Process for Securing UPHS Approval for New Technology to be Used in Clinical Research

1. Purpose:

The University of Pennsylvania Health System ("UPHS") manages the use of new technology via the New and Existing Technology Committee ("NETC"). Each of Penn Presbyterian Medical Center ("PPMC") and the Hospital at the University of Pennsylvania ("HUP") has a NETC, which is known as the Supply Chain Committee at HUP ("HUP SCC"). PPMC also has an Operating Room ("OR") Committee that reviews all technologies being used in the OR. Decisions by the PPMC NETC and HUP Supply Chain Committee are reviewed by the Corporate NETC. Technologies for which UPHS does not have established commercial contracts are considered "new" for purposes of NETC review. Each hospital makes its own decisions as to whether technologies under established commercial contracts are approved for use within the hospital. The ability to obtain NETC approval is a critical element of the feasibility analysis for the research project.

The purpose of this document is to provide guidance to research administrative professionals regarding the NETC review process so as to enable appropriate NETC review of new technology being used in clinical research.

2. Scope:

This guidance applies to any technology (e.g., devices, ancillary supplies needed to use devices, equipment) to be used in the OR, catheterization lab or elsewhere in HUP, PPMC or Pennsylvania Hospital that have not been approved for use in UPHS by the hospital’s NETC.
3. Instructions:

NETC review is required for all new technology used in clinical research studies. The principal investigator is required to ensure NETC review as part of the analysis of the feasibility of the research. Securing NETC review is a necessary step prior to finalization of a clinical trial agreement.

4. Procedures:

The business office (or other delegate) of the department of the principal investigator on the research study initiates a request for NETC approval as early as feasible. The NETC expects to review the contract, protocol and any supply agreements provided by the sponsor (drafts are acceptable). It is important that any supplies and equipment needed for use in connection with new technology are identified in connection with NETC review.

For corporate-funded clinical research projects, the NETC request is to be submitted no later than the submission of the parallel review request to the Office of Clinical Research Clinical Trial Contracting Unit ("OCR CTCU") for negotiation of the funding agreement. OCR CTCU should be copied on the request for review by NETC, which should include a request to copy OCR CTCU at psom-ctcu: ocr@pennmedicine.upenn.edu on subsequent communications regarding the NETC review.

Considerations relevant to NETC review include whether the technology is being provided at no charge, whether Medicare reimbursement is available for the device and, when the company plans to charge for the technology, the price of the technology. Questions regarding the process for determining the availability of Medicare reimbursement for a specific technology to be used in clinical research may be referred to Office of Clinical Research Finance (OCRF). Even if covered by Medicare, new technologies need NETC approval.

NETC review should occur in parallel with contract and other budget negotiations and submission to the NETC should occur no later than the point at which a parallel review request is submitted to the OCR CTCU. Study teams are also encouraged to pursue IRB review in parallel to contract and budget/NETC review.
OCR CTCU negotiators will be responsible for including appropriate provisions in the funding agreement, specifically:

Company shall retain title and ownership of the Device/Equipment for the duration of the loan period. Company, at its sole expense, shall be responsible for delivering and removing the Device/Equipment to Institution and for the repair, maintenance and risk of loss of the Device/Equipment for the duration of the loan period. Company shall provide all necessary training and documentation for the safe and appropriate use of the Device/Equipment by Institution.

Institution will provide a no-charge purchase order number for the Devices to be consigned to Institution. Until a Device is implanted or used by Institution, the Device shall remain the sole property of Company.

Ideally, devices, equipment, supplies and other items used in research are secured at no cost. When there is a cost associated with any such items, NETC review takes into account the relative potential benefit of the item(s) as well as the cost relative to other items in the same category already available in UPHS.

For technology for which the Company is charging, OCR will rely on NETC review of project specific terms, including pricing, when finalizing contracts relating to acquiring the technology.

5. Roles and Responsibilities:

Principal Investigator:

Responsible for ensuring any required NETC review of new technology.

The Business Office (or delegate) supporting the Principal Investigator:

Responsible for making the NETC submission and securing NETC approval.

NETC:

Responsible for reviewing submissions and approving project-specific terms, including pricing, in accordance with its usual procedures.

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Responsible for advising departments regarding the process for determining the availability of Medicare reimbursement for the use of technology in clinical research.

OCR CTCU:

Responsible for including terms for no cost technology and advising company sponsors of additional terms for technology for which a company is charging.