



Who's Who on the 1572?

What, When, Where, Why...and How

Dispelling MYTHS
And
Solving MYSTERIES

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WHO???

An agreement between the **investigator** and the **sponsor**

- *Not the FDA.* The sponsor is required to collect the 1572 from each investigator but it is not required to be submitted to the agency.
- *Not required to be a physician* however must be qualified by training and experience. If not, a qualified physician should be listed as a sub-investigator.

WHAT???

The 1572 provides critical site information to the sponsor as well assurance that the investigator will comply with FDA regulations for the conduct of the study.

WHEN???

- *After* the Investigator has read the protocol and IB
- *Before* the Investigator's participation in the trial.
- *Updated* when 1) when a new protocol is added to the IND, and 2) when a new Investigator is added to the study
- The sponsor will typically require a new 1572 any time a change is made to *any of the boxes*.

WHERE???

In the Site File Notebook (aka Investigator Regulatory Binder)

Typically just in front of the CV, training, licensure, and financial disclosures for each individual listed in Box 1 and Box 6.

NOTE: in the case of an FDA audit, you may be asked what were the changes and why. For this reason it may be a good idea to keep a log of each version of your 1572 referring to the version date, date signed, and reason for revision.

WHY???

- Provides *information* about the investigator's qualifications
- Informs Investigator of his/her *obligations*:
 - *To conduct the study in accordance to the protocol*
 - *To personally conduct or supervise the study*
 - *To inform subject of investigational purpose and utilize proper informed consent procedures*
 - *To report adverse events per requirements*
 - *To read the Investigator's brochure and understand the risks and side effects*
 - *To ensure study staff are informed and abide by the above commitments*
 - *To maintain records and make them available as necessary*
 - *To ensure IRB oversight*

HOW???

Per *FDA*: typed or hand-written; signed by hand or acceptable electronic method

Per most *SPONSORS*: typed, printed double-sided (with additional pages now printing too), and hand signed by the PI.

Typically sponsors want to collect the original and leave a copy in the regulatory binder.

On occasion a sponsor will request that two “originals” are signed; I routinely dismiss that request. Originals, by definition, can only be *one*.

HOW???

Box 1: NAME AND ADDRESS OF INVESTIGATOR

- Full legal name of the investigator including titles, degrees, and professional qualifications
- The address where the investigator can be reached by mail or in person
 - Typically the business mailing address (as opposed to the physical location in some instances)
 - Should match the address on the Investigator's CV; if not, document difference on a Site Affiliation Form or a Note to File

Box 2: EDUCATION, TRAINING, EXPERIENCE, etc.

Most always checked as CURRICULUM VITAE

FDA Facts: contrary to sponsor/CRO assertions, CVs do *not need to be updated* during the study nor do they need to be *signed and dated!*

HOW???

Box 3: NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATIONS WILL BE CONDUCTED.

- The *physical address* where the study will be conducted
Once explained as, “If the FDA, or a patient, wanted to use Google maps to find you, what address would they use?” It is *not necessary* for both the mailing address and the physical address to appear on CVs.
- The *address* to where investigational product will be shipped

HOW???

Box 4: NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY

- The address of all labs or testing facilities contributing to or supporting the study (blood diagnostics, imaging, etc.)

Box 5: NAME AND ADDRESS OF THE IRB RESPONSIBLE FOR REVIEW AND APPROVAL

- Local and/or Central Institutional Review Board (Site or WIRB, Copernicus, etc.)

HOW???

Box 6: NAMES OF THE SUBINVESTIGATORS WHO WILL BE ASSISTING THE INVESTIGATOR IN THE CONDUCT OF THE INVESTIGATIONS

Those who will assist the investigator and make *A DIRECT AND SIGNIFICANT CONTRIBUTION TO THE DATA*: any individual DIRECTLY involved in protocol procedures and/or collection of data

YES! ... Ancillary clinicians performing assessments per protocol, especially for inclusion/exclusion criteria i.e. an internist performing a physical, dermatologist, etc.

YES! ... A research coordinator (or administrator) who recruits, enrolls, performs visits per protocol, and collects and/or records data

NO! ... hospital staff (nurses, residents, fellows) who provide care but do not contribute to the research; pharmacists who prepare or account for IP.

HOW???

Box 6: NAMES OF THE SUBINVESTIGATORS WHO WILL BE ASSISTING THE INVESTIGATOR IN THE CONDUCT OF THE INVESTIGATIONS

CVs? No, per the FDA – however most sponsors will still collect them

Financial Disclosures? Yes, for all individuals on the 1572

*****DO YOU HAVE AN SOP?*****

This is an investigator form, signed by the PI who is ultimately responsible for the content.

PDMDP research staff who are listed on the Delegation of Authority log must be listed here with the exception of the pharmacist who only receives (does not prepare) investigational product.

HOW???

Box 7: NAME AND CODE NUMBER, IF ANY, OF THE PROTOCOL(S) IN THE IND FOR THE STUDY(IES) TO BE CONDUCTED BY THE INVESTIGATOR

{Protocol Number} {Full Title} {IND number}

Box 8: CLINICAL PROTOCOL INFORMATION (as appropriate)

Box 9: COMMITMENTS – does your PI understand what he/she is signing???

Box 10 and 11: Signature and Date