Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs

Frequently Asked Questions – Statement of Investigator (Form FDA 1572)

U.S. Department of Health and Human Services
Food and Drug Administration
Office of Good Clinical Practice
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

May 2010
Procedural

Contains Nonbinding Recommendations

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This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

This guidance is intended to assist sponsors, clinical investigators, and institutional review boards (IRBs) involved in clinical investigations of investigational drugs and biologics. This guidance applies to clinical investigations conducted under 21 CFR Part 312 (Investigational New Drug Applications or IND regulations). It describes how to complete the Statement of Investigator form (Form FDA 1572).

The Food and Drug Administration (FDA or agency) has received a number of questions about Form FDA 1572. The most frequently asked questions are answered below. If you do not see your question answered here, you may submit it to gcp.questions@fda.hhs.gov or druginfo@fda.hhs.gov.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

I. GENERAL

1. What is the Statement of Investigator, Form FDA 1572?

The Statement of Investigator, Form FDA 1572 (1572), is an agreement signed by the investigator to provide certain information to the sponsor and assure that he/she will comply with FDA regulations related to the conduct of a clinical investigation of an

[1] This guidance document was developed by the Office of Good Clinical Practice in cooperation with the Agency's Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research.

investigational drug or biologic. The most recent version of the 1572 is available online at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM074728.pdf.

2. Why does this form need to be completed by an investigator?

The 1572 has two purposes: 1) to provide the sponsor with information about the investigator's qualifications and the clinical site that will enable the sponsor to establish and document that the investigator is qualified and the site is an appropriate location at which to conduct the clinical investigation, and 2) to inform the investigator of his/her obligations and obtain the investigator's commitment to follow pertinent FDA regulations. Investigators should complete the form as accurately as they can. Investigators should be aware that making a willfully false statement is a criminal offense under 18 U.S.C. 1001. Further, submission of a deliberately false statement to the sponsor or to the agency can be taken into consideration in a disqualification proceeding.

3. When must this form be completed and signed by an investigator?

Whenever a sponsor selects a new investigator to participate in a clinical investigation that is being conducted under an investigational new drug application (IND), the sponsor must obtain a completed and signed 1572 before permitting the investigator to begin participation in the clinical investigation (21 CFR 312.53(c)). The investigator should sign the form only after being given enough information to be informed about the clinical investigation and to understand the commitments described in Section #9 of the 1572. Having enough information about the study typically means that the investigator has received copies of, has read, and understands the protocol and investigator's brochure (if required[2]), and is familiar with the regulations governing the conduct of clinical studies.

The investigator's signature on this form constitutes the investigator's affirmation that he or she is qualified to conduct the clinical investigation and constitutes the investigator's written commitment to abide by FDA regulations in the conduct of the clinical investigation.

4. Must the investigator be a physician?

The regulations do not require that the investigator be a physician. Sponsors are required to select only investigators qualified by training and experience as appropriate experts to investigate the drug (21 CFR 312.53(a)). In the event the clinical investigator is a non-physician, a qualified physician (or dentist, when appropriate) should be listed as a subinvestigator for the trial and should be responsible for all trial-related medical (or dental) decisions. (ICH E6 section 4.3.1; http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073122.pdf).

[2] See 21 CFR 312.55; a study initiated by a sponsor-investigator is not required to have an investigator's brochure.

5. What are the minimum qualifications of an investigator?

As stated in #4, the regulations require that sponsors select investigators who are qualified by training and experience as appropriate experts to investigate the drug. The regulations do not specify the minimum requirements nor do the regulations specify what qualifications an investigator must have in order to be considered qualified by training and experience to conduct a clinical investigation. Sponsors have discretion in determining what qualifications, training, and experience will be needed, based on the general recognition that this would include familiarity with human subject protection (HSP) regulations (i.e., 21 CFR Parts 50 and 56) and practices as well as good clinical practice (GCP) regulations (see 21 CFR Part 312) and standards (e.g., ICH E6) for the conduct of clinical studies.

6. Does the 1572 need to be submitted to FDA?

No. Although the sponsor is required to collect the 1572 from the investigator, FDA does not require the form to be submitted to the agency. Many sponsors submit the 1572 to FDA, however, because it collects, in one place, information that must be submitted to FDA under 21 CFR 312.23(a)(6)(iii)(b).

7. When must a 1572 be updated or a new 1572 completed and signed by an investigator to reflect new or changed information?

There are two instances when it is necessary for an investigator to complete and sign a new 1572: when an investigator is participating in a new protocol that has been added to the IND and when a new investigator is added to the study (21 CFR 312.53(c)).

If there are other changes to information contained on a signed and dated 1572 (e.g., an IRB address change, the addition of new subinvestigators, the addition of a clinical research lab), the investigator should document the changes in the clinical study records and inform the sponsor of these changes, so that the sponsor can appropriately update the IND. The 1572 itself does not need to be revised and a new 1572 need not be completed and signed by the investigator. The sponsor can accumulate certain changes and submit this information to the IND in, for example, an information amendment or a protocol amendment.

8. If a clinical investigation is not conducted under an IND or is for a medical device, must investigators sign a 1572?

No. Under the regulations, a 1572 is only required for studies of investigational drugs and biologics conducted under an IND. It is not required for studies that are not done under an IND, and is not applicable to investigational device studies. Sponsors of device studies must obtain a signed investigator agreement (containing information similar to that requested on the 1572) from each participating investigator, per 21 CFR 812.43(c).

9. Must a sponsor conduct a foreign clinical study under an IND?

No. A sponsor may choose, but is not required, to conduct a foreign clinical study under an IND. When a foreign clinical study is conducted under an IND, all FDA IND requirements must be met unless waived (see #12 and #13 below). When the foreign clinical study is not conducted under an IND, the sponsor must ensure that this study complies with 21 CFR 312.120, "Foreign clinical studies not conducted under an IND," if the sponsor intends to submit the study to FDA to support clinical investigations conducted in the United States and/or marketing approval. An application based solely on foreign clinical data must meet criteria listed in 21 CFR 314.106.

10. Must investigators who conduct studies outside of the United States sign a 1572?[3]

If a foreign clinical study is conducted under an IND, then all FDA IND regulations, including the requirement to obtain a signed 1572, must be met. If a clinical study is conducted outside of the U.S. and is not conducted under an IND, then the investigator need not sign a 1572. If local laws or regulations prohibit the signing of a 1572, FDA would expect the sites to operate as non-IND sites and the study conducted as a non-IND study. If the study data is to be submitted to support a marketing application (e.g., a new drug application (NDA)), the study must be conducted in compliance with 21 CFR 312.120.

11. If a foreign clinical study is being conducted under an IND, what are the investigator's responsibilities with respect to local laws and regulations?

Investigators are responsible for complying with the applicable laws and regulations of the country in which the study is being conducted, regardless of whether the study is being conducted under an IND. We recommend that sponsors obtain signed, written statements from investigators acknowledging their commitment to comply with local laws and requirements. In addition, if a foreign clinical study is being conducted under an IND, the investigator must sign Form FDA 1572 (investigator statement) and ensure that the study is conducted in accordance with the investigator statement and all other applicable regulations under 21 CFR Part 312.

12. For foreign clinical studies conducted under an IND, how can an investigator sign the 1572 when the investigator knows he/she cannot commit to all of the requirements on the form, specifically IRB membership (21 CFR 56.107)?

IRB review and approval is required before a clinical study can be initiated under an IND (21 CFR 56.103(a)). FDA may waive any of the IRB requirements for specific research activities or for classes of research activities otherwise covered by the IRB regulations (21 CFR 56.105), but FDA uses the waiver provision only when alternative mechanisms for ensuring protection of the rights and welfare of human subjects are acceptable. The most common circumstance for which FDA receives a waiver request is when a sponsor

[3] Investigators conducting studies outside of the U.S. may want to consult with local regulatory authorities for additional guidance when considering whether to conduct studies under an IND.

wishes to conduct a foreign clinical study under an IND. In this case, typically an Independent Ethics Committee (IEC) that operates in accordance with Good Clinical Practice (GCP) is utilized instead of a U.S. IRB. Although its membership and functions for assuring human subject protection are comparable to an IRB, an IEC may not meet all of the IRB requirements contained in 21 CFR Part 56.

For a foreign study, an IRB waiver request should contain a description of alternative mechanisms for assuring human subject protection. It would generally be acceptable for a waiver request to state the intention to use an IEC that complies with GCP (e.g., ICH E6) instead of an IRB that complies with 21 CFR Part 56.

The sponsor should submit the waiver request to the IND under which the study will be conducted. The IND will have been submitted to the appropriate review division in either the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER).

The sponsor will be informed by the agency in writing whether the waiver request is denied or granted. If a waiver is granted, the sponsor should have investigators attach a copy of the letter granting the waiver to the signed 1572 in the investigator's record.

13. If a sponsor chooses to conduct a foreign clinical study (or operate non-US sites in a multinational study) under an IND and the investigators at these non-US sites comply with the ICH E6 Good Clinical Practice Consolidated Guidance, would the non-US investigators also be in compliance with FDA's IND requirements under 21 CFR Part 312?

Yes, with two exceptions. The first is that the FDA requirements for IRBs under 21 CFR Part 56 are slightly different with respect to membership and function. To address this issue, as described in #12 above, FDA can provide a specific waiver from the Part 56 IRB requirements, allowing an IEC that complies with good clinical practice to substitute for the IRB.[4] The second exception is that the requirements for informed consent under 21 CFR Part 50 for particular clinical trials (e.g., emergency research under 21 CFR 50.24, clinical investigations involving pediatric subjects under Subpart D) are more extensive with respect to IRB responsibilities. Because these types of trials are uncommon, our experience has not revealed that this has caused a conflict; but in the event of one, we would be willing to discuss a resolution with the sponsor on a case-by-case basis. If the investigator or sponsor believes that there are other conflicting requirements, the sponsor may request a waiver from FDA from the specific requirement under 21 CFR 312.10.

[4] See "Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs: Waiver of IRB Requirements for Drug and Biological Product Studies," January 2006, available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM080613.pdf.

14. Must foreign clinical study sites in a multinational study that includes domestic sites be conducted under an IND?

No. A multinational study may include domestic sites under the IND and foreign sites not under the IND. Investigational drug and biologics studies conducted in the U.S. must be conducted in compliance with the IND requirements contained in 21 CFR 312, which includes the requirement that investigators sign the 1572. If a study also involves foreign clinical sites, the sponsor may choose, but is not required, to include the foreign clinical sites under the IND. The investigators from the U.S. sites and any foreign sites included under the IND would be required to sign the 1572. The investigators from the foreign sites that are not included under the IND are not required to sign the 1572.

If the sponsor chooses to conduct a multinational study with U.S. and some foreign sites under the IND, and other foreign sites not under the IND, the sponsor can submit a single protocol to the IND and all sites would follow this protocol. Alternatively, the sponsor can conduct a multinational study with one protocol for sites under the IND (U.S. sites and some foreign sites) and a different protocol(s) for foreign sites not under the IND. If the intent is to pool the data from U.S. and foreign sites, the protocols would ordinarily be very similar or identical. The U.S. sites and any foreign sites included under the IND must follow the protocol that was submitted to the IND. For foreign sites that are not included under the IND, the protocol(s) does not need to be submitted to the IND. In general, if the sponsor intends to submit the data in an application for marketing approval, we recommend that the sponsor identify the foreign sites that will not be conducted under the IND and discuss plans to pool the data from U.S. and foreign sites with the appropriate FDA review division.

Note, however, that 21 CFR 312.32(b) requires sponsors to promptly review information about the safety of the investigational drug obtained or otherwise received by the sponsor from any source, foreign or domestic. Under 21 CFR 312.32(c), sponsors must also notify FDA and all participating investigators in an IND safety report of any adverse experience associated with the use of the drug that is both serious and unexpected. This means that FDA and all participating investigators under the IND would be informed of such an adverse experience, even if it occurred in a foreign study not conducted under the IND.

15. How does a sponsor submit information to FDA about a foreign clinical study that was not conducted under an IND?

Under 21 CFR 312.120, the sponsor can submit information to FDA from a foreign clinical study that was not conducted under an IND to support clinical investigations in the United States and/or marketing approval. When submitting information about a foreign clinical study, it is helpful to clearly identify in the cover letter that the material is being submitted in accordance with 21 CFR 312.120. The submission requirements for supporting documentation can be found at 21 CFR 312.120(b).

16. Should a new form be prepared and signed when the OMB expiration date is reached?

No. There is no need to prepare and sign a new 1572 when the OMB expiration date has been reached.

17. Does FDA expect a double-sided 1572, or is a two-page document printed from the FDA website acceptable?

Either is acceptable; however, FDA recommends that a two-page document be stapled so that there is no question about what form the investigator signed.

18. How should the 1572 be completed?

The 1572 on FDA's website may be completed by typing the information directly into the fillable form and printing the completed form. Alternatively, it is acceptable to print the blank form from FDA's website and hand-write or type the information onto the form. Typed forms are preferable because they are usually more legible. The completed form must be signed and dated by the investigator (either by hand or using an acceptable electronic method).

II. SECTION #1: NAME AND ADDRESS OF INVESTIGATOR

19. How should an investigator's name appear on the 1572?

Section #1 should contain the investigator's full legal name (e.g., name on the investigator's birth certificate or marriage certificate). Titles, degrees, and/or professional qualifications may follow the investigator's legal name, if desired.

20. What address should be entered into Section #1?

The address where the investigator can be reached by mail or in person should be entered in Section #1 of the 1572. Usually, this corresponds to the investigator's work or business address.

21. Should co-investigators be listed on the 1572 in Section #1? Is it acceptable to have more than one investigator at a single site?

The term co-investigator is not defined in FDA regulations. As commonly used, the term is meant to indicate that each co-investigator is fully responsible for fulfilling all of the obligations of an investigator as identified in 21 CFR 312.60. Thus under 21 CFR 312.3(b), each co-investigator is an investigator, and as such must sign a separate 1572.

In some situations, it is preferable to have more than one investigator responsible for a clinical investigation. For example, when a study is conducted at multiple research facilities that are not in close proximity, FDA expects an investigator who has signed a

1572 to be available at each location to either personally conduct or supervise the study. This responsibility cannot be delegated to a subinvestigator.

Although not necessary, it is acceptable to have more than one investigator at a single site. For example, the conduct and supervision of a large investigation with many subjects or complicated procedures might be shared among several investigators, each of whom has signed a 1572 when the investigation is conducted under an IND. This is distinct from a subinvestigator (see #31) whose role in the clinical investigation is more limited.

III. SECTION #2: EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFY THE INVESTIGATOR AS AN EXPERT IN THE CLINICAL INVESTIGATION

22. What is the purpose of Section #2?

Section #2 requires the investigator to attach a curriculum vitae (CV) or other statement of qualifications, showing the education, training and experience that qualifies the investigator as an expert in the clinical investigation of the drug/biologic for the use under investigation. Information identified in this section and attached to the 1572 enables the sponsor to assess an investigator's qualifications.

23. Does the CV or other statement of qualifications need to be updated during a clinical study?

No. FDA regulations do not require a CV or other statement of qualifications to be updated during a clinical study.

24. Are CVs required to be signed and dated?

No. FDA regulations do not require a CV to be signed and dated. The investigator's dated signature on the 1572 is sufficient to attest to the accuracy of the CV or other statement of qualifications submitted with the 1572.

IV. SECTION #3: NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED

25. What address(es) should be entered in Section #3?

The address(es) of the location(s) where the investigation will be conducted and to where the test articles will be shipped, if different from the investigator's address of record, should be entered in Section #3.

26. What qualifies as a research facility for Section #3?

Section #3 is intended to identify facilities where study activities will be conducted and clinical data will be generated or collected. This includes facilities where subjects will be seen and study procedures performed. For example, this might include locations such as health care facilities where the test article will be administered, or where physical exams will be performed. Facilities where other important clinical investigation functions are performed may also be identified in Section #3. For example, a research laboratory where the test article is prepared, a special storage facility where the test article will be kept, or a location where tissue specimens are collected should be listed in this section.

27. If an investigator sees study subjects at more than one site, should the investigator list all sites on the 1572?

Yes. The names and addresses of each of the study sites should be identified in Section #3. However, if the protocol specifies that the investigative product can be administered at a subject's home (for example, the protocol allows for daily injections to be administered by a registered nurse in the subject's home), the subjects' home addresses do not have to be listed on the 1572. Study records should reflect that the test article was administered at subjects' homes per the protocol.

V. SECTION #4: NAME AND ADDRESS OF CLINICAL LABORATORY FACILITIES TO BE USED IN THIS STUDY

28. What qualifies as a clinical laboratory facility for Section #4?

Section #4 is intended to identify clinical laboratories or testing facilities directly contributing to or supporting the clinical study (for example, diagnostic labs performing blood work, imaging centers, cardiology labs, etc.). This may include analytical labs that provide pharmacokinetic analysis, and laboratories supplying efficacy data for clinical investigations conducted under an IND.

29. If a laboratory is sending samples to satellite or other contract labs for additional testing, should these labs be identified in Section #4?

It is only necessary to list the primary laboratory, provided that laboratory can trace the samples to each of the satellite and/or contract labs where the tests were performed.

VI. SECTION #5: NAME AND ADDRESS OF THE INSTITUTIONAL REVIEW BOARD (IRB) RESPONSIBLE FOR THE REVIEW AND APPROVAL OF THE STUDY(IES)

30. Does the IRB reviewing and approving the clinical study have to be at the same location as where the research is conducted?

The regulations permit review of research by IRBs at locations other than where the research is being performed (e.g. independent or non-institutional IRB; use of a cooperative IRB review process; see 21 CFR 56.114). Therefore an IRB may review clinical studies that are not performed on-site as long as requirements in 21 CFR Parts 50 and 56 are met. For more information on cooperative research arrangements, see the FDA Guidance for Industry-Using a Centralized IRB Review Process in Multicenter Clinical Trials (http://www.fda.gov/RegulatoryInformation/Guidances/ucm127004.htm).

VII. SECTION #6: NAMES OF THE SUBINVESTIGATORS WHO WILL BE ASSISTING THE INVESTIGATOR IN THE CONDUCT OF THE INVESTIGATION(S)

31. Who should be listed as a subinvestigator in Section #6?

FDA's regulation at 21 CFR 312.3(b) states: "In the event an investigation is conducted by a team of individuals, the investigator is the responsible leader of the team. 'Subinvestigator' includes any other individual member of that team." 21 CFR 312.53(c)(1)(viii) requires the investigator to provide "a list of the names of the subinvestigators (e.g., research fellows, residents) who will be assisting the investigator in the conduct of the investigation(s)."

The purpose of Section #6 is to capture information about individuals who, as part of an investigative team, will assist the investigator and make a direct and significant contribution to the data. The decision to list an individual in Section #6 depends on his/her level of responsibility (i.e., whether he/she is performing significant clinical investigation-related duties). In general, if an individual is directly involved in the performance of procedures required by the protocol, and the collection of data, that person should be listed on the 1572. For example, if the protocol notes that each subject needs to visit a specified internist who will perform a full physical to qualify subjects for the clinical investigation, that internist should be listed in Section #6.

32. ***Should research nurses, other nurses, residents, fellows, office staff, or other hospital staff be listed in Section #6?***

Hospital staff, including nurses, residents, or fellows and office staff who provide ancillary or intermittent care but who do not make a direct and significant contribution to the clinical data, do not need to be listed individually. It is not necessary to include in this section a person with only an occasional role in the conduct of the research, e.g., an on-call physician who temporarily dealt with a possible adverse effect or a temporary substitute for any research staff (see ICH E3, Section 6) (http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073113.pdf).

Concerning staff residents on rotation, it may be difficult to prospectively identify those individuals who might perform specified protocol procedures or collect clinical data. Specific names of the rotational staff do not have to be listed in Section #6. Instead, to successfully address this scenario, the names of rotational individuals and the procedures they are expected to perform should be included in the clinical study records. This information should also be sent to the sponsor for submission to FDA in, for example, an information amendment.

33. Should pharmacists or research coordinators be listed in Section #6?

The decision about whether to list a pharmacist or research coordinator on the 1572 is a matter of judgment, dependent upon the contribution that the individual makes to the study. For example, a research pharmacist may prepare test articles and maintain drug accountability for many clinical studies that are ongoing concurrently at an institution. Because the pharmacist would not be making a direct and significant contribution to the data for a particular study, it would not be necessary to list the pharmacist as a subinvestigator in Section #6, but he/she should be listed in the investigator's study records.

Generally, a research coordinator has a greater role in performing critical study functions and making direct and significant contributions to the data. For example, a research coordinator often recruits subjects, collects and evaluates study data, and maintains study records. Therefore, the research coordinator should usually be listed in Section #6 of the 1572.

34. Is a statement of qualifications required for subinvestigators?

No. The regulations at 21 CFR 312.53(c)(1)(viii) require only that subinvestigators' names be listed in Section #6 of the 1572. It is the responsibility of the sponsor to select investigators qualified by training and experience, as appropriate experts, to investigate the drug. The investigator must ensure that all associates, colleagues, and employees assisting with the conduct of the clinical investigation are aware of their obligations including complying with the IND regulations.

35. Do individuals who are listed in Section #6 on the 1572 have to submit information about their financial interests?

Yes. Under 21 CFR Part 54 (Disclosure of Financial Interests by Clinical Investigators), a person listed or identified as an investigator or subinvestigator who is directly involved in the treatment or evaluation of research subjects must submit financial disclosure information to the sponsor. For purposes of this financial disclosure regulation, the term investigator also includes the spouse and each dependent child of the investigator and subinvestigator. (21 CFR 54.2(d) and 54.4). For additional information about financial disclosure, see FDA's Guidance for Industry Financial Disclosure by Clinical Investigators (http://www.fda.gov/RegulatoryInformation/Guidances/ucm126832.htm)

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

36. What information should be included in this section?

List the name and code number (if any) of all the protocols under the IND that will be conducted by the investigator signing the 1572. A code number is an identifying number assigned by the sponsor.

As a reminder, some investigators may be responsible for submitting certain clinical trial information to the National Institutes of Health clinical trials data bank under 42 U.S.C. 282(j), 402(j) of the Public Health Service Act. Although not all investigators will be expected to meet this requirement, go to www.clinicaltrials.gov for further information about potential responsibilities.

IX. SECTION #8: CLINICAL PROTOCOL INFORMATION

37. How should Section #8 be completed for a phase 4 study?

Phase 4 refers to the timing of a clinical study (i.e., postmarketing) rather than the characteristics of the study, which are described under 21 CFR 312.21, Phases of an investigation. A postmarketing clinical trial would meet the description of a phase 2 or 3 investigation and a full protocol would be submitted. The investigator does not need to mark either of the boxes in Section #8, but should identify in Section #7 that the study is a phase 4 study.

38. Can an investigator submit the study protocol instead of an outline of the study protocol?

Yes. The protocol or a detailed description is required for any phase 2 or 3 clinical trial. Phase 1 studies can be supported by an outline (see 21 CFR 312.53).