Icahn School of Medicine at Mount Sinai

Conduits
The Institutes for Translational Sciences

IND Withdrawal or Discontinuation Notice[1]--Investigator-Sponsor Responsibilities

At any time, the Investigator-Sponsor may withdraw an IND without prejudice.

1. Notify the FDA, all participating study site Principal Investigators, and all reviewing Institutional Review Boards (IRBs).
2. Terminate all clinical studies being conducted under the IND.
3. Return all stocks of the investigational drug to the Investigator-Sponsor of the IND application or otherwise dispose of it in accordance with the procedures specified by the Investigator-Sponsor.
4. If an IND is withdrawn because of safety reasons, the Investigator-Sponsor should promptly notify the FDA, all participating study site Principal Investigators, and all reviewing IRBs. Include a description of the specific safety issue(s) leading to the decision to withdraw the IND.
5. Contact Angela Lee at angela.lee@mssm.edu to update the ClinicalTrials.gov listing.
6. What to include in the report:
    a. IND or IDE number
    b. Investigational product (IP) name
    c. Indications for use
    d. Brief summary of study progress
    e. Number of subjects enrolled, dropped, completed; when the first subject was screened and enrolled
    f. The last follow-up for any study subject
    g. Amount of investigational product received, used, and the final disposition of unused IP
    h. Brief summary of results and conclusions
    i. Summary of adverse drug/device experiences
    j. Description of any deviations from investigational plan
    k. Reprints of publications by the investigator in relation to the study
7. What to send to the FDA
    a. Send original and 2 copies to FDA; keep a copy for the file
    b. Cover letter: Request for Termination of the IND at the top
    c. Include the reason(s) for termination
    d. Form FDA 1571 (needed for all correspondence to the FDA)—be sure to put the correct serial # on the form
    e. Any document pertinent to the IND that was not previously sent in (i.e. approval letters, approved consents/protocols; approval documents from external sites; DSMB reports, if applicable)

[1] 21 CFR Sec. 312.38