

Instructions

Informed Consent for Case Report

Use this form for single case reports to be submitted for publication or public presentation (at a conference, on a poster, etc.) **REQUIRED IF PUBLISHING/PRESENTING IDENTIFYING IMAGES OR OTHER PROTECTED HEALTH INFORMATION; AN ADDITIONAL DCH MEDIA PERMISSION FORM WILL BE REQUIRED. CONTACT DCH IRB OFFICE FOR QUESTIONS.**

Do not use this form for research. Do not use this form if you plan to combine multiple case reports, analyze the reports, and draw conclusions.

Submit your proposal for Dayton Children's Hospital IRB review and obtain IRB determination first if you plan to conduct research or combine multiple case reports as described above.

Edit this consent form before printing / use as follows:

- Replace all instructions (in green) with appropriate wording.
- If you will **not** use any photographs, audio/video files or other images for the case report, remove the third paragraph starting with "You may choose whether we may use images..." and the fourth paragraph "It is OK to publish and/or present my..." Delete the following line reading: "Please initial: _____ Yes _____ No."

Provide the patient/subject with a copy of the signed form. Keep the original form for your records.

NOTE: Do not use any HIPAA identifiers* (including age over 89) in your case report with the exception of images specifically listed on this consent form or through a Multimedia Imaging Consent form. A separate Multimedia Imaging Consent is not needed when this form is used to obtain consent for the use of images.

It is not necessary to print this instructions page.

* HIPAA Identifiers:

- Names;
- All geographical subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
- All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death;
- 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;
- Phone numbers; fax numbers; 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 numbers;
- 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; and
- Any other unique identifying number, characteristic, or code

DAYTON CHILDREN'S HOSPITAL

INFORMED CONSENT FOR CASE REPORT

PRINCIPAL INVESTIGATOR AUTHOR: *(insert name)*

CASE REPORT TITLE: *(insert title or subject matter)*

- *If you are a parent/legal representative of the child patient, or if you, yourself are the adult patient (18 or over) identified below, permission from you is required for the use of your information for a case report.*
- *The words "you" and "your" are used in this informed consent. These words refer to the case report patient, whether a child or an adult.*

Patient's name (printed): _____

Patient's date of birth: _____

Why are you receiving this form?

You are being asked to allow the investigator(s) to use information from your health record that does not directly identify you for a case report. Case reports are usually used to share new or unusual information about one patient that may be helpful to other doctors and health care workers. We may publish your case report in a scientific journal for others to read, display it on a poster, or present it at a conference. The purpose of this case report is to *(provide specific reason/condition/treatment etc.)*

You may choose to let the investigator(s) to use your information for this case report or not. Take all the time you want to decide. Ask any questions you want. Your choice will not affect your health care in any way. You will not be penalized or lose any benefits to which you are entitled if you say no.

You may choose whether we may use images from your health record or medical care for the case report. Images may be photographs, scans, x-rays, recordings, or other types of images. Even without any identifiers, the images may be unique enough to identify you. By initialing "yes" below, you are authorizing the investigator(s) to use certain images for this case report.

It is OK to publish and/or present my/my child's *(specify images / image types)* for this case report.

Please initial: _____ **Yes** _____ **No**

How will your identity be protected?

To protect your privacy, we will not disclose your identity in the case report. We will not include personal information that can identify you such as your name, date of birth, or medical record number. Any information that directly identifies you will remain confidential and will be disclosed only with your permission or as required by law. However, there is a slight risk of loss of confidentiality due to unique or unusual elements that may be presented in the case report.

What costs and benefits are involved?

Information from the case report may help improve the health care given to others in the future. You will not receive any direct benefits from the case report. You will not be paid anything for the case report. You will have no added costs from the use of your information for the case report.

What if you change your mind?

You may change your mind at any time before the case report is published or presented. After the case report is published or presented, it will not be possible for you to withdraw the information. If you have any questions, please contact *(name of author)* at *(phone number)*.

Signature

I have read the information above. I have had a chance to ask questions. I give permission for my/my child’s health information to be used for a case report as described in this form.

Parent/legal representative: I verify that I have the legal authority (legal custody) to give permission for this child’s information to be used for this case report.

Patient (18 or over) **(Signature)**

Date Time AM/PM

Patient’s Legal Representative **(Printed Name)**

Relation to Patient

Patient’s Legal Representative **(Signature)**

Date Time AM/PM

Case Report Investigator or Designee Statement

I certify that the patient/legal representative has given permission for authorization of the use of their/their child’s information as described above.

(Printed Name)

Investigator or Designee (Signature)

Date Time AM/PM