Original:	*01/2018*
Last Approved:	*01/2018*
Last Revised:	*01/2018*
Next Review:	*01/2021*
Owner:	*Susan Szpunar: Director, Research*
Policy Area:	*Multi-disciplinary*
References:	
Applicability:	*St. John Providence Health System*

Informed Consent for Case Reports

PURPOSE

To provide assurance that the patient or their legal advocate gives consent for using information about their health status and treatment as part of a journal article, academic case study, conference presentation, or academic poster.

DEFINITIONS

"Consent" means a written agreement executed by the patient, or patient's legal representative with authority to execute consent.

"Case Report" means a formal summary of a unique patient and their illness, including the presenting signs and symptoms, diagnostic studies, treatment course, and outcome.

PHI (Personal Health Information) - means information, including demographic information, which relates to: the individual's past, present, or future physical or mental health or condition, the provision of health care to the individual, or the past, present, or future payment for the provision of health care to the individual, and that identifies the individual or for which there is a reasonable basis to believe can be used to identify the individual. Protected health information includes many common identifiers (e.g., name, address, birth date, Social Security Number) when they can be associated with the health information listed above.

POLICY STATEMENT

1. Consent shall be obtained in connection with this policy and Policy # 3036255, Consent/Informed Consent. The general consent will be given to the patient at admission when the general consent to treatment is signed, or as soon as possible thereafter.
2. To consent the patient or legal representative must have basic information about how their treatment information may be used in the article, presentation, or poster presentation. The requestor must be available to answer the patient's questions.
3. The patient must be able to understand the personal implications of providing consent.
4. The patient must voluntarily consent without of an element of force, deceit, duress, overreaching, or coercion. The patient should be instructed that their decision to consent will not affect the medical care and treatment they receive. The patient should be informed that they can withdraw their consent any time before there is a commitment to publish an article or give a presentation based on their Information.

5. If the patient is deceased, every effort must be made to contact the next of kin to obtain consent for the case study. If the next of kin cannot be reached, the case report must be de-identified.
6. There are 18 elements of PHI which are direct identifiers and must not be included in case reports. Each element below and any combination of elements could potentially identify a patient. To help avoid the use of PHI, use an age group instead of exact age, use season instead of exact month, avoid using a specific race (i.e. use Asian instead of Vietnamese), and make sure the totality of information given, including the author's institutional address do not provide enough information to potentially identify a patient.
    - Names
    - All geographic subdivisions smaller than a State, includes street address, city, county, precinct, zip code and the equivalent geocodes.
    - All elements of dates (except year) for dates related directly 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 numbers
    - Fax numbers
    - Electronic (e-mail) addresses
    - Social security numbers
    - Medical record numbers
    - Health plan beneficiary numbers
    - Account numbers
    - Certificate/license numbers
    - Vehicle identifiers and serial numbers, including license plate number
    - Device identifiers and serial numbers
    - Web Universal resource locators (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.
    - Indirect identifiers, in conjunction with other information, could potentially identify a patient. These indirect identifiers might include: gender, hospital, hospital affiliation of the author, extremely rare disease or treatment, sensitive data such as illicit drug use or "risky behavior", place of birth, "rare" occupations, place of work, anthropometry measures, multiple pregnancies and information which can potentially be used to uniquely identify, contact, or locate a single person

Procedure

1. A consent is executed when it is signed by the patient or patient's legal representative and the requesting

author. A copy of the signed consent will be given to the patient or the patient's legal representative.

2. If the case report contains photography or video, the Authorization for Photography, Video, and Recording must be signed.
3. If a patient requests to withdraw their consent, the request should be submitted in writing to the individual who obtained consent or to the Director of Research at the institution. When consent is obtained, the patient or family will receive a business card for the provide. A contact for the Director of Research will be on the consent form.

Responsible Persons

Susan Szpunar, Director of Research SJH&MC, David Svinarich, Vice President of Research, SJPHS, Cicely Vaughn- legal services

VERIFICATION AND APPROVAL	
COMPILED BY	Susan M. Szpunar, MPH, PhD, SJH&MC
POLICY OWNER	Susan M. Szpunar, MPH, PhD, SJH&MC
REVIEWED / APPROVED BY	David Svinarich, PhD, Vice President of Research, SJPHS
REVIEWED / APPROVED BY	Cicely Vaughn, JD- Legal Services
REVIEWED / APPROVED BY	11/2017

Attachments:

Photography-Video Policy Attachment 1-Request and Agreement.doc
SJPHS Consent Form Case Reports - 4849-1660-5252 v3.doc

Approval Signatures

Step Description	Approver	Date
Clinical Research	David Svinarich: V.P. Research	01/2018
	Susan Szpunar: Director, Research	01/2018