Regulatory and Financial Guide for Conducting Research at Norton Healthcare

Norton Healthcare Office of Research Administration
Standard Operating Procedures
Norton Employed Researchers

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1. GENERAL INFORMATION AND INTRODUCTION TO THE NORTON HEALTHCARE (NHC) OFFICE OF RESEARCH ADMINISTRATION

Norton Healthcare Office of Research Administration (NHORA)

Norton Healthcare has a tradition of excellence in research and a continuing commitment to protect the interests and well being of human subjects. We are committed to the policies and practices for ethical conduct of human research and reaffirm this commitment through our policies.

VISION

- To assist Norton Healthcare in becoming a recognized leader in conduct of clinical research

MISSION

- To increase the depth and breadth of studies conducted at Norton Healthcare
- To assist investigators in the conduct of research in a customer service oriented manner
- To uphold regulatory, compliance and ethical principles for the proper conduct of research within our facilities

In the interest of promoting the mission, vision and values of Norton Healthcare and to assure and promote a safe environment for subjects participating in research within Norton Healthcare facilities all policies and procedures shall be followed.

In 2001 Norton Healthcare established the Norton Healthcare Research Office (NHRO) now known as the Norton Healthcare Office of Research Administration (NHORA). NHORA is responsible for the oversight of clinical research activities within Norton Healthcare. Such activities include:

- Review of regulatory documents
- HIPAA compliance
- Financial management of research revenues and expenses
- Management of research billing for research subjects treated in NHC facilities
- Regulatory submissions to the IRB and facilitating clinical research educational programs
- Liaison with the University of Louisville Institutional Review Board and Western Institutional Review Board
- Maintain Norton Healthcare's Federalwide Assurances (FWA) with DHHS
- Serve as liaison with federal and state agencies

Norton Healthcare Systems Clinical Research Operations

For questions or procedure information relating to the clinical operations of a trial, please refer to the Norton Healthcare Research Program Standard Operating Procedures for Systems Operations. These SOPs contain guidance for the informed consent process, Good Clinical Practice (GCP), protocol compliance, source documentation/CRF completion, eligibility and enrollment, investigational product management, adverse event reporting and monitoring visits. For more information please contact the Director, Systems Clinical Research Operations at 502-629-3550.

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2. INSTITUTIONAL REVIEW BOARDS

The role of the institutional review board (IRB) is to ensure that human research activities are conducted in accordance with applicable federal and local regulations pertaining to human subjects protection in research, as well as the principles of the Belmont Report. IRBs have authority to approve, modify, or disapprove human research conducted within an institution, as well as terminate research not conducted in compliance with the regulations or deemed unsafe for human subjects. IRBs follow guidance and enforce regulations mandated by the Office of Human Research Protections (OHRP) within the United States Department of Health and Human Services and for drug and biologic research, the Federal Food and Drug Administration (FDA). NHC holds a formal agreement, or Federalwide Assurance (FWA), with OHRP listing the University of Louisville IRB and the Western IRB (WIRB) as approved IRBs of record for federally funded human research conducted within a NHC facility. However, NHC requires IRB review of all research by UofL IRB or WIRB for all research regardless of funding. Both the UofL IRB and WIRB also serve as the Privacy Boards which review and approve research documents in accordance with the HIPAA Privacy Rule.

NHC policy states the investigator must follow the rules and regulations set forth by the respective IRB or the research will not be allowed in a NHC facility.

The University of Louisville Human Subjects Protection Program Office (HSPPO)

The HSPPO serves as the administrative office for the University of Louisville's Behavioral and Social IRB and the Biomedical IRB. The HSPPO is fully accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP). All researchers affiliated with the University of Louisville or utilizing a University of Louisville facility for research must use the U of L IRB as the IRB of record.

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Western Institutional Review Board (WIRB)

Any researchers not affiliated with the University of Louisville or its facilities have the option of using the U of L IRB or the Western Institutional Review Board (WIRB) as the IRB of record. WIRB is an AAHRPP fully accredited IRB located in Olympia, WA.

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3. SUBMISSION OF APPLICATION TO CONDUCT RESEARCH

It is the policy of NHC that all research activities conducted in a NHC facility, or by Norton employees, be submitted to the NHORA for review prior to initiation of research in a NHC facility.

Definition of Research - Is Your Project Considered Research?

Research is defined in Federal regulations (45 CFR 46) as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." In 21 CFR 50, the Federal Food and Drug Administration (FDA) defines a clinical investigation as "any experiment that involves a test article in one or more human subjects…". This section will define research and also gives examples of projects that may not be considered human research.

Human Subjects are defined in 45 CFR 46 as "living individuals about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information." The FDA regulations define human subjects as "an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or patient."

All human subject research conducted by or under the auspices of Norton Healthcare will be performed in accordance with Title 45 Code of Federal regulations, Parts 46, 160 and 164 and Title 21 Code of Federal Regulations Parts 50, 56, 312 and 812. In addition, Norton Healthcare will also conform to all applicable Federal (Food and Drug Administration, National Institutes of Health, Office for Human Research Protections, etc), State and local laws and regulations.

Institutional Review Board Exempt Research

Institutional Review Boards may make a determination if research is exempt from IRB oversight. An investigator may make the claim of exemption, but only the IRB may determine if the research meets the criteria for exempt research set forth in federal and local requirements. This determination is made if the research is conducted in one or more of the following categories as listed in 21 CFR 56.104 (a-d) or 45 CFR.101 (b)(1-6)

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as

   (i) research on regular and special education instructional strategies, or

   (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

   (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
   (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:

   (i) the human subjects are elected or appointed public officials or candidates for public office; or
   (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

   (i) Public benefit or service programs;

   (ii) Procedures for obtaining benefits or services under those programs;

   (iii) Possible changes in or alternatives to those programs or procedures; or

   (iv) Possible changes in methods or levels of payment for benefits or services under those programs.

6. Taste and food quality evaluation and consumer acceptance studies,

   (i) if wholesome foods without additives are consumed or

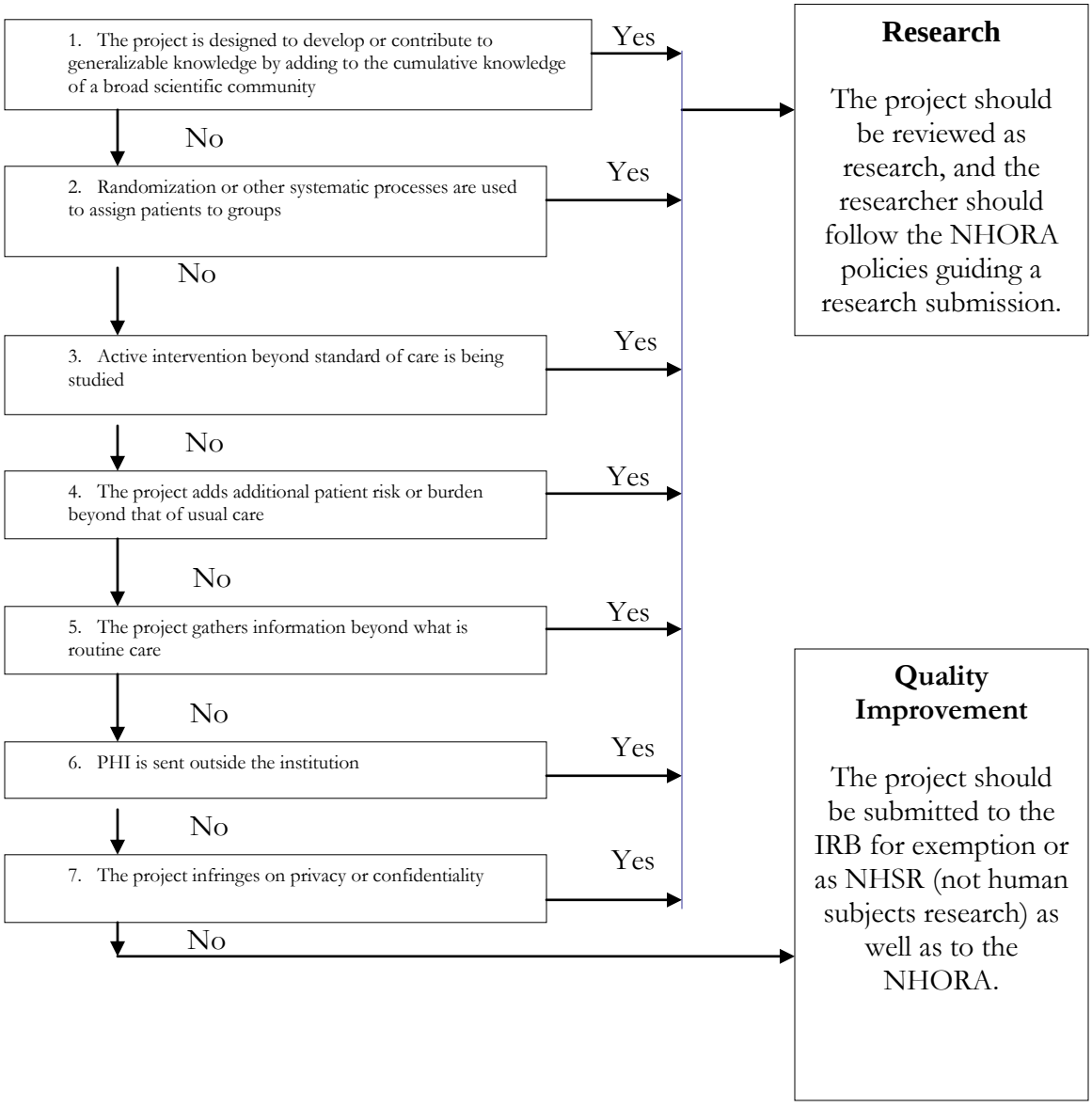
   (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

7. Clinical investigations regulated by 21 CFR 56.104 consist of the following categories:

   a. Any investigation which commenced before July 27, 1981 and was subject to requirements for IRB review under FDA regulations before that date, provided that the investigation remains subject to review of an IRB which meets the FDA requirements in effect before July 27, 1981
   b. Any investigation commenced before July 27, 1981 and was not otherwise subject to requirements for IRB review under Food and Drug Administration regulations before that date.
   c. Emergency use of a test article, provided that such emergency use is reported to the IRB within 5 working days. Any subsequent use of the test article at the institution is subject to IRB review.
   d. Taste and food quality evaluations and consumer acceptance studies, if wholesome foods without additives are consumed or if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural, chemical, or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service or the U.S. Department of Agriculture.

Quality Improvement Studies

Quality improvement (QI) studies are often internal investigations of current practices aimed to identify weak areas and improve current practices. The OHRP does not clearly distinguish between quality improvement studies and research, and it may often be unclear if QI studies should be treated as human subjects research or exempt from IRB oversight. The NHORA uses the following schematic as a decision model for QI studies:



Not Human Subjects Research (NHSR)

NHSR activities do not meet the definition of research. This does not require a full IRB review, and no IRB oversight is necessary. An abbreviated application through the U of L IRB BRAAN2 system is required for NHSR determination, but no special research training is required for this application. Although the results of NHSR may be shared outside the institution, it must be stated that the intent of the activity must not be for general applicability outside the institution. If the results are not shared outside the institution, IRB contact is not required.

Registries

Registry studies are studies that do not require an intervention such as a drug or research procedure. Registry studies usually require subject data collected over a period of time in order to determine outcomes of a specific research question. Although no intervention is involved, they are still considered to be research and have the same IRB and NHORA requirements as standard research protocols.

Humanitarian Use Devices

Humanitarian Use Devices (HUDs) are devices intended to benefit patients by treating a condition that affects less than 4,000 individuals in the United States per year. The FDA grants a Humanitarian Device Exemption (HDE) to a device maker as an incentive for the development of devices for diseases affecting these populations. An HDE approval authorizes marketing of the HUD similar to a pre-market approval (PMA), but is exempt from the FDA effectiveness requirements. However, the HUD application must contain sufficient information for FDA to determine that the device does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit to health outweighs the risk of injury or illness from its use. Although not considered "research", FDA requires that IRB approval be obtained before using the HUD. It is the IRB's responsibility to supervise the use of the device and to ensure that the device is being used as indicated in the HDE. It is also the IRB's discretion as to how much oversight is needed (e.g. under a protocol or a case-by-case basis).

Each HUD intended for use in a Norton facility must also have approval by the NHORA. The submission requirements are the same as for a research study application. As HUDs are technically not research, the device sponsor company will often not provide the device and will expect the patient's insurance to reimburse all costs.

Before submission to an IRB, each HUD must receive approval from the Technology Assessment Committee (TAC) before use within NHC facilities. The investigator must complete the New Product and Technology Request form (Attachment A) and return to Materiel Management for consideration at the next TAC meeting. Contact Material Management at 502-629-2149 for information.

Emergency Use of Investigational Drugs or Biologics

The federal regulations [21 CFR 56.102 (d)] define emergency use as the use of an investigational drug or biological product with a human subject in a life-threatening or severely debilitating situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain IRB approval. Life threatening and severely debilitating are defined as the following:

1. Life-threatening means diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted and diseases or conditions with potentially fatal outcomes, where the end point of clinical trial analysis is survival. The criteria for life-threatening do not require the condition to be immediately life-threatening or to immediately result in death. Rather, the subjects must be in a life-threatening situation requiring intervention before review at a convened meeting of the IRB is feasible.
2. Severely debilitating means diseases or conditions that cause major irreversible morbidity. Examples of severely debilitating conditions include blindness, loss of arm, leg, hand or foot, loss of hearing, paralysis or stroke.

The emergency use provision in the FDA regulations allows for one emergency use of a test article without prospective IRB approval, and that all subsequent uses have prospective IRB review and approval. If the article is to be used within a NHC facility, this review and approval is also extended to the NHORA. The investigator must report the emergency use to the IRB within 5 working days, and should also notify the NHORA if the use occurred within a NHC facility. Such notification should not be considered an approval.

Federal regulations also specify criteria for the exception of the informed consent requirements for emergency use situations. Informed consent is required unless the investigator and a physician not associated with the clinical investigation certify in writing in the subject's medical record:

1. The subject is confronted by a life-threatening situation necessitating the use of the test article.
2. Informed consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent from, the subject.
3. Time is not sufficient to obtain consent from the subject's legal representative.
4. No alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the subject's life.

Emergency Use of Unapproved Devices

An unapproved device is a device that does not have an FDA pre-market approval or 510(k) clearance. These devices may be only used in human subjects with an approved Investigational Device Exemption (IDE). In emergency situations where an IDE does not exist, or the physician or institution are not approved under the existing IDE, the FDA requires the physician to justify in writing to the FDA that that following conditions existed:

1. The patient is in a life-threatening condition that needs immediate treatment
2. No generally acceptable alternative for treating the patient is available; and
3. Because of the immediate need to use the device, there is no time to use existing procedures to get FDA approval for the use.

The investigator should document substantial reason to believe that benefits will exist from using the unapproved device, and to follow as many human subjects protection procedures as possible including:

1. Obtaining an independent assessment in writing, documented in the patient/subject's medical record by an uninvolved physician
2. Obtaining informed consent from the patient or a legal representative;
3. Notifying institutional officials as specified by institutional policies;
4. Notifying the Institutional Review Board (IRB); and
5. Obtaining authorization from the IDE holder, if an approved IDE for the device exists.

In addition to notifying the IRB, the physician must also notify the NHORA if the unapproved device was used in an emergency situation. After the unapproved device is used, the physician must:

1. Report to the IRB within five days [21 CFR 56.104(c)] and otherwise comply with provisions of the IRB regulations [21 CFR part 56];
2. Evaluate the likelihood of a similar need for the device occurring again, and if future use is likely, immediately initiate efforts to obtain IRB approval and an approved IDE for the device's subsequent use; and
3. If an IDE for the use does exist, notify the sponsor of the emergency use, or if an IDE does not exist, notify FDA of the emergency use (CDRH Program Operation Staff 301-594-1190) and provide FDA with a written summary of the conditions constituting the emergency, subject protection measures, and results.

Subsequent emergency use of the device may not occur unless the physician or another person obtains approval of an IDE for the device and its use.

Submission to the Institutional Review Board and NHORA

The NHORA Regulatory Affairs and Financial staff will assist in the preparation and submission of the regulatory documents, study budget and clinical trial agreement to the sponsor and IRB of record on your behalf. Our staff will work closely with yours in order to obtain any necessary information and required signatures. Regulatory and financial documents will be maintained in our offices and we will coordinate regulatory monitoring visits throughout the life of the study.

The following documents are required in your submission to NHORA (as appropriate to type of study):

- JHSMH/NHC MIRA form (if study performed at multiple institutions) (Attachment B)
- Completed IRB application (WIRB only) www.wirb.com
- Scientific and Scholarly Merit Review Form (U of L only) (Attachment C)
- Informed Consent Form (ICF) using the approved language template OR an application of a waiver of informed consent
- Applicable HIPAA documents (e.g. Research Authorization, Complete or Partial Waiver)
- Protocol and Synopsis
- Time & Events schedule delineating research v. standard of care procedures, signed and dated by PI which will be used to create the Billing Compliance Table (BCT)
- Recruitment Advertisements
- FDA Form 1572, if applicable
- Contract or Letter of Agreement (draft is acceptable until finalized)
- Budget (draft is acceptable until finalized)
- CV (Curriculum Vitae) and current professional license for the PI and Sub-Is
- Certification of Human Subjects Protection Training (CITI) for key personnel
- For drug studies: Investigational Drug Brochure or background information for food supplements
- Gene Therapy protocols: either a request for Institutional BioSafety Committee (IBC) review or the IBC approval
- For device studies: a copy of the signed investigator agreement for protocols with an IDE and **one** of the following:
  - FDA letter approving the Investigational Device Exemption (IDE)
  - 510(k) clearance
  - Letter from the sponsor stating significant or non-significant risk (final designation determined by the IRB)
  - Pre-Market Approval (PMA) letter
  - PMA supplemental letter
  - PMA amendment letter

Submission Process Using the University of Louisville Institutional Review Board

For all research intended to be conducted at a NHC facility in which the University of Louisville Institutional Review Board is the IRB of record, an electronic application must be submitted to UofL IRB through the BRAAN2 (electronic) system. Instructions for using BRAAN2 may be found on the IRB's website, http://louisville.edu/research/humansubjects. If a NHC facility is selected as a research site on the application, the NHORA will have access to all documents in the system associated with the research study. Please direct all BRAAN2 questions to the HSPPO at 502-852-5188.

Prior to the NHORA review of a new study, the researcher/research team must furnish a copy of the BCT (Attachment D) that has each service or procedure classified as either "C"= conventional care or "R" = research. Items should only be classified as conventional if they would be performed in the normal course of care for the patient absent participation in the clinical trial. The BCT must contain the printed name of the PI, signature of the PI and date, as well as the person completing the form.

Scientific or Scholarly Merit Reviews

The University of Louisville requires a Scientific or Scholarly Merit review of every research study involving human subjects proposed to take place in NHC facilities where the University of Louisville is the IRB of record. The purpose of this review is to ensure that the scientific approach is sound, that the research design will yield valid results and appropriate departmental resources are approved and available for the completion of the project. Each NHC employed researcher is responsible for identifying one or more impartial and competent peers to assess the project for scientific or scholarly merit.

The review takes place according to the following procedure:

1. The Investigator identifies the scientific and scholarly merit reviewer(s) and provides the reviewer with a copy of the research documents.
2. The reviewer assesses the research for scientific or scholarly merit, completes the NHC Scientific or Scholarly Merit Review of Research Protocols Involving Human Subjects form (Attachment C) and returns the signed document to the Investigator.
3. The Investigator, or NHORA personnel, uploads the NHC Scientific or Scholarly Merit Review of Research Protocols Involving Human Subjects form as part of the BRAAN2 submission.
4. Once submitted in BRAAN2 the Systems Director of NHORA will sign off as the Institutional Official on the IRB submission to complete the process.

Submission Process Using the Western Institutional Review Board

For all research intended to be conducted in a NHC facility in which the Western IRB (WIRB) is the IRB of record, the application must be submitted to NHORA for conditional approval prior to submission to WIRB. The WIRB submission materials are available on their website, www.wirb.com. WIRB will not accept a NHC application without the NHORA conditional approval letter.

Review Process

- Once the above-listed documents are available as a complete package, the study is assigned a NHORA tracking number. The NHORA tracking number is sent to the researcher along with confirmation of receipt of submission. This number should be used in all correspondence relating to the study.
- The NHORA will conduct an internal evaluation of the submission to include regulatory, compliance and financial review. Any questions or comments raised during the review will be forwarded to the researcher within 5 business days. If a response is not received in 10 business days, the researcher will be queried.
- Once all questions and comments have been addressed, the NHORA will issue the NHORA Conditional Approval Letter to the researcher. WIRB will not review a study submission with NHC as a facility without the NHORA Conditional Approval letter.
- Researcher will submit WIRB application and study documents, along with NHORA Conditional Approval Letter using the WIRB online submission website.
- Final NHORA approval will be granted upon receipt of resolved questions/issues, IRB approval, department approval and final contract

Prior to the NHORA review of a new study, the researcher/research team must furnish a copy of the BCT (Attachment D) that has each service or procedure classified as either "C"= conventional care or "R" = research. Items should only be classified as conventional if they would be performed in the normal course of care for the patient absent participation in the clinical trial. The BCT must contain the printed name of the PI, signature of the PI and date, as well as the person completing the form.

4. REGULATORY MAINTENANCE OF RESEARCH AT NORTON HEALTHCARE

Annual Continuing Review

The federal regulations do not allow an IRB to approve a study for more than one year. An IRB may approve studies for a period shorter than one year based on the degree of risk. For multi-year research, the principal investigator is responsible for submitting a continuation application prior to the expiration date of the current IRB approval. Although the NHORA does not grant annual continuing renewals, the investigator must forward a copy of this application and progress report to the NHORA. If the approval expires prior to submission of the continuation application, the investigator is required to suspend subject contact, recruitment, and data collection until the continuation is approved by the IRB, unless the IRB allows follow up for safety reasons. The investigator is also responsible for ensuring that NHORA receives a copy of the approval letter and current informed consent form with the dated IRB stamp.

Amendments

During the conduct of a study, changes to the protocol may be proposed, or unintentional changes may be discovered. Changes to the IRB-approved protocol, planned or otherwise, are governed by federal regulations and IRB policies and procedures. The NHORA must be notified of all amendments relating to personnel changes, accrual goals, treatment plans, or safety.

Study Closure and Termination

Investigators are responsible for informing the IRB and NHORA when a study has been closed to accrual, is completed, or is being terminated by the sponsor. The investigator must forward a copy of the IRB's acknowledgement letter to NHORA. Upon receipt, the NHORA will move the study to closed status.

Record Retention

The federal regulations under 21 CFR 312.64 regarding record retention for clinical research state the investigator must retain records for 2 years after the drug has obtained approval by the FDA for all drug research. Depending on the application complexity and level of FDA review, requirements for retaining documents will vary. Institutional review boards and sponsors may also have requirements for retaining research records. Researchers must be cognizant of federal, sponsor, institutional and IRB retention policies and must maintain the records for whichever requires the greatest retention time. During this time all records must be accessible for audit and inspection by authorized parties.

5. RESEARCHER RESPONSIBILITIES

Investigator Certification

As part of the initial submission of research to the NHORA, an investigator is certifying, to the best of his or her knowledge, the research proposal is scientifically sound, ethical, respects and protects the rights and welfare of human subjects in research, and the information contained in the application is complete and true. The investigator must also agree to adhere to the credentialing requirements of the respective institution(s), the compliance policies and procedures, all billing practices of the institution(s), all regulations (e.g. not to bill any third party payer for items specifically reimbursed by a sponsor), and to conduct the study within the guidelines of good clinical practice.

Credentialing for External Research Monitors

All external research monitors who will be viewing protected health information of NHC patients via our electronic medical records systems will need to obtain the appropriate privileges. Monitors will be required to complete the necessary Information Security (IS) forms. These forms can be obtained from the NHORA. Once forms are completed they must be returned to the NHORA at NHORA@nortonhealthcare.org at least 7 business days before the monitoring visit. These forms will be forwarded to HIM and IS for processing. A temporary user id and initial sign on password will be set up and provided to the monitor. On the day the monitor is visiting, IS will activate the user and inactivate the user at the end of the review. HIM will run weekly audits to generate reports of what records the monitor accessed. The research coordinator must provide HIM with a list of patients enrolled in the study being monitored within 48 hours of the monitoring visit. If there is a discrepancy, appropriate management and staff will be notified. Please contact the NHORA for information and/or to request the necessary forms.

Required Research Training

Any researcher performing research on human subjects is required to have adequate human subjects protection training. In conjunction with IRB training requirements, NHORA requires documentation of completion of the Collaborative Institutional Training Initiative, Group 1, Biomedical Research Investigators and Key Personnel, at www.citiprogram.org. The CITI Refresher courses and other IRB approved courses are accepted for biennial human subjects training once the initial CITI course is successfully completed. The NHC affiliation to this program is through the University of Louisville or Western IRB, depending upon the IRB used.

Additionally, if the University of Louisville IRB is the IRB of record, investigators are required to have certification of University of Louisville provided training concerning the Health Insurance Portability and Accountability Act of 1996 (HIPAA) that ensures privacy of protected health information.

Disclosure of Financial Conflict of Interest

Conflicts of interest in research occur when one or more researchers have a significant financial interest in their proposed research. Significant financial interest does not refer to receiving funding to cover the costs of conducting research. A conflict of interest exists when an independent observer may reasonably determine that the significant financial interest may affect or appear to affect the design, conduct, management or reporting of the research. Norton Healthcare requires full disclosure of any financial arrangements or other benefits that investigators and key personnel have in relation to research studies, funded or non-funded, in which they participate, whether it is in the form of items, grants, other funds, contracts, ownership, investments or otherwise. Covered by the Financial Disclosure of Significant Financial Interest policy are the investigators and all other key personnel involved in the treatment or evaluation of a research subject. Each person is defined to include their spouse, dependent children, and partnership interests.

Financial conflicts of interest are reviewed in the following manner:

- Norton Healthcare employed researchers are required to submit annually to the NHORA the Norton Healthcare Financial Disclosure Declaration (Attachment E).
- For research affiliated with the University of Louisville, the U of L Office of Research Integrity requires an annual Disclosure of Significant Financial Interest.
- IRB applications require answers to questions regarding financial conflicts of interest.

A person identified as having a conflict of this nature must submit a conflict management plan to the NHORA. The NHORA will forward this to the Norton Healthcare Financial Conflict of Interest Committee. This committee has representation from the NHORA, Norton Healthcare Corporate Compliance and the Norton Healthcare Legal/Risk Management Department. The management plan should provide information that shows that the conflict of interest is being managed in such a fashion that the researcher's bias is removed from the management of the study. Norton Healthcare reserves the right to take necessary action and/or terminate the research being conducted in its facilities for non-disclosure of financial conflicts of interest.

6. HIPAA AS IT PERTAINS TO RESEARCH AT NORTON HEALTHCARE

The HIPAA Privacy Rule

The Health Insurance Portability and Accountability (HIPAA) Privacy Rule regulates how protected health information (PHI) may be used and disclosed for research purposes. HIPAA requires that notice is given to patients on the use and disclosure of PHI. However, patients whose records are accessed for screening or other feasibility investigations have not consented to participate in research or given authorization to release PHI. The process to gain access to PHI without authorization from the research subject is either through a waiver of authorization or through preparatory to research activities.

A waiver of research participants' authorization for use or disclosure of information must be approved by the Privacy Board/IRB through full board or expedited review procedures. The composition and operation of a Privacy Board for research are similar to those governing an IRB.

Both the UofL IRB and WIRB serve as Privacy Boards that approve waivers of authorization in accordance with the HIPAA privacy rule for NHC.

Preparatory to Research

Often in order to design a research protocol for IRB review or a research grant proposal, an investigator may need access to medical records and other patient PHI preparatory to research. The HIPAA Privacy Rule restricts the use of PHI in activities preparatory to research defined as:

- Developing a research question
- Determining the feasibility of the study (e.g. are there adequate numbers of potential subjects in this patient population?)
- Developing appropriate inclusion and exclusion criteria

This may be done at NHC through Health Information Management (HIM). An investigator may have access to these records before IRB submission if he or she agrees to the following:

- The research will only be used for the purposes of preparing a research protocol for IRB review or grant proposal for preparatory research activities listed above
- Only the PHI that is necessary to prepare a research protocol or grant proposal for the activities listed above will be used
- The data obtained through these activities will not be removed from the NHC protected entity under the HIPAA privacy rule.
- The data will not be disclosed to anyone outside of the NHC protected entity

Recruitment of Research Subjects with a Partial Waiver of Authorization

Once IRB and NHORA approvals have been obtained, study screening and recruitment may begin with the appropriate HIPAA-compliant tools. At the time of screening, the potential research subject has not consented to participate in research or given authorization to release protected health information. Therefore, a partial waiver of authorization must be utilized to allow the review of patient PHI in the screening and recruitment of potential research subjects. NHC requires that the partial waiver be filed in the patient's medical record if such a patient record would not otherwise be accessible by the investigator in his or her routine professional practice. This serves as a record of who has accessed this patient PHI and for what purpose. For the IRB to approve such a waiver, the investigator will be required to state why the research could not be conducted without access to the PHI, who will access this information, and how patient identifiers will be destroyed after subject recruitment.

The Complete Waiver of Authorization

Where a partial waiver of authorization is utilized for the sole purpose of screening patients, a complete waiver of authorization allows for use and disclosure of PHI when there is no patient authorization. This would be applicable for research involving retrospective record reviews that do not involve interaction with subjects. The research must satisfy the following criteria:

1. The use or disclosure of protected health information involves no more than minimal risk to the privacy of individuals.
    a. There is an adequate plan to protect the identifiers from improper use and disclosure.
    b. There is an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers, or unless retention is required by law.
    c. There are adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted.
2. The research could not practicably be conducted without the waiver or alteration.
3. The research could not practicably be conducted without access to and use of the protected health information.

The HIPAA Research Authorization

The HIPAA authorization is used to obtain a subject's permission to use and disclose their protected health information for the research project/study. The Privacy Regulations require a certain level of specificity. General authorizations that are not study or protocol specific are not permitted. The University of Louisville Privacy Board and IRB requires that this authorization be a separate document in addition to an informed consent document. The Western IRB requires that the authorization language be included within the informed consent document
This authorization requires specific answers to the following questions:

- What information about you may be used or given out in the research study?
- From who or where can we get information about you?
- Who may see your health information?
- Why will this information be used and given out?
- Is your health information protected after it has been given to others?
- What if you decide not to give your permission to use and give out your health information?
- May you withdraw or cancel your permission?
- Does this authorization have an end date?
- Have you given up any legal rights by signing this form?

Please contact the IRB of record for suggested language and authorization templates.

Documentation of Disclosure

The HIPAA Privacy Rule gives individuals the right to receive an accounting of disclosures of PHI made by a covered entity. For disclosures of PHI for research purposes without the individual's authorization in which a partial or complete waiver is used, NHC requires the appropriate waiver to be filed in the individual's medical record chart for accounting purposes at the time the disclosure was made.

7. INFORMED CONSENT

The Informed Consent Process

Unless a waiver is granted by the IRB of record, the PI is responsible for ensuring that, prior to any study activity, each subject participating in research in a NHC facility signs the current IRB-approved Informed Consent Form (ICF)The ICF must be obtained in accordance with applicable law and regulation, and be kept in the official NHC medical record. The ICF process must be clearly documented in the medical record and research record and contain the components set forth in 21 CFR 50.

As mandated in the Code of Federal Regulations, the ICF:

- Ensures that potential study participants are given an adequate description of the benefits and risks associated with their study participation.
- Provides the potential subject with the information needed to reach a decision on whether or not to participate in a research study.

The ICF and the Research Authorization may or may not be combined into a single document. However, without a signed Research Authorization any data collected cannot be used or shared.

Procedure

1. Prior to beginning a study involving human subjects, it is essential to obtain the informed consent of the person or his/her authorized representative. Informed consent is an expression of the willingness of a person to participate as a subject in research. To be effective, the consent must be freely given, without coercion, and must be based on a clear understanding of the nature and purpose of the study and what will be required of the subject to participate.

   The discussion with the potential participant by the researcher should include the purpose of the research, the procedures to follow, and all known discomforts, risks, benefits (both short and long-term), any costs to the subject, Conflict of Interest information, and release of information for billing compliance. The signing of the consent document should signify that thorough discussion has taken place and will continue to take place during the conduct of the study. Informed consent is an ongoing process throughout the subject's participation in the study.
   Subjects being asked to participate in diagnostic or therapeutic studies should be informed of alternative choices for diagnosis or treatment. All subjects should know if their treatment is to be determined by random selection and if placebos are to be used. No information should be withheld that might influence the subject's decision; nor should there be promise of beneficial results. The subject should feel at liberty to refuse to take part in the study, or to discontinue participation at any time, without prejudice to present or future care.

2. The same principles that pertain to obtaining informed consent from subjects should also be applied by researchers in making a request for consent from parents, next-of-kin, or legally authorized representatives of those persons unable to give informed consent due to minor age, physical incapacity or cognitive impairment. In such cases, the IRB of record will determine if a subject advocate is allowed. The subject advocate is expected to act in the best interests of the subject by sharing in discussions with the researcher and with those responsible for giving consent. Although minors are unable to give informed consent for themselves, the IRB may determine that children of seven (7) years or older should participate in the consent process by giving their assent to join the study.

3. An individual's willingness to take part in a study must be documented by the written consent form, as determined by the IRB of record, or if approved by the IRB, by short form or oral consent and noted in the subject's medical and research record.

4. There must be no coercion and care must be exercised to avoid any appearance of coercion used to induce subjects to take part in or remain in a study. This is especially important if the subject is in a dependent relationship to the researcher or if monetary rewards are offered for participation.

5. Non-English speaking subjects must be given a certified translated ICF that is approved by the IRB of record. For additional information regarding the informed consent process with non-English speaking subjects, please contact the IRB of record.

6. Illiterate subjects can agree to participate by "making their mark" on the ICF, as long as it is consistent with applicable state laws and is not prohibited by the IRB of record.

7. Under very specific circumstances, the IRB of record may waive the requirements of the Informed Consent. (DHHS 45 CFR 616.116)

8. The original subject informed consent, HIPAA authorization, and assent form (if applicable) shall be retained in the investigator's research files, and a copy shall be given to the research subject. A copy of these documents must be filed in the subject medical record (if applicable) at the time of consent. It is important that a copy, and not the original, be filed in the subject medical record, as it is NHC policy to shred all hard copies of medical record documents 30 days after being scanned in the electronic record. An investigator will have two (2) weeks from the time of consent to sign these documents. Because of this two-week grace period, NHC accepts the filing of the informed consent documentation in the medical record without the investigator's signature, but the form must contain the signatures of the subject and the person obtaining consent.

Waiver of Informed Consent

In some specific instances, an IRB may waive the requirement for informed consent in accordance with 45 CFR 46.116(d). The IRB must be able to determine and document that the study meets the criteria for waiver of informed consent. The investigator must provide protocol specific written justification for the request to waive informed consent.
The CRF 46.116(d) states:

An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

1. The research involves no more than minimal risk to the subjects;
2. A waiver will not adversely affect the rights and welfare of the subjects;
3. The research could not be practicably carried out without waiver or alteration; and
4. Where appropriate, the subjects will be provided with additional pertinent information after participation.

8. NORTON HEALTHCARE FACILITY USE FOR RESEARCH

Research Registration

All research subjects arriving in a Norton Healthcare facility for an outpatient study procedure must utilize the Registration/Centralized Scheduling Form for Research (Attachment F) at the time of registration. With this form, the registrar is able to alert the NHORA that a research activity has taken place, or will take place, which then allows for proper billing. This applies to procedures for which a research study is responsible for the payment, as well as all procedures associated with ancillary services for research at Norton Healthcare.

Norton Healthcare Pathology

All specimens released for research purposes from NHC Pathology must be accounted for and documented. All research protocols requiring specimen collection must have NHORA approval prior to the release of any specimens. The following procedures are required for specimen release at Norton Healthcare:

- Upon receipt of a new application for specimen research to be conducted in Norton Healthcare, the NHORA will provide a copy of the protocol to the Pathology department for their review.
- The Pathology department may be contacted to clarify all concerns raised during the NHORA review.
- Upon study approval, the NHORA signs the Application for Release of Laboratory Specimens for Research (release form, Attachment G) and sends a copy to the researcher and to the pathology department.
- Prior to subject enrollment, the researcher contacts the Pathology department to schedule an appointment to discuss the study details.
- Specimen study activity must be reported to the NHORA monthly by Pathology and appropriate invoices or journal entry transfers shall be generated.

Norton Healthcare Pharmacy Use for Research

If a Norton Healthcare pharmacy is required for the storage, handling, or dispensing of drugs for research, the Principal Investigator is responsible for contacting NHORA. NHORA will ensure that the appropriate pharmacist has the protocol for review. Many protocols call for labor-intensive activity in the pharmacy, and a pharmacy manager or director should always be included in the pre-study meetings and discussion. The pharmacy fees will be provided by NHORA to the investigator. The NHC Pharmacy must approve the study prior to NHORA approval. Pharmacy activity is reported to the NHORA monthly and appropriate invoices or journal entry transfers shall be generated.

Norton Healthcare Imaging Services

For all research studies requiring an imaging service, or exam report, the NHC Imaging Service Department (radiology) must be contacted prior to the procedure. This requirement must be specified on the BCT at the time it is submitted to the NHORA (See Section 11). There is a fee associated with all electronic radiology and imaging studies copied to CDs. It is also important to give specific instructions to Imaging Services Department regarding protected health information contained on the CD. Study activity is reported to the NHORA monthly by Radiology and appropriate invoices or journal entry transfers shall be generated.

Data and Tissue Biorepositories in NHC Facilities

IRB Oversight

The Office of Human Research Protections (OHRP) defines Human Tissue Biorepositories as an entity that collects, stores, and distributes human tissue materials for research purposes. Biorepository activities involve three components:

1. The **collectors** of tissue samples
2. The **biorepository** storage and data management center
3. The **recipient** investigators.

All data and tissue biorepository activities are subject to IRB oversight. Only an IRB may determine if the biorepository activities:

1. Meet the regulatory definition of human subjects research and are subject to the IRB requirements set forth in 45 CFR 45 ("The Common Rule")
2. Meet the definition of human subjects research but are exempt from the regulatory requirements in 45 CFR 45 ("The Common Rule")
3. Do not meet the regulatory definition of human subjects research

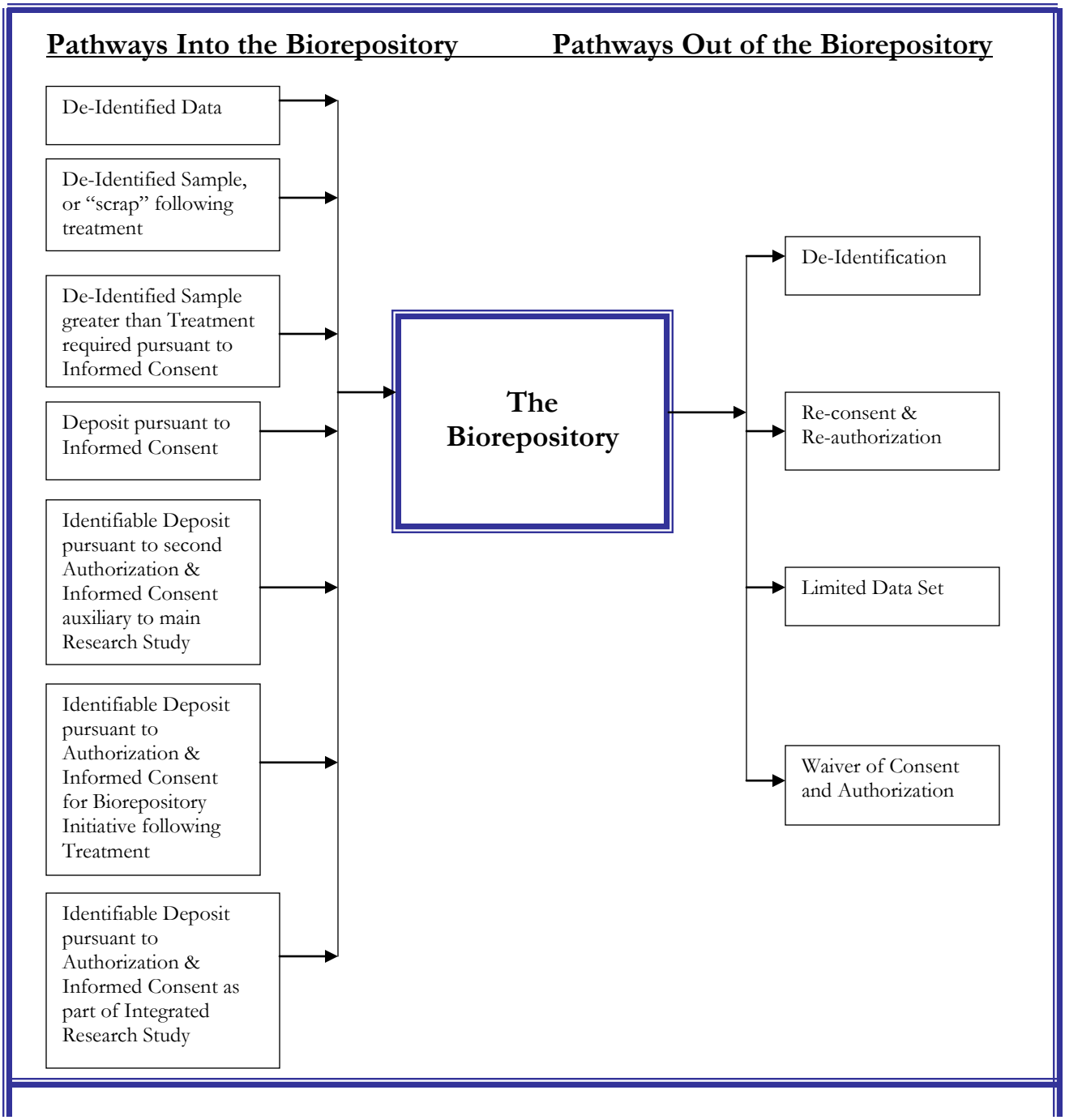
The collection and storage of data and/or tissue is considered to be research when:

1. The data and/or tissue collected prospectively or retrospectively will be shared by multiple investigators, used repeatedly, or stored for future research; or
2. Excess research tissue or data that were collected a part of an IRB-approved protocol will be stored for multiple future research used by multiple investigators. The prospective collection and storage of data and/or tissues for defined research purposes as part of a single IRB-approved protocol is not considered Research Biorepository.

HIPAA Protections

The Privacy Rule places conditions on the use of disclosure of PHI by covered entities for research. The creation of a research database or repository, and the use or disclosure of PHI from a database or repository for research, may each be considered a research activity under the HIPAA Privacy Rule. The Privacy Board must examine the pathway by which the tissue enters and exits the repository (i.e. is there PHI entering and exiting the repository?) and therefore determine the appropriate actions for the use of the data.

The following schematic gives examples how data and/or tissue may enter or exit the biorepository:



Norton Healthcare Oversight

The proposed data and tissue biorepository activities in a NHC facility must be submitted to the NHORA in addition to the IRB, just as a standard research study submission. The NHORA and the NHC Legal/Risk Department will make the determination if a Data Use Agreement is needed between the holder of the data and/or tissue and the recipient.

The Norton Technology Assessment Committee (TAC)

The Norton Technology Assessment Committee (TAC) reviews all new medical technologies entering all Norton facilities that impact the supply budget by at least $5,000. This includes new devices approved by the FDA, new uses for existing devices, and existing technologies new to NHC. TAC is comprised of physician members, the Senior VP and CFO, and representatives from Materiel Management and Reimbursement.

Research devices given the Investigational Device Exemption (IDE) or 510(k) clearance by the FDA do not need to be reviewed by TAC if the device is supplied by the sponsor. Humanitarian Use Devices (HUDs) approved by the FDA under the Humanitarian Device Exemption (HDE) are not considered research (see Section 3), and are therefore often not supplied by the sponsor. TAC must be notified in the case of these HUDs. If TAC involvement is necessary, investigators are encouraged to contact TAC before submission to the NHORA and IRB. Investigators must also re-submit their new technology to TAC once the research is completed if the device will be used for non-research purposes in a Norton facility.

Biomedical Engineering

For every study that uses investigational equipment or has equipment that is being provided by a study sponsor, the NHORA completes the biomedical engineering form for their review. The NHORA works with the biomedical engineering department to ensure that all equipment intended for human subject contact has been inspected and is approved for use.

If any equipment is deemed unsafe or is not up to current medical standards, a notification will be forwarded to the research program as well as NHC risk management. Any equipment that is labeled "out of service" by the biomedical engineer will be moved to their area until it has been repaired or brought up to code.

Refer to the contact information to find the appropriate person at each NHC facility.

9. HEALTH INFORMATION MANAGEMENT

Access to Protected Health Information (PHI)

NHC Health Information Management (HIM) will not release medical records for research purposes without proof of IRB approval, documentation of authorization or waiver of authorization per HIPAA, and NHORA approval. The following process must be followed for access to patient PHI through HIM:

- All approvals are obtained
- HIM personnel verifies all appropriate approvals are accurate and active, and that all those viewing the PHI have been approved to do so
- Researcher is responsible for presenting all appropriate approvals and waivers to HIM personnel
- HIM will pull the requested medical records within their specified time frame, and notify the researcher when the records are ready for review

Electronic Access to PHI

All personnel accessing electronic medical records for research purposes must do so under an IRB and NHORA approved protocol.

Data Queries

For de-identified data queries, PHI is not disclosed. The data extraction is completed by the covered entity, and the information is no longer covered by the Privacy Rule. If the information has been de-identified according to the Privacy Rule, it may be used or disclosed without limitation. De-identified data may also be released if the data has been de-identified by an expert who can determine and document, using generally accepted statistical and scientific principles and methods that there is only "very small" risk that information in a data set could be used to identify the subject. For identifiable data queries such as preparatory to research activities (see Section 6) please contact HIM.

Medical Record Documentation

Investigators are responsible for placing a copy of the following items, however applicable, with each medical record of all research subjects:

- The signed informed consent and documentation of the informed consent process
- The assent
- The HIPAA Research Authorization
- Complete and/or partial waivers of authorization

10. CLINICAL TRIAL AGREEMENTS

Sponsored Research

For all research involving outside funding and/or a sponsor, a fully executed contract is required between the sponsor and the researcher's NHC covered entity. NHORA will forward all agreements, including Confidentiality Disclosure Agreements, to NHC Legal / Risk Management Department for review and will not issue final study approval until agreements are fully executed by an official NHC signor as defined in NHC policies.

Cooperative Group Research

Principal Investigators usually have in place a Master Purchase Service Agreement or a Master Agreement between the sponsoring cooperative group and the institution that employs the PI. Renewals, annual or otherwise, must be submitted to the NHORA at the time they are approved.

Letter of Indemnification

NHC requires indemnification from the sponsor of a study.

If Indemnification is provided to the PI in the Clinical Trial Agreement and NHC is not a party to that agreement, then this indemnification may occur through a Letter of Indemnification (LOI), a Facility Use Agreement or including NHC as a party to the original agreement.

NHORA will forward all agreements to NHC Legal/Risk Management Department for review and will not issue final study approval until agreements are fully executed by an official NHC signor as defined in NHC policies.

Research Related Injury Language

Clinical Trial Agreements will also be reviewed for language pertaining to treatment for research-related injury. It is the responsibility of the institution in which the research is being conducted to ensure that such language in the clinical trial agreement does not conflict with language given to the subject through the informed consent process. It is a requirement that the informed consent document states what treatment and reimbursement is available to the subject in the case of a research related injury. Subjects must also be informed if research related injury will be billed to the subject, subject's medical insurance or is covered by the research program (mutually exclusive). Nothing shall require Norton, as a condition of payment under this section, to bill or submit claims to any third party payer in a manner that would violate laws, regulations or billing rules applicable to Norton.

11. FINANCIAL MANAGEMENT OF RESEARCH

NHC is committed to sound financial management in all aspects of its operations and must adhere to and enforce the governing rules and regulations as dictated by current law. The protocol schedule of events signed and dated by the PI and BCT aid NHORA in fulfilling this requirement. The cost of any service provided solely for research purposes must be covered by the research program or the study sponsor. Furthermore, any amount listed as payment for a specific service in a study budget must be forwarded to the hospital provider as payment for that service. Finally, items that are stated as being provided at no cost to the patient or their insurance carrier in the informed consent form will be billed to the research program.

Release of Financial Data

NHC will allow the release of financial data that is already within the public domain, which includes utilization information, charge information, and Medicare patient charge and cost information. However, NHC will not allow the release of cost information or reimbursement information as it relates to any non-Medicare patients such as private payer or self-patients. All requests for financial information must be submitted and approved by Vice President, Planning and Business Analysis or Vice President, Finance.

Pricing of Research Services

In order for a rate to be offered for research services, a budget for each research study conducted at NHC must be submitted to the NHORA for review. A rate will be approved based on the cost of the item and the budget that is submitted to the NHORA. The final budget must reflect the rate provided by the NHORA. Patient activity must be reported to the NHORA. Real-time notification to the NHORA will ensure claims are billed appropriately to Research Program or Third-Party Payors.

Research Patient Reporting

Research subjects being enrolled in any NHC facility must be identified as such to the NHORA on the date of enrollment in the research study. The investigator, or their designee, must notify the NHORA of all research subjects via the Research Patient ID Form (or REVEAL for those with access) within 48 hours of the service date for hospital activities and within 24 hours of the service date for physician activity. The Research Patient ID Form will be given to the research team upon study approval and is study specific. If a hospital service date is not applicable, all research subjects must still be recorded on the Research Patient ID Form. Adherence to the time limits helps to ensure compliance with the regulations governing billing for clinical research. Non-compliance will be included in audit reports generated by the NHORA. The NHORA will always accept initial notification via email or phone so that we may hold the claim in the system until the Research Patient ID Form (or REVEAL report) is submitted. For all studies, it is imperative that subject activity be reported to the NHORA as soon as possible. Real-time notification to the NHORA will ensure claims are billed appropriately to Research Program or Third-Party Payors.

For studies that involve inpatients, surgical procedures or devices, the investigator or their designee should notify the NHORA as soon as the procedure date is scheduled. A copy of the insurance pre-certification letter, or other documentation of the subject's insurance authorization to perform the procedure prior to the scheduled date, should also be submitted to the NHORA.

For studies that involve outpatient procedures specific to the research study, the research registration form (Attachment F) must be utilized. This form must be brought to registration with the patient at the time of service to ensure proper billing of the claim.

Research Accounting Units (AUs)

The NHORA manages the finances and the general ledger (GL) for all research conducted at a NHC facility or by a NHC-employed physician. This is designed to assure appropriate use of all money generated by research studies and programs within Norton Healthcare, Inc. All revenues and expenses associated with a specific study will be housed in a single AU on the GL system.

Once the research study receives NHORA approval, an AU number will be assigned.

Fees to Conduct Research in Norton Healthcare

The NHORA does assess a review fee for any funded study that is conducted within a NHC facility.

Pharmacy

Each facility has a pharmacy contact for research. Fees vary for each service and can be waived if the study is not funded, upon approval by the pharmacy department

Pathology

A Specimen release form (Attachment G) must be completed for each study that requires a service from pathology, to include the number of each item or service requested. Once completed, the specimen request is sent to the NHORA office. After the NHORA office approves the request, it is sent to pathology. The NHORA calculates the total charges for service. Fees vary for each service and can be waived if the study is not funded, upon approval by the pathology department.

Radiology

Each facility has a radiology contact for research. If the protocol requires copies of radiological exams, then the researcher must submit the radiology request form to the appropriate radiology contact prior to the procedure. Those exams will be copied to a CD. The radiology request form (Attachment H) is sent to the NHORA by radiology when the CD is completed. The NHORA calculates the total charges for service. Fees can be waived if the study is not funded, upon approval by the radiology department.

12. COMPLIANCE EVALUATION PROGRAM (CEP)

Any researcher conducting research within a Norton Healthcare Facility must follow the medical research policies and procedures as set forth in Norton Healthcare policies and procedures. The medical research policies reaffirm Norton Healthcare's commitment to the ethical conduct of human research. The Compliance Evaluation Program was developed in order to ensure that researchers are adhering to the medical research policies. Compliance evaluations will be initiated under the following circumstances:

1. Not-for-Cause: part of a random selection of studies and programs for review by the NHORA

2. For-Cause: review, when an occurrence of non-compliance is identified or reported.

Any researcher conducting research within a NHC facility is obligated to allow the NHORA to evaluate his/her compliance. Failure to comply with research policies will result in corrective or disciplinary action.

The evaluations will focus on compliance to NHC policies and adherence to human subject protection regulations for all those subjects enrolled in a NHC facility.

Procedure

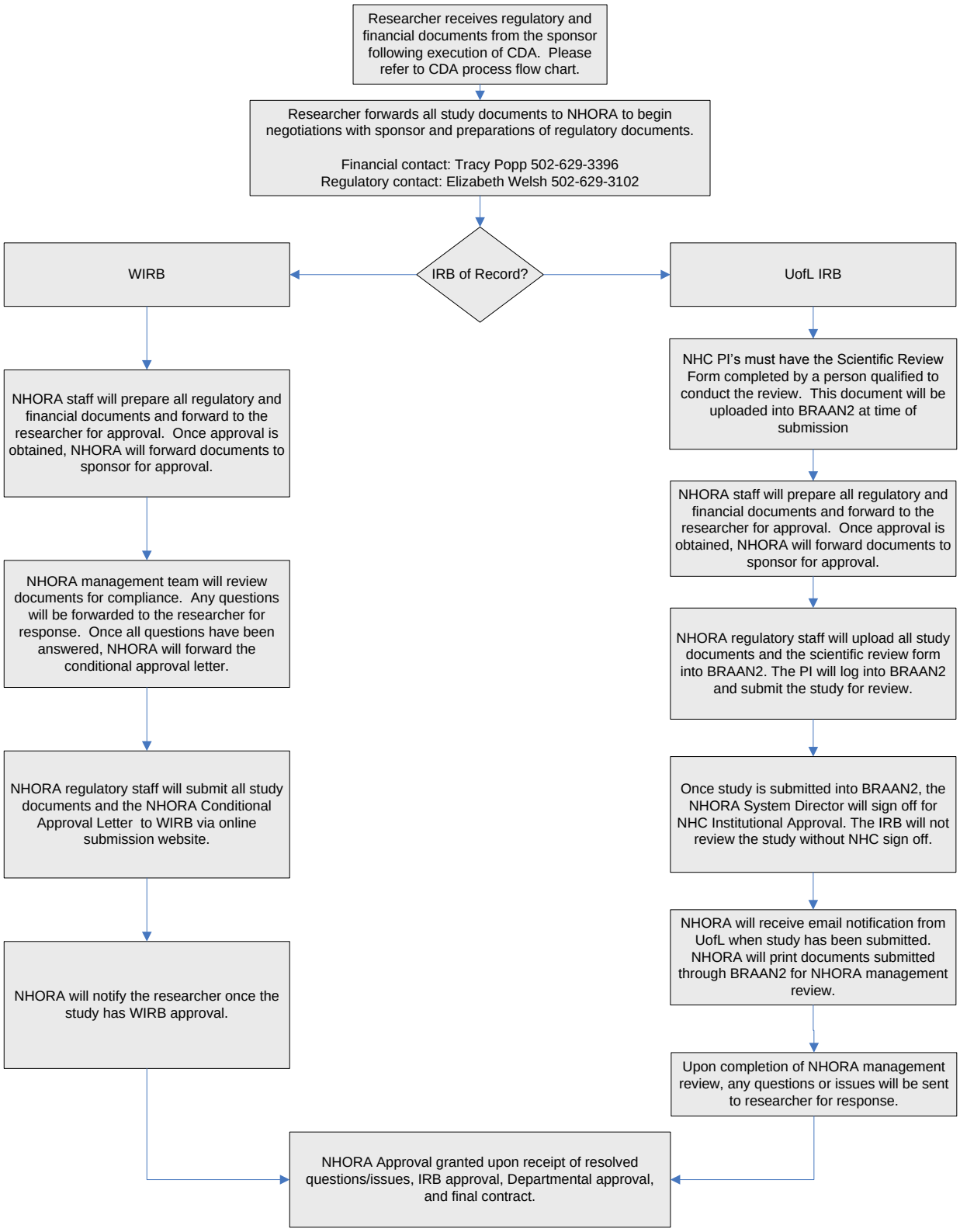
1. NHORA will notify researchers via email that their study has been selected for review. This notice will be given two weeks prior to the evaluation.
2. The evaluation will verify that the research being conducted is in compliance with NHC research policies. The evaluation may take one to two days depending on the study or program. The compliance evaluator will review all regulatory information for the study, as well as subject information (or a sample) for those subjects enrolled in the study from NHC.
3. A preliminary written evaluation will be sent to the researcher within fifteen business days of completion of the compliance evaluation to allow the researcher to identify and correct any factual errors.
4. A final report will be sent to the researcher within seven business days of receipt of response.
5. The researcher will provide a written response to the final evaluation report within a specified time frame, if any deficiencies are noted.
6. The evaluation report, along with the researcher's response letter, may be sent to the PI, NHORA System Research Director and Compliance Director, the IRB of record, the NHC Corporate Compliance Office, VP of Clinical Research, and the System SVP, Chief Medical Officer of NHC.
7. If necessary, disciplinary guidelines will be addressed based on the findings of the evaluation. Disciplinary actions, if necessary, will be addressed in relation to the severity of any findings of non-compliance. There are three levels of response by the NHORA.

    - If non-compliance is identified, the researcher must provide the NHORA with a Corrective Action Plan with the response letter. The IRB may take separate action.

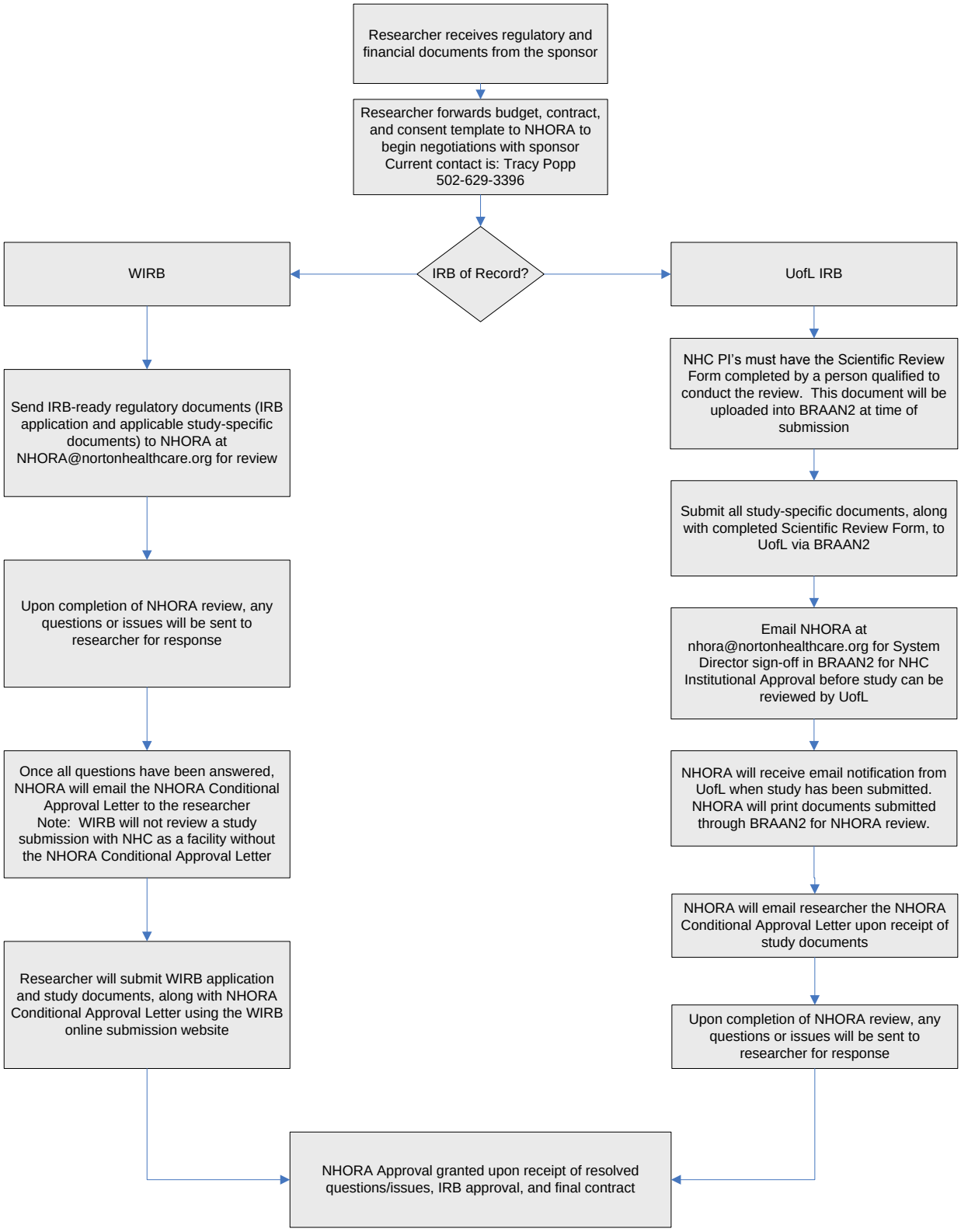
- If the researcher does not respond to concerns, or is consistently non-compliant, all research conducted by that researcher will be suspended at NHC and the IRB of record will be notified.

- If the research activity continues after suspension, the NHC System SVP, Chief Medical Officer will send written notification of the breach of NHC policy to the IRB of record, and the Credentials Committee of the Norton facility at which the researcher has primary privileges. In addition, notification will indicate that the researcher's authority to conduct research within NHC has been withdrawn as a result of this breach of policy. Notification may also be provided to OHRP and/or the FDA as appropriate.

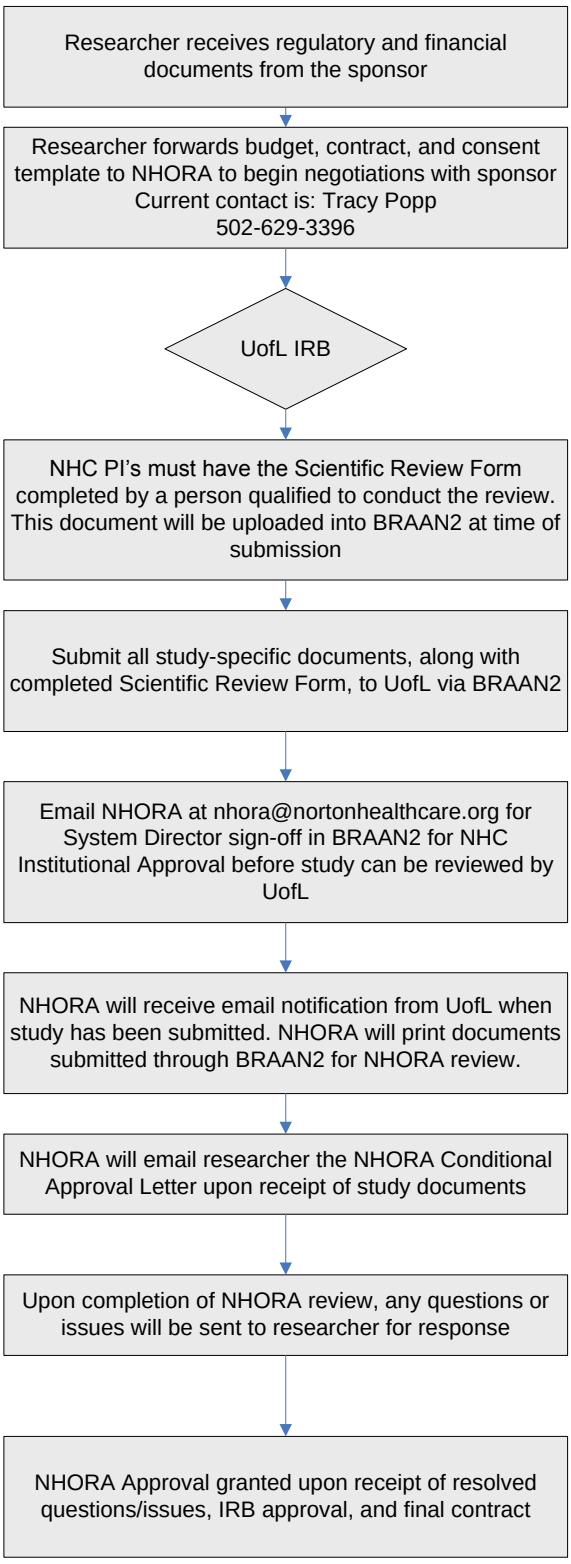
NHORA Submission Process – Norton Employed PI, NHORA Regulatory/Financial Services



NHORA Submission Process – Norton Employed PI, No NHORA Regulatory Services
No UofL Affiliation



NHORA Submission Process – Norton Employed PI, No NHORA Regulatory Services, UofL IRB Only



Attachment A

NORTON HEALTHCARE - NEW PRODUCT and TECHNOLOGY REQUEST FORM

For completion by MD or requestor:

Name of Product(s): _____ Date of request: _____

Will this be used on a one-time only basis for a specific patient? ☐ YES ☐ NO

If yes, were you asked by the sales rep to evaluate this product on this procedure? ☐ YES ☐ NO

If no, please indicate the anticipated ***annual*** procedure volume on which you intend to use this product? _____

Will the new item replace your current preferences/ practices? ☐ YES ☐ NO

Please indicate the facilities where you intend to use this item:

☐ Norton Hospital ☐ Suburban Hospital ☐ Audubon Hospital ☐ Kosair Hospital ☐ Pavilion ☐ Brownsboro / KCMC ☐ Other

This item will result in: (check all that apply)

☐ Improved patient outcomes ☐ Reduction in cost ☐ Compliance with regulatory requirements ☐ Increased patient volumes in NHC

MD/ Requestor's Name (please print) : _____ **Signature** _____ **Phone:** _____

For completion by Department Manager or Director:

Facility Name: _____ Department : _____ Phone: _____

Manufacturer: _____ Item Catalog # if known) : _____

Projected cost each/ or per case): (Check one or more if applicable)
☐ Equipment (purchase, lease or rent): $_____ ☐ Supplies $_____ ☐ Service/maintenance agreement. $ _____

Sales Rep Name _____ Phone contact (s) Office VM- _____ Cell: _____

Approval of the request by the Department head and the hospital president prior to submission for review is required in order to process this application further.

Dept. Head Signature _____ **Hospital President Signature** _____

Please fax completed document to the attention of Claire Rupert RN, Div. Dir. Value Analysis, Corporate Materiel Management; Fax # (502)-629-2165

Attachment A

NORTON HEALTHCARE
TECHNOLOGY ASSESSMENT WORKSHEET

PART ONE – To be completed by Technology Assessment team– Attach copy of original request or complete the following:

Name of Product(s): _____

Manufacturer: _____ **Manufacturer Catalog #:** _____

Type of purchase (Check all that apply) :Equipment: _____ **Supply** _____ **Service** _____

Capital Purchase: YES____NO____ IF YES, are funds allocated / budgeted for purchase? YES____NO____

Is the requested product (s):

Patient Chargeable? ☐ **YES** ☐ **NO**

Is there a pre-established reimbursement code in place? ☐ **YES** ☐ **NO**

Are there similar products in the Norton product formulary in use currently? ☐ **YES** ☐ **NO**

If yes, list here: _____

_____

_____

PART TWO : To be completed by requesting physician

1. How did you find out about this product? (mark all that are applicable)

☐ Prior experience with product ☐ Trade show ☐ Saw at other facility ☐ Sales call
Other (specify): _____

Sales Representative's Name: _____ Sales Representative's Phone : _____
(Please attach any manufacturer's specifications, sales literature and representative's business cards that you have been given.)

2. Do you have an economic interest in this vendor's product? ☐ YES ☐ NO

If YES, please disclose any special relationship with this vendor, past or present, as follows: (check all that apply)
____ Stockholder
____ Appointment to professional, advisory committees or board
____ Educational facilitator, product development, or consulting role, ad hoc or otherwise
____ Received funding for grants, research, or CME
____ Patent development
____ Familial or other personal relationships

3. Briefly describe the service or function that the requested item will provide.

_____
_____
_____
_____
_____

4. What existing technology / products does this replace?

_____
_____
_____

5. Will this new product impact achieve of the following:

☐ Safety or regulatory compliance needs (identify regulation) _____

☐ Reduction of other supply and / or pharmaceutical costs

_____

☐ Service line growth (indicate service lines affected) _____

☐ Improved operational efficiencies (measurable reductions in procedure time, staffing, length of stay, etc.)

_____

_____

☐ Clinical Outcome improvements (identify measurable criteria that can be tracked following implementation) :

_____

_____

_____

6. For Norton facilities will this product be purchased? List all.

_____ Norton Hospital
_____ Norton Pavilion
_____ Kosair Children's
_____ Norton Audubon
_____ Norton Suburban
_____ Norton Southwest

7. How many procedures annually do you anticipate you will do using this technology/ product? _____

8. Are there other physicians you have contacted who support the introduction of this product? If so, please provide their names below.

_____

8. Will there be any additional costs, or services relative to implementing this technology?

_____ Education/ training
_____ Installation
_____ Physical / structural improvements
_____ Requirements for additional tests or procedures
_____ Increased / specialized staffing
_____ Consultative or manufacturer support services, at cost to provide this technology?
_____ PR / marketing to physicians and community

_____

_____

_____

_____

_____

8. What credentialing / experience do you feel needs to be a minimum requirement to use this item?

_____

_____

_____

_____

9. If this is a "breakthrough technology", and a need for post-implementation outcomes data review is required to assess clinical and strategic impact, will you be willing to participate in that process?

☐ Yes ☐ No

Physician Name (please print) _____ Signature _____

Date: _____ Phone number where I can be contacted for additional information: _____

Attachment B

JHSMH & NHC MULTI INSTITUTIONAL RESEARCH APPLICATION (MIRA)

FOR OFFICE USE: JHSMH OR NHORA ASSIGNED TRACKING NUMBER _____

TITLE OF STUDY_____

_____

_____

NAME OF RESEARCH GROUP/PRACTICE _____

I. PRINCIPAL INVESTIGATOR OR PROJECT DIRECTOR

Name_____ Employed By _____

Address_____ Title _____

_____ Email _____

_____ Telephone Number _____

Pager/Cell Number_____ Fax Number_____

II. PRIMARY CONTACT FOR BUDGET, BUSINESS AND CORRESPONDENCE (Complete if different from PI/PD)

Contact_____ Employed By_____

Address_____ Title_____

_____ Email_____

_____ Telephone Number_____

Pager/Cell Number_____ Fax Number_____

III. PRIMARY REGULATORY OR CLINICAL CONTACT

Contact_____ Employed By_____

Address_____ Title_____

_____ Email_____

_____ Telephone Number_____

Pager/Cell Number_____ Fax Number_____

IV. SPONSOR CONTACT INFORMATION (Complete if externally sponsored) _____ Check if Not Applicable

Contact_____ Sponsor's Name_____

Address_____ Contact Title_____

_____ Email_____

_____ Telephone Number _____

Pager/Cell Number_____ Fax Number_____

IV. AGENCY (NIH) OR CONTRACT RESEARCH ORGANIZATION (CRO) ____ Check if funding will come from CRO

Contact_____ CRO/Agency Name_____

Address_____ Title_____

_____ Email_____

_____ Telephone Number_____

Pager/Cell Number_____ Fax Number_____

V. CHECK EACH SITE WHERE YOU WILL BE CONDUCTING THE RESEARCH:

Norton Healthcare Facilities

___ Norton Hospital
___ Kosair Children's Hospital
___ Norton Audubon Hospital
___ Norton Suburban Hospital
___ Norton Physicians Practice

Jewish Hospital/St. Mary Elizabeth Healthcare Facilities

___ Jewish Hospital
___ Frazier Rehab
___ Clark Memorial Hospital
___ Jewish Medical Center East
___ St. Mary & Elizabeth Hospital
___ Our Lady of Peace
___ Jewish Hospital Shelbyville

Other: _____
_____

VI. CHECK ALL THAT APPLY IN EACH QUESTION:

1. Multi-Center Study? **___YES ___NO**

2. Compassionate Use Study? ___**YES** ___**NO**

3. Will Subjects Be: ___Inpatients? ___Outpatients?

4. Do you expect more than 50 subjects will be screened? ___YES ___NO **If yes, where? _____JHSMH _____NHC**

5. Initiator of Study
___Investigator
___Sponsor/Industry
___Cooperative group

6. Author of protocol
___Investigator
___Industry
___Cooperative group

7. Type of Study
___Drug study
___Device study
___Chart review
___Specimen study
___Clinical Trial
___Quality Improvement

8. Funding Source(s)
___Industry
___Foundation
___Internally Sponsored ULH
___Internally Sponsored U of L
___Internally Sponsored NHC
___Internally Sponsored JHSMH
___ Internally Sponsored Multiple Facilities
___NIH Grant
___NIH/Cooperative Group
___Non-NIH Government

VII. COMPLETE BILLING COMPLIANCE TABLE OR CHECK NOT APPLICABLE IF CHART REVIEW:

____ NOT APPLICABLE

VIII. PRINCIPAL INVESTIGATOR/PROJECT DIRECTOR –SIGNATURE REQUIRED FOR SUBMISSION:

- I certify that, to the best of my knowledge, this proposal is scientifically sound, ethical, and respects and protects the rights and welfare of human subjects in research.
- I certify the information contained in this application is complete and true, to the best of my knowledge.
- I agree to adhere to the credential requirements of the respective site(s) at which the research will be conducted.
- I agree to adhere to the Compliance Policies & Procedures and all billing practices of the respective site(s) where the research is being conducted, to comply with all regulations, not to bill any third party payer for items specifically reimbursed by the sponsor, and to conduct study within the guidelines of good clinical practice.

NAME (PRINTED) _____

TITLE: _____

SIGNATURE_____DATE:_____

PLEASE INCLUDE A COPY OF THE FOLLOWING ITEMS WITHS WITH MIRA:

UofL IRB Review	**WIRB Review** - in addition to the items listed on the left, include:
IRB Application/Submission Form	Current Professional License for PI
Informed Consent	CVs for PI and Sub-Investigator's
Research Authorization & Revocation	Human Subject Training Certification
Complete or Partial Waiver, if applicable	HIPAA Training Certification
Protocol	Investigator's Brochure, if applicable
FDA form 1572, if applicable	Signed investigator agreement for IDEs
Scientific and Scholarly Merit Review	Device studies- submit one: FDA letter or sponsor's letter
Draft or final contract and budget	stating significant or non-significant risk

Materials provided to subject (Advertisements, questionnaires, diaries)

Norton Healthcare Employed Investigators *Version January 2010*

Scientific Merit Review of Research Protocols Involving Human Subjects

Instructions: All Norton Healthcare employees who are conducting research studies involving human subjects must submit this form. Their proposal must undergo scientific review by the Investigator's Departmental Reviewer. The purpose of the review, which must take place prior to submission to the Institutional Review Board (IRB), is to ensure that the scientific approach is sound, the research design will yield valid results and appropriate departmental resources are available for completion of the project.

Section I. Proposal Identification

Principal Investigator: Department

Project Title:

Section II. Funding Information

Sponsor/Funding Agency**:**

Section III is not completed if review is ceded to external funding agency (e.g. Cooperative Group).

Section III. This Section Completed by the Investigator's Departmental Reviewer

All answers must be explained.

Yes☐ No ☐ Is this a worthwhile study?

Yes ☐No ☐ Is the research design sufficient to answer the hypothesis?

Yes ☐ No ☐ Do the background and rationale provide sufficient information to justify the conduct of the study?
Yes ☐ No ☐ Do the investigators have adequate experience to complete the project?

Yes ☐ No ☐ Are the inclusion/exclusion criteria appropriate for this study?

Yes ☐ No ☐ Are the outcomes, objectives and/or endpoints defined?

How will this study contribute to either the field or generalizable knowledge?

_____

_____

_____

_____

Section IV. Scientific Reviewer's Approval

_____

Signature **Printed Name** **Date**

Section V. Norton Healthcare Approval

_____

Signature **Printed Name** **Date**

Draft Billing Compliance Table (BCT) created by NHRO in conjunction with the flow chart and draft consent form. Prepared on

Principal Investigator ________Protocol # __________NHRO# ____ _____ __ local subjects

Billing Contact____Email ______Phone: _________NCT#___________
Study Title:

Service/Procedure	"S" or "R"	Payer/Bill To:	Site of Service/Procedure	Time Point	Admin Use Only
		Insurance Research Program x Sponsor Other ______	x Hospital Private Practice UPA Other ______		
		Insurance Research Program x Sponsor Other ______	x Hospital Private Practice UPA Other ______		
		Insurance Research Program x Sponsor Other ______	x Hospital Private Practice UPA Other ______		
		Insurance Research Program x Sponsor Other ______	x Hospital Private Practice UPA Other ______		
		Insurance Research Program x Sponsor Other ______	x Hospital Private Practice UPA Other ______		
		Insurance Research Program x Sponsor Other ______	x Hospital Private Practice UPA Other ______		
		Insurance Research Program x Sponsor Other ______	x Hospital Private Practice UPA Other ______		
		Insurance Research Program x Sponsor Other ______	x Hospital Private Practice UPA Other ______		
		Insurance Research Program x Sponsor Other ______	x Hospital Private Practice UPA Other ______		

Draft Billing Compliance Table (BCT) created by NHRO in conjunction with the flow chart and draft consent form. Prepared on

		Insurance Research Program x Sponsor Other _____	x Hospital Private Practice UPA Other _____		
		Insurance Research Program x Sponsor Other _____	x Hospital Private Practice UPA Other _____		

Principal Investigator _____ Protocol #_____ Prepared by _____

Attachment E

Norton Healthcare Office of Research Administration Financial Disclosure Declaration For Those Conducting Research in Norton Healthcare Facilities

- *All personnel who are directly involved in research must complete this form each year by January 31st.*
- *All questions must be answered and any yes answer must be explained in the commentary section.*
- *In accordance with the federal regulations, "You" is defined to include a spouse, each dependent child and partnership interests.*
- *If the conflict identified exceeds $10,000, then a conflict of interest management plan will be required.*

Name_____ Employed By_____

Address_____ Title _____

_____ Email _____

_____ Telephone Number _____

Pager/Cell Number_____ Fax Number_____

YES ☐ NO ☐ Do you or immediate family members have financial interests/arrangements exceeding $10, 000 in any company or business that sponsors your research and could therefore influence the outcome of your research? This should include, for example, compensation to you in the form of an equity interest in a sponsor or a royalty income tied to the sales of a product. If yes, describe below.

YES ☐ NO ☐ Do you or your immediate family members receive significant payments, non royalty payments or entitlements to payments exceeding $10, 000 in connection with your research that are not directly related to the reasonable costs of conducting research? This could include, for example, payments made to you or your institution such as compensation in the form of equipment, retainers for ongoing consultation or honoraria. If yes, please describe below.

YES ☐ NO ☐ Do you or your immediate family members have a proprietary or financial interest in a test product such as a patent, trademark, copyright or licensing? If yes, please describe below.

YES ☐ NO ☐ Do you or your immediate family members have a significant equity interest exceeding $10,000 in any sponsor of your research? This would include, for example any ownership interest, stock options, or other financial interest whose value cannot be easily determined through reference to public prices, or an equity interest in a publicly traded company. If yes, describe below.

YES ☐ NO ☐ Do you or any member of your immediate family occupy any position in a company that sponsors your research? This could include being an officer, director, associate, partner, member or proprietor of a corporation, sole proprietorship, partnership, Limited Liability Company or other business venture that sponsors your research? If yes, describe below.

Commentary (additional pages may be attached if necessary) _____
_____
_____

I hereby acknowledge that the above information is complete and accurate. I acknowledge that I have a continuing obligation to promptly update information to the NHRO within 30 days, if, during the year, any changes occur regarding the information provided in this declaration.

*Printed Name*_____ *Title:* _____

Signature _____ *Date:* _____

Attachment F

Registration/centralized scheduling form for Research

Date of Service: _____

Insurance mneumonic is: RESEARCH

Guarantor is patient or parent

Subscriber is patient: _____

IRB # _____

Group number is short study name if applicable: _____

Group Name is research program name: --------- RESEARCH

Services ordered for research protocol today:

_____

_____

_____

_____

Mail to: **Norton Healthcare Office of Research Administration**

1930 Bishop Lane 15th Floor

Louisville, KY 40218

Note that there must be a written order from physician

Note: Research staff, please send copy of form to regina,schaefer@nortonhealthcare.org and julie.gray@nortonhealthcare.org prior to procedure

Attachment G

Norton Healthcare Specimen Request for Research

If this request is for the conduct of a research study, then the researcher must complete the top portion of this form
Fax this form to Norton Healthcare Office of Research Administration (502) 456-7199 or
email to NHORA@nortonhealthcare.org. NHORA Contact Phone Number (502) 456-7193

Name of Requesting Agency or Physician:

Facility (Check all that apply): ___Norton Hospital ___Suburban Hospital ___Norton Brownsboro Hospital

___ Audubon Hospital ___Kosair Hospital ___Kosair Children's Medical Center

Research Protocol or Intended Use:

IRB Expiration Date: IRB#: NHORA #: PI Name:

Requested Material	Quantity requested	Fee per item	Total cost	
Processing fee	1	$ 25.00	$25.00	
H&E slides		$15.00		
Unstained Slides		$10.00		
Paraffin Block		$15.00		
Special Stain Slide		$45.00		
Immunohistochemistry Stain		$80.00		
Core Biopsy		$ 25.00		
Other:				
TOTAL	0		$ 25.00	
Additional comments:				

Check here if no funding for Research

Pathology approval signature:

Bill Fees to:	
Name:	
Address:	
City:	
State:	Phone:

Contact for Pick-up (if different than Bill fees to)	
Name:	
Address:	
City:	
State:	Phone:

Patient Name: (If multiple specimens, please complete page 2):

Patient Specimen #: Date of collection:

Release Authorized by NHORA: Date:

Release Authorized by Pathology: Date:

I understand that this specimen/tissue/bone/blood product relayed to me is a potentially hazardous/infectious material. Blood borne pathogens may be present. These pathogens include, but are not limited to Hepatitis B Virus (HBV) and Human Immunodeficiency Virus (HIV). Universal precautions should be used when transporting and handling this material.

I understand that there may be unknown and unforeseen risks related to the handling of this material, but I am willing the possibility of those risks.

Release of the requested material is approved for the use and purpose stated above. Norton Healthcare is not responsible for any disease or infection that this material may cause.

Signature of Person Receiving Material: **Date:**

Patient Name	Specimen #	Date of Collection	Other notes

Attachment H

Request for Radiology Exam Copies for Research

The researcher must complete the top of this form and submit to the NHORA for signature prior to request. This can be done via email to NHORA@nortonhealthcare.org or via fax 456-7199

Study Contact Name_____ Phone Number _____

Research Protocol: _____

_____

IRB # _____ NHORA # _____ P.I. Name _____

_____ _____ **IRB Approval expires _____**

Release Authorized by: (NHORA) **Date**

This release is authorized by the NHRO until the IRB expiration date listed above. The researcher should complete a new form for each study when the IRB approval is renewed each year.

Exam	Quantity	Fee	Total Cost
CT of _____		$ 25.00	
CT of _____		$ 25.00	
CT of _____		$ 25.00	
CT of _____		$ 25.00	
MRI of _____		$ 25.00	
MRI of _____		$ 25.00	
MRI of _____		$ 25.00	
MRI of _____		$ 25.00	
XRAY of _____		$ 25.00	
Other:		$ 25.00	

Bill Fees to

Name: _____

Address: _____

City: _____

State: _____

Phone: _____

Patient Name: _____

Date of Exam: _____ NHC Facility _____

PHI to be included on CD: ____ Yes ____ No

Specific Instructions regarding PHI: _____

_____

_____

_____

_____

_____

_____ _____

Completed by Radiology Department **Date**

____ Audubon Hospital ___ Kosair Hospital ___ Norton Hospital

____ Norton Premier Diagnostic Imaging ___Old Brownsboro Crossing ___ Suburban Hospital

Radiologist, please fax or email copy of form to NHORA when service is complete.
Fax 456-7199 or email to NHORA@nortonhealthcare.org

08/27/09