MEMO

GEISINGER
HEALTH SYSTEM

Department of Legal Services
M.C. 40-31
100 North Academy Avenue
Danville, PA 17822
Tel (570) 271-6781 (opt 1-2)

Date: **June 12, 2015**

To: **Clinical Trial Sponsors**

From: **Department of Legal Services**

Re: **Guidance Regarding Geisinger Clinical Trial Agreements**

The purpose of this memo is to provide guidance to industry-sponsors regarding Geisinger's policies for Clinical Trial Agreements. These policies form the background for the negotiations of each agreement, as appropriate.

Patient Safety and Monitoring:

Geisinger must include the following language in our clinical research agreements:

During and for a period of at least two (2) years after the completion of the study, Sponsor shall promptly (or in a timely manner appropriate to the level of risk involved but in no event longer than thirty (30) days from date of knowledge) report to the Investigator any information that could directly affect the health or safety of past or current study subjects or influence the conduct of the study, including but not limited to the study results and information in site monitoring reports and data safety monitoring committee reports as required by the Protocol. In each case, the Investigator and Institution shall be free to communicate these findings to each study subject and the IRB.

Contracting Parties:

Geisinger Clinic should be named as the contracting party in all agreements. Geisinger employed physicians sign the agreements as 'Read and Understood' and are not a party to the agreement. However, non-employed physicians should be added to the contract as a party. Geisinger Clinic is the payee for all studies and sites. The Geisinger Health System is comprised of several affiliated entities including all its hospitals and clinics with Geisinger Health System Foundation as parent.

Subject Injury:

It is the policy of this institution, not to accept contract provisions that condition payment by the sponsor for research-related subject injuries to those claims being submitted first to third-party payors.

This position reflects our understanding of the April 2004 CMS interpretation of the Medicare regulations (the so-called Medicare Secondary Payor Rule). Specifically, it is our understanding that CMS has interpreted the regulations to mean that Medicare is always secondary to benefits payable by a third party -- regardless of whether the third party (in this case, a trial sponsor) takes the position that its benefits are secondary to Medicare. Accordingly, even if the contract were to provide that the sponsor's responsibility to cover research-related injury costs was secondary to Medicare, CMS would view the sponsor as the primary payor and Medicare the secondary, with the result that the costs cannot legally be billed to Medicare. Accordingly, Geisinger requires the sponsor to pay for research-related subject injury costs in all studies where the protocol is company-initiated and where the drug or device is not approved for the indication being evaluated.

This policy applies regardless of whether the injured subject has commercial insurance or no insurance coverage. Geisinger's position reflects the following principles:

- **Patients who are participants in Clinical Trials should not bear costs of injuries caused as a result of participation in the study, regardless of whether the risks were anticipated or unanticipated. Our patients are volunteering to participate and therefore, should not incur any costs as a result of the trial, including insurance co-pays, deductibles and impact on insurance lifetime limits. We do not discriminate between human subjects based on whether they have Medicare coverage or private insurance, and it is not feasible for Geisinger to administer a system for processing charges that distinguishes between the two types of coverage.**
- **The Institution will not bear the costs of subject injury, including legal costs. The Sponsor sees the long term financial benefits of our subjects' participation in the trial and is therefore, absent unusual circumstances, liable for all such costs.**
- **The Institution will not bill insurance companies or third party payers for subject injury which would result in liability for billing fraud.**

If the Sponsor will not agree to pay for Subject Injury the Institution will not participate in the trial.

This policy will also be reflected within the Institution's informed consent form.

Sponsor shall pay for all medical expenses incurred by a study subject caused by the study [Drug] [Device] or by a procedure required by the Protocol, which was not part of standard of care.

Indemnification:

Geisinger requires the sponsor to indemnify the Institution and its agents, employees, investigators, directors and affiliated medical institutions from and against any claims (litigated or not), damages, liabilities, costs (including attorney's fees) and injuries, including, without limitation, injuries to persons or damage to property.

Sponsor shall defend, indemnify and hold harmless Institution and its agents, employees, investigators, directors and affiliated medical institutions at which the study is conducted, from and against any claims (whether litigated or not), damages, liabilities, costs (including attorneys' fees) and injuries, including, without limitation, injury to persons or damage to property, arising from or based on (i) subject injury from administration or use of the Study Drug/Device or from a procedure required by the Protocol; (ii) Sponsor's use, non-use, interpretation or disclosure of Study data or results; (iii) Sponsor's violation of any law or regulation or term of this Agreement; or (iv) negligent or intentional acts by Sponsor or Sponsor's employees, agents and subcontractors. This section shall survive termination of this Agreement. If both parties are deemed to be at fault, the indemnity of each party shall be to the extent of their percentage of fault or liability as determined by a court or by law. A failure to promptly notify Sponsor shall serve to reduce the indemnity rights of Institution only to the extent that such failure materially prejudiced Sponsor's defense of the claim. Sponsor shall not agree to a settlement that declares fault on the part of Institution without Institution's prior written consent.

Insurance:

Sponsors are required to provide adequate insurance coverage for indemnification purposes and product and clinical trial liability. The minimum coverage required is at least five (5) million per occurrence/aggregate. Evidence of adequate insurance coverage must be provided to Geisinger prior to execution of the agreement. Geisinger also requests (1) Tail coverage to be purchased for a 'claims-made' policy, (2) that it be added to the Sponsor's clinical trials insurance policy as an additional insured and (3) notification of an impairment of more than fifty percent of aggregate coverage.

Each party agrees to maintain during the term of this Agreement, at its own cost and expense, insurance coverage in amounts consistent with industry standards and necessary and reasonable to insure itself and its employees and agents against any claims of any nature, which may arise from performance of its duties and responsibilities under this Agreement. Notwithstanding the foregoing, Sponsor shall maintain general liability insurance coverage including products liability and clinical trial liability with minimum limits of 5 million per occurrence/annual aggregate. If any such insurance coverage is on a "claims-made basis", in the event the policy expires or is terminated, "tail coverage" must be purchased to cover any subsequent claims based on acts or omissions that occurred during the term of this Agreement. Upon request, the parties agree to provide one another with a Certificate of Insurance evidencing said insurance covering such liability with an insurer AM Best rated A or better or through a qualified self-insurance program. Sponsor shall add Institution as an additional insured to Sponsor's clinical trial liability policy. Both parties agree to notify the other party immediately if the aggregate coverage as stated on the Certificate of Insurance is impaired more than fifty percent (50%).

Security Provision:

Geisinger requires a provision that addresses sponsor's access to our records. Geisinger requires all sponsors take responsibility for their employees, contractors and/or agents including CROs ("Users"), who need access to our electronic health record to verify source documents. This provision ensures that Users will keep all Geisinger information, whether it be patient or system information, confidential. We will not execute any contracts that require on-site monitoring without this provision.

Sponsor acknowledges that certain employees, contractors and/or agents ("Users") of Sponsor may receive one or more user ID(s) and password(s), which allow Users to access the proprietary software of Institution or Institution's licensed vendors (cumulatively referred to as "System"). As a result, Sponsor's Users may have access to or discover confidential information including, but not limited to, medical information, records, software designs and/or information systems or data found in such Systems ("Information"). The Information contained in Institution's System as well as the System configuration is confidential and is subject to Sponsor's Users accessing and disclosing the Information in a confidential manner. Users will only access the Information and/or disclose the Information to Sponsor or authorized representatives of Sponsor as necessary to perform Sponsor's monitoring duties under this Agreement. Institution reserves the right to monitor access to the System by the Users. Any violation of this section by a User will result in the immediate loss of User's access privileges. Both Sponsor and Institution will report violations to the other so that appropriate action may be taken. Violations reported by Sponsor shall be directed to Institution's Information Security Office by calling (570) 271-8119. This section shall survive termination of this Agreement.

False Claims Act (FCA):

Geisinger includes our Institutional FCA policy for sponsors' review and includes our FCA provision in all contracts to notify the sponsor of Institution's obligations under the FCA.

Sponsor acknowledges the False Claims Act (31 U.S.C. § 3729-3733) ("FCA") imposes civil liability on any person or entity that knowingly, among other things, submits, or causes to be submitted, a false or fraudulent claim for payment to the U.S. government (e.g. Medicare/Medicaid). The parties recognize the mandates of the FCA as well as the summary of the FCA outlined in Institution's FCA policy which can be accessed at: http://www.geisinger.org/professionals/vendors/cred/index.html.

Publications:

As a non-profit organization, we cannot accept Publication language that requires Sponsor approval of our Publication. We can accept language that requires prior review and comment. We can also agree to a limited publication delay to remove confidential information of the Sponsor and/or to determine whether there is any intellectual property that merits protection.

Institution shall furnish Sponsor with a copy of any proposed publication for review and comment at least thirty (30) days prior to submission for publication, during which time period Sponsor may provide written comments with respect to the material. If Institution receives no written response from Sponsor at the expiration of such review period, Institution may proceed with submission for publication. If Sponsor's written comments, provided to Institution prior to the expiration of the relevant review period, specifically identify Sponsor Confidential Information that might be disclosed by Institution's publication, Institution will refrain from disclosing the specified Sponsor Confidential Information. If Sponsor's written comments, provided to Institution prior to the expiration of the relevant review period, specifically identify any Sponsor invention for which Sponsor intends to obtain a patent or perfect another intellectual property right, Institution shall then delay publication for a period of up to thirty- (30) days after the expiration of the review period in order to allow Sponsor to secure patent protection or perfect other intellectual property rights in the Sponsor Invention. Unless otherwise required by the publisher, Institution shall retain all rights to such publications and other copyrightable material that it shall produce pursuant to this Agreement.

Promotional Materials:

Geisinger requests permission to post study specific information on its web site and in its research newsletter. This information is used for study recruitment, as well as, to allow the community and employees to be aware of the research activities that Geisinger is participating in at any given time.

The parties agree that Institution may post the following information on its web site and research newsletter, with prior approval of the IRB if required: name of institution, sponsor and principal investigator; title, area and/or description of the study; institution's internal project number; institution's contact information.

The Pennsylvania Breach of Personal Information Notification Act ("Act 94"):

Geisinger is required to include language regarding Act 94 to protect individuals' personal information. Personal information is defined as:

(1) An individual's first name or first initial and last name in combination with and linked to any one or more of the following data elements, when the data elements are not encrypted or redacted (removed or blackened out):

(i) Social Security Number.
(ii) Driver's license number or a state identification card number issued in lieu of a driver's license.
(iii) Financial account number, credit or debit card number, in combination with any required security code, access code or password that would permit access to an individual's financial account.

The Pennsylvania Breach of Personal Information Notification Act ("Act 94") was enacted to protect individuals' personal information. Notwithstanding anything in this Agreement to the contrary, if Sponsor requires an individual's Personal Information (as defined under Act 94) to be transferred from Institution, Sponsor shall ensure its employees, agents and/or subcontractors use appropriate encryption or redaction to protect such Personal Information from being accessed and/or acquired in an unauthorized manner. Sponsor further agrees to (i) immediately notify Institution upon the discovery of any incidents or occurrences where Personal Information has been accessed and/or acquired in an unauthorized manner; (ii) cooperate with Institution as requested by Institution so that Institution may provide notification to those individuals whose Personal Information was accessed and/or acquired in such unauthorized manner; and (iii) cover any costs, losses or damages incurred by Institution due to Personal Information being accessed and/or acquired in an unauthorized manner while in the possession of Sponsor or its employees, agents and/or subcontractors.

Ancillary Studies:

Institution will allow study subjects to participate in other studies as long as they do not jeopardize or conflict with your study.

Institution will not knowingly allow a Study subject to participate concurrently in any study (other than those set forth in the Protocol for the Study, if any) where the subject is receiving an investigational product as part of any other study that would jeopardize or conflict with the Study without the prior written approval of Sponsor.

Biological Samples:

Geisinger has pre-existing contractual limitations on the use of biological samples with commercial partners. Sponsor may use biological samples collected for the Study only for conducting the Protocol.

Specimens collected during the Study as set forth in the Protocol ("Biological Samples") include, without limitation, blood, serum, fluid and tissue biopsy samples collected from subjects enrolled in the Study. Biological Samples further include, without limitation, any tangible material directly or indirectly derived from such blood, fluid or tissue samples, such as: genes, gene fragments, gene sequences, proteins, protein fragments, protein sequences, probes, DNA, RNA, cDNA libraries, plasmids, vectors, expression systems, cells, cell lines, organisms, antibodies or other biological substances; and any constituents, progeny, mutants, variants, derivatives, replications, reagents or chemical compounds thereof or derived therefrom.

Institution and Investigator will collect Biological Samples from Study subjects pursuant to the Protocol. Institution retains all right, title and interest in and to the Biological Samples, and Institution hereby grants Sponsor an exclusive, royalty-free license to use the Biological Samples in accordance with the terms of the Informed Consent (a) for the purposes of conducting the Study as set forth in the Protocol, (b) for the purposes of obtaining and maintaining regulatory approval of the Study Drug/Device; and (c) for use in conjunction with the publication rights set forth in this Agreement.

Enrollment Incentives:

No payment will be based on the outcome of the study, volume of work, number of subjects enrolled/screened, rate of enrollment or any other similar type of milestone.

Federal Reimbursement:

If any element of the contract is reimbursable by a federal program, the following points will need to be included:

- **Access to records by the Comptroller General of the United States Health and Human Services**
  If the services provided under this Agreement have a cost or value of $10,000 or more over a twelve (12) month period, the parties agree to preserve and provide access to each one's contracts, books, documents, and records to the Comptroller General of the United States, Health and Human Services, and their duly authorized representatives until the expiration of four (4) years after the furnishing of services under this Agreement or as may be provided by regulation from time to time to implement the provisions of the Social Security Act relating to the determination of reasonable costs as a provider of, or a subcontractor of, services under the Medicare program.
- **Specific compliance with laws respecting discrimination**
  Each party agrees to comply with all applicable Federal, state and local laws respecting discrimination. The parties hereby incorporate the requirements of 41 C.F.R. § 60-1.4(a), 41 C.F.R. § 60-741.5(a), 41 C.F.R. § 60-250.5(a), 41 C.F.R. § 60-300.5(a), and 29 C.F.R. § 471 Appendix A to Subpart A (Executive Order 13496), as applicable. This contractor and subcontractor shall abide by the requirements of 41 CFR 60-741.5(a). This regulation prohibits discrimination against qualified individuals on the basis of disability, and requires affirmative action by covered prime contractors and subcontractors to employ and advance in employment qualified individuals with disabilities. This contractor and subcontractor shall abide by the requirements of 41 CFR 60-300.5(a). This regulation prohibits discrimination against qualified protected veterans, and requires affirmative action by

covered prime contractors and subcontractors to employ and advance in employment qualified protected veterans.

- **Certification that you and your principals are not presently debarred, suspended, proposed for debarment, or declared ineligible for the award of contracts by any federal agency and have not been convicted of a criminal offense related to the provision of health care items or services**

  The parties certify, to the best of their knowledge and belief, after due inquiry using industry standards, that the parties and/or any of their principals: (i) are not presently debarred, suspended, proposed for debarment, or declared ineligible for the award of contracts by any federal agency; and (ii) have not been convicted of a criminal offense related to the provision of health care items or services. Industry standards shall include, but not be limited to, performing monthly exclusion checks on federal and state exclusion databases for its employees, agents and contractors performing its duties under this Agreement. Upon request, each party shall provide the other party documentation evidencing such completed exclusion checks and compliance with this Section. During the term of this Agreement, the parties shall provide immediate written notice to the other parties if any party learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances. In the event any party's certification is or becomes erroneous, the other party may terminate this Agreement immediately upon notice.

On-site Monitoring:

If Sponsor/CRO comes on-site to perform monitoring activities, we require adherence to our policies that prohibit the use of drugs, alcohol and tobacco.

While on-site at Institution, Sponsor and/or its authorized representatives agree to observe applicable Institution rules, policies and standards including, but not limited to: (i) Drug and Alcohol Policy prohibiting the use, possession, transportation, promotion or sale of alcohol, drugs and drug paraphernalia; and (ii) Tobacco Free Policy prohibiting the sale or use of tobacco products. Notwithstanding any other provision herein, in the event the Sponsor and/or its authorized representatives fail to observe such policies while on-site at Institution, Institution may request and Sponsor will immediately comply with having any such offending individual removed from Institution's site. Sponsor may replace the removed representative as determined necessary by Sponsor.

Access to Patient Information:

Geisinger requires anyone who is given or has access to PHI to have had a Police criminal history record check in Sponsor's respective area, which does not show any relevant criminal history.

Sponsor warrants that the following criteria have been met for each of its applicable (as set forth below) employees, agents and/or subcontractors ("Representatives") and shall provide evidence of such to Institution immediately upon request:

A. For those Representatives who have access to individually identifiable health information pursuant to this Agreement, a Police criminal history record check in Sponsor's respective area, which does not show any relevant criminal history.

Notwithstanding other termination provisions contained herein, any failure under this section may result in immediate termination of this Agreement by Institution.

Inventions / Intellectual Property:

Geisinger cannot contractually agree to give ownership of Geisinger invented IP related to management of quality and cost of care to a third party.

Existing inventions, ideas, discoveries, technologies and methodologies of each party are their separate property, whether or not protected by patent or other intellectual property rights, and are not affected by this Agreement. Neither party shall have any claims to or rights in such inventions, ideas, discoveries,

technologies and methodologies of the other party. Any inventions or discoveries arising from Institution's participation in the study ("Sponsor Inventions") shall be owned by Sponsor. Upon Sponsor's request and at Sponsor's expense, Institution agrees to assist Sponsor with such reasonable actions necessary to protect Sponsor's ownership of such Sponsor Inventions.