# The Institutional Review Board of The Guthrie Clinic

## Promptly Reportable Information Submission Form

### Use to submit promptly reportable new information

Return this form to: Lori Robinson, IRB Coordinator, Donald Guthrie Foundation
570-887-4885; LoriA.Robinson@guthrie.org

**Identifying Information:**

Principal Investigator's Name: Click or tap here to enter text.

IRB Number: Click or tap here to enter text.

Protocol National Number: Click or tap here to enter text.

Date of this report: Click or tap here to enter text.

Date of occurrence (if known): Click or tap here to enter text.

Person submitting report: Click or tap here to enter text.

Subject ID (if applicable): Click or tap here to enter text.

Is the subject still enrolled in the study? Click or tap here to enter text.

**Type of Problem**

***Select all that apply:**

☐ **Audit, inspection or inquiry by a federal agency**
Provide the date of the inspection including the beginning and end dates. Clarify if a study approved by this IRB was audited and identify the study.

☐ **Written report from a federal agency (e.g., FDA Form 483)**
Submit a complete copy of all reports and correspondence related to the inspection (e.g. FDA Form 482 and 483, site's response to the 483, FDA letter responding to the site, EIR Summary, FDA WARNING Letter).

☐ **State medical board action**
Submit a copy of state medical board licensing documentation [e.g. a physician's (suspended) license, a physician profile, or a physician licensing profile indicating a disciplinary, or even a non-disciplinary action]

☐ **Suspension or premature termination by the sponsor, investigator, institution, or an external IRB**
Submit a copy of correspondence related to the suspension or premature termination and provide additional explanation if applicable.

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☐ **Potentially Serious noncompliance**

Noncompliance refers to any actions that deviate from the approved protocol, deviates from the IRB requirements, or fail to adhere to federal, state or local regulations governing human subjects research. Serious noncompliance means an action or activity that adversely affects the **safety, rights or welfare** of participants, compromises the confidentiality of participants, or compromises the scientific integrity or validity of the research.

In the "Describe the problem" section below, please:

- *Explain if the event has substantial adverse effect on the safety or welfare of subjects, if the event is unexpected in terms of nature, severity or frequency, if the event, experience or outcome places the subjects at greater risk of economic or social harm than previously known or recognized, if the event has a substantial adverse effect on the value of the data.*

☐ **Potentially Continuing Noncompliance**

A pattern of repeated noncompliance which continues after initial discovery, including inadequate efforts to take corrective actions within a reasonable timeframe. Continuing noncompliance can occur on a single protocol or across multiple protocols under a single investigator.

In the "Describe the problem" section below, please answer:

- *What are the number of events?*
- *In what timeframe have the events occurred after corrective actions were implemented?*
- *Has the reason for the inadequacy of the corrective actions been identified?*

☐ **Protocol deviation that harmed a subject or placed subject at risk of harm**

In the "Describe the problem" section below, please explain:

- *Any harm the subject experienced OR how the subject was placed at risk of harm*.

In the "What actions need to be taken" section below, please explain:

- *The corrective action taken for this event AND your plans to avoid future occurrences*.

☐ **Protocol deviation made without prior IRB approval to eliminate an apparent immediate harm to a subject**

In the "Describe the problem" section below, please explain:

- *Describe the subject's situation and why immediate action was required*.
- *State if sponsor was notified (attach any correspondence)*

In the "What actions need to be taken" section below, please explain:

- *Your plans to avoid future occurrences, if applicable*.

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☐ ***Unanticipated problems involving risks to human subjects or others (UPIRSOs)***
Unanticipated problems include adverse events *and* other incidents, experiences, and outcomes that are not adverse events that meet all of the following criteria:
1) **unexpected** (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol and related documents, such as the investigator's brochure and the informed consent document; and (b) the characteristics of the subject population being studied;
2) **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
3) 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.
An event may be considered a UPIRSO involving increased *risk* of harm, whether or not any *actual* harm occurred.
In the "Describe the problem" section below, please explain:
- *Describe the adverse event, incident, experience, or outcome and the basis for determining that the adverse event, incident, experience, or outcome represents an unanticipated problem;*

In the "What actions need to be taken" section below, please explain:
- *Describe any changes to the protocol or other corrective actions that have been taken or are proposed in response to the unanticipated problem.*

☐ **Local Adverse Event that is a UPIRSO which is unanticipated** (in terms of nature, severity, or frequency, **related or possibly related** to participation 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)

☐ **Unanticipated adverse device effect**
"Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects" (21 CFR 812.3(s)"

☐ **Incarceration of a subject in a research study not approved to involve prisoners**
If a subject becomes incarcerated at any time during a research study, provide details including the date of occurrence or discovery, timeline and actions taken.

☐ **Breach of confidentiality**
In the "What actions need to be taken" section below, please state whether this breach has been disclosed to subject(s)

☐ **Unresolved subject complaint**
This is a complaint that you would like assistance resolving. This would not include subject withdrawals due to expected events.

☐ A **determination by an external IRB** of a local UPIRSO or local serious or continuing noncompliance

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☐ **Other information**
The sponsor/CRO/other has directed the PI to report to the IRB, even if not on this list and does not meet any of the reporting requirements. Please use this when none of the above issues apply, but you are being required to submit to the IRB for filing with the research.

☐ **Site Monitoring Report**
Any site monitoring report that directly and materially affects subject safety or their willingness to continue participation.

**Description and Needed Actions**
***Describe the problem** (date of occurrence or discovery, timeline, cause, actions taken, changes made):
Click or tap here to enter text.

*** What corrective and preventative actions need to be taken, or what changes are proposed to protect research subjects or others? If none, justify**.
Click or tap here to enter text.

Has the PI reviewed the form? ☐ Yes ☐ No

Does the PI agree with this assessment? ☐ Yes ☐ No
Explain: Click or tap here to enter text.

Person completing this form: Click or tap here to enter text.

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| FOLLOWING SECTION IS TO BE COMPLETED BY IRB CHAIR OF DESIGNATED REVIEWER | | |
|---|---|---|
| ☐ | Further investigation required. Requested information. | |
| ☐ | The above reporting and corrective action plan satisfies IRB required reporting for event. | Acknowledged: No action required by investigator. |
| ☐ | The above event is referred for a review at a convened meeting | |
| Reviewer comment: Click or tap here to enter text. | | |

I do not have a personal, scientific or financial interest in this project.

_____ _____

IRB Chair/ Designated Reviewer Date