



Icahn
School of
Medicine at
Mount
Sinai

Conduits
The Institutes for Translational Sciences

DATE

Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
5901-B Ammendale Road
Beltsville, MD 20705-1266

Request for Single Patient IND for Compassionate Use

Drug name

Enclosed is an IND application for the compassionate use of DRUG in patient initials, a XX year old man/woman with a preceding history of XXXXX.

Pharmaceutical company name has agreed to provide drug at no charge to the subject or the subject's insurance.

No study drug treatment will be initiated prior to IRB approval. The IRB approval letter and approved consent will be sent to the FDA once obtained.

If you have any questions, please direct them to me as the sponsor-investigator of this IND application at (212) XXX-XXXX.

Please find three copies (1 original and 2 photocopies) of:

- FDA Form 1571
- Brief Clinical History
- Proposed Treatment Plan including the dose, route, planned duration, monitoring procedures and modifications (e.g. dose reduction or treatment delay) for toxicity.
- FDA Form 1572
- Letter of Cross Reference from the XXXXXX (the drug manufacturer)

Sincerely,

Name
Address
Email address
Telephone number
Fax number