Informed Consent - Requirements for Study Physician Involvement - Investigational Drug (IND) & Device (IDE) Studies[1]

The purpose of this document is to provide more detailed implementation guidance to the Geisinger research community regarding obtaining informed consent in clinical research as a result of the June 20, 2017 ruling in the Pennsylvania Supreme Court case, Shinal v. Toms. This guidance relates only to implementation of the direction regarding the Pennsylvania Supreme Court decision; it is not general guidance regarding obtaining informed consent.

Studies to which new specifications apply:

The new specifications apply to all interventional clinical research studies investigating an "experimental product". "Experimental product" means a product that requires an Investigational New Drug application (IND) or Investigational Device Exemption (IDE) approval from the FDA.

This guidance does not apply to studies that are not conducted under an IND or IDE, including studies comparing standard of care regimens, studies that are IND-exempt, studies of non-significant risk devices and non-interventional protocols.

The new specifications are effective as of **June 21, 2017** and do not apply to participants who consented before that date. Participants who consented into applicable clinical research studies after June 21 must be re-consented if an independently qualified study physician did not participate (and/or document such participation) in the informed consent discussion about the experimental product and its risks, benefits and alternatives.

Obtaining Consent under the new specifications - Who Can Obtain Consent?

A U.S.-licensed physician who is a study team member[2] is required to consent participants regarding the experimental product (as defined in the previous section) and its risks, benefits and alternatives. Before or after this discussion about the experimental product by the US-licensed physician, an IRB-approved, appropriately trained study team member may consent the research participant with respect to all other aspects of the research. The U.S.-licensed physician or other health care professional authorized to prescribe and administer the experimental product may of course administer the entire consenting process.

Obtaining Consent under the new specifications—How is Consent Documented?

The informed consent discussion must be documented in writing by each staff member who participated in the consent process (e.g., sign and date the informed consent form (ICF) or document in Epic or research record). The research participant or legally authorized representative (LAR) must also sign and date the ICF.

FAQs - Consenting Clinical Research Participants in Interventional Studies (September 2017)[1]

Read the FAQs below for more detailed responses to specific questions to assist in operationalizing this guidance.

For any questions regarding how this guidance may apply to your study, please contact Deb Henninger, MHSA BSN RN CCRC, Director, IRB Operations & HRPP (dhenninger@geisinger.edu or 570-271-8663) or Geisinger IRB staff (570-271-8663 or irb.geisinger.edu).

Delegation of Consent/ Consent Process

Q: Can non-physicians (study nurses, clinical research coordinators, study staff) consent participants at the time of screening and then, if participants are found to be eligible, can physicians re-consent participants before they begin enrollment in the trial?

A: Yes. Specifically, physicians on the study team may review information about the experimental product and its risks, benefits and alternatives after a study team member has consented the participant for screening purposes and the participant has been screened; both the study team member and the physician must document their participation in the consenting process (e.g., sign and date the ICF or document in Epic or research record).

Q: Can a study team member discuss everything but the administration of the experimental product and then have the physician come in and discuss the administration of the experimental product?

A: Yes. A physician who is a member of the study team must discuss information about the experimental product and its risks, benefits and alternatives, and a qualified, appropriately trained study team member may discuss all general elements of a consent. In this scenario, both the study staff and the

physician must document their participation in the consenting process (e.g., sign and date the ICF or document in Epic or research record).

Q: A patient may have consented as an outpatient to join a research protocol by a physician investigator on the protocol, but another study physician is using the product when the patient is admitted. Does this change in state law affect such arrangements? What does "physician using or administering the product" mean? In addition, if the use of the product stretches out over time, the physician "using the product" may change—as, for example, when attending physicians on an inpatient service change over.

A: In this scenario, the consent obtained by a licensed physician who is an investigator on the protocol is sufficient to satisfy the new specifications. As long as the IRB does not require re-consenting for a protocol change affecting the risks and benefits, the original physician obtained consent remains valid regardless of the physician administering the experimental product. However, we advise physicians, at all possible times, to personally obtain informed consent for experimental procedures that the physician expects to perform.

Q: Can the study PI delegate consent to a sub-Investigator who is also a physician?

A: Yes, a study physician who is independently qualified to perform a procedure may obtain informed consent for that procedure, which includes experimental procedures.

Q: One of our current studies involves prescribing and comparing two FDA approved standard of care drugs. Patients self- administer these medications. I am a nurse practitioner and I am listed as prescriber. Moving forward, does this allow me to administer informed consents?

A: The new specifications do not pertain to FDA approved drugs prescribed in a standard of care manner in a research study and the consenting process remains unchanged. If, however, the study drug was FDA approved but is now the subject of a clinical trial for a novel indication, that study would likely require an IND, fall under the new consenting specifications and would require a physician obtain consent for the administration of that drug.

Q: Must this informed consent process be face to face, or is telephone contact adequate if the participant, or their legally authorized representative, have a copy of the consent form?

A: Best practice is that consent is obtained in a face-to-face discussion. If face-to-face consent is deemed not to be feasible, an alternate consenting process must be approved by the IRB (e.g., consenting via

telephone by the study physician for the experimental product with a witness present with the research participant to document that the conversation with the physician took place. This consenting process should be documented.

Q: For studies of an FDA-approved medication being tested with a new disorder, must a physician obtain informed consent from participants, even if the study PI is a PhD? If so, must that physician be an investigator on the study.

A: In this scenario, unless the drug has been determined to be IND-exempt, a physician who is a member of the study team must administer the portion of the consent that addresses the information about the experimental product and its risks, benefits and alternatives. Other appropriately trained and qualified study team members, including PhDs, may also participate in the consent process.

Q: Can the study coordinator consent for any parts of the consent form, such as study logistics, HIPAA, conflict of interest?

A: Yes, so long as a physician authorized to order and administer the experimental product conducts the portion of the consent process related to information about the experimental product and its risks, benefits and alternatives.

Q: For many investigational drug studies, the drug is administered by a research nurse or self-administered by the participant. Can any U.S. licensed MD investigator consent in this case?

A: Yes.

Q: Some research studies involve invasive procedures which might be done by someone other than the investigator who is obtaining consent to participate in the study. Does the law require “an investigator” to obtain consent for that part of the research study or must it be the person actually performing the invasive procedure? The latter might be impractical since participants often already consent to participate in the study before knowing who will do the procedure.

A: In this scenario, a physician who is a study team member must obtain consent with respect to information about the experimental product and its risks, benefits and alternatives (and that physician or other study team member may perform the remainder of the consent).

The physician performing the consent does not need to be the person who is administering the

experimental product. However, we advise physicians, at all possible times, to personally obtain informed consent for experimental procedures that the physician expects to perform.

Medical Licensure

Q: What licenses are included under the definition of “physician” (only MD’s or are DO’s and DMD’s included)?

A: Doctors of Osteopathic Medicine and Doctors of Medicine in Dentistry who are members of the study team are included in the definition of "physician” for purposes of this direction so long as the physician is authorized to prescribe and administer the experimental intervention.

Q: Is a Resident Physician or Fellow allowed to obtain informed consent?

A: Resident Physicians and Fellows may obtain informed consent from participants regarding only those medical regimens that a Resident or Fellow is independently qualified to perform

Q: Is a a physician who is not licensed in the US allowed to obtain informed consent?

A: An investigator that who is not licensed in the US may participate in the consenting process so long as a US-licensed physician performs the portion of the consent related to information about the experimental product and its risks, benefits and alternatives.

Multi-Site Trials

Q: If Geisinger is the lead site for a multi-site study, must all the other sites in Pennsylvania have licensed MD obtain informed consent?

A: The applicability of the new specifications to sites in Pennsylvania in a Geisinger-sponsored study will be determined on a case-by-case basis. Sites in multi-site studies conducted in other states must follow their laws and regulations of the state in which the site is located.

Re-Consenting

Q: If a participant was consented by a non-physician prior to this announcement, should a physician re-consent the participant?

A: The new specifications are being applied prospectively only, and so there is no requirement to go back and re-consent participants currently receiving experimental product.

Q: Does the study physician need to consent for all future consent amendments as well? What about those that are more of a logistical change?

A: The study physician needs to consent with respect to any future changes in the consent regarding the risks, benefits and alternatives of the experimental product. Other study team members may consent with respect to future changes in the consent regarding other aspects of the study, including logistical changes.

Q: Given the recent guidance following the PA supreme court decision regarding consenting, are study coordinators allowed to re-consent participants on minor changes to the consent not related to risk? For example, I have a consent change adding gift cards as the method of payment. That is the only change. Would I be allowed to re-consent if delegated to that duty?

A: Yes.

Trial Qualification

Q: Do the new specifications apply to my research study if the research intervention is clinically available or SOC?

A: If the research study involves only standard of care treatments, the new specifications do not apply. If the research intervention is clinically available and being used as recommended by the manufacturer or is determined by FDA to be IND-exempt, the new specifications do not apply. If an IND or IDE is required for the research intervention, the new specifications apply.

Q: Does this ruling regarding consent in research after the Pennsylvania Supreme Court decision apply to my study?

A: The new specifications apply to studies in which the intervention is a drug for which an IND is required or a device for which an IDE is required. The new specifications do not apply to studies in which the intervention is a drug for which no IND is required, or a device that is a non-significant risk device or standard of care. For help in determining which category applies to a drug or device, please consult Geisinger IRB staff at 570-271-8663 or irb.geisinger.edu.

Q: The device used in our study is not considered a medical device. Must a study physician take part in the informed consent process?

A: No. if the device being studied is determined by the IRB to be a "non-significant-risk" device and there

are no other products in the study in the scope of the new specifications (i.e., device requiring an IDE or drug requiring an IND), the consenting process is not subject to the new specifications.

Q: The product that is the only intervention being investigated in the protocol has an IND exemption. Does this fall under the description of using "an approved product in an experimental manner", thus necessitating that a physician obtain informed consent?

A: Since the product has been determined to be IND exempt, the study is outside the scope of the new specifications. Accordingly, consent may be delegated to an appropriately trained and qualified study team member who is not required to be a physician.

Q: We have many minimal risk studies that collect only tissue, blood and medical history (no investigational procedures/treatments). Will the consent process in these types of studies be a delegable duty?

A: Consent for the types of studies described is outside the scope of the new specifications and accordingly may be delegated to an appropriately trained and qualified study team member even if that individual is not a physician.

Q: Do you know what qualifies as an "experimental" medication?

A: If the drug or device being studied is FDA approved and used as recommended by the manufacturer or in a standard of care manner, the new specifications do not apply. If the research intervention is determined to be IND-exempt, the new specifications do not apply. If an IND or IDE is required for the research intervention, the new specifications apply.

Q: I have a clinical trial using a device (nonsignificant risk) and following Abbreviated IDE requirements. Does our study fall under the new specifications?

A: No, non-significant risk device studies are excluded.

Q: When the only procedure is drawing blood to look for a genetic marker or for biobanking, does the study physician have to consent?

A: No, the new specifications do not apply to a blood draws or other screening or minimal risk procedures.

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[1] Guidance & FAQs adapted with permission from Perelman School of Medicine at the University of Pennsylvania Office of Clinical Research.

[2] A study team member is any individual who completed Geisinger requirements for research training, is listed as an investigator as study personnel on the study application and approved by the IRB as such.