GUTHRIE

Version: 2025 April

Institutional Review Board of The Guthrie Clinic

570-887-4885

APPLICATION TO CONDUCT HUMAN SUBJECTS RESEARCH

Type of IRB Review:	**IRB Number:**
☐ Convened Meeting ☐ Expedited Review ☐ Exempt	

Investigator:	**Date of Submission**:
Sponsor:	
Title of Study:	

Documents submitted for Review

Protocol – Date and/or Version:		
Informed Consent Document(s): How many? Name and Version(s)		☐ NA
Investigator's Brochure (if one exists) Name and Version		☐ NA
Data and safety monitoring plan (if separate from the protocol)	☐	☐ NA
Recruitment materials including advertisements, and Educational material intended to be seen or heard by potential subjects.	☐	☐ NA
The following notice may be placed in Friday Facts and/or Guthrie News at Workplace by Facebook: Guthrie Foundation has announced that the following study is open to enrollment at the Sayre Campus: , sponsored by . The principal investigator is , and the research coordinator(s) is/are . Please call for further information.	☐	☐ NA
Collaborative Agreement with a Guthrie Investigator for Principal Investigators who are not affiliated with Guthrie	☐	☐ NA
IRB Authorization Agreement for studies involving research with unaffiliated investigators	☐	☐ NA
Request for Waiver of Consent or Waiver of Consent Documentation	☐	☐ NA
Request for Waiver of HIPAA Authorization (Partial or Full)	☐	☐ NA
Approval by Nursing Research Council for studies conducted by nurses at Robert Packer Hospital or that changes nursing practices at Robert Packer Hospital	☐	☐ NA
Approval from Radioactive Drug Safety Committee [RDSC] if the research involves experimental radiopharmaceuticals (radioactive drugs).	☐	☐ NA
Approval from Service Line Leader for utilization of RPH or GC services	☐	☐ NA
If this trial is registered at ClinicalTrials.gov, provide the **NCT Number**		
Other items:		

Part II. Investigators and Research Team

Either the Principal Investigator or a Sub/Co-Investigator must have a formal affiliation with the facility where the research will be done. If the Principal Investigator is a resident or trainee, the Co-Investigator must have a formal affiliation with the facility where the research will be done.

a.	**Researchers**	**Name; Role on Study**
	Principal Investigator	
	Research Team Members (indicate role i.e. Sub-I, Coordinator, Regulatory)	
b.	**Where will the study be done?** ☐ Guthrie (specify site and department) ☐ Non-Guthrie Site (specify)	
c.	**Experience/Training in Research** Provide documentation that the principal investigator and research team members have the necessary experience to carry out this research protocol at Guthrie ☐ CV on file ☐ Other (specify)	
d.	**Training in Human Subjects Protection** Have all the members of the research team received training in human subjects protection? ☐ YES → ☐ Certificates on file with IRB office ☐ Training certificates attached ☐ **NO** Describe how and when investigators will obtain appropriate training.	
e.	**Clinical Investigators – serious and/or continuing noncompliance** Has the Principal Investigator or any Sub-Investigator been involved in any instances of serious and/or continuing noncompliance with research regulations, IRB requirements or research protocol requirements within the last five years? ☐ YES ☐ No If yes, please explain:	

Part III. Protocol Information

A protocol is to be attached that includes the following:

- Objective(s) or purposes of the study
- Background and scientific/scholarly rationale for the research
- Main outcome to be measured
- Methods or procedures
- Data or samples to be collected
- Study design
- The anticipated duration of the study for individuals and for the project
- The anticipated number of subjects to be enrolled
- Inclusion and Exclusion Criteria
- Risks (If an Investigator Brochure or package insert is available, please attach)
- Steps to be taken to minimize risks
- Benefits to subject and others
- Grant submission if applicable

a.	**Standard of Care** Does the protocol call for medical/surgical procedures that are NOT part of standard of care (SOC) for treating or diagnosing a disease or condition or for restoring function? (For example, additional endoscopies, imaging studies, or blood samples.) ☐ No. All procedures are considered SOC at Guthrie. ☐ NA. This protocol does not involve medical/surgical procedures ☐ **YES**. Indicate which procedures are not SOC.		
b.	**Experimental Radiopharmaceuticals (radioactive drugs)** Does the research involve the use of experimental radioactive drugs (having an IND) for diagnostic or therapeutic studies? If YES, then the research must be reviewed by a Radioactive Drug Safety Committee [RDSC]	**Yes** ☐	No ☐
c.	**Emergency Procedures** Does this site have all the emergency equipment, personnel, and procedures required by the protocol? If NO, Explain:	Yes ☐ NA ☐	No ☐
d.	**Breaking the Blind** If this protocol involves administering a treatment in a blinded fashion, please describe procedures to break the blind when necessary, or site the page number of the protocol where breaking the blind is describe. ☐ NA. Study is not blinded		
e.	**Number of Participants** What is the planned number of participants to be enrolled locally? For internal studies, this will be the number stated in the IRB-approved protocol. For multi-site studies, this will be an estimate, and the IRB will not consider this estimate to be an enrollment limit for the site.		

f.	**Evaluation of potential subjects** Will you enroll any subjects from the following categories? **Pregnant women** ☐ May not participate (Are excluded) ☐ Are not eligible to participate but if a pregnancy were to occur participants and/or pregnant partners will have pregnancy follow up ☐ May participate ☐ Will be recruited specifically for this study **Children** ☐ May not participate (Are excluded) ☐ May participate ☐ Are not eligible to participate but if a pregnancy were to occur the study will include follow up of the newborn ☐ Will be recruited specifically for this study If pregnant women or children may participate, briefly discuss the following: (1) The rationale for drawing subjects from this population. (2) The additional safeguards that will be used to protect the rights and welfare of these vulnerable subjects.

Part IV. Test Articles

a)	**Does the research involve medicines, drugs, or devices?** ☐ **Yes** ☐ **No. Go to Part V**		
b)	**Describe the test article(s)**		
c)	**Are any of the test articles considered investigational?** If Yes, provide: ☐ IND Number ☐ IDE Number:	☐ Yes	☐ No
d)	**If the test article is a device indicate whether the device has been determined to be a:** ☐ **Significant Risk (SR) Device** ☐ Nonsignificant Risk (NSR) Device Who made the SR/NSR determination? *Note*: IRB must make an independent determination of SR/NSR status	☐ NA Test article is not a device	
e)	**Is there an FDA Letter of approval of the test article?** If yes, attach	☐ Yes	☐ No

Part V. Resources Needed for this Protocol

a.	**Additional resources or personnel needed** Does this protocol require access to equipment, services of personnel, or other resources not normally available to the investigator? If **Yes**, describe what arrangements will be made to acquire the necessary resources.	**Yes** ☐	No ☐

Part VI. Beneficence: Risk/Benefit Considerations

The protocol must describe all procedures (including safeguards for preservation of confidentiality) for: maximizing potential benefits to subjects or to society; protecting against or minimizing known or potential risks. The potential benefits must outweigh the risks.

The protocol and consent (when applicable) addressing risks and benefits must be attached.

a)	**Potential benefits to subjects or others** **Describe benefits participants may reasonably expect, and any benefits to others that the study may provide. Select ALL that apply** ☐ There is no expected benefit to participants. ☐ The study may provide knowledge that will be of benefit to future patients. ☐ Benefits are clearly stated in the informed consent form and protocol ☐ Other benefits (please specify)
b)	**Risks to subjects or others** **From the list below, please select ALL of the potential risks that are involved in your study.** ☐ This study is Minimal Risk ☐ Physical Risks including side effects of the test article, or risk of injury or bodily harm ☐ Psychological Risk ☐ Manipulation of psychological or social state such as sensory deprivation, social isolation, psychological stress ☐ Presentation of materials which some participants may consider sensitive, offensive, threatening or degrading ☐ Social Risk that can be damaging to the reputation of the subject or have cultural implications ☐ Probing for personal or sensitive information in surveys or interviews (e.g.: private behaviors, employer assessments) ☐ Economic Risk including risks to financial standing, insurability and employability ☐ Risks to the safety of research personnel associated with the project or others ☐ Risks to a pregnant partner or unborn child ☐ Other risks (please specify) **These risks, and the nature and degree of the risks, must be clearly stated in the protocol and disclosed to participants in the informed consent form.**
c)	**Risk mitigation** Describe the steps that will be taken to minimize the risks to participants. (check all that apply) ☐ Rigorous screening procedures to ensure participants meet the trial's eligibility requirements. ☐ Investigator and research team will monitor the patient for adverse events and side effects. ☐ Sponsor has predefined reporting system for Adverse Events and Serious Adverse Events. ☐ Sponsor Safety Monitoring by Monitor or Data Safety Monitoring Board (DSMB) ☐ Participants can withdraw at any time without penalty, with predefined procedures for safely terminating their participation and ensuring proper support. Other (Describe):

Part VII. Respect for Persons: Privacy, Confidentiality & Informed Consent,

The investigator must ensure that adequate provisions are made to protect the privacy of persons participating in the protocol as well as the confidentiality of their personal information.

With very few exceptions, the protocol must describe the procedure to be followed in obtaining an informed and legally effective consent to participate in the research and to use and disclose protected health information.

a)	**Will you or any member of your research team collect or have access to any of the personal identifiers including:** Name; Date of birth; Mailing or email address; home or fax numbers; Social Security number; Medical records; License, certificate or Vehicle ID; IP address; Biometric identifiers; Photos/images/audio recording; Signatures, handwriting samples; Any unique identifier If yes, what PHI will be used:	**Yes** ☐	No ☐
b)	**Safeguarding confidentiality of information** Does this protocol present any unusual risks to the confidentiality of subjects' medical information while participating or afterwards? (For example, history of drug use; genetic testing.) If Yes, explain what will be done to protect confidentiality of subjects' information.	**Yes** ☐	No ☐
c)	**Respecting privacy** Please explain what will be done to respect subjects' privacy or minimize subjects' potential embarrassment. **Check all that apply** ☐ Consenting process will take place in a private room ☐ Study procedures will take place in a private room ☐ Subject will not be contacted after study completion, unless agreed upon by subject. ☐ **Other – Explain:**		
d)	**Electronic Data Transfer to non-Guthrie site or entity** Will any PHI be transferred electronically to a non-Guthrie site or entity? If Yes, describe the data transfer protocol.	Yes ☐	No ☐
e)	**Waiver of HIPAA authorization** Will Protected Health Information (PHI) be used and/or disclosed under a Waiver of Authorization? If Yes, answer the below: Can the research be practically carried out without the waiver or alteration? Yes ☐ No ☐ Can the research be practically carried out without access to and use of the PHI? Yes ☐ No ☐ Indicate if this is a partial or full waiver request: Check only one: ☐ Partial waiver of HIPAA Authorization (for screening or pre-screening of patients for recruitment; or waiver of a signature) ☐ Full waiver of HIPAA Authorization	**Yes** ☐	No ☐
f)	**Waiver of informed consent** Are you requesting a waiver of informed consent from research subjects? If **Yes**, explain why the waiver is necessary.	**Yes** ☐	No ☐

g)	**Modification of informed consent** **Are you requesting a modification of informed consent from research subjects?** **If Yes, explain why the modification is necessary.**	**Yes** ☐	No ☐
h)	**Waiver of consent documentation** Are you requesting a waiver of the requirement to obtain written documentation of informed consent? If **Yes**, explain why the waiver is necessary.	**Yes** ☐	No ☐
Informed Consent: If you requested a consent waiver, go to section VIII			
a)	**Short consent form** Do you anticipate using a short form of the informed consent document? If **Yes**, then additional conditions must be met. Consult IRB office.	**Yes** ☐	No ☐
b)	**Language understood by subjects** Do you expect to enroll any subjects who do not understand English? If **Yes**, then the Informed Consent Document must be in the subject's language (and submitted with this application) and a qualified interpreter must participate in the consent process. Who translated the Informed Consent Document? Who will translate during the consent process?	**Yes** ☐	No ☐
c)	**Capacity to consent**		
	Does the research protocol permit the use of a Legally Authorized Representative for subjects who cannot consent on their own behalf?	**Yes** ☐	No ☐
	If **YES**, please answer the following questions: (1) Who will be approached as the legally authorized representative of the subject? ☐ If subject is unable to Consent a Legally Authorized Representative (LAR) may be used according to institutional policy and applicable state law. ☐ Other- Explain:		
	(2) What process will you employ to obtain the assent of the research subject? ☐ To the extent determined by the person's ability to comprehend, the researcher will explain the protocol and attempt to elicit the person's assent to participate. ☐ Other- Explain.		
d)	**Identification of potential subjects** Who will identify potential subjects or approach potential subjects for purposes of recruitment? ☐ Research Team Members ☐ **Other – Explain:**		

e)	**Initial presentation of protocol** Will the initial discussion describing the research occur in conjunction with discussion of a diagnosis or treatment plan for a subject's disease or condition? **If Yes, how will you explain to the patient the difference between treatment and research?** ☐ Patient is given all treatment options with the research study being one of the options. The research will be explained to the patient using the consent document. The patient is given the opportunity to take the consent home and encouraged to discuss with family and friends. The patient is encouraged to ask questions to ascertain their understanding of the research. ☐ Other – Explain:	Yes ☐	No ☐
f)	**Informed Consent Process**: Please specify the steps taken by the Investigator and research team to ensure that the participant (or their LAR) is provided sufficient opportunity to consider participation in the research (check all the apply): ☐ The subject (or their LAR) is given adequate time and place to read and review the Informed Consent Form and ask questions. ☐ The subject (or their LAR) is provided a sufficient waiting period between being informed of the research and signing the consent form. ☐ Other – Explain:		
g)	**Venue for presenting protocol** Where will the discussion about participation and consent take place? ☐ Private Room ☐ Other – Explain:		
h)	**Assessing comprehension** How will you determine whether the research subject understands what is discussed during the initial consent conversation? ☐ Researchers will assess subject's understanding through interactive and probing discussion during the consent process. ☐ Other – Explain:		

Part VIII. Justice

Subject selection must be equitable: The potential risks of participation should be shared by those who might be expected to benefit from the results of the study. Care must be taken not to recruit from groups that might be especially vulnerable to coercion.

a)	**Source of research subjects** Will research subjects be drawn from the patient population at Guthrie? If No, from where will subjects be recruited?	Yes ☐	No ☐
b)	**Guthrie employees or students as subjects** Will Guthrie employees or students be specifically recruited to participate in this study? If **Yes**, please discuss the rationale for recruiting subjects from this group.	**Yes** ☐	No ☐

c)	**Vulnerable populations** Does the population from which you anticipate recruiting subjects specifically include persons with impaired decision-making capacity, economically or educationally disadvantaged, or any other persons whose ability to give voluntary and informed consent may be in question? If **Yes**, briefly discuss the following: (1) The rationale for drawing subjects from this population. (2) The protections that will be afforded these subjects.	**Yes** ☐	No ☐
d)	**Research subjects' access to medical care** Will subjects be specifically recruited from a group that normally does not have access to standard medical care for the condition being studied in this protocol? If Yes, please discuss the rationale for recruiting subjects from this group	**Yes** ☐	No ☐ N/A ☐

Part IX. Financial Considerations: Research Subjects

a)	**Costs to subjects for participating** Will subjects or their insurance be charged for any procedures, tests, costs or supplies that are for research purposes only and are not required for treatment (eg, data gathering and tests performed to support FDA filings which would not normally be done for patient care)? If **Yes**, please describe.	**Yes** ☐	No ☐
b)	**Payment or reimbursement for participating** Will subjects receive any payment for participating in the protocol or for reimbursement for personal expenses? If Yes, this must be clearly documented in the consent form. If the information in the consent needs further clarification, please explain:	Yes ☐	No ☐

Part X. Financial Considerations: Investigators.

Investigators' financial disclosures For studies sponsored by a commercial entity, sponsored by a federally funding national clinical trial network (ie, NCI NCTN), or sponsored by a non-profit group or association, has any investigator or co/sub-investigator answered **Yes** on a sponsor's disclosure form (or otherwise disclosed a financial interest in the research)? If Yes, please submit a copy of the disclosure form to the IRB office in a confidential envelope.	**Yes** ☐	No ☐ N/A ☐

Part XII. Affirmation of Principal Investigator

As principal investigator, I accept responsibility for conducting this research and will:

- Not commence research until receipt of the IRB approval letter.
- Comply with all requirements and determinations of the IRB.
- Protect the rights, safety, and welfare of subjects involved in the research.
- Personally conduct or supervise the research.
- Conduct the research in accordance with the relevant current protocol approved by the IRB.
- Ensure that there are adequate resources to carry out the research safely.
- Ensure that research staff are qualified to perform duties assigned to them during the research.
- When required by the IRB ensure that consent, permission, and assent are obtained and documented in accordance with the relevant current protocol as approved by the IRB
- Submit proposed modifications to the IRB prior to their implementation.
    - Not make modifications to the research without prior IRB review and approval unless necessary to eliminate apparent immediate hazards to subjects.
- Submit continuing review reports when requested by the IRB.
- Submit a closure form to close research (end the IRB's oversight) when:
    - The protocol is permanently closed to enrollment
    - All subjects have completed all protocol related interventions and interactions
    - For research subject to federal oversight other than FDA:
        - No additional identifiable private information about the subjects is being obtained
        - Analysis of private identifiable information is completed
- If research approval expires, stop all research activities and immediately contact the IRB.
- Promptly report to the IRB the information listed in the IRB's "Promptly Reportable Events" form available on the IRB's website, including reports of potentially serious or continuing noncompliance or reports of unanticipated problems involving risks to subjects or others
- Report all events of noncompliance to the Human Protections Administrator and Research Manager in accordance with policy GFD-320-008
- Not accept or provide payments to professionals in exchange for referrals of potential subjects ("finder's fees.").

If the IRB granted an approval of **HIPAA partial waiver** of authorization for recruitment: "By signing below I am providing written assurance that only information essential to the purpose of recruitment will be collected, and access to the information will be limited collected, and access to the information will be limited to the greatest extent possible. Protected health information will not be re-used or disclosed to any other person or entity.

If the IRB granted approval of **HIPAA full waiver** of authorization: By signing below, I am providing written assurance that only information essential to the purpose of this research will be collected and used, and protected health information will not be re-used or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or as permitted under the Privacy Rule.

Signature of Principal Investigator	Date
Signature of Co-Investigator (if PI is a Resident or Trainee)	Date