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	INFORMED CONSENT REQUIREMENTS FOR PATIENT SPECIMENS USED IN CLINICAL RESEARCH	Effective Date: 09-27-11
		Retires Policy Dated: 07-01-10
		Previous Versions Dated:

I. SCOPE:


This policy applies to (1) Tenet Healthcare Corporation and its wholly-owned subsidiaries and affiliates (each, an “Affiliate”); (2) any other entity or organization in which Tenet Healthcare Corporation or an Affiliate owns a direct or indirect equity interest greater than 50%; and (3) any hospital and healthcare facility in which Tenet Healthcare Corporation or an Affiliate either manages or controls the day-to-day operations of the facility (each, a “Tenet facility”) (collectively, “Tenet”).

II. PURPOSE:

The purpose of this policy is to establish the informed consent requirements for the use of patient specimens for research purposes.

III. DEFINITIONS:

- A. **“Informed Consent”** means the process of providing information to a patient explaining the risks, benefits and alternatives of participating in a research study or providing specimens for a research study and obtaining the patient’s consent to participate in the study.
- B. **“General Consent”** means hospital consent used for procedures done for any patient having surgery/procedure done at the hospital.
- C. **“Specific Consent”** means an IRB approved patient study consent which is used for patients who are participating in a clinical research study.
- D. **“Specimen”** means tissue and/or cells removed from a patient’s body during surgery biopsy or other procedures.
- E. **“Research”** means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to a generalized knowledge.
- F. **“Patient Identifiers”** means information that would enable someone to readily identify the source of the specimen. Examples of patient identifiers include, but are not limited to, name, social security number, medical record number and account number.

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IV. POLICY:


It is in each patient's best interest to receive information and the right to consent or object to use of specimens for purposes other than his or her personal medical care. Except as described in this policy, patients must provide specific consent prior to the use of their specimens for research purposes.

V. PROCEDURE:

A. When General Consent is Sufficient

1. A general consent is considered sufficient when:
 - a. the specimens are not collected for research purposes;
 - b. the operative and/or procedure consent form for the procedure contained language notifying patients that their specimens may be used for research purposes at a future date, and the patient did not provide any objections or limitations; and
 - c. all patient identifiers are removed from the specimen prior to providing the specimen to the research study.
2. General consent, such as operative and procedure consent forms, shall include language notifying patients that their specimens may be used for research purposes at a future date. The language shall also notify patients that if the specimens are used, patient identifiers will be removed from the specimens so that the patients cannot be identified from the specimens. Patients will be given the opportunity to restrict the use of their specimens. Sample language includes:

I hereby grant permission to the Hospital to use any human tissue and/or cells removed during this procedure for future diagnostic study, teaching or research purposes. I understand that the Hospital will have my identification removed from the specimens prior to use. The Hospital will use reasonable efforts to retain sufficient sample for future testing related to treatment determinations for me. Any

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objections or limitations to such permission, I have stated here:

(Patient's initials)


B. When Specific Consent is Required

A specific consent is required when a known study exists that has been IRB approved and (1) the patient presents to the Hospital to have surgery/biopsy in which the study will use specimens taken from that procedure or (2) the patient's existing specimen is not sufficient in size to use in research without dissipating the specimen below the retention guidelines established in accordance with Section V.C.4 of this policy.

C. When Specific Consent May Be Waived

The requirement for the patient to provide a specific consent to release specimens may be waived if all of the following conditions are satisfied:

1. the patient's surgery occurred and the slides/block is stored in the pathology department prior to IRB approval of the relevant study.
2. the Hospital's standard operative and/or procedure consent contains language notifying patients that their specimens may be used for research in the future (see Section V.A.2);
3. the Hospital's IRB discussed and documented in its minutes that each of the following criteria have been met:
 - a. the research involves no more than minimal risk to the subjects;
 - b. the waiver or alteration will not adversely affect the rights and welfare of the subjects;

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c. the research could not practicably be carried out without the waiver or alteration; and

d. whenever appropriate, the subjects will be provided with additional pertinent information after participation.

4. Sufficient quantity of the specimen remains available for the reasonably anticipated future clinical needs of the patient. The Hospital's Medical Executive Committee will determine the amount of specimens to remain in reserve. This amount will only be used if a separate consent is signed by the patient for use of the specimen.

D. Procedure for Specimens of Deceased Patients

Specimen(s) taken from deceased patients may be used for research studies if all patient identifiers have been removed prior to providing the specimens to the Principal Investigator.

E. Specimens Obtained Prior to Effective Date


The requirements of Sections V.A.2 and V.C.2. are not applicable to specimens obtained prior the effective date of this policy.

F. Responsible Person

The Clinical Research Coordinator is responsible for ensuring that all individuals adhere to the requirements of this policy. If the Clinical Research Coordinator is unable to create adherence to this policy, the Clinical Research Coordinator shall immediately report the non-adherence to the Tenet Facility CEO.

G. Enforcement

All employees whose responsibilities are affected by this policy are expected to be familiar with the basic procedures and responsibilities created by this policy. Failure to comply with this policy will be subject to appropriate performance management pursuant to all applicable policies and procedures, up to and including termination. Such performance management may also include modification of compensation, including any merit or discretionary compensation awards, as allowed by applicable law.

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VI. REFERENCES:

- [21 CFR 50.20 -50.24](#)

- [45 CFR 46.102 \(f\)](#)

- [45 CFR 46.116](#)

- [45 CFR 46.116\(d\)](#)