**Informed Consent Form (ICF)**

**Study Title:**  
A Phase 2, Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study to Evaluate the Safety and Efficacy of Novostatin (Novitor) in Patients with Hypercholesterolemia

**Protocol Number:** NSP-002-2024  
**Sponsor:** Novitor Pharmaceuticals Inc.  
**Investigational Product:** Novostatin (Trade Name: Novitor)  
**Study Duration:** March 2, 2024 – September 22, 2024  
**Version:** 1.0  
**Date:** April 1, 2024

**1. Introduction**

You are invited to participate in a clinical trial evaluating a new medication called **Novostatin (Novitor)**, a novel statin designed to lower high cholesterol at low dosages. This form explains the purpose, procedures, risks, and benefits of the study. Please read it carefully and ask any questions before deciding to participate.

**2. Purpose of the Study**

The purpose of this study is to assess the safety and efficacy of Novostatin in reducing LDL cholesterol levels in patients with hypercholesterolemia. This Phase 2 trial will also evaluate other lipid parameters, safety markers (such as liver and muscle enzymes), and the pharmacokinetic profile of the drug. Positive results from this trial are expected to support moving into Phase 3 studies.

**3. Study Procedures**

If you agree to participate, you will be randomly assigned to receive either Novostatin or a placebo. The study procedures include:

* **Screening:** Medical history review, physical examination, blood tests (including lipid profile, liver function, creatine kinase levels), and an ECG.
* **Treatment Period:** Daily administration of the study medication for 24 weeks. Regular clinic visits (at Weeks 4, 8, 12, 16, 20, and 24) will include blood tests, vital signs measurement, and assessments of side effects.
* **Follow-Up:** A final visit 4 weeks after the last dose to evaluate your overall health and collect final laboratory data.

**4. Potential Risks and Discomforts**

As with any clinical trial, there are potential risks and discomforts, which may include but are not limited to:

* **Medication Side Effects:** Common side effects may include mild gastrointestinal discomfort, headache, or muscle pain. Rarely, higher dosages of statins can cause liver enzyme abnormalities or muscle toxicity, though Novostatin is designed to minimize these risks.
* **Blood Draws:** Some discomfort, bruising, or bleeding at the site of blood collection.
* **Unknown Risks:** Since Novostatin is investigational, there may be risks that are not yet known.

You will be closely monitored by the study team to ensure your safety throughout the trial.

**5. Potential Benefits**

While there is no guarantee that you will benefit from participating, possible benefits include:

* A reduction in your LDL cholesterol levels.
* Close monitoring of your health by medical professionals.
* Contributing to research that may help improve treatment for high cholesterol.

The positive results from early studies indicate that Novostatin may offer effective cholesterol management with fewer side effects than traditional statins, which is why a move to Phase 3 trials is planned if this study is successful.

**6. Confidentiality**

Your privacy is very important to us. All information collected during the study will be kept confidential and will be used solely for the purpose of this research. Data will be coded to protect your identity, and only authorized study personnel will have access to your records. Any publications or reports resulting from this study will not identify you.

**7. Voluntary Participation and Withdrawal**

Your participation in this study is completely voluntary. You may choose not to participate or to withdraw from the study at any time without any penalty or loss of benefits to which you are otherwise entitled. Should you decide to withdraw, your decision will be respected, and your medical care will not be affected.

**8. Compensation and Costs**

* **Costs:** There will be no charge for study medications or any procedures performed as part of this trial. Routine medical care related to your condition will continue to be provided by your healthcare provider.
* **Compensation:** You may be compensated for your time and travel expenses. Specific details regarding compensation will be provided by the study coordinator.

**9. Contact Information**

If you have any questions about the study or your rights as a participant, please contact:

**Study Coordinator:**  
Name: Sarah Thompson  
Phone: (123) 456-7890  
Email: sarah.thompson@novitorpharma.com

For questions about your rights or to report a research-related injury, you may contact:

**Institutional Review Board (IRB):**  
Name: Dr. Michael Reed  
Phone: (123) 987-6543  
Email: irb@biotechcityhospital.org

**10. Statement of Consent**

I have read the above information, and I have had the opportunity to ask questions about the study. I understand the purpose, procedures, risks, benefits, and my rights as a participant. I voluntarily agree to participate in this study.

**Participant’s Name (Printed):** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Participant’s Signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Investigator’s Name (Printed):** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Investigator’s Signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_