INFORMED CONSENT FORM

Study title: Does prophylactic antibiotics reduce infectious complications post endoscopic retrograde cholangio pancreatography in common bile duct stones patients: a clinical trial?

1. **Study Objective**

This study aims to find out if using preventive antibiotics can lower infection rates after ERCP in patients with bile duct stones.

2. **Participation Procedure**

Participants will be patients with bile duct stones who need ERCP but do not have cholangitis. They will be randomly assigned to one of three groups:

+ Prophylactic Antibiotic Group: Will receive Amikacin (an antibiotic) before the ERCP procedure.

+ Full-dose Antibiotic Group: Will receive Amikacin and a third-generation cephalosporin antibiotic from before the ERCP until hospital discharge.

+ Control Group: Will not receive antibiotics, only normal saline.

After ERCP, patients will be monitored for signs of infection through symptoms and lab tests.

3. **Benefits and Risks**

- Benefits: This study may help promote the appropriate use of antibiotics during ERCP in patients with common bile duct stones. As a result, it could reduce antibiotic resistance in the community, as well as lower healthcare costs and shorten hospital stays.

- Risks: The main risk of this study is the possibility of allergic reactions in the group receiving antibiotics. In the group not receiving antibiotics, there may be a higher risk of post-ERCP infectious complications.

4. **Confidentiality**

- Information about your name will be kept confidential. The results of this study may be presented at conferences or published in journals; however, your identity will not be disclosed.

- You have the right to refuse to answer any personal questions.

5. **Voluntary Participation and Withdrawal**

Participation is entirely voluntary. You may withdraw at any time without affecting your treatment

6. **Contact Information**

If you have any questions, please contact:

Principal Investigator: Tran Van Thanh

Phone number: +84977157219

7. **Consent to Participate**

I confirm that I have been clearly informed, understand and voluntarily agree to participate.

Participant's Name: .....

Signature: ..... ……Date: .....

Research Staff: .....

Signature: ..... ……Date: .....