**Ans.** While filling the fresh application after providing all the member details in the portal, the portal will allow you to auto-generate the EC undertaking and Form CT-01 in the prescribed format. This will be visible from the bottom of the Preview page after filling the complete EC member details, and if in case you forgot to download both the documents from the preview page, then the same documents can also be downloaded from the bottom of the checklist page.

**Q 18. How to get the auto-generated EC undertaking and CT-01 to reply the query raised in the application?**

**Ans.** Go to 'Query Raised' page from the dashboard and click on the button available under Actions column. You will be allowed to download both the CT 01 form and EC undertaking from the 'Generate Form' and 'Generate Undertaking' options respectively.

**Q 19. What are the common issues that leads to rejection of login requests?**

**Ans. The following can be the reasons for rejections: -**

1. ID proof details mentioned incorrectly in the portal.
2. Documents should be uploaded clearly and in the correct place.
3. Name of the Ethics Committee, name of the institution and the address of the institution should be provided correctly in the undertaking.
4. The undertaking should be signed by the Head of the Institute.
5. According to the ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Participants, 2017, section 4.3.7, the Head of the institute cannot be part of the Ethics Committee.
6. The address filled while registering should match with address proof submitted.
7. The documents uploaded should not be password protected.
8. All the documents should be self-attested before uploading.
9. The designation of the applicant should be mentioned correctly.

**Q 20. Who can be an applicant on behalf of the organization?**

**Ans.** Preferably the Head of the institute should be the applicant on Naitik portal.

**Q 21. Can Head of the Institute be part of the EC?**

**Ans.** So as to maintain independence, the Head of the institution should not be part of the EC but should act as an appellate authority to appoint the committee or to handle disputes.

**Q 22. Who can sign the authority letter?**

**Ans.** Head of institute or Appellate authority of the Ethics Committee may sign the Authority letter. They cannot be a part of the EC but should act as an appellate authority to appoint the committee or to handle disputes.

**Q 23. Where can I refer for details regarding eligibility and qualification of EC member?**

**Ans.** Kindly refer to ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Participants, 2017, section IV for details regarding composition of EC and member requirements.

**Q 24. Who can be a social scientist?**

**Ans.** According to ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Participants, 2017, a social scientist may be affiliated/ non-affiliated and should be an individual with social/ behavioural science/ philosophy/ religious qualification and training and/or expertise and be sensitive to local cultural and moral values. He/she can be from an NGO involved in health-related activities. It is recommended to justify the suitability of the member as a social scientist in the biodata submitted while applying for EC registration.

**Q 25. Is Ethics training mandatory for EC members?**

**Ans.** Yes. Members should undergo initial and continuing training in human research protection, EC functions and SOPs, and should be conversant with ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Participants, 2017, GCP guidelines (if applicable) and relevant regulations of the country. All trainings should be documented. Any change in the relevant guidelines or regulatory requirements should be brought to the attention of all EC members. EC members should be aware of local, social and cultural norms and emerging ethical issues. Training certificates on GCP alone is not recommended.

**Q 26. How to complete the submission of application if any member is not trained or do not possess a relevant training certificate at the time of submitting application?**

**Ans.** If the members do not have an EC training certificate at the time of submitting application, they may submit an undertaking stating that the person will go under relevant training within six months and the same should be submitted to this office through NAITIK portal. The format is given in the download section on the Naitik portal. ([https://naitik.gov.in/DHR/resources/app\\_srv/DHR/global/pdf/downloads/GCPUndertaking.pdf](https://naitik.gov.in/DHR/resources/app_srv/DHR/global/pdf/downloads/GCPUndertaking.pdf))

**Q 27. Can EC have alternate member secretary and a vice chairperson?**

**Ans.** Yes, there is a provision in the portal to designate a member as alternate member secretary / vice chairperson

**Q 28. What are the documents to be uploaded for submitting EC application?**

**Ans.** Documents to be uploaded during submitting application is provided in the downloads section of Naitik portal. ([https://naitik.gov.in/DHR/resources/app\\_srv/DHR/global/pdf/downloads/Checklist.pdf](https://naitik.gov.in/DHR/resources/app_srv/DHR/global/pdf/downloads/Checklist.pdf))

**Q 29. What should be the essential components of the biodata/ Curriculum Vitae (CV)?**

**Ans.** Names, qualifications, organizational title, telephone number, fax number, e-mail and mailing address of the members of the ethics committee. The information shall also include member's specialty (primary, scientific or non-scientific), member's affiliation with institutions and patient group representation, if any. It is recommended to have a brief description on suitability of the members in the respective role.

**Q 30. What should be verified while self-reviewing the auto generated undertaking downloaded from Naitik portal while submitting application?**

**Ans.** Please ensure the following before moving on to uploading the checklist documents

1. The Affiliation of non-affiliate members are provided correctly.
2. Contact details provided are correct.
3. The address for Ethics Committee and Chairperson.
4. 50 % or more non affiliate member are present in the EC.
5. The qualification and eligibility of all members are according to ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Participants, 2017 (table 4.1).

**Q 31: What is the validity of provisional certificate?**

**Ans.** The provisional certificate issued is valid for a period of 2 years from the date of issue.

**Q 32: When will be the final certificate issued?**

**Ans.** The provisional certificate issued is valid for a period of 2 years from the date of issue. The final certificate will be issued accordingly within the time frame.

**Q 33: How can I verify, if the Ethics Committees is registered with NECRBHR, DHR?**

**Ans.** List of provisionally registered EC can be found on [https://naitik.gov.in/DHR/app\\_srv/soam/reports\\_pc\\_issued.jsp](https://naitik.gov.in/DHR/app_srv/soam/reports_pc_issued.jsp)

**Q 34: Where can I refer for details regarding the composition, affiliations, qualifications, member specific roles and responsibilities?**

**Ans:** Table 4.1 in ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Participants, 2017 can be referred for details ([https://naitik.gov.in/DHR/resources/app\\_srv/DHR/global/pdf/ICMR\\_National\\_Ethical\\_Guidelines2017.pdf](https://naitik.gov.in/DHR/resources/app_srv/DHR/global/pdf/ICMR_National_Ethical_Guidelines2017.pdf))

**Q 35: How to get in touch with the Office if in case of further queries?**

**Ans.** You may email at [necrbhr-dhr\[at\]gov\[dot\]in](mailto:necrbhr-dhr[at]gov[dot]in) or call at 011- 2373 6904 on all working days between 9.30 AM to 5.30 PM.