From: OC GCP Questions
To: [redacted]
Subject: RE: written documentation of informed consent
Date: Wednesday, April 06, 2016 9:41:00 AM

Dear [redacted],
As you note in your email, 21 CFR § 56.109(c) allows an IRB to waive the requirement for written documentation of informed consent in situations where there is minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context.

I am not quite sure what you mean by "conduct initial consent discussions", but I hope the information below addresses your questions.

Below is information from FDA's Information Sheet, *Screening Tests prior to Study Enrollment*, which can be found at http://www fda.gov/RegulatoryInformation/Guidances/ucm126430 htm
Clinical screening procedures for research eligibility are considered part of the subject selection and recruitment process and, therefore, require IRB oversight. If the screening qualifies as a minimal risk procedure [21 CFR 56.102(i)], the IRB may choose to use expedited review procedures [21 CFR 56.110]. The IRB should receive a written outline of the screening procedure to be followed and how consent for screening will be obtained. The IRB may find it appropriate to limit the scope of the screening consent to a description of the screening tests and to the reasons for performing the tests including a brief summary description of the study in which they may be asked to participate. Unless the screening tests involve more than minimal risk or involve a procedure for which written consent is normally required outside the research context, the IRB may decide that prospective study subjects need not sign a consent document [21 CFR 56.109(c)]. If the screening indicates that the prospective subject is eligible, the informed consent procedures for the study, as approved by the IRB, would then be followed.
While an investigator may discuss availability of studies and the possibility of entry into a study with a prospective subject without first obtaining consent, informed consent must be obtained prior to initiation of any clinical procedures that are performed solely for the purpose of determining eligibility for research, including withdrawal from medication (wash-out). When wash-out is done in anticipation of or in preparation for the research, it is part of the research.
Procedures that are to be performed as part of the practice of medicine and which would be done whether or not study entry was contemplated, such as for diagnosis or treatment of a disease or medical condition, may be performed and the results subsequently used for determining study eligibility without first obtaining consent. On the other hand, informed consent must be obtained prior to initiation of any clinical screening procedures that is performed solely for the purpose of determining eligibility for research. When a doctor-patient relationship exists, prospective subjects may not realize that clinical tests performed solely for determining eligibility for research enrollment are not required for their medical care. Physician-investigators should take extra care to clarify with their patient-subjects why certain tests are being conducted.
Certain clinical tests, such as for HIV infection, may have State requirements regarding (1) the information that must be provided to the participant, (2) which organizations have access to the test results and (3) whether a positive result has to be reported to the health department. Prospective subjects should be informed of any such requirements and how an unfavorable test result could affect employment or insurance before the test is conducted. The IRB may wish to confirm that such tests are required by the protocol of the study.
Also FDA's Information Sheet, *Recruiting Study Subjects* http://www fda.gov/RegulatoryInformation/Guidances/ucm126428 htm [redacted] has information about receptionist scripts that can be used to determine basic study eligibility. A script could also be used by the study physician when speaking to potential subjects, to be sure all subjects get the same basic information about the study. Scripts are considered part of the informed consent process, and require IRB approval prior to their use.
Here is a link to FDA's Information Sheet Guidances main page; you may also find these helpful:
http://www fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm113709 htm

You may also wish to discuss any recruitment tools and informed consent processes with the Sponsor and/or IRB contacts for the IND. The Sponsor may wish to consult with their CDER contact for the IND, if they have any questions.

I hope this information is helpful to you. If you need further assistance, please feel free to contact the GCP mailbox at gcp.questions@fda hhs.gov.

Best regards,

Sheila

Sheila Brown, RN, MS
Policy Analyst, Office of Good Clinical Practice
Office of Special Medical Programs, Food and Drug Administration

This communication does not constitute a written advisory opinion under Title 21 CFR 10.85, but rather is an informal communication under Title 21 CFR 10 85(k), which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [redacted]
Sent: Friday, April 01, 2016 2:21 PM
To: OC GCP Questions
Subject: written documentation of informed consent

Hello,
I have a question about 21 CFR § 56.109(c). This regulation allows the IRB to waive the requirement for written documentation of informed consent in situations where there is minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context.
We have situations involving studies which are under an IND, thus greater than minimal risk, where the researchers would like to contact interested participants by phone to conduct initial consent discussions. The phone discussion would include initial eligibility screening and instructions to fast for the study visit where the test article is administered. When subjects come for the study visit they would sign the written consent document for the full study.
Under the regulations, could the IRB allow an oral consent to be obtained for phone screening & fasting with written documentation of consent for the full study participation?
Thanks,
[redacted]

[redacted]

[redacted]