

Rule 2

Complete, Sign and Submit to Sponsor FDA Form 1572

For IND studies in the USA investigators should complete FDA Form 1572 and give this to the trial sponsor who will include it in the IND application (21 CFR Part 312.53).

The form asks for information about the investigator:

- sub-investigators
- all clinical laboratory facilities to be used
- the Institutional Review Board to be used to review study
- all of the proposed study sites.

By signing the form the investigator agrees to 9 listed commitments.

The image shows the top portion of the FDA Form 1572, titled 'STATEMENT OF INVESTIGATOR'. The header includes the text 'DEPARTMENT OF HEALTH AND HUMAN SERVICES' and 'FDA FORM 1572 (REV. 11-15-83)'. Below the header, there are several sections with labels such as 'NAME OF INVESTIGATOR', 'ADDRESS', 'CITY', 'STATE', 'ZIP', 'PHONE', 'FACILITY', 'SUBJECT', 'INDICATION', 'DOSAGE', 'ROUTE', 'FREQUENCY', 'DURATION', 'SCHEDULE', 'START DATE', 'STOP DATE', 'STATUS', 'SPONSOR', 'INDICATION', 'DOSAGE', 'ROUTE', 'FREQUENCY', 'DURATION', 'SCHEDULE', 'START DATE', 'STOP DATE', 'STATUS', 'SPONSOR'. The form is mostly blank, with only the header and some labels visible.

The image shows the bottom portion of the FDA Form 1572, titled 'STATEMENT OF INVESTIGATOR'. This section contains the 'COMMITMENTS' of the investigator. It lists nine numbered commitments that the investigator agrees to by signing the form. The commitments include: 1. Compliance with FDA regulations, 2. Compliance with local, state, and federal laws, 3. Compliance with the sponsor's protocol, 4. Compliance with the sponsor's instructions, 5. Compliance with the sponsor's schedule, 6. Compliance with the sponsor's budget, 7. Compliance with the sponsor's personnel, 8. Compliance with the sponsor's facilities, and 9. Compliance with the sponsor's other requirements. The form is mostly blank, with only the commitments section visible.

IND = Investigational New Drug Application – this is filed with the FDA by the sponsor who needs IND approval before starting research on unlicensed medicines.