Regulatory Approval Check list

Requirement	Applicable	Completed
Scientific Review	☐	☐
Ethics Approval	☐	☐
CTRI Registration	☐	☐
CDSCO Approval	☐	☐
HMSC Approval	☐	☐
Biosafety Approval	☐	☐
Radiation Safety	☐	☐
MTA	☐	☐
DTA	☐	☐
Clinical Trial Agreement	☐	☐

CTRI Registration

When is CTRI registration required?

CTRI is India's public clinical trial registry maintained by the Indian Council of Medical Research (ICMR). Registration is **prospective**, meaning it must be completed **before enrolment of the first participant**.

The following studies should be registered in CTRI:

- Clinical trials involving drugs, biologics, vaccines, or medical devices.
- Interventional studies involving surgery, procedures, behavioural, dietary, educational, rehabilitation, or lifestyle interventions.
- Bioavailability (BA) and Bioequivalence (BE) studies.
- Post-marketing clinical studies.
- Academic clinical trials, including postgraduate dissertations, where an intervention is evaluated.
- Multi-country clinical trials conducted in India, even if already registered in another international registry.

CTRI also accepts registration of observational studies, registries, and other clinical studies. Although registration may not always be mandated by law for every observational study, it is strongly encouraged to improve transparency and is often expected by ethics committees and biomedical journals. When there is uncertainty, the CTRI recommends: **"When in doubt, register."**

Studies that generally do not require CTRI registration

The following generally do not require CTRI registration unless they include a clinical intervention:

- Laboratory-based basic science research.
- Animal studies.
- In-vitro studies.
- Purely retrospective record review studies with no intervention.
- Systematic reviews and meta-analyses.
- Narrative reviews and bibliometric studies.

CTRI Checklist

Study Title

PI

Protocol Version

Ethics Approval Number

Funding Source

Primary Outcome

Secondary Outcome

Sample Size

Recruitment Sites

Expected Recruitment Start

Checklist

☐ Protocol uploaded

☐ Ethics approval attached

☐ Investigator details complete

☐ Funding declared

☐ Outcomes defined

☐ Trial registration completed

CDSCO Submission

Central Drugs Standard Control Organization (CDSCO)
When is CDSCO approval required?

CDSCO approval is required for **regulatory clinical trials** governed by the **New Drugs and Clinical Trials Rules, 2019**, particularly when the study involves regulated products. Depending on the study, approval from the Drugs Controller General of India (DCGI)/CDSCO is required before initiation.

Examples include:

- Clinical trials of a **new drug**, **investigational new drug (IND) or a new device**.
- Clinical trials evaluating a **new indication**, **new dosage**, **new route of administration**, or **new dosage form** of a drug when covered under the regulatory framework.
- Clinical investigations of **investigational or regulated medical devices** requiring CDSCO authorization.
- Bioavailability (BA) and Bioequivalence (BE) studies requiring regulatory approval.
- Certain post-marketing regulatory studies when specified by CDSCO.
- Global multicentre regulatory trials in which India participates, where CDSCO permission is required.

CDSCO Checklist

☐ Cover Letter

☐ Protocol

☐ Investigator Brochure

☐ Ethics Approval

☐ Insurance

☐ Compensation Plan

☐ Informed Consent

☐ CRF

☐ Investigator CV

☐ Financial Disclosure

☐ Other Regulatory Documents

HMSC Submission

Health Ministry's Screening Committee (HMSC)
When is HMSC clearance required?

The **Health Ministry's Screening Committee (HMSC)**, under the **Department of Health Research (DHR), Ministry of Health & Family Welfare**, reviews and grants clearance for **international collaborative health research** involving India. HMSC clearance is a mandatory Government of India requirement for eligible international collaborative health research proposals before they are undertaken.

HMSC clearance is generally required when a study involves:

- **International collaboration** with a foreign university, research institution, hospital, or investigator.
- **Foreign funding** (full or partial) for biomedical or health research.
- **Transfer of human biological materials** (e.g., blood, tissue, DNA, RNA, serum, plasma, microbiological isolates) outside India or receipt of such materials from abroad.
- **International multicentre studies** involving one or more Indian sites.
- **Data sharing** with foreign collaborators where the approved study protocol includes sharing of de-identified or analysed data.
- Collaborative research involving **human, animal, plant, or environmental health**, where it falls within the HMSC mandate.

Key Requirements

Before submission to HMSC, investigators should ensure that:

- Institutional Ethics Committee (IEC) approval has been obtained for each participating Indian site.
- Scientific review has been completed.
- A detailed protocol and study budget are available.
- Roles and responsibilities of Indian and foreign collaborators are clearly defined.
- Material Transfer Agreement (MTA), Data Sharing Agreement (DSA)/Data Transfer Agreement (DTA), and Intellectual Property (IP) arrangements are documented where applicable.
- The proposal is registered through the Government's **BioRRAP** portal and submitted through the HMSC portal as required.

Studies that generally do not require HMSC clearance

HMSC clearance is generally **not required** for:

- Research conducted entirely within India without foreign collaboration or foreign funding.
- Institutionally funded or Indian government-funded studies with no international partner.
- Routine observational or clinical research involving only Indian investigators and institutions.

- Studies that do not involve international transfer of biological materials or collaborative research with foreign institutions.

HMSC Checklist

☐ Collaboration Agreement

☐ Protocol

☐ Funding Details

☐ Foreign Collaborator Details

☐ Ethics Approval

☐ Data Sharing Plan

☐ Sample Transfer Details

☐ Government Permissions

Quick Guidance for Investigators

Study Type	IEC	CTRI	CDSCO	HMSC
Retrospective chart review	✓	Usually No	No	No
Observational cohort study	✓	Recommended	No	No
Investigator-initiated intervention (diet, exercise, behavioural)	✓	Yes	Usually No	No
Drug clinical trial (new drug/new indication requiring regulation)	✓	Yes	Yes	No*
Medical device clinical investigation	✓	Yes	Yes	No*
International collaborative observational study	✓	Recommended	No	Yes
International collaborative clinical trial	✓	Yes	Yes (if applicable)	Yes
Foreign-funded health research	✓	As applicable	As applicable	Yes

TEMPLATES

Material Transfer Agreement (MTA)

Sections

1. Parties
2. Purpose
3. Material Description
4. Ownership
5. Permitted Use
6. Restrictions
7. Confidentiality
8. Intellectual Property
9. Publications
10. Liability
11. Return/Destruction of Material
12. Governing Law
13. Signatures

Data Transfer Agreement (DTA)

Sections

- Parties
- Dataset Description
- Purpose
- Security Requirements
- Confidentiality
- Data Ownership
- Permitted Analysis
- Publication
- Data Destruction
- Signatures

Confidentiality Agreement (NDA)

Includes

- Confidential Information
- Obligations
- Exceptions
- Duration
- Intellectual Property
- Dispute Resolution

Investigator Declaration

I certify that:

☐ The information provided is accurate.

☐ The protocol is scientifically sound.

☐ Ethics approval will be obtained before recruitment.

☐ Regulatory approvals will be obtained where required.

☐ Participant safety will be protected.

☐ Conflicts of interest have been disclosed.

☐ Institutional policies will be followed.

PI Signature

Date

Conflict of Interest Declaration

Investigator

Project

Do you have any:

Financial Interest?

☐ Yes

☐ No

Consultancy?

☐ Yes

☐ No

Equity?

☐ Yes

☐ No

Honoraria?

☐ Yes

☐ No

Family Interest?

☐ Yes

☐ No

Other Relationship?

☐ Yes

☐ No

Declaration

Signature