UNITY HEALTH TORONTO | PROVIDENCE Healthcare | ST JOSEPH'S HEALTH CENTRE TORONTO | St. Michael's Inspired Care. Inspiring Science.

PRIVACY GUIDELINE: ADDING RESEARCH DATA TO A CLINIAL RECORD

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Application:

The following steps must be followed if any research-related information (including but not limited to a copy of the consent form, diagnostic test results and/or notices to care providers regarding treatment undergone by the participant) will be stored in a clinical record (paper or electronic) or sent to a participant's clinician at Unity Health.

For example, during a drug trial it may be appropriate to: (a) perform more diagnostic tests than currently planned by the patient's care providers (e.g. double CTs), (b) notify the participant's family doctor that the participant is taking a certain medication or a blinded research medication, or (c) add a copy of the consent form to the participant's patient record so that any future care providers are alerted to their participation and any possible safety issues that may arise or complicate care.

Process:

1. Modify the following as necessary and add this to the informed consent form:

> Your participation in this study will also be recorded in your medical record at this hospital. This is for clinical safety purposes. If you participate in this study, information about you from this research project may be stored in your hospital file and in the hospital computer system. [The Unity Health participating site] shares the patient information stored in our electronic health record with other hospitals and health care providers in Ontario so they can access the information if it is needed for your clinical care. The study team can tell you what information about you will be stored electronically and may be shared outside of [the Unity Health site]. If you have any concerns about this, or have any questions, please contact the Unity Health Privacy Office at 416-864-6088 (or by email at privacy@smh.ca).

2. Remove references to anonymity or remaining unidentifiable in the informed consent form.

NOTE:

Where research information will NOT be added to a clinical record, and de-identification/anonymity is offered, researchers must ensure that diagnostic tests conducted are labelled as research and that participants are not registered as patients when doing the testing. Contact each service to understand if test orders and results can be processed separately from patient records and the method for doing so.

Within Unity Health the following tests <u>can</u> be conducted using research names and numbers for registration (i.e. results/orders <u>do not</u> go into the participant's patient record):

- Labs at SMH & SJHC
- Diagnostic Imaging at SMH
- Diagnostic Imaging at SJHC
- Cardiology (echo, ECG) at SJHC
- Cardiology (echo, ECG) at SMH
- Respiratory tests at SMH
- Respiratory tests at SJHC
- Pharmacy services at SMH (via research pharmacy)

Within Unity Health the following tests cannot be conducted using research names and numbers for registration (i.e. results/orders will go into the participant's patient record):

- Pharmacy services at SMH (for some inpatients and outpatients, i.e. where clinical staff are involved in orders)
- Pharmacy services at SJHC (for inpatients and outpatients)