FAQ for Phase 1 Research

Q: What does "Phase 1 clinical trial" mean?

A: Clinical trials refer to research studies that involve human participants and are categorized by "phases". Phase 1 is the first of four phases and includes two parts: Phase 1a and 1b.

Prior to reaching Phase 1a, drugs are in the "pre-clinical phase" where they are extensively tested in cells, tissue samples, and/or animal studies for safety. The new drugs being tested would need to meet required safety criteria to receive approval from the Research Ethics Board and Health Canada to move to the next step, which is Phase 1 testing in human participants.

Phase 1a describes a "first-in-human" trial, and usually involves a small number (cohort) of healthy participants receiving a single, low dose of the trial drug. Starting at a low dose allows the research team to record any side effects and determine the safety of the drug in humans. If the single dose of the drug is tolerated well and meets the required safety criteria that are needed to move onto the next step of testing, then the next cohort of participants will receive a higher single dose. The next step after determining safe single dose: a cohort of healthy participants will receive multiple doses of the new drug over a period of time. Each subsequent dose increases from the last. The aim, again, is to continue observing what doses are safe to take, and document all side effects.

Most of the Phase 1 studies will require participants to stay overnight at the hospital after receiving the drug so that they can be monitored very closely by physicians, nurses, and research staff. This time spent in the hospital is called an Inpatient Period. Depending on the study, the Inpatient Period can range from 24 hours to 14 days.

After an Inpatient Period, participants can usually expect short follow-up visits in the weeks and months after receiving the trial drug to ensure their continued safety.

For more information, see the links below:

- https://www.canada.ca/en/health-canada/services/clinical-trials.html
- https://cihr-irsc.gc.ca/e/52988.html

Q: Why is participation in Phase 1 research so important?

A: Clinical trials are critical to the advancement of medical research, and they rely on people who are willing to devote themselves, their time, and their energy in the name of science. Phase 1 clinical trials play a crucial role in drug development. These trials provide

vital information on a treatment's safety, dosage, and how the body reacts to it, allowing researchers to make informed decisions about its further development.

For more information:

- https://itstartswithme.ca

Q: What measures are in place to ensure my safety as a participant?

A: Prior to conducting the study, the research drug and procedures need to be reviewed and approved by Health Canada, a Research Ethics Board (REB), and the institution that the study takes place in (Providence Health Care – Mt. St. Joseph Hospital).

Any anticipated risks, such as known side effects of a research drug or discomfort that may be associated with procedures (e.g., blood tests), will be disclosed and explained to you during the Informed Consent Form discussion before you begin any study activities.

The investigator (physician), research team, and nurses will ask you for any medical and health history information that they should be aware of. This may include allergies, medical conditions, current medications, and past surgeries. All information will be documented and reviewed prior to you receiving any research drug product so that the team can ensure there is no known indication that you should not receive the research drug product. The physician and/or nurse may also perform a physical exam, take blood/urine samples, and/or administer questionnaires to assess if you can safely participate.

Two members of the research team will be in the unit at all times during the hospital Inpatient Period, as the health and safety of all participants is our top priority. Your health will be monitored closely by the research team during the entire duration of your participation on a study, including after the Inpatient Period. All changes, including allergic reactions and/or side effects that you feel or observe, will be documented, tracked, and reviewed by the physician. The physician will also determine and inform you if you require any additional medical care (e.g., medication, admission to hospital, additional testing) during the study.

Q: Is my participation confidential? How will my privacy be protected?

A: Your participation will be kept confidential. This means that information that can be traced back to identify you (e.g., name, phone number, email, address, medical record number, personal health number, etc.) that we might collect, will not be published nor released to anyone who is not directly involved in your care. Your direct care team may include physicians, nurses, and research coordinators/assistants who work on the study

at Mt. St. Joseph Hospital's Phase 1 Clinical Trials Unit. Any other personnel who might need to know your information would be disclosed to you during the Informed Consent Form discussion prior to your enrolment into the study.

For more information, please visit:

- https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter5-chapitre5.html#b

Q: What is "informed consent" for a research study?

A: The Informed Consent Form is designed for each study to help participants understand their rights to privacy, study purpose, study activities/schedule, responsibilities, reimbursements, and risks associated with the study. Before you are enrolled into a study, the investigators (i.e., doctors who are conducting the study) and research staff must disclose all information regarding participation in the study to you. You will be given as much time as you need to review the information before deciding whether to sign the consent form to confirm enrolment. You may also choose to withdraw consent and discontinue your participation at any time. No research activities nor data collection involving you will occur without your active and ongoing voluntary informed consent.

For more information:

- https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter3-chapitre3.html
- https://www.canada.ca/en/health-canada/services/science-research/science-advice-decision-making/research-ethics-board/consent-process.html

Q: How do I know if I qualify for a study?

A: Each study has different eligibility criteria. The research team will assess if you qualify for a specific study based on the information that you provided in the Pre-Screening Survey. The Pre-Screening Survey serves as a preliminary assessment of eligibility for participation. If you meet the preliminary criteria, the research team will contact you to discuss next steps.

Q: Will I be paid for my participation?

A: Details on reimbursement and/or payment will be specific and different for each research study and will be presented to you during the Informed Consent Form discussion.

FAQ for Inpatient (Overnight) Stay Period

Please note that the answers below are generalized, as each study has its own specific requirements and the answers may differ. We will highlight the differences during the Informed Consent Form discussion.

Q: Who should I contact for inquiries regarding my participation, study activities, and/or hospital stay?

A: Primary contacts for the Phase 1 Clinical Trials Unit at Mt. St. Joseph Hospital:

Lena Legkaia
Research Operations Manager
elegkaia@providencehealth.bc.ca
Danica Perng
Research Assistant
dperng@providencehealth.bc.ca

Q: What kind of assessments will I be required to complete for the study?

A: Every protocol is different; however, these are the most common assessments done in clinical trials: bloodwork (multiple time points), vital signs monitoring (blood pressure, temperature, pulse, respiration rate, oxygen saturation), physical examination (performed by physician or nurse), ECGs (electrocardiograms), and health questionnaires.

Some studies will have follow-up visits after the Inpatient Period to monitor your health after receiving the trial drug.

Q: Transportation and parking information for MSJ?

A: Please see the Providence Health Care Visitor Guide for information regarding getting to Mt. St. Joseph Hospital: https://www.providencehealthcare.org/en/visitor-guides/mount-saint-joseph-hospital-patient-visitor-guide/preparing#getting-here--72821

- Mount Saint Joseph Hospital is accessible by public transit (Bus #19 and Bus #3).
    - To plan your route on public transit, please visit the Translink website: https://tripplanning.translink.ca/#/app/nextdepartures.
- Arriving by car
    - If driving, you can find free parking on the streets near the hospital. Pay parking is also available at the hospital and on the nearby streets. Please note that parking is restricted during certain hours on Kingsway.

Q: Where do I check in?

A: The main entrance of the hospital is on Prince Edward Street. Please enter through the main entrance to arrive at the Check-In desk.

Q: Safety and security at MSJ?

A: Please see the hospital's guidelines and information on safety and security when staying at the hospital: https://www.providencehealthcare.org/en/visitor-guides/mount-saint-joseph-hospital-patient-visitor-guide/during-your-stay#safety--security--73066

Q: What do I pack? What do I leave at home?

A: Items to Bring:

- Registration/Check-In Items: BC CareCard/BC Services Card, which states your PHN (Personal Health Number) on it. If you have been in Canada for less than a year, please bring your immigration documentation. We will need this information to register you for your stay in the hospital.

Personal items:

- **Regular prescription medications, including inhalers**
- Pajamas (hospital ones will be provided)
- Bathrobe and slippers
- Cell phone and charger
- Toiletries (e.g., toothbrush, toothpaste, dental floss, shampoo, moisturizer, hygiene products, etc.)
- Entertainment (e.g., books, magazines, headphones, tablet, laptop, portable gaming devices, chargers, etc.)
- Water bottle

If you forget anything at home, we will do our best to acquire missing necessities.

Items to leave at home:

- Large sums of money
- Valuables, such as jewelry or watches
- Pets
- Drugs and alcohol
- Food and beverages of your own. The hospital unit will provide all of your meals during your stay. To maintain a controlled research environment, we ask that you please avoid bringing your own food and drinks to the unit.

You can also refer to the Providence Health Care Packing List here:

- https://www.providencehealthcare.org/en/visitor-guides/mount-saint-joseph-hospital-patient-visitor-guide/preparing#packing--72846

Q: Will I be provided with food and drink?

A: Yes! The unit will be providing all of your meals and drinks during your inpatient stay. **Please inform the team of any food restrictions and allergies you have. We will do our best to accommodate you.**

Depending on the study, the meals may be very specific, and your food and liquid intake may be closely monitored.

Q: What about coffee?

A: Unfortunately, coffee and other caffeinated products can affect the metabolism and absorption of the study drug being tested For this reason, caffeinated beverages are typically not allowed during your inpatient stay.

Q: Will I be charged for research visits, including overnight stays at the hospital?

A: You will not be charged for any visits, inpatient stays, or research-related activities and testing. Your participation in the research study will not result in expenses to you.

Q: What kind of room will I be staying in?

A: You will be staying in a semi-private room. The rooms, which you will be sharing with other participants, have 2 or 3 beds. You will be separated from your neighbours with curtains. Your fellow participants who share the room with you may be of varied gender. **If you have a preference on sharing a room with the same-sex neighbour, please let a staff member know ahead of time**.

Q: What other amenities are there?

A: There are 3 shared bathrooms available with 2 showers.

There is also a shared participant lounge area with a kitchenette, table, couch and TV for the participants to use at any time.

Access to free Wi-Fi.

Q: Will I have free time?

A: Absolutely. Anytime the study allows for breaks between assessments, you are free to spend your time as you wish. Some examples are socializing with fellow participants,

reading, using your devices, relaxing, puzzling, playing games, studying, working from "home", etc.

Q: Can I exercise in my free time?

A: Strenuous activity is not permitted during the inpatient period.

Q: Can my family or friends visit me during the Inpatient Period?

A: Visitors are not allowed during the Inpatient Period. You are welcome to use your phone to connect with family or friends during your free time. However, please be mindful of your fellow participants' privacy and noise levels.

Q: Can I leave the CTU (Clinical Trials Unit) once I am admitted for an Inpatient Period?

A: To ensure your safety and the integrity of the study data it is required that you stay in the unit during the Inpatient Period. However, your decision to participate is completely voluntary, and you can withdraw your consent to participate and leave at any time. **Please speak to the research staff before doing so.**