

Current regulatory requirements for conducting clinical trials in India
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Lecture – 10 B
EC Registration

Hello friends, hope you are doing well and enjoyed all the 9 lectures. The lecture 10 was this is a lecture 10B, it is a part Ethics Committee Registration.

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WHAT WILL WE LEARN IN LECTURE 10B?

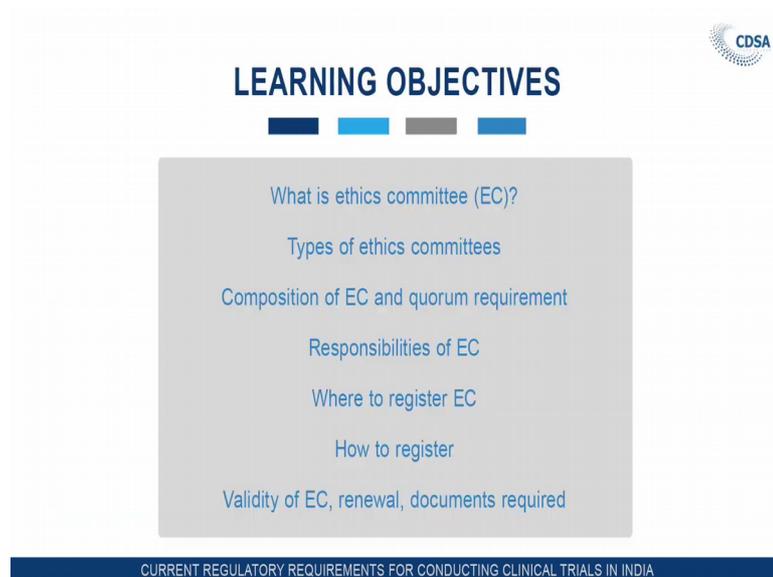
- EC registration: Is it mandatory?
- Which rules are applicable?
- What is the validity of EC Registration?
- How are Ethics Committees (ECs) registered in India?

- How to apply for EC registration?
- Can we apply online?
- What is SUGAM?
- How to apply for re- registration?

CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA

So, in this lecture, what will we learn, so we learn about ethics committee, what is ethics committee, how to apply for the ethics committee registration, then what would be its validity, then whether the registration is online or offline, then how to apply, which rules are applicable and whether really the ethics committee registration is mandatory or not?

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So, this is the outline or you can say the learning objective. We will see what is ethics committee, then the types of ethics committee, composition of ethics committee, its quorum requirement, then responsibility of ethics committee, where to register, how to register, validity? In short all about the ethics committee.

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So, let us start first with the what is ethics committee?

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The slide features a title 'WHAT IS ETHICS COMMITTEE (EC) & TYPES?' in bold blue text, with the CDSA logo in the top right corner. Below the title are four colored bars (dark blue, light blue, grey, and blue). The main content is in a light grey box with two paragraphs: 'Ethics committee is a committee comprising of scientific, non-scientific, medical, **non-medical** members including lay person, whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a clinical trial.' and 'This committee is responsible for reviewing and approving the protocol, the suitability of the investigators, facilities methods and adequacy of information to be used for obtaining and documenting informed consent of the study subject and adequacy of confidentiality safeguards.' Below this is a dark blue box with the text 'Types of ethics committees' and a light grey box with two bullet points: '■ Institutional ethics committee' and '■ Independent ethics committee'. At the bottom is a dark blue footer with the text 'CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA'.

Ethics committee is a committee comprising of scientific, non-scientific, medical, non-medical members including a lay person and the responsibility of this ethics committee is to ensure the protection of the rights, safety and well-being of human subject involved in clinical trial. And it shall be responsible for reviewing and approving the protocols that is a clinical trial protocol.

The suitability of the investigators involved in this study. Facilities methods and adequacy of information to be used for obtaining and documenting informed consent of the study subject and adequacy of confidentiality safeguards. So, the ethics committee primarily approve the protocol, but the final approval of the protocol is by the licensing authority, we have seen in early lecture that is the decision.

We consider two type of ethics committee that is independent and institutional. Institutional ethics committee, the committee which is attached with the hospital, we call it as an institution. And independent ethics committee which is not attached to the hospital; the functions are same for the both.

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The slide features the CDSA logo in the top right corner. The main title is 'COMPOSITION OF EC' in bold blue letters, centered at the top. Below the title are four colored bars: dark blue, light blue, grey, and dark blue. A light grey box contains the text: 'Ethics Committee shall consist of not less than seven members. For review of each protocol the quorum of ethics committee shall be at least five members.' Below this is a dark blue box with the text 'EC members to consist of:'. Underneath is a light grey box containing a bulleted list of five member categories. At the bottom of the slide is a dark blue bar with the text 'CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA'.

COMPOSITION OF EC

Ethics Committee shall consist of not less than seven members.
For review of each protocol the quorum of ethics committee shall be at least five members.

EC members to consist of:

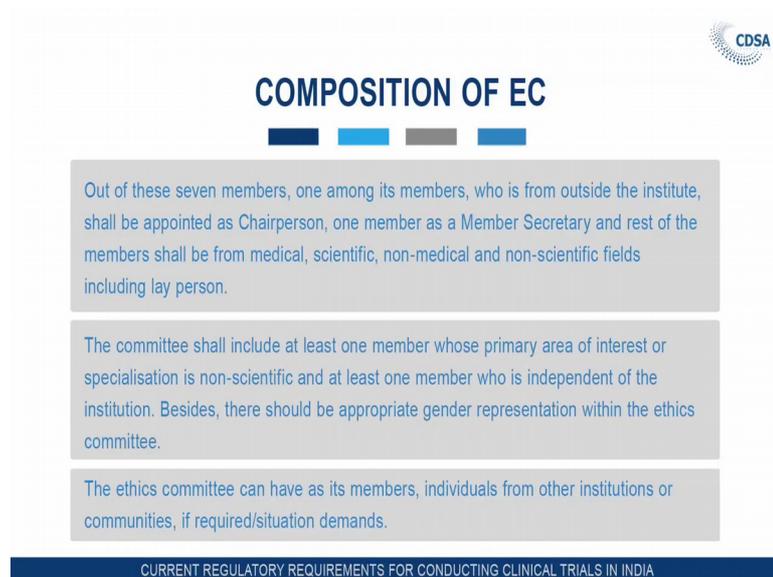
- Basic medical scientist (preferably one pharmacologist)
- Clinician
- Legal expert
- Social scientist/representative of non-governmental voluntary agency or philosopher/ethicist/theologian or a similar person/lay person from that community

CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA

Let us see some important considerations about the ethics committee. So, this ethics committee shall consist of not less than seven members. The maximum number has not been given here; ideally the maximum number should be avoided to avoid the chaos in the decision making process. Sometimes if more the number of the people, then it would be very difficult to reach at a certain consensus. For review of each protocol the quorum of ethics committee shall be at least five members.

So, if the five member which is mentioned below are present, then we can say the quorum is completed and decision can be made. So, this five members consists of basic medical scientists preferably one pharmacologist; one pharmacologist should be there, then clinician, then legal expert, social scientist or representative of non-governmental voluntary agency that is NGO or philosopher or ethicist or theologian or a similar person who can take care of this subjects. Then lay person from the community who will think non-scientifically, non-medically and who knows about the society and people.

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The slide features the CDSA logo in the top right corner. The main title is 'COMPOSITION OF EC' in bold blue letters, centered at the top. Below the title are four colored bars: dark blue, light blue, grey, and dark blue. The slide contains three text boxes with the following content:

Out of these seven members, one among its members, who is from outside the institute, shall be appointed as Chairperson, one member as a Member Secretary and rest of the members shall be from medical, scientific, non-medical and non-scientific fields including lay person.

The committee shall include at least one member whose primary area of interest or specialisation is non-scientific and at least one member who is independent of the institution. Besides, there should be appropriate gender representation within the ethics committee.

The ethics committee can have as its members, individuals from other institutions or communities, if required/situation demands.

At the bottom of the slide, a dark blue bar contains the text: CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA

Out of this seven members, one among its member, who is from outside the institute, shall be appointed as the chairman? The chairman should be from the outside the institution. If the chairman is from the same institution, then there may be a bias or there may be a difficulty to his subordinate to freely give their consent. So, it has been decided to keep it from the outside the institution.

One member as member secretary and rest of the member shall be from medical scientific, non-medical, non-scientific fields including one lay person. The committee shall include at least one member whose primary area of interest or specialization is a non-scientific and at least one member who is independent of the institution. Besides, there should be appropriate gender representation in ethics committee. The ethics committee can have as its member individuals from other institutions or communities if required. They can take the member from the other hospital or other institutions.

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The slide features the CDSA logo in the top right corner. The title 'COMPOSITION OF EC' is centered at the top, with four colored bars (dark blue, light blue, grey, dark blue) below it. Three grey text boxes are arranged vertically, each containing a requirement for ethics committee members. A dark blue footer bar at the bottom contains the text 'CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA'.

COMPOSITION OF EC

Members should be conversant with provisions clinical trails under this schedule - Good Clinical Practice guidelines for clinical trials in India and other regulatory requirements to safeguard the rights, safety and well being of the trial subjects.

The members representing medical scientist and clinicians should have attained a post graduate qualification and adequate experience in their respective fields and be aware of their role and responsibilities as committee members.

Based on the requirement of research area such as HIV, genetic disorder, etc., specific patient group may be represented in the ethics committee.

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Member should be whatever the members available they should be conversant with the provision of clinical trials under this schedule. They should be conversant with the good clinical practices, they should be having computer knowledge about clinical trials have to be conducted in India and other regulatory requirements, so that to safeguard the right safety and well being be of the trail subjects.

The members representing medical scientist and clinicians should have postgraduate qualification and adequate experience in the respective field and aware of this role and responsibilities as committee member. Those who are involved they should have the post graduate qualification and experience and they should be aware about the responsibilities. As for as possible based on the requirement of research areas such as HIV, genetic disorder, etcetera, specific patient group may be represented in ethics committee.

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The most important thing that there should be no conflict of interest. The members shall voluntarily withdraw from the ethics committee meeting while making a decision on an application which evokes a conflict of interest which may be indicated in writing to the chairperson they have to write to the chairperson, they have withdrawn. And this should be recorded in the minutes of the meeting why they have withdrawn.

All members shall sign a declaration on conflict of interest. So, prior joining this ethics committee or before sitting for the meeting, they have to sign a no conflict of interest format. Subject experts or other experts may be invited to the meetings for their advice but this subjects subject expert they do not have right for the voting.

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RESPONSIBILITIES OF EC

■ ■ ■ ■

It is the responsibility of the EC to **review and accord** its approval to a trial protocol to **safeguard the rights, safety and well being** of all trial subjects.

The EC should exercise **particular care** to protect the rights, safety and well being of all **vulnerable subjects** participating in the study, e.g., prisoners, armed forces personnel, students, unemployed or impoverished persons, ethnic minority groups, homeless, nomads, refugees, minor or others incapable of personally giving consent. Should have Standard Operating Procedure '**SOP**' to maintain a record of its proceedings.

EC should make, at appropriate intervals, an **ongoing review of the trials** for which they review the protocols **based on the periodic study progress reports** furnished by the investigators or **internal audit reports** furnished by the sponsor and/or by visiting the study sites.

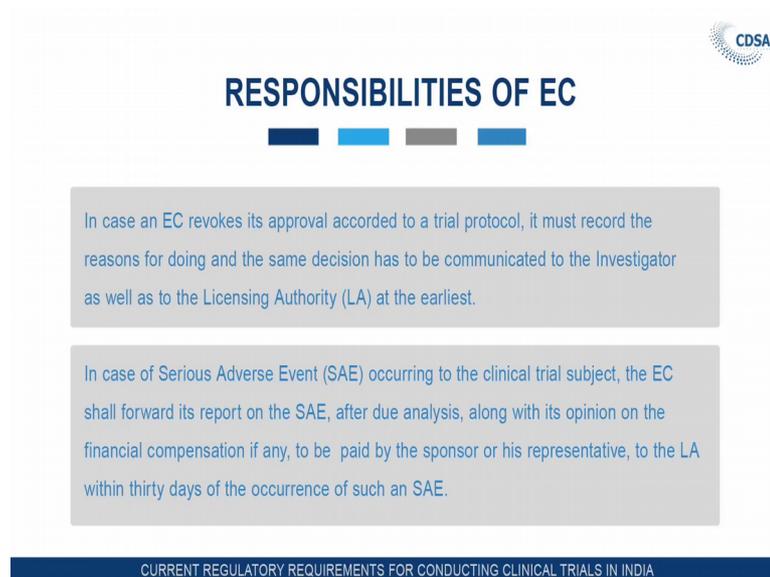
CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA

Now, let us see about the responsibility of this ethics committee. It is the first responsibility of the ethics committee to review and accord its approval to a trial protocol in order to safeguard the rights, safety and well being of all trial subjects. The ethics committee should exercise particular care to protect the rights, safety and well being of all vulnerable subjects.

Vulnerable subjects are those subjects who are not capable of giving their consent or the subject who may be unduly influenced by the other persons involved. So, for these subjects, there should be an SOP which would mention what precautionary measures have been taken and the record of all these measures taken should be maintained.

Ethics committee should make at appropriate intervals an ongoing review of trial for which they review the protocol. The protocol which they have reviewed they have to take a review of that trial and that may be based on the periodic safety progress report. The PI or the sponsor will submit the periodic progress report and based on that they can conduct ongoing review. They can conduct the internal audit also based on their previous audit or based on the information obtained from the sponsor.

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The slide features the CDSA logo in the top right corner. The main title is 'RESPONSIBILITIES OF EC' in bold blue text, centered at the top. Below the title are four colored bars: dark blue, light blue, grey, and dark blue. Two grey text boxes are positioned in the center, each containing a paragraph of text. At the bottom, a dark blue horizontal bar contains the text 'CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA' in white capital letters.

RESPONSIBILITIES OF EC

In case an EC revokes its approval accorded to a trial protocol, it must record the reasons for doing and the same decision has to be communicated to the Investigator as well as to the Licensing Authority (LA) at the earliest.

In case of Serious Adverse Event (SAE) occurring to the clinical trial subject, the EC shall forward its report on the SAE, after due analysis, along with its opinion on the financial compensation if any, to be paid by the sponsor or his representative, to the LA within thirty days of the occurrence of such an SAE.

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In case an ethics committee revoke its approval accorded to trial protocol, it must be recorded and the reason for doing so shall be communicated to the investigator and to the licensing authority. If after giving a approval, the ethics committee thinks that the approval should be revoked, then that should be immediately informed to the principal investigator who is involved in the study and also to the licensing authority.

In case of SAE occurring to the clinical trial subject, the ethics committee shall forward its report on the SAE, after due analysis along with its opinion on the financial compensation if any to be paid by the sponsor. So, if any SAE is occurred during the trial to the subjects then it is a responsibility of ethics committee that they should analyze whether this injury or SAE is related to the study drug or not related.

If it is related, then how much compensation they should the sponsor should provide. So, this detailed analysis and its opinion the ethics committee should forward to the licensing authority within 30 days of the occurring of the SAE. So, these are few of the things should be kept in mind.

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The slide features the CDSA logo in the top right corner. The title 'BASICS OF ETHICS COMMITTEE' is centered at the top. Below the title are four colored bars (dark blue, light blue, grey, dark blue). The main content consists of three grey boxes, each with a blue header and a grey body. The first box asks 'Where to register?' and answers 'Ethics Committee to be registered with CDSCO, FDA Bhavan, New Delhi.' The second box asks 'Under which D&C rule?' and answers 'Rule 122DD of Drugs & Cosmetics Rules mandate - prior registration of ECs with CDSCO.' The third box asks 'What is the validity of EC registration?' and answers '3 years (from the date of issue, unless suspended or cancelled)'. At the bottom, a dark blue bar contains the text 'CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA'.

Question	Answer
Where to register?	Ethics Committee to be registered with CDSCO, FDA Bhavan, New Delhi.
Under which D&C rule?	Rule 122DD of Drugs & Cosmetics Rules mandate - prior registration of ECs with CDSCO.
What is the validity of EC registration?	3 years (from the date of issue, unless suspended or cancelled).

Now, let us see where to register and why to register the ethics committee. So, where to register, we have seen the Licensing Authority and the Central Drug Authority that is a CDSCO, the headquarter of which is at headquarter New Delhi. Ethics committee registration is there only and it is available online. We will see in detail the online process in our subsequent slides.

So, whether it is mandatory or not under which rule? Rule 122 D of drug and cosmetic rules mandate prior registration of ethics committee with a CDSCO. When what is the validity of this once registered ethics committee? It is a 3 years from the date of issue of ethics committee registration certificate, unless suspended or cancelled.

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The slide features the CDSA logo in the top right corner. The main title is 'WHY IS EC REGISTRATION MANDATORY?' in bold blue text, centered at the top. Below the title are four colored bars: dark blue, light blue, grey, and medium blue. The slide contains three text boxes with the following content:

- M/o H&FW Government of India published GSR 72 (E) dated February 8, 2013, Rule 122 DD.
- 'No ethics committee shall review and accord its approval to a clinical trial protocol without prior registration with the Licensing Authority as defined in clause (b) of Rule 21', i.e. DCG(I).
- Application for EC registration as specified in the Appendix VIII of Schedule Y.

At the bottom of the slide, a dark blue bar contains the text 'CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA' in white capital letters.

Now, let us see why to register? So, why to register the ethics committee? Government of India, Ministry of Health and Family Welfare published a gadget notification 72 dated 8th February 2013 rule 122 DD. As per these rules and gadget notification no ethics committee shall review and accord its approval to a clinical trial protocol without prior registration with the Licensing Authority as defined in clause b of rule 21. We have seen this clause b of rule 21 that is a central license approving authority we call it as a DCG I, also Drug Control General of India.

So, this is a very clear from this rule that no ethics committee shall review and accord its approval. If there is a violation, then there maybe a cancellation, suspension of the permission. So, as per this rule, everything ethics committee who is approving reviewing the protocol for clinical trial for the regulatory purposes, they shall have to register first with the CDSCO.

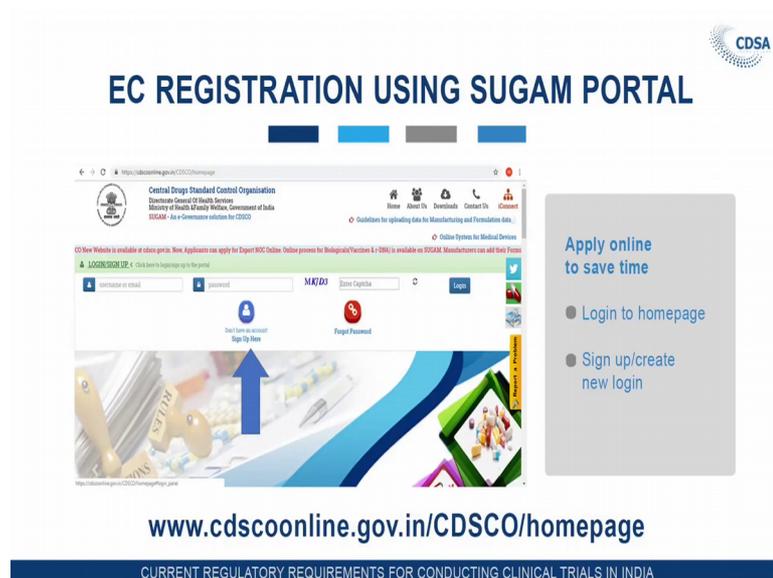
Application for ethics committee registration as specified in Appendix 8 of schedule Y; How to apply, what are the contents, what should be the composition that everything is given under the Appendix 8 of schedule Y.

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Now, let us see the ethics committee registration. So, SUGAM portal is available for the regulatory ethics committee registration.

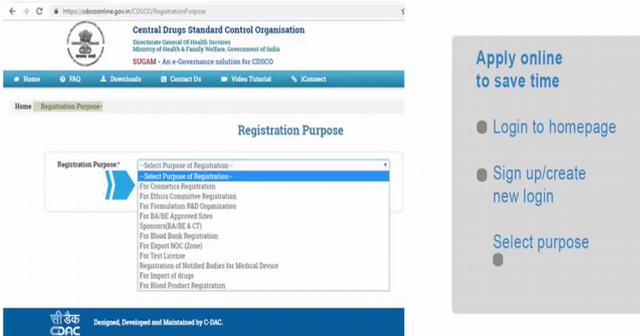
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So, first you have to go to the online that is it is available on our website that is cdsconline.gov.in. So, this page will open. You have to see this page. Here you have to create the username and password, then you will be logged in.

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EC REGISTRATION USING SUGAM PORTAL



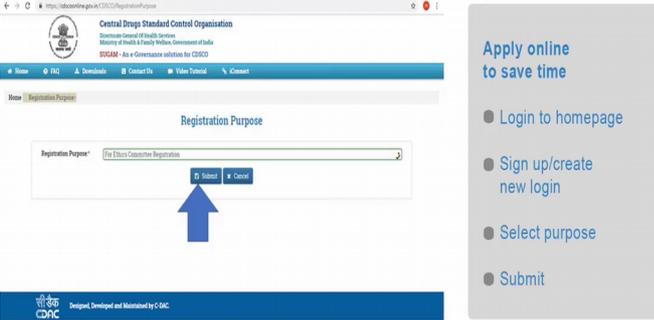
www.cdsconline.gov.in/CDSCO/homepage

CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA

After login, you have to select the purpose because we are dealing with the many of the other activities like a cosmetic registration, BA, BE approval. So, here you have to select for ethics committee registration.

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EC REGISTRATION USING SUGAM PORTAL



www.cdsconline.gov.in/CDSCO/homepage

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Then after selection of this, you have to submit that you are registering for the ethics committee. The registration purpose you have to give and then submit it.

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EC REGISTRATION USING SUGAM PORTAL

Central Drugs Standard Control Organization
Ministry of Health & Family Welfare, Government of India
SUGAM - An e-Governance solution for CDSCO

Applicant Registration

Note:
1. Authorized Signatory / Responsible person of the organization should fill the form.
2. All fields marked with asterisk (*) are mandatory. Only PDF documents with size not more than 10 MB are permitted.
3. **Registration Steps**
a. After submitting the Registration Form, Check Registered email for E-mail Verification & Submit ID proof (Authorized Person), Undertaking Formed by Government authority on the name of the Company and address). Address Proof Document is sent only to CDSCO office.
b. Registration will be approved by CDSCO only after evaluation of the submitted documents. Check your registered email id for all communications.
4. If the Undertaking PDF form not contains interactive fields, you can use the Fill & Sign tools to fill out the form. Save the form on your computer, and then open it directly in Acrobat Reader.
5. All the documents should be self attested by the person who signs on undertaking with stamp and seal of the company.

Applicant Details

Applicant Type*
User-Name*
Enter Corporate Email ID

[Apply online to save time](#)

- Fill in personal details

www.cdsconline.gov.in/CDSCO/UserRegistration

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Then again it is applicant registration, you have to give the details of applicant type and username.

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EC REGISTRATION USING SUGAM PORTAL

Central Drugs Standard Control Organization
Ministry of Health & Family Welfare, Government of India
SUGAM - An e-Governance solution for CDSCO

Applicant Details

Applicant Type*
User-Name*
Enter Corporate Email ID
Password*
Confirm Password*
Name*
Mobile Number*
Gender*
Nationality*
ID Proof Details*
Undertaking*
Designation*

[Apply online to save time](#)

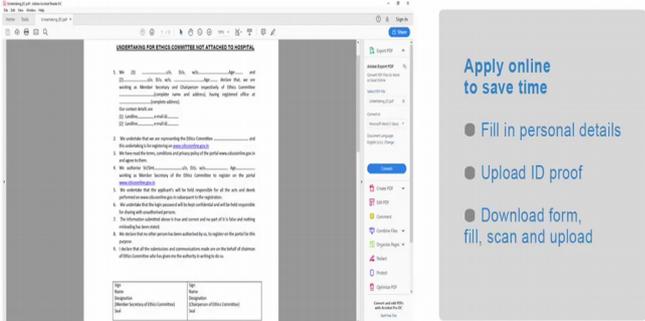
- Fill in personal details
- Upload ID proof

www.cdsconline.gov.in/CDSCO/UserRegistration

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And other details like mobile number, then nationality, ID proof, undertaking all these things you have to fill in this form online.

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The image shows a screenshot of the CDSO portal interface. The main content area displays a form titled "UNDERTAKING FOR ETHICS COMMITTEE NOT ATTACHED TO HOSPITAL". The form contains several numbered sections for providing details about the ethics committee and the applicant. To the right of the form, there is a sidebar with navigation options and a list of actions: "Apply online to save time", "Fill in personal details", "Upload ID proof", and "Download form, fill, scan and upload". The CDSO logo is visible in the top right corner.

EC REGISTRATION USING SUGAM PORTAL

www.cdscoonline.gov.in/CDSCO/UserRegistration

CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA

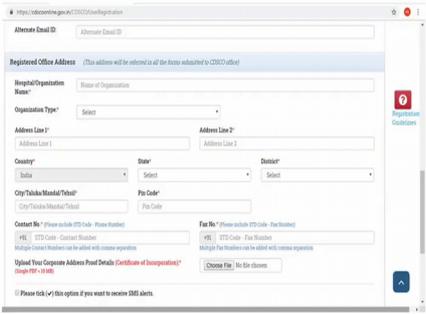
Then next you have to upload the undertaking. So, there are two types of undertaking given here. Undertaking for the ethics committee not attached to hospital. For those ethics committee which are not attached to the hospital, we call it as a independent ethics committee. So, in this undertaking, you have to give the details about the ethics committee.

So, what is the ethics committee, who is the responsible person, then who would be the member secretary? So everything you have to fill and sign this. Then next is undertaking for ethics committee attached to the hospital; similarly for not attached to the hospital and it is further attached to the hospital you have to give the undertaking.

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EC REGISTRATION USING SUGAM PORTAL



Apply online to save time

- Fill in personal details
- Upload ID proof
- Download form, fill, scan and upload
- Upload corporate address

www.cdsconline.gov.in/CDSCO/UserRegistration

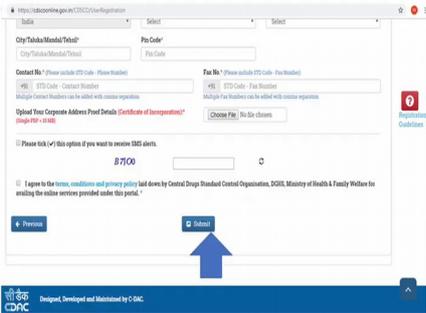
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Then the details about the registered office. If it is attached to the hospital, then the details of the hospital, organization name, organization type, then address, first address, second address, then country, where it is whether it is in India or outside the India. So detailed address, the contact number, fax number in case of emergency if regulator want to know or if they would like to convey the SAE and other things, then everything should be there. So, this form has to be filled up by the applicant.

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EC REGISTRATION USING SUGAM PORTAL



Apply online to save time

- Fill in contact number
- Enter captcha
- Tick on terms & conditions
- Submit form

www.cdsconline.gov.in/CDSCO/UserRegistration

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So, this is about the same thing what we have mentioned contact number and the details, you have to tick mark it.

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The image shows a screenshot of the CDSCO website's Frequently Asked Questions (FAQ) page. The page title is "EC REGISTRATION USING SUGAM PORTAL". The URL is www.cdscoonline.gov.in/CDSCO/FAQ. The page lists several questions related to registration, login, and application submission. A text box on the right side of the screenshot states: "One can also refer to the FAQ page for clarity on basic questions and process flow queries".

EC REGISTRATION USING SUGAM PORTAL

Frequently Asked Questions

- Who can register on CDSCO online portal?
- How do I get my login credentials on CDSCO online portal?
- Can I not able to receive any confirmation mail from CDSCO Online Portal?
- Can I not able to use SMS service of CDSCO Online Portal?
- How do I submit a form to any division of CDSCO?
- Can I not able to find my applications which I have saved earlier?
- Can I not able to find my submitted applications?
- How do I get Endorsement/Re-registration on the EC issued to me earlier by CDSCO office?
- How do I get Endorsement/Review on the Import License issued to me earlier by CDSCO office?
- How do I view the details of historical data I have submitted online in CDSCO portal?

www.cdscoonline.gov.in/CDSCO/FAQ

One can also refer to the FAQ page for clarity on basic questions and process flow queries

CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA

In our site we have given some question and answers also for the convenience of the applicants if they are having some doubts about who can register, then how do I get my login credential on CDSCO online portal. If they are not able to receive any confirmation mail from CDSCO or how to submit a form to any division of the CDSCO, such type of questionnaires are given under the frequently asked question. So, this is about the registration. And once you have registered the ethics committee, then it is valid for 3 years.

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The image shows a screenshot of the Central Drugs Standard Control Organisation (CDSO) online portal. The page title is "EC REGISTRATION USING SUGAM PORTAL". The URL is www.cdscoonline.gov.in/CDSCO/homepage. The page features a navigation menu with options like Home, About Us, Downloads, and Contact Us. A prominent blue arrow points to the "Sign Up/Log In" button. A sidebar on the right contains the text "Apply online to save time" and two radio button options: "Login to homepage" and "Sign up/create new login". The footer of the slide reads "CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA".

The checklist and documents required we will see in the next slide. So, after the expiry of this registration certificate whether we can re-register or it would be a fresh that we will see.

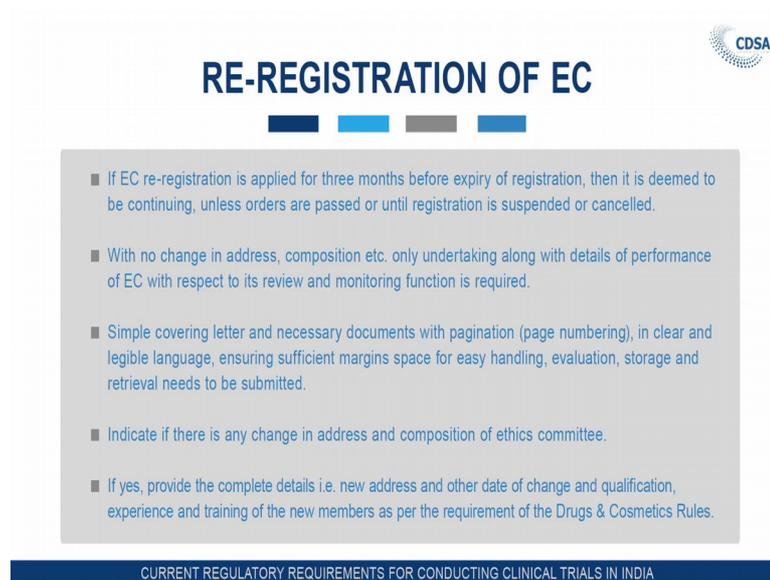
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The image shows a slide with a dark blue background. On the left, there is a circular icon containing the text "L10B". To the right of the icon, the text "RE-REGISTRATION OF EC" is displayed in white. The slide is framed by a decorative border of vertical bars in shades of blue and grey.

So, the re-registration of ethics committee.

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RE-REGISTRATION OF EC

- If EC re-registration is applied for three months before expiry of registration, then it is deemed to be continuing, unless orders are passed or until registration is suspended or cancelled.
- With no change in address, composition etc. only undertaking along with details of performance of EC with respect to its review and monitoring function is required.
- Simple covering letter and necessary documents with pagination (page numbering), in clear and legible language, ensuring sufficient margins space for easy handling, evaluation, storage and retrieval needs to be submitted.
- Indicate if there is any change in address and composition of ethics committee.
- If yes, provide the complete details i.e. new address and other date of change and qualification, experience and training of the new members as per the requirement of the Drugs & Cosmetics Rules.

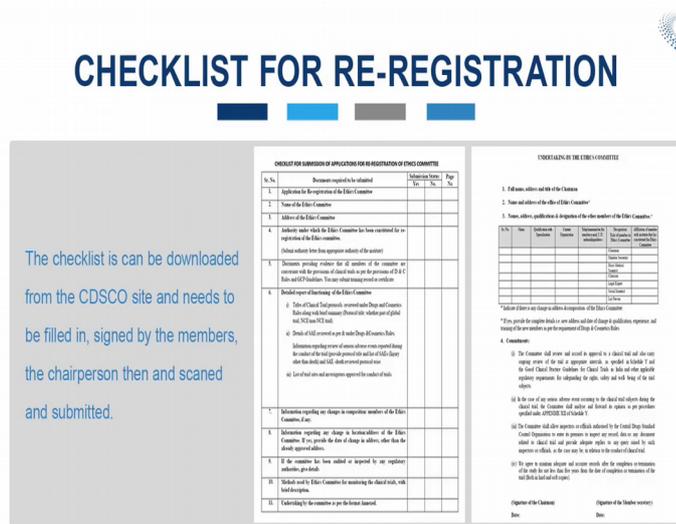
CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA

If ethics committee registration is applied for 3 months before expiry of registration, then it is deemed to be continue, unless orders are passed or until registration is suspended or cancelled. So, before the expiry of this already given ethics committee registration, if you apply before 3 months of the expiry and if it get delayed from licensing authority that giving the re-registration, then it is deemed to be continued. Whatever the registration certificate you are having earlier that deemed to be continued, provided that it should not be cancelled or suspended.

With no change in address composition etcetera only undertaking along with details of performance of ethic committee with respect to its review and monitoring function is required. Single covering letter and necessary documents with pagination, all the documents with clearly pagination, in clear and legible language, ensuring sufficient marginal space for any handling, evaluation, storage that has to be given.

Indicate that there is any change in address and composition, if there is a change in the address or if there is a change in any ethics committee composition while re registering the ethics committee that have to be mentioned. If there is a change, then you have to provide the details that is a new address and other date of the change, the qualification of the members who are newly recruited, experience, tenure of this new member as per the requirement given under the schedule.

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CHECKLIST FOR RE-REGISTRATION

CHECKLIST FOR SUBMISSION OF APPLICATIONS FOR RE-REGISTRATION OF ETHICS COMMITTEE

S. No.	Documents required to be submitted	Submission Status	Page No.
1	2	3	4
1	Application for Re-registration of the Ethics Committee		
2	Name of the Ethics Committee		
3	Address of the Ethics Committee		
4	Whether the Ethics Committee has been constituted for re-registration of the Ethics Committee. (Date when the Ethics Committee was constituted)		
5	Documentary evidence for the appointment of the members of the committee as per the provisions of CDSCO Act & Rules and ICHG Guidelines. The document should contain the following: a. Details of Chairperson, members and Deputy Chairperson. b. Details of Chairperson and Deputy Chairperson. c. Details of Chairperson and Deputy Chairperson. d. Details of Chairperson and Deputy Chairperson. e. Details of Chairperson and Deputy Chairperson. f. Details of Chairperson and Deputy Chairperson. g. Details of Chairperson and Deputy Chairperson. h. Details of Chairperson and Deputy Chairperson. i. Details of Chairperson and Deputy Chairperson. j. Details of Chairperson and Deputy Chairperson. k. Details of Chairperson and Deputy Chairperson. l. Details of Chairperson and Deputy Chairperson. m. Details of Chairperson and Deputy Chairperson. n. Details of Chairperson and Deputy Chairperson. o. Details of Chairperson and Deputy Chairperson. p. Details of Chairperson and Deputy Chairperson. q. Details of Chairperson and Deputy Chairperson. r. Details of Chairperson and Deputy Chairperson. s. Details of Chairperson and Deputy Chairperson. t. Details of Chairperson and Deputy Chairperson. u. Details of Chairperson and Deputy Chairperson. v. Details of Chairperson and Deputy Chairperson. w. Details of Chairperson and Deputy Chairperson. x. Details of Chairperson and Deputy Chairperson. y. Details of Chairperson and Deputy Chairperson. z. Details of Chairperson and Deputy Chairperson.		
6	Minutes regarding the change in composition members of the Ethics Committee.		
7	Minutes regarding the change in the address of the Ethics Committee. If the address of the Ethics Committee is the same as the address of the Ethics Committee, the details of the change in the address should be provided.		
8	If the committee has been re-constituted or re-registered, the details of the re-constitution or re-registration should be provided.		
9	Undertaking by the committee to provide the required documents.		

THE ETHICS COMMITTEE

1. Full name and address of the Chairperson

2. Name and address of the Ethics Committee

3. Name and address of the members of the Ethics Committee

S. No.	Name	Address	Signature	Date
1				
2				
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Signature of the Chairperson: _____
Date: _____

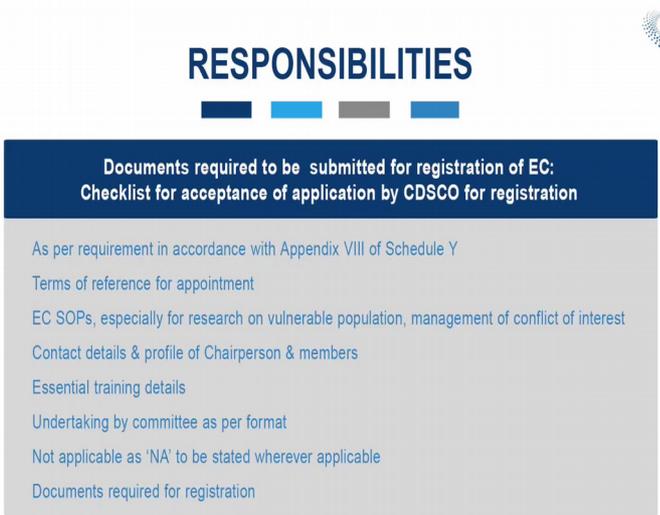
Signature of the Member(s): _____
Date: _____

The checklist can be downloaded from the CDSCO site and needs to be filled in, signed by the members, the chairperson then scanned and submitted.

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In continuation, this checklist has been provided on our website. So, this is the checklist for submission of application for re-registration of ethics committee. So, in this checklist, it is given application for re-registration of ethics committee, name of the ethics committee, address of the ethics committee. So, all this detail you have to fill whether yes or no, whether you have given or not given and also have to mention the page number to verify the regulators. Undertaking by the ethics committee this undertaking has to be provided by the ethics committee while re-registering.

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RESPONSIBILITIES

Documents required to be submitted for registration of EC: Checklist for acceptance of application by CDSCO for registration

- As per requirement in accordance with Appendix VIII of Schedule Y
- Terms of reference for appointment
- EC SOPs, especially for research on vulnerable population, management of conflict of interest
- Contact details & profile of Chairperson & members
- Essential training details
- Undertaking by committee as per format
- Not applicable as 'NA' to be stated wherever applicable
- Documents required for registration

CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA

Now, let us see the documents required to be submitted for registration of ethics committee. The checklist for acceptance of application by CDSCO for registration. So, once your the application is there, the CDSCO will verify whether the documents are there or not. So, checklist has been provided. As per requirement in accordance with Appendix 8 of schedule Y. Terms of reference for the appointment that has to be given on which terms the committee member has been recruited.

Then ethics committee SOP, especially for research on vulnerable population. We have mentioned earlier also the ethics committee and the sponsors side, they should maintain a separate SOP for the vulnerable population because they require the utmost care and their safety, right should be protected properly. Management of conflict of interest; no conflict of interest documents that also has to be submitted.

Contact detail and profile of chair person and the members. Chairperson is the important persons and other members also. So, the details about the chairperson and other members that has to be given here. Essential training details; we have seen that the member should be conversant with the schedule Y, then clinical practicing guidelines ICMR guidelines. So, they should undergo the training. And in this regard they should provide the training certificate that the members appointed are really conversant with the good clinical practice guidelines.

Undertaking by committee as per format, format we have seen earlier. And wherever there is a non applicability of this checklist or any item of this checklist they have to mention not applicable and the other documents required for the re-registration. So, this is about the ethics committee registrations. Now, let us challenge the mind with some questions for you. So, we will see one by one the questions and answers from you.

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RECAP

1 Is EC registration mandatory for ECs reviewing clinical trials?
Yes, under rule 122DD of Drugs & Cosmetic (Third Amendment) Rules, 2013.

2 Under which authority EC registration should be done?
Central Drugs Standard Control Organisation (CDSCO).

3 How long is the EC registration (CDSCO) valid?
Three years, from the date of registration, unless cancelled.

CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA

The first question for you, is ethics committee registration mandatory for reviewing of clinical trial? We have seen in the lectures. Yes, under rule 122 DD of Drug and Cosmetic Rules, 2013, ethics registration is mandatory. The next question, ready for the next question under which authority ethics committee registration should be done? We have seen this in many our lectures.

So, it is the Central Authority that is Central Drug Standard Control Organization, where you can register the ethics committee. Coming to the next question, question number 3, how long ethics committee registration be valid? It is 3 years, unless it is suspended or cancelled, it is valid for 3 years.

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SUMMARY

In lecture 10B (Part 2), we briefly learnt about:

- We have learnt why EC registration is mandatory
- We learnt about applicable i.e. Rules 122DD etc. Drugs & Cosmetics (Third Amendment) Rule
- Composition of EC
- Quorum required
- We understood the step-by-step procedure of how to register EC using SUGAM portal of CDSCO
- We also learnt how to re-register an EC

CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA

Let us summarize the lecture 10 that is part 2. So, in this lecture, we have learnt why ethics committee registration is mandatory, it is mandatory because Government of India and Ministry of Health and Family Welfare has published a notification and rule 122 DD according to which no ethics committee can review or record its approval, unless it is having a prior registration.

Then we learned about applicability of rule 122 D as I have mentioned. Then composition of ethics committee we have seen. Not less than 7 people should be there and to maintain the quorum, 5 person with the qualification and everything that we have seen.

Then we understood the step by step procedure of how to register ethics committee we have seen the SUGAM portal, its phases. They have to first applicant has to first register himself or herself, then all the credentials has to be given, then one step has to be followed as instructed on the SUGAM portal that we have seen. We have also seen the re-registration. After 3 years, if the registration date expired, then how to re-register that also we have seen. Fees we have not seen in all these lecture. So, for your kind information, there is no fee required till date for registration of this ethics committee. So, this is all about the lecture 10. Hope you understood it properly.

So, until the next lecture take care, thanks and bye bye.