



Investigator Handbook

For the conduct of human subjects research

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Introduction

This guide is meant to serve as a resource for Guthrie investigators conducting human subjects research, especially those who may be new to the institution or those who may be starting a research project for the first time.

This handbook as well as additional information is available on the Guthrie websites:

Intranet <http://www.guthrie.net/> at the top under “Physician Resources”, choose “Guthrie Research”
<http://www.guthrie.org/> at the bottom under “Research”

Accessing Guthrie Policies on PolicyStat

All Institutional Review Board (IRB) and Research policies are available on PolicyStat

You must be connected to the Guthrie INTRANET to access policies

1. Start at the Guthrie Home Page: <http://www.guthriehealth.net/>
2. Go to **Policies Section** on the top of the page
3. You will be directed to PolicyStat
4. “Click Here for PolicyStat” will direct you to enter your institutional login.
5. Click Home and Change Location to The Guthrie Clinic.

Policies referenced in this handbook may be found by searching PolicyStat.

- For IRB policies, search “IRB”.
- For Clinical research policies, search “GFD-320” (which stands for Guthrie Foundation and the clinical research department number)
- For Research Administration policies, search GF-RA-330 (which stands for Guthrie Foundation- Research Administration and the department number)

If you have questions or concerns, please contact: Vicky Hickey, Manager Research & Education at Vicky.Hickey@guthrie.org

Research Policies

The policies governing operation of the *Institutional Review Board* and *Clinical Research* are directly relevant to almost all research conducted at The Guthrie Clinic.

Government regulations require the following policies for institutions receiving federal funds for research:

- Managing Individual Financial Conflicts of Interest in Clinical Research (GF-RA-330-001).
 - A form disclosing Individual Financial Interest in Research must be submitted yearly
- Intellectual Property (GF-RA-330-002)
- Research Misconduct (GF-RA-330-003)
- Non-Delinquency on Federal Debt (GF-RA-330-005)

Additional research administration policies relevant to the conduct and reporting of research include:

1. Authorship of Scholarly Publications (GF-RA-330-004)
2. Managing Institutional Financial Conflicts of Interest in Clinical Research (GF-RA-330-006)
3. Quality Improvement Activities (GF-RA-330-008)
4. Investigator Initiated Research at The Guthrie Clinic (GF-RA-330-003)

Institutional Policies relevant to the conduct and reporting of research include:

- Security of Portable Computers and Portable Media (GH-936-SEC-009)
- Breach Notification for Protected Health Information (COM-928-1059)
- Internal Audit and Compliance Hotline Reporting and Operation (COM-928-3014)
- Conflict of Interest Disclosure for All Board, Board Committee Members, and Key Employees (COM-928-3022)
- Conflict of Interest Disclosure for Specified Employees (COM-928-3023)
- Informed Consent Pennsylvania (GC-950-005) [Policystat location Guthrie Medical Group]
- Informed Consent New York (GC-950-006) [Policystat location Guthrie Medical Group]
- Informed Consent - RPH policy [Policystat location Robert Packer Hospital]
- Nursing Research (RPH-A-605-1022) [Policystat location Robert Packer Hospital]
- Investigational Medications (RPH-A-744-7100) [Policystat location Robert Packer Hospital]
- Investigational Drug Services (RPH-A-744-7101) [Policystat location Robert Packer Hospital]

Research at Guthrie Oversight

The Donald Guthrie Foundation has oversight responsibility for all research activities conducted within The Guthrie Clinic or by Guthrie employees, regardless of who does the work, where it is done, or how it is supported. The Human Protections Administrator (HPA) is the Executive Director of the Donald Guthrie Foundation, Burt Cagir, MD, FACS. The offices for the Institutional Review Board of The Guthrie Clinic (GC IRB), the Human Protections Administrator and the Research and Education Coordinator are located on the fifth floor of the Foundation Building.

Research and Human Subjects

All research involving human subjects conducted at any Guthrie facility or by anyone acting as an agent of Guthrie is subject to oversight by the GC IRB, unless a contracted independent review board is approved by the IRB Chair or designee. (Reference: IRB Bylaws, Art II).

All human subjects research and all clinical investigations conducted at The Guthrie Clinic must be reviewed and carried out in accordance with the policies and procedures of the Guthrie Human Research Protection Program (HRPP). These policies and procedures, in turn, are based on federal and state laws and regulations. Definitions of the terms *research*, *human subjects*, and *clinical investigation* vary per the federal agency with oversight authority. Please refer to Policy GF-IRB-322-005 *Activities Subject to IRB Oversight* for a complete description of all applicable definitions.

Federal regulations define *research* as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to **generalizable** knowledge.

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information and biospecimens; **or** (2) obtains, uses, analyzes or generates identifiable private information or identifiable biospecimens.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and which the individual can reasonably expect will not

be made public (for example, a medical record).

Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

An identifiable biospecimen is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.
(45 CFR Part 46).

Before conducting research at Guthrie, the IRB office or HPA should be consulted. The IRB or HPA may decide whether an activity is research involving human participants using the definitions specific to research, human subjects, and clinical investigation within Policy GF-IRB-322-005 *Activities Subject to IRB Oversight*. The IRB office or HPA will inform individuals whether an activity is research involving human participants.

Some activities such as classroom research, program evaluation, surveillance activities, and research on non-living individuals *may or may not* meet the criteria for human subject(s) research. Therefore, it is important to contact the HPA or the IRB office for guidance to determine if the research needs to be overseen by the (HRPP).

Expanded Access and Communication with the FDA

Expanded access, sometimes called “compassionate use”, is the use of an investigational product (drug, biologic or device) outside of clinical trials to diagnose, monitor, or treat patients with serious or life-threatening diseases or conditions for which there are no comparable or satisfactory therapy options available.

Any provider wishing to obtain an investigational product (drug, biologic or device) for a patient through expanded access must collaborate with the Donald Guthrie Foundation and include a Foundation staff member on correspondence with the FDA. For assistance contact the office of the Institutional Review Board (IRB), the HPA or the Research & Education Coordinator.

Quality Improvement (QI)

Quality improvement projects *may or may not* meet the criteria for human subject(s) research, depending on whether the projects are designed to create generalizable knowledge. A Worksheet is available from the IRB office or on www.guthrie.org/irb to assist in determining if a quality improvement project is also research. If all the below are checked and apply to a project, the project is QI that does not meet the definition of “research” and need not be submitted to the IRB.

- The project evaluates current standard practices or current standard of care.
- Knowledge sought directly benefits the process/program/system being evaluated.
- The project is unique to the institution, department, class, etc., and it is unlikely that knowledge from the outcome of the project would be of interest or benefit to other institutions, departments, classes, etc. other than as a means for evaluation of their programs (i.e., the project is not “universally applicable” or “generalizable”).
- Intend only to share the results of the evaluation with those individuals associated with the process/program/system. If the results of the initiative will be shared outside of this group (via conference, publication, etc.), it will be as its role as a QI project, not research.

Consult Guthrie IRB Policy 322-008 for further discussion. See Appendix 6 for process for a QI project.

Case Reports

In accordance with IRB policy 322-009, case reports are not considered reports of research and do not require review by the IRB if all the following conditions are satisfied:

- 1) review of a patient's records is done by persons already involved in patient's care (so that no new confidentiality risks are created by the activity); and
- 2) information about the patient is presented in an anonymous fashion or with the explicit consent of the patient to the report; and
- 3) no changes were made in the patient's care or diagnostic testing for the sake of reportability.

On the other hand, case reports require IRB review if any of the following criteria are met:

- 1) they are presented in a manner that states or implies generalizability; or
- 2) changes were made in a patient's care for the sake of reportability; or
- 3) a patient's records were examined for reasons not directly related to patient care or quality assurance.

Case reports that involve a retrospective review of three or fewer patients is generally not considered research and does not require IRB review. If case reports of more than three patients are being reviewed, then an investigator may be asking specific questions that would meet the definition of research.

Grants, Contracts and Signature Authority

All external grants and contracts for research must be processed through Donald Guthrie Foundation. Only members of the Guthrie Clinic Senior Leadership Team have the authority to commit the institution to any external research activity. Individual investigators should not sign any contract or related documents such as non-disclosure agreements, confidentiality agreements, or data use agreements.

Resources for Investigators

Several resources are available to investigators wishing to conduct research at Guthrie, including support for industry sponsored clinical trials and investigator-initiated projects.

Industry Sponsored Clinical Trials

Clinical Coordinators, Regulatory and Contract Specialists in the Office of Clinical Research provide a full range of services to assist investigators who wish to participate in clinical trials. These services include but are not limited to: feasibility analysis, budget development, contract negotiation, preparation of regulatory documents and IRB submissions. Clinical research coordinators are further available to assist in carrying out study specific protocol assessments. Please contact Kamie Hoey, RN at x6070 for further information.

Investigator Initiated Research

Guthrie has set a high priority on investigator-initiated research and funds are available through a small grants program to support original studies. Details are available in Appendix 1 of this Handbook. Additionally, the Foundation can aide in the design of a protocol for the implementation of Guthrie specific investigator-initiated research in collaboration with external partners. See Appendix 2 for Research Protocol Guidelines and Appendix 3 for a checklist for investigator-initiated research. Contact Burt Cagir ext. 2454 or Vicky Hickey ext. 4882 for further information. Refer to policy GF-RA-330-009 for additional requirements for investigator-initiated research.

Posting to clinicaltrials.gov

Prospective research projects that meet the FDAAA 801 definition of applicable clinical trial are required to be posted to clinicaltrials.gov as stated below. Additionally, investigators who intend to publish in a medical journal that follows ICMJE guidance are required to post to clinicaltrials.gov. It is the investigator's responsibility to ensure that the research project is posted. Assistance is available for registering a trial to clinicaltrials.gov through the Donald Guthrie Foundation. See policy GF-RA-330-009 for additional information.

Nursing Research Council (NRC)

All nursing research conducted at RPH must be approved by the NRC. Members of the NRC are available to assist investigators in developing protocols. Contact Sally Bennett, Ph.D., R.N. at x4530 or bennett_sally@guthrie.org Sally.Bennett@guthrie.org

IRB Applications

IRB forms can be found on Guthrie's website, www.guthrie.org/irb For assistance in determining which form to use, please contact Lori A. Robinson, ext. 4885, LoriA.Robinson@guthrie.org or Vicky Hickey, ext. 4882, Vicky.Hickey@guthrie.org.

Protocols determined by the IRB to be no greater than minimal risk may be eligible for exempt review or expedited review. Protocols greater than minimal risk would be reviewed at a convened meeting of the IRB at which the Investigator would be invited to present his protocol. The guidelines for oral presentation of a research protocol to the IRB are available in Appendix 4. The IRB generally meets the first Monday of the month, and the schedule is available at <https://www.guthrie.org/content/irb-meeting-schedule>

Investigators will be informed of the IRB action by email. After IRB approval is granted, additional investigator and research team training will be required, including training in information contained within Appendix 5.

Training

Web based training in research ethics education including Human Subjects Protection, Good Clinical Practice (GCP) and data security are available to Guthrie investigators at <https://www.citiprogram.org/>

Required Training in Human Research Protections

Anyone wishing to conduct research involving human subjects must demonstrate understanding of the underlying ethical concepts. This requirement may be satisfied in one of the following ways:

1. Taking the CITI Biomedical Research basic course:
 - log onto <http://www.citiprogram.org>
 - register as a "new user"
 - choose a user name and password
 - select The Guthrie Clinic as the "participating institution"
 - select Biomedical Research Investigators

Upon completion, CITI provides a training certificate.

2. Presenting evidence of completion of equivalent requirements in human research protections at another institution.

Posters

A poster can showcase the internal research projects that are conducted at Guthrie. Posters at scientific or medical meetings are a common way of presenting results and are especially valuable for obtaining peer comments before submission for publication. A poster presentation can also affect how Guthrie is perceived by scientific communities. It is important that the presentation is in accordance with approved Guthrie policies. The Corporate Communications Department has developed a set of guidelines for use of the Guthrie logo, and Guthrie colors (blue, gold, and yellow).

Posters authored by residents must either include a faculty member as co-author or be sponsored by a member of the residency teaching faculty. Great care must be taken to avoid disclosure of PHI on posters.

Posters must be submitted to the Research and Education Coordinator or HPA for approval before publishing or presentation. To ensure originality in publications, iThenticate software will be used to

review the submission.

Grant Applications

Guthrie Foundation can assist investigators in preparing grant applications to external agencies. The Foundation maintains an S2S service for submitting applications electronically to federal agencies through the grants.gov portal. Contact Burt Cagir, 2454, for further information.

See Appendix 1 for the application for Small Grants for Investigator-Initiated Research.

Statistics and Graphics

The Foundation can assist investigators with statistical analysis of data and scientific graphics.

Financial Disclosure

Investigators and research staff are required to provide financial disclosures for Financial Interest Related to Research which means financial interest in the sponsor, product or service being tested.

Researchers and research staff are educated about financial disclosures and responsibilities related to financial conflict of interest by completing training at

<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>

This education is to be completed prior to signing the form, “Specified Employee Conflict of Interest Form” as distributed by the Guthrie’s Compliance Office. This form is required initially and annually and includes an attestation, “Should a possible conflict of interest arise in my responsibilities to The Guthrie Clinic, I recognize that I have the obligation to notify the Internal Audit and Compliance Department and to abstain from any participation in the matter until the Internal Audit and Compliance Department can determine how that matter shall be resolved. If any relevant changes occur in my affiliations, duties, or financial circumstances, I recognize that I have a continuing obligation to file an amended ‘Conflict of Disclosure Form’ with the Internal Audit and Compliance Department.

Further, any investigator should submit an updated form within 30 days of discovering or acquiring a new significant financial interest (Reference GF-RA-330-001 *Managing Individual Financial Conflicts of Interest in Clinical Research*).

Investigators and research staff also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their Institutional responsibilities, provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by excluded sources provided in regulation. At a minimum, travel disclosures will include the purpose of the trip, the identity of the sponsor or organizer, the destination, and the duration.

Human Research Protections

Protection of the rights and welfare of human research subjects is a responsibility shared by administration, investigators, the Institutional Review Board, Compliance and Internal Audit, and Patient Safety.

Administration

Joseph Scopelliti, MD is the Institutional Official and Burt Cagir, MD, FACS is the Human Protections Administrator (HPA) for the Human Research Protection Program.

Investigators

Responsibilities

Investigator’s Responsibilities

The Principal Investigator (PI) has the ultimate responsibility for the protection of the privacy rights and

welfare of human subjects and the ethical conduct of this research project. Co-investigator means an investigator who does the same tasks in a clinical study as the individual designated as the principal investigator for investigator-initiated projects at Guthrie.

The PI and co-investigator are obligated to comply with all Guthrie policies and procedures (Reference Policy 322-010), as well as with all applicable federal, state, and local laws regarding the protection of human subjects in research, including, but not limited to, the following:

- Personally, conducting or supervising the investigation.
- Ensuring that the selection of participants is equitable. (Reference Policy 322-022)
- Meeting the requirements for obtaining and documenting informed consent (Reference Policy 322-041)
- Permitting performance of the project only by qualified personnel per the research project/protocol.
- Submitting disclosures of financial interest in research annually as per institutional policy and, as warranted, for each protocol
- Maintaining of adequate and accurate records which includes copy of all questionnaires, survey instruments, interview questions, data collection instruments, all IRB communications and information sheets for human subjects as required by federal regulations following termination of the project unless otherwise necessary to protect subject confidentiality as described in the project/protocol.
- Conducting the study in accordance with the final current protocol and will only make changes after notifying the sponsor, and IRB except when necessary to protect the safety, rights and welfare of subjects.
- Reporting adverse experiences to the sponsor and unanticipated problems to the sponsor and to the IRB (Reference Policy 322-052).
- Reporting breaches of confidentiality to the IRB and Corporate Compliance Department.
- Knowing the information regarding the investigational product, side effects, treatments, and procedures.
- Knowing the experimental design, safety monitoring, and analysis and presentation of the data for projects that are developed locally.
- Ensuring all research team members and ancillary staff are trained and qualified to carry out their assigned functions for the research.
- Maintaining as secure any protected health information collected for this research project/protocol, and not sharing access to such information with any individual without prior review and approval of the IRB and/or privacy officer unless such subset has been created to exclude all identifiable demographic information as defined in this documents, or unless additional data use agreements have been obtained for distribution of limited data sets.
- Forbidding attempts to re-identify the subjects from the data collected and attempts to contact the subjects or family members from de-identified data.
- Submitting the Continuing Review of Research Application before study approval expiration.
- Responding to all GC IRB inquiries within a reasonable time.
- If applicable a 1572 is signed, the Investigator agrees to all commitments listed within this document.
- When available, provide the data safety monitoring board (DSMB) plan for Sponsored trials to the IRB. The DSMB is generally required for human subjects research projects that present more than minimal risk to participants. For research that involves no more than minimal risk, a DSMP is usually not required. The DSMB should be specific to address the risk level that is described in the proposed research. The GC IRB will determine whether an activity represents minimal risk or more than minimal risk to participants and then determine

whether a data safety monitoring plan is required (please refer to the below GC IRB section for additional description of research requirements).

- When following International Conference on Harmonization – Good Clinical Practice Guidance [ICH-GCP (E6)], Clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with good clinical practice and the applicable regulatory requirements.

Faculty Sponsor’s Responsibilities

For projects where the researcher is a student, resident, fellow, or Collaboration Investigator outside the Covered Entity

The faculty sponsor is responsible for ensuring that the student or investigator is knowledgeable about the regulations and policies governing research with human subjects and has sufficient training and experience to conduct this study in accord with the approved project. In addition, the faculty sponsor is responsible for:

- Meeting with the student, fellow, or collaborating investigator outside the covered entity on a regular basis to review study progress.
- If unavailable, as when on sabbatical, leave or vacation, arranging for an alternate to assume the faculty sponsor responsibilities.
- Assuming the role of P.I. when the student or fellow leaves Guthrie.

*The faculty sponsor must be a member of the standing Guthrie faculty. The faculty sponsor is considered the responsible party for legal and ethical performance of the project.

Use of De-Identified Data in Research

Use- means to collect, share, employ, apply, utilize, examine, or analyze PHI within The Guthrie Clinic.

De-identified Data- Data that is “de-identified” under HIPAA is not regulated by HIPAA and may, accordingly, be used or disclosed for research and other purposes without patient authorization. Data is “de-identified” under HIPAA if the following identifiers of the individual or of relatives, employers, or household members of the individual are removed:

Names

All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geo-codes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census, (a) the geographical unit formed by combining all ZIP codes with the same three initial digits contains more than 20, 000 people: and (b) the initial three digits of a zip code for all such geographic units containing 20, 000 or fewer people is changed to 000.

All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.

- ***Telephone number***
- ***Fax number***
- ***Electronic mail addresses***
- ***Social security numbers***
- ***Medical record numbers***
- ***Health plan beneficiary numbers***
- ***Certificate/license numbers***
- ***Vehicle identifiers and serial number, including license plate numbers***
- ***Device identifiers and serial numbers***
- ***Web Universal Resources (URLs)***
- ***Internet Protocol (IP) address numbers***
- ***Biometric identifiers, including finger and voice prints***
- ***Full face photographic images and any comparable images***

Any other unique identifying number, characteristic, or code, except that a code may be assigned to allow information de-identified by removal of all above information to be re-identified if: (a) the code is not derived from or related to the information from and the individual and is not otherwise capable of being translated to identify the individual; and, (b) the code is not used for any other purpose nor disclosed to any

outside entity.

Guthrie Clinic IRB

The Institutional Review Board of The Guthrie Clinic oversees all research involving human subjects conducted within Guthrie facilities as well as any research conducted by Guthrie employees at non-Guthrie facilities. In some circumstances, the GC IRB will permit another IRB to exercise primary responsibility for oversight. Guthrie Foundation provides administrative support for the IRB.

Research involving human subjects may not be conducted unless it has been approved by the GC IRB. In some cases, additional review by the institution may be necessary. Please refer to the following link for additional requirements of the Guthrie IRB www.guthrie.org/content/institutional-review-board

The IRB can suspend or terminate approval of research that:

- Is not being conducted in accordance with the IRB's requirements.
- Has been associated with unexpected serious harm to participants.

Review of Research Determined to be More Than Minimal Risk

As part of their review, the GC IRB will determine whether an activity represents minimal risk or more than minimal risk to participants. Proposals for research involving more than minimal risk should also contain information regarding data and safety monitoring plans. These plans should be submitted to the IRB for their review. Generally, plans include: time points for review of safety data, actions to be taken in response to significant safety events or end points, and how these events will be reported. Below are some examples of acceptable monitoring plans:

- The principal investigator will have sole responsibility for monitoring and oversight of problem/events;
- A group of designated Guthrie/staff will have responsibility for monitoring, oversight of adverse events, and other protocol events;
- An independent individual or group of non-Guthrie staff (e.g., coordinating center) will have responsibility for monitoring, oversight of adverse events, and other protocol events;
- A designated medical monitor, or group of monitors for commercially funded or for not-for-profit sponsored studies, will have responsibility for monitoring, oversight of adverse events, and other protocol events;
- A formal Data and Safety Monitoring Board (DSMB) will have responsibility for monitoring, oversight of adverse events, and other protocol events.

When the IRB determines that data and safety monitoring is required, the IRB should evaluate whether the plan is adequate and consider issues such as:

- Documented plan for reporting data safety monitoring committee findings to the IRB and the sponsor and the frequency of reporting. Of note, the plan should include a differentiation for submission of data to the IRB between urgent and routine safety reports when necessary.
- What safety information will be collected, including serious adverse events, clinically significant lab values, etc.
- How the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants, etc.).
- The frequency of data collection, including when safety data collection starts.
- The frequency or periodicity of review of cumulative safety data.
- Conditions that trigger an immediate suspension of the research, if applicable

(Reference Policy GF-IRB-322-022 Criteria for Approval of Research).

If a formal DSMB is to be constituted by a federal funding agency, or by a clinical consortium conducting the protocol, or is required by the IRB, the IRB may determine that a formal DSMB represents sufficient data and safety monitoring oversight. The IRB's decision regarding the adequacy of the plan will be documented in the IRB meeting minutes.

IRB Leadership

Chair: Michael Georgetson, MD
Vice Chairs: Joseph Choi, MD and James Walsh, MD

To reach the Chair or Vice Chair, please contact the IRB Coordinator, Lori Robinson at extension 4885 or by email at LoriA.Robinson@guthrie.org

IRB Forms

IRB forms can be downloaded from the IRB web page at <https://www.guthrie.org/applications-and-forms>

Compliance and Internal Audit

The Office of Compliance and Internal Audit provides guidance on institutional policies and procedures relating to use of protected health information (PHI). It reviews and approves "boilerplate language" in consent documents and sponsored research contracts relating to PHI; advises on current institutional procedures for securing PHI; and investigates and evaluates reports of unauthorized disclosures of PHI.

Patient Safety

The Guthrie Clinic Office of Patient Safety, interfaces with the Human Research Protection Program in developing institutional policies on informed consent and patient safety. Certain unanticipated problems involving risks to subjects or others and serious adverse events are reported to this office. (Reference IRB Policy 322-052 *Unanticipated Problems*)

When Things Go Wrong

In research, as in life, bad things sometimes happen. Four kinds of bad things must be reported as soon as they become known: 1) Unanticipated problems involving risks to research subjects or others (UPIRSOs), 2) Noncompliance, 3) Misconduct in research, and 4) Disclosure of PHI.

Unanticipated problems involving risks to research subjects or others (UPIRSOs)

Unanticipated problems involving risks to subjects or others (UPIRSOs) are research related incidents outcomes or experiences that may impact the rights and safety of subjects or others. Note that actual harm does not have to occur – just a realization of an unanticipated risk of harm. The IRB has a specific form for reporting UPIRSOs, but a phone call or e-mail to the IRB office is enough to start the reporting process. UPIRSOs can be reported by any member of the research team, but the Principal Investigator will usually sign a formal report. OHRP considers *unanticipated problems*, in general, to include any incident, experience, or outcome that meets **all** the following criteria:

- **unexpected** (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
- **related** or possibly related to participation in the research. *Possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research; and

- suggests that the research **places subjects or others at a greater risk** of harm (including physical, psychological, economic, or social harm) than was previously known or recognized. (45 CFR Part 46) <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>

OHRP notes that an incident, experience, or outcome that meets the three criteria above generally will warrant consideration of substantive changes in the research protocol or informed consent process/document or other corrective actions to protect the safety, welfare, or rights of subjects or others.

Examples of UPIRSOS can include a breach of confidentiality due to the loss of a laptop, identification of a new side effect in a clinical trial, or a subject receives a dose of an experimental agent that is 20-times higher than the dose dictated by the IRB-approved protocol.

The HHS document at <http://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/> entitled *Unanticipated Problems Involving Risks & Adverse Events Guidance* (2007) provides examples of unanticipated problems that need to be reported and examples that do not need to be reported (see appendices B, C and D in the document link above).

An unanticipated problem meeting the level of an UPIRSO and prompt reporting to the IRB can occur in any type of research (i.e. social/behavioral and biomedical). Investigators who have conducted sponsored clinical trials may immediately think that UPIRSOs are adverse events. Some adverse events meet the UPIRSO criteria, but many don't because they were anticipated (based on the known risks of the experimental agent). Furthermore, there are other types of incidents, experiences, and outcomes that occur during the conduct of human subjects research that represent unanticipated problems but are not considered adverse events. For example, some unanticipated problems involve social or economic harm instead of the physical or psychological harm associated with adverse events.

Noncompliance

This very broad category encompasses not obeying federal regulations governing research with human subjects or Guthrie policies on human subjects, research, as well as not following what you said you would do in the protocol. The IRB has a policy that explains noncompliance in detail and how it should be reported. Noncompliance does not necessarily imply that an act was willful. Sometimes circumstances are beyond the control of the researchers; nevertheless, if you suspect that any noncompliance has occurred this should always be reported to the IRB office.

Results of sponsor audits or internal audits identifying noncompliance that is potentially serious or continuing must be reported to the IRB (Reference policy 322-053 *Noncompliance*).

If you have any questions about whether or how to report a UPIRSO or Noncompliance, call the IRB Office at ext 4885.

Misconduct in research

Misconduct in research has a very specific definition within the federal regulations: it means falsification of data; fabrication of data; or plagiary of scientific material. We don't see much of this problem at Guthrie, but when and if it occurs, it must be reported to the HPA.

Disclosure of PHI

“Disclosure” means the release, transfer, provision of access to, or divulging of protected health information by any means to persons or entities outside The Guthrie Clinic or other covered entity.

“Protected Health Information (PHI)” Protected health information (PHI) is defined under the HIPAA regulations as information that is a subset of health information, including demographic information

collected from an individual, and: (1) is created by a health care provider, health plan, employer, or health care clearinghouse; and (2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and (i) that identifies the individual; or (ii) with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

The probability of inadvertent disclosure of patients' protected health information (PHI) increases when we employ portable devices such as thumb drives and CDs to store data abstracted from patients' electronic health records. **PHI must be stored securely and may only be stored on Guthrie Servers.**

The financial and reputational penalties associated with inadvertent disclosure of PHI can be severe. These include the requirements to notify the individuals and possibly the media of the details of the breach. Loss of portable media or unauthorized disclosure of PHI should be reported immediately to a compliance officer and the GC IRB so that a full investigation and breach impact analysis can be conducted.

Concerns about Research

Concerns, complaints, and suggestions about any aspect of IRB operations or human research protections can be submitted directly to:

IRB Chair - Dr. Michael Georgetson at Michael.Georgetson@guthrie.org

Vice Chairs - Dr. Joseph Choi at Joseph.Choi@guthrie.org or
Dr. James Walsh at James.Walsh@guthrie.org –

IRB Staff - IRB Coordinator Lori Robinson, CIC 4885 or LoriA.Robinson@guthrie.org
Manager Research & Ed. Vicky Hickey, CCRP 4882 or Vicky.Hickey@guthrie.org

Alternatively, concerns can be submitted anonymously by following the link:
<https://www.guthrie.org/contact/submit-concern-institutional-review-board>

Concerns, complaints and suggestions about any aspect of research operations at Guthrie can be submitted directly to Burt Cagir at x2454 or by email Burt.Cagir@guthrie.org

In addition, concerns can be relayed though the Guthrie Compliance Hotline: 1-888-841-4644 or the Internal Audit and Compliance,
Roger Lathrop, MS, RRT, Sr. Director, x5803 Roger.Lathrop@guthrie.org

Foundation Directory

Foundation offices are located on the fifth floor of the Foundation Building.

<https://www.guthrie.org/research>

1-888-4GUTHRIE (1-888-448-8474) or 1-800-836-0388

Fax : 570-887-4884

Name	Title	Tel. ext.	E-Mail
Burt Cagir, MD, FACS	Human Protections Administrator (HPA) /Executive Director of Donald Guthrie Foundation	2454	Burt.Cagir@guthrie.org
Vicky Hickey, CCRP	Manager, Research & Education	4882	Vicky.Hickey@guthrie.org
Kamie Hoey, RN, CCRP	Manager, Clinical Research	6070	Kamie.Hoey@guthrie.org cl
Michelle Hunter, CCRP	Regulatory	2156	Michelle.Hunter@guthrie.org
Cathy Lanning, CCRP	Manager, Research	4880	Cathy.Lanning@guthrie.org
Jennifer Panek	Regulatory/Contract Specialist	4852	Jennifer.Panek@guthrie.org
Lori A. Robinson, CIC	IRB Coordinator	4885	LoriA.Robinson@guthrie.org
Mikki Smith, MLS, PhD, AHIP	Medical Librarian	6371	Mikki.Smith@guthrie.org

Appendix 1: Small Grants for Investigator-Initiated Research

Introduction

The Foundation has initiated a strategy to enhance the way research is done at Guthrie. A new program will make small grants available to support investigator-initiated research that will: (1) build on our clinical strengths and our vertically integrated structure; (2) address questions that arise directly from our clinical practice; (3) address the healthcare needs of the community we serve; (4) translate the results of basic biomedical research into the way medicine is practiced in the community; and (5) be integrated with our educational and professional development programs.

Funds Available

In general, grants will be limited to \$5,000 per project in a 12-month period. An additional amount of \$10,000 per project in a 12-month period may be obtained to purchase equipment. All purchased equipment may only be used to perform the required clinical assessments needed for the particular project. Further, any project specific equipment may only be utilized by the investigator or study team during the conduct of the trial. Upon project completion and in collaboration with the departmental administrator the equipment will be transferred from the Foundation to department in which the trial was performed. Any equipment purchase should maintain an intended use of providing improved patient care methods. Grant funds may not be used to purchase computer equipment or for travel. Prior to approval, all fund requests must outline clear objectives in the application regarding intended use and purpose of funds.

Application Process

Please refer to the application on the following page for all required fields. Questions regarding the application should be discussed with the HPA prior to submission to ensure an expedited process.

Eligibility

This program is open to all healthcare providers of The Guthrie Clinic. The principal investigator is responsible for overall conduct of the project, and sub-investigators must be qualified to carry out their roles on the project. Residents at Robert Packer Hospital may apply as principal investigators, but a Guthrie Medical Group P.C. physician must be a co-investigator on the project. First-time applicants should submit a CV and documentation of completion of CITI training.

Review Criteria

Applications will be evaluated according to the following criteria:

1. Scientific or medical significance of the objective
2. Quality of the proposed approach
3. Relevance to the mission of Guthrie

Review Process

Applications will be reviewed initially by the HPA to determine eligibility and then by the President Guthrie Clinic for content and relevance. When necessary, additional reviews will be sought from Guthrie physicians with appropriate expertise. The review process will occur on an ongoing basis as grants are received. Grant approval will be shared once all reviewers complete their assessment of the application.

Human Subjects

If the application proposes a study involving human subjects or examination of patients' medical records, then it is the responsibility of the applicant to obtain approval for the research from the Institutional Review Board. Further, a finalized protocol should be submitted in conjunction with the IRB Application for approval.

Format for Application for Investigator-Initiated Research Grant
DONALD GUTHRIE FOUNDATION
APPLICATION FOR INVESTIGATOR-INITIATED RESEARCH GRANT
 Return completed application to: Burt Cagir, MD, FACS

Title of Proposal:			
Principal Investigator:			
Phone:		Email:	
Dept/Division:			
Sub-Investigator(s) including Residents/Fellows:			
Protocol Synopsis			
Description:			
Study Design:			
Study Type:			
Estimated Enrollment:			
Investigational and reference therapy (if any):			
Primary Outcome:			
Secondary Outcome:			
Inclusion/Exclusion Criteria:			
Data Source:			
Statistical analysis:			
Funds Requested:			
Category	Description	Budget Detail	Cost
Supplies, effort, mileage, etc			
Statistical Analysis			
Publication			
Total Cost			

Attestation of Principal Investigator: I understand that funding by Donald Guthrie Foundation contributes to scholarly activity of Residents, Fellows and Faculty Attendings. I agree to include participating Residents, Fellows, and Faculty Attendings in the publication of results of the research.

PI Signature: _____ **Date:** _____

**Approval of grant does not imply IRB approval. All requests for funds must be in consultation with the Research Dept.

Approval: _____ **Donation Fund:** _____

Appendix 2: Research Protocol Guidelines

The following elements are required to be incorporated into the research protocol:

1) Protocol Title and version date

2) Principal Investigator

- Include your name, i.e. the name of the person conducting the research
- If you are completing a residency program, please list your faculty sponsor as the Co-Investigator

3) Research Site(s)

- Describe the Guthrie entity and department where the research will be conducted

4) Funding

Explain if there are grants, funding or other financial support (e.g. This research is being funded by Donald Guthrie Foundation.)

5) Brief Study Description

6) Objectives

- Describe the purpose, specific aims, or objectives of the Human Research.
- State the research question or hypotheses to be tested.
- Describe your plans for data dissemination and usage.

7) Background and Rationale

- Provide the scientific or scholarly background and rationale for the Human Research based on the existing literature.
- Describe the relevant prior experience and gaps in current knowledge (i.e. what has been done and why you are proposing to do this study).
- Describe any relevant preliminary data.
- Explain the significance of the Human Research in terms of why this Human Research is important and how it will add to existing knowledge.

8) Study Design

Describe if the study is interventional or observational.

For Interventional studies, describe the number of arms, the masking (open label or blinded), describe how patients are allocated (single arm, randomized, non-randomized).

For observational studies, describe the observational study model (cohort, case-control, case-only, case-crossover). Describe if study is prospective or retrospective.

Describe any biospecimens that will be collected (with or without potential for DNA extraction)

See “ClinicalTrials.gov Protocol Data Element Definitions” accessible at

<https://prsinfo.clinicaltrials.gov/definitions.html>

a) Enrollment

Anticipated number of subjects in the trial.

b) Recruitment Methods

- Describe the following:
 - The methods that will be used to identify potential participants.
 - Any materials that will be used to recruit participants. Include copies of these documents with the application.
 - For research in which biological specimens or tissue samples will be used, describe the source of the materials (e.g., “retrospective research” using previously collected specimens from certified specimen banks, another previously approved study, discarded specimens gathered for non-research purposes, etc. vs. “prospective research” using specimens that will be collected specifically for this study.
 - For research in which biological specimens or tissue samples will be used, describe whether any individually identifiable information will be associated with the samples.

c) Participant Compensation/Cost

- Describe the plan for addressing the amount and timing of any payments/compensation to participants.
- If applicable, describe any financial costs that participants may incur through participation in the research.

d) Inclusion and Exclusion Criteria

- Describe how you will screen for eligibility.
- Describe the criteria that define who will be included or excluded in your final study sample.

e) Study Outcomes

- Describe the primary and secondary study outcomes. (For example, studies may be conducted until a certain time point, until a re-occurrence of disease, or a certain clinical condition is met.)
 - Describe time point(s) at which outcome measures are assessed.
 - Describe if outcome measures are assessing a safety issue
- Primary Outcome Measure Definition: Specific key measurement or observation used to measure the effect of experimental variables in a study, or for observational studies, to describe patterns of diseases or traits or associations with exposures, risk factors or treatment.

- Secondary outcome: Secondary measurements that will be used to evaluate the intervention(s) or, for observational studies, that are a focus of the study.

f) Study Timelines

- Describe:
 - The duration of an individual subject’s participation in the study.
 - The duration anticipated to enroll all study participants.
 - The anticipated start date for enrollment to begin
 - The Anticipated Primary Completion Date: the date that the final subject is expected to be examined or to receive an intervention for the purposes of final collection of data for the primary outcome.
 - The anticipated Study Completion Date: Final date on which data is expected to be) collected

g) Procedures involved in the Human Research.

- Provide a timeline of all procedures/activities being performed as part of the research.
- Describe all instruments i.e. surveys, questionnaires, interview guides, etc. (Attach a copy of these instruments to your protocol.)
- Describe the source records that will be used to collect data about participants.
- Describe what data will be collected including long-term follow-up
- If medical records are being used, include a list of specific data to be obtained. Health Insurance Portability and Accountability Act (HIPAA) regulations will apply if the data provider is a HIPAA covered entity. HIPAA documentation may be required. For more information please visit <http://privacyruleandresearch.nih.gov/>

h) Withdrawal of participants

- Describe anticipated circumstances under which participants will be withdrawn from the research without their consent.
- Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection. If the research is retrospective by design, then this is not applicable.

9) Risks to participants

- List the risks, discomforts, hazards or inconveniences to the participants. For each, indicate the probability, magnitude, and duration. Consider physical, psychological, social, legal and economic risks.

10) Potential direct benefits to participants

- Describe the benefits that individual participants may experience. For each indicate the probability, magnitude, and duration of the benefit.
- Indicate if there is no direct benefit.

11) Provisions to maintain the confidentiality of data

- Describe the steps that will be taken to de-identify the data. Describe where data will be stored, who will have access to the data, measures taken to secure the data, and how long data will be stored. Include procedures for maintaining participant confidentiality, any special data security requirements, and record retention.
- For hardcopy data, CDs, tapes, specimens, etc., describe any physical safeguards that will be in place. For example: locked cabinet/office, data de-identified by research team, data coded by research team.
- For coded data, describe how the key to the code will be stored and when/how it will be destroyed.
- Describe safeguards for devices used to access study data, e.g., password access, automatic log-off.
- State whether electronic files will be password-protected, encrypted, on a secure network, etc. **Please note no data should be stored on portable devices.**
- Describe the plans for the final disposition or de-identification of data that are identifiable in any way (directly or indirectly via codes) once the study has ended. If the data will be kept indefinitely describe the format of the data and purpose of retention. If data will be destroyed, describe the timeline and method.

12) Vulnerable Populations

What vulnerable populations will be considered for this study? Examples include:

- a) Cognitively impaired/educationally disadvantaged individuals
- b) Economically disadvantaged individuals
- c) Subjects who report to or are students of the investigator
- d) Non-English-speaking individuals
- e) Children under the age of 18
- f) Prisoners
- g) Pregnant Women Neonates (non-viable/uncertain viability)

Describe the additional safeguards that are included to protect their rights and welfare.

13) Consent process/process to document consent or to request a consent waiver

- Indicate whether you will you be obtaining consent, and if so describe:
 - Where will the consent process take place?
 - Any waiting period available between informing the prospective subject and obtaining the consent.

- Any process to ensure ongoing consent.
- Describe whether and how consent of the participant will be documented in writing.
- If the Human Research involves adults who may be unable to consent, describe the process to determine whether an individual is capable of consent.
- If the research is only a survey or questionnaire of subjects, describe if completion of the survey/questionnaire will serve as **implied consent**.
- If the Human Research involves a **waiver or alteration of the consent process**, explain how each of the criteria below are met:
 - the research involves no more than minimal risk to the subjects;
 - the research could not practicably be carried out without the requested waiver or alteration;
 - if the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
 - the waiver or alteration will not adversely affect the rights and welfare of the subjects;
 - whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.
- If the Human research involves a **waiver of consent documentation**, explain why no signed consent document is appropriate:
 - The only record linking the subject and the research would be the informed consent form
 - The principal risk would be potential harm resulting from a breach of confidentiality.
 - Each subject or legally authorized representative will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern

or

 - The research presents no more than minimal risk of harm to subjects
 - The research involves no procedures for which written consent is normally required outside of the research context.

14) Data Monitoring Plan

- For studies that are greater than minimal risk, describe the provision for monitoring the data collected to ensure the safety of subjects.

15) Sharing of results with participants

- Describe any plans for providing aggregate data and sharing the results of the research with participants.

16) Sharing of individual participant data (IPD) with other researchers

Indicate whether there is a plan to make individual participant data (IPD) collected in this study available to other researchers. Describe what participant data sets and/or documents are to be shared, when data will be available, and how the data may be obtained.

Appendix 3 Checklist for Investigator Initiated Research

- Complete human subjects protection training from <https://www.citiprogram.org/>
- If Resident/Student/Fellow, choose faculty sponsor who has human subjects protection training.
- Read Investigator Handbook
- Complete financial disclosure form available at <https://www.guthrie.org/content/research>
- Write draft protocol: Template at <https://www.guthrie.org/content/applications-and-forms>
- Submit protocol to Vicky Hickey at Vicky.Hickey@guthrie.org for verification of originality of written work using the **iThenticate** anti-plagiarism software
- Compile other research documents:
 - Informed Consent (Template at <https://www.guthrie.org/content/applications-and-forms>)
 - Questionnaires, surveys, interview questions, etc.
 - Recruitment materials i.e. mails, letters, scripts, advertisements, posters, flyers
 - Any other information that will be used by research subjects
- If the research project involves nurses at RPH, submit protocol to Sally Bennett, Ph.D., R.N. at Sally.Bennett@guthrie.org
- If applying for institutional grant, submit grant application available at <https://www.guthrie.org/content/research>
- Obtain IRB application form from Vicky Hickey Vicky.Hickey@guthrie.org or Lori Robinson at LoriA.Robinson@guthrie.org Submit protocol and we will assist in providing the correct form.
- Submit protocol, other research documents and signed IRB application to IRB. If the research is determined to be greater than minimal risk, you will need to present to the IRB
- Receive IRB approval via email from LoriA.Robinson@guthrie.org
- If project involves consenting subjects, complete consent training before enrolling subjects.
- Register your trial with <https://clinicaltrials.gov/> Contact Vicky Hickey at Vicky.Hickey@guthrie.org for assistance.

Appendix 4 Guidelines for Oral Presentation or Protocol to IRB

Provide a Brief Overview

- (1) Objective of the study
- (2) Rationale for the study
- (3) Research subjects
 - a. Disease condition, inclusion and exclusion criteria
 - b. Number to be enrolled at Guthrie
 - c. Inclusion of subjects who may be considered vulnerable
- (4) What procedures are not standard of care? (i.e. additional tests, experimental drugs)
- (5) Any unusual aspects about the process of informed consent
(i.e., legally authorized representatives for decisionally impaired subjects;
waiver of requirement for written documentation of informed consent)
- (7) Potential benefits to subjects
- (8) Risks to subjects
- (9) Assessment of the risk-benefit ratio
- (10) Anything else the IRB should know

Please allow for IRB members to ask questions on areas where they need clarification.
The IRB will receive a copy of your protocol and IRB application •

Appendix 5 Consent Process and Documentation

The Consent Process

Informed consent is more than just a signature on a form; it is a process of information exchange that may include, in addition to reading and signing the informed consent document, subject recruitment materials, verbal instructions, question/answer sessions and measures of subject understanding. Institutional Review Boards (IRBs), clinical investigators, and research sponsors all share responsibility for ensuring that the informed consent process is adequate. Thus, rather than an endpoint, the consent document should be the basis for a meaningful exchange between the investigator and the subject.

The clinical investigator is responsible for ensuring that informed consent is obtained from each research subject before that subject participates in the research study. FDA does not require the investigator to personally conduct the consent interview. The investigator remains ultimately responsible, even when delegating the task of obtaining informed consent to another individual knowledgeable about the research.

In addition to signing the consent, the subject/representative should enter the date of signature on the consent document, to permit verification that consent was actually obtained before the subject began participation in the study. If consent is obtained the same day that the subject's involvement in the study begins, the subject's medical records/case report form should document that consent was obtained prior to participation in the research. A copy of the consent document must be provided to the subject and the original signed consent document should be retained in the study records. Note that the FDA regulations do not require the subject's copy to be a signed copy, although a photocopy with signature(s) is preferred.

The IRB should be aware of who will conduct the consent interview. The IRB should also be informed of such matters as the timing of obtaining informed consent and of any waiting period (between informing the subject and obtaining the consent) that will be observed.

The consent process begins when a potential research subject is initially contacted. Although an investigator may not recruit subjects to participate in a research study before the IRB reviews and approves the study, an investigator may query potential subjects to determine if an adequate number of potentially eligible subjects is available.

21 CFR 50.27 Documentation of Informed Consent

(a) Except as provided in 56.109(c), informed consent shall be documented by the use of a written consent form approved by the IRB and signed and dated by the subject or the subject's legally authorized representative at the time of consent. A copy shall be given to the person signing the form.

<http://www.fda.gov/regulatoryinformation/guidances/ucm126431.htm#process>

Take Note of Guthrie Institutional Required Signature Page in compliance with policy GC -950-005. Each research team member must understand the requirement of this signature page. A witness signature is required, and the boxes must be checked 'yes'. An impartial witness is only used if the patient cannot read.

Special Considerations for Guthrie and non-Guthrie Collaboration

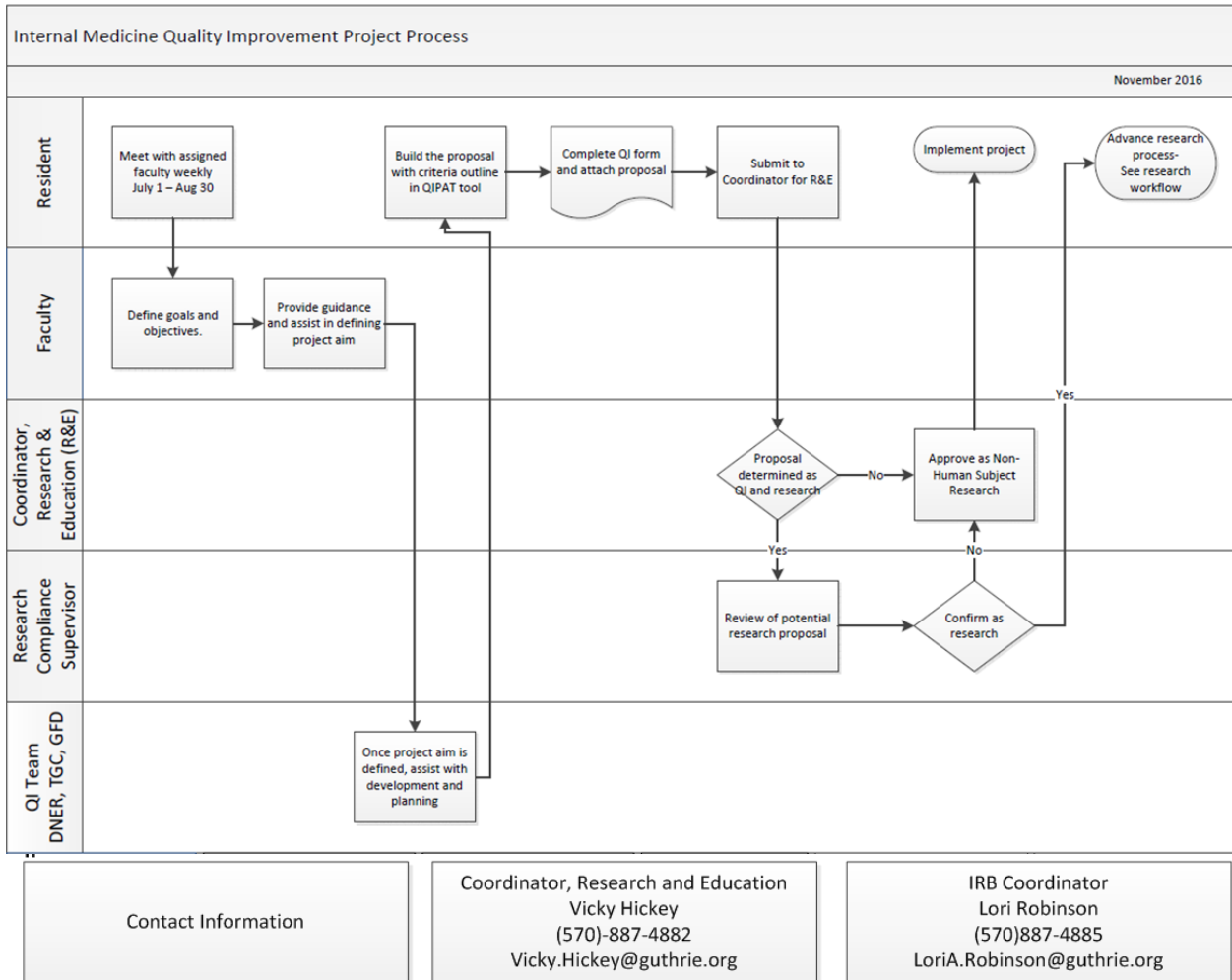
Consent Documentation:

Original Consents will be stored at _____

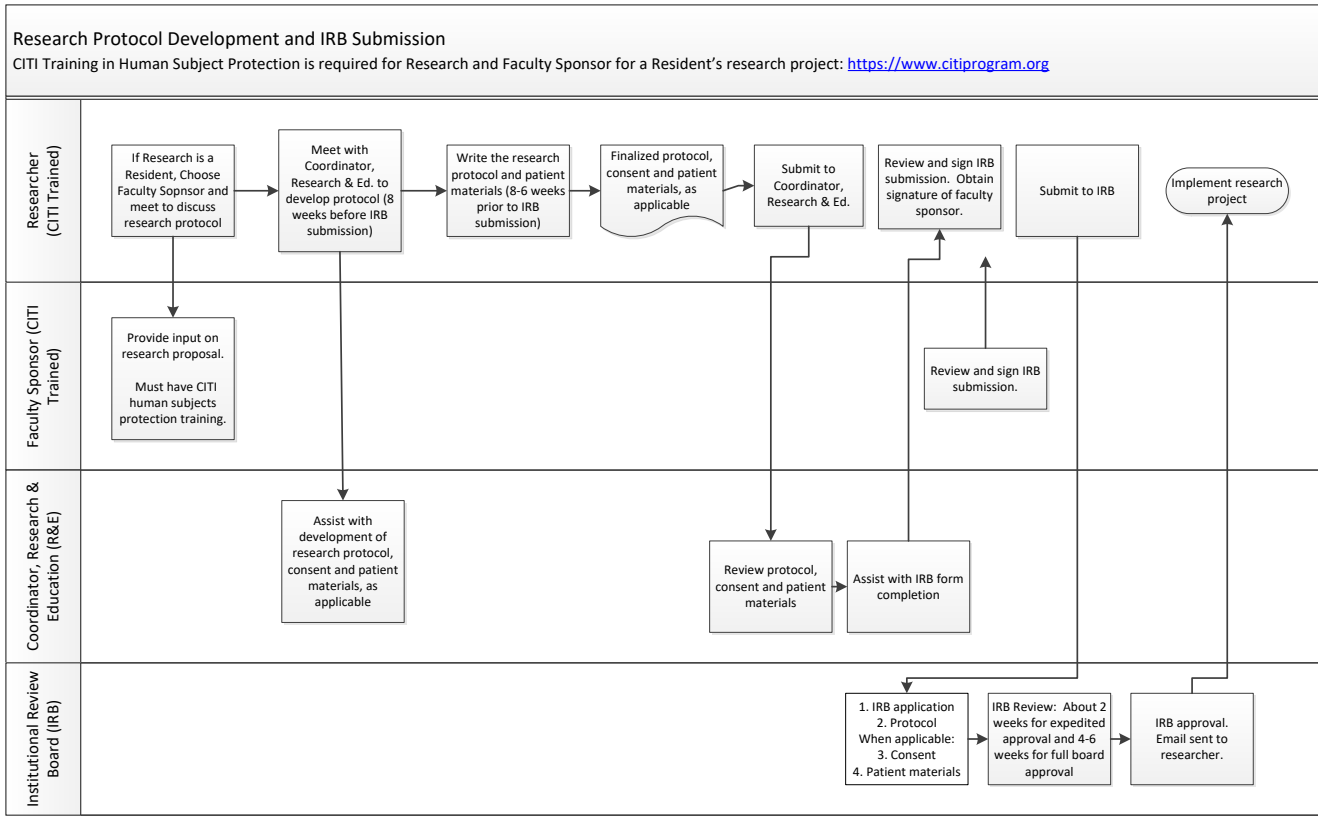
Fax a redacted consent signature page to 570-887-4884 to Vicky Hickey or email to Vicky.Hickey@guthrie.org
The redaction must remove the printed name and signature of the subject except for the first and last initial.

Per Guthrie policy, consents are to be scanned to the electronic medical record.

Appendix 6 QI Process



Appendix 7 Research Flow



Contact Information

Coordinator, Research and Education
 Vicky Hickey
 (570)-887-4882
 Vicky.Hickey@guthrie.org

IRB Coordinator
 Lori Robinson
 (570)887-4885
 LoriA.Robinson@guthrie.org