GUIDANCE DOCUMENTS FOR REGULATORY SUBMISSIONS

In an effort to help stakeholders get over the regulatory complexities involved in their interactions with the Health Authorities, ministries or regulators, Indian Society for Clinical Research (ISCR) has attempted to provide a gist of the various process documents that are required for submission in the various categories of trials and what needs to be done / submitted, in a simple, easy to understand format.

DISCLAIMER

For document see below

Clinical Trial For Registering A New Drug In India

(Drug Manufactured In India)

Submission of IND (Investigational New Drug Application) with Clinical Trial (CT) Protocol (For list of the documents to be submitted – click here)

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Permission to conduct Clinical Trial (CT)

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Initiation of Clinical Trials

Clinical Trial For Registering A New Drug In India

(Drug Manufactured Outside India)

Submission of IND (Investigational New Drug Application) with Clinical Trial (CT) Protocol & Test Import Licence application – (For list of the Documents to be submitted - click here)

CT Requirements.doc

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Permission to conduct Clinical Trial (CT) + Test Import Licence for import of reference standards & CT Supplies

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Permission from DGFT* (Export of Human Biological Samples outside India for test and analysis). (For list of the documents to be submitted – click here

List of documents for DGFT application

Import of Clinical Trial Samples

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Licence from Jt. DGFT* (Export of Human Biological Samples outside India for test and analysis). (For list of the documents to be submitted – click here

list of documents for JT. DGFT application.

Release Certificate from CDL/CDTL only if requested by Regulatory Authorities. (For list of the items to be submitted – click here

list of items for CDL & CDTL application.do

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Initiation of Clinical Trials

**Note: Permission / Licence from DGFT / Jt. DGFT is not required for testing of human biological samples within India.*

Clinical Trial For A New Drug Already Registered In India