

**WAIVER OF CONSENT AND AUTHORIZATION TO USE AND DISCLOSE
PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES**

IRB #:

PROTOCOL TITLE:

PRINCIPAL INVESTIGATOR:

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Decatur, Illinois 62526
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PURPOSE OF THIS FORM

Per 45CFR 46.101(4) the above referenced protocol meets criteria for EXEMPT/EXPEDITED status. **[Place explanation of how study meets this criterion and quote the appropriate regulation here].**

Elements of authorization may be waived if and only if:

The research involves no more than minimal risk to the privacy of the participants and must contain the following elements: **[Explain how each (1-5) applies to your particular study].**

1) An adequate plan to protect the identifiers from improper use and disclosure, an adequate plan to destroy the identifiers at the earliest possible occasion unless retention is required by law, and adequate written assurances that the protected health information would be permitted by this subpart

This data will be de-identified by not containing the following 18 HIPAA identifiers: names (*individual, employer, relatives, etc*), address (*street, city, county, zip code, or other geographical code*), email/URL/IP addresses, telephone/fax numbers, social security numbers, dates (except years) of birth, admission, discharge, death, ages, medical record numbers, health plan beneficiary numbers, account numbers, certificate/license numbers, vehicle identifiers and serial numbers, device identifiers and serial numbers, biometric identifiers (*finger or voice prints, identifiable photographs*), any other unique identifying number, characteristic or code. **[If this does not apply, delete the entire paragraph].**

2) The waiver will not adversely affect the rights and welfare of the participants

3) The research could not be practicably carried out without the waiver

4) Whenever appropriate, the participants will be provided with additional pertinent information after participation

5) The research could not practicably be conducted without access to and use of the protected health information

NECESSARY PHI FOR USE AND DISCLOSURE

The following protected health information will be collected, used for research and may be disclosed or released during involvement with this research study.

- Race
- Gender
- Date of birth
- History and diagnosis of your disease
- Family medical history
- Current and past medical records
- Prior medical history
- Current and past medications
- Current and past therapies
- Information from a physical examination that generally also includes blood pressure readings, heart rate, breathing rate, temperature, height and weight
- Medical data, including laboratory test results, tumor measurements, CT scans, MRIs, x-rays, operative reports and pathology results
- Information on side effects (adverse events) you may experience, and how these were treated
- Data that may be related to tissue, blood, urine, bone marrow, nail clippings, etc. that may/will be collected from you
- List any other protected health information that will be obtained from other sources to be used in the research record, including prior medical history, tests or records from other sites/studies

INDICATE THE SOURCE OF HEALTH INFORMATION TO BE OBTAINED OR DISCLOSED

- Data containing no health information
- Medical records
- Physician/clinic records
- Interviews/questionnaires
- Other (please explain)

ENTITIES WHO MAY RECEIVE PHI

As part of the study, the Principal Investigator and study team may obtain, use, or disclose protected health information, including the results of the research study and procedures to the following: [Modify this list as appropriate-delete or add items as necessary. For EACH LISTING include a brief description of WHY they will receive the information-the examples below are suggestions only]

- The [name of research base operations center or sponsor] for data compilation and study oversight
- The Data Safety Monitoring Board or Data Monitoring Committee for study oversight
- The statistical center [insert name-e.g. ECOG Biostatistical Center] for data analysis
- The [name of central lab] for specimen processing
- Public Health agencies and other government agencies (including non-U.S.) as authorized or required by law
- the National Cancer Institute (NCI) for study oversight and compliance

- the Food and Drug Administration (*FDA*) for study oversight and compliance
- the Office for Human Research Protections (*OHRP-a Health and Human Services department*) for study oversight and compliance
- the Decatur Memorial Hospital Institutional Review Board (*which is a group of people who review the research to protect your rights*) for study oversight and compliance
- Decatur Memorial Hospital appropriate research staff, pharmacists, compliance officer and/or his/her designee, administrative staff, information systems staff for data compilation and study oversight

In all disclosures outside of [insert name] participants will not be identified by any direct personal identifier. be referred to by a code.

RESEARCH RETENTION INFORMATION

The authorization for use of participant protected health information for this specific study will be used until [insert end point-such as: the study closes; the data collection is completed; the database/registry is destroyed; __ years after closure of the study; or indicate that the authorization will not expire]. This information may be maintained in a research repository (*database*). However, the Principal Investigator may not re-use or re-disclose protected health information collected in this study for another purpose other than the research described in this document unless the Decatur Memorial Hospital Institutional Review Board has granted permission to the Principal Investigator or others to use this information for another purpose after ensuring that appropriate privacy safeguards are in place. The Institutional Review Board is a committee whose job it is to protect the safety and privacy of research participants.

I certify the information/ personal health information (PHI) received or reviewed by research personnel for the above referenced protocol is complete and specific. I will not re-use or disclose information/ PHI to any other person or entity, except as required by law, research oversight, or those uses outlined above.

Principal Investigator	Date	Faculty Sponsor (if applicable)	Date
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WAIVER OF AUTHORIZATION APPROVAL

[%Electronic Signature%]	OR	[%Electronic Signature%]
Signature		Signature
Dr. David M. Johnson		Gregory Lichtenwalter, R.Ph.
Co-Chairperson		Co-Chairperson
Institutional Review Board		Institutional Review Board
2300 N. Edward Street		2300 N. Edward Street
Decatur, Illinois 62526		Decatur, Illinois 62526
(217) 876-5021		(217) 876-3441