Informed Consent Form

Protocol name: A prospective, single-arm, phase II clinical study of zimberelimab in combination with concurrent radiotherapy for locally advanced (IIB-IVA) cervical cancer

Sponsored by: Zhongshan Hospital of Fudan University

Research Institute: Zhongshan Hospital, Fudan University

Funding source: Guangzhou Yu Heng Biotechnology Co.

Principal Investigator: Genlai Lin

Patient Name.

Dear Subjects.

We hereby invite you to participate in a clinical study as a subject. Participation in this clinical study is completely voluntary. Before you decide whether to participate in this study, please read the following carefully to understand why this study is being conducted, the possible risks of participating in the study, the possible benefits, and what may happen if you decide to participate in the study. If you have any questions or concerns, you can discuss them with the clinicians involved in the study, and you can discuss them with your friends and family before making a decision.

I. What is the background and purpose of the study?

The purpose of this study is to explore the effectiveness and safety of zimberelimab in combination with concurrent radiotherapy for the treatment of locally advanced cervical cancer.

1） Find out if there is a role for studying zimberelimab in combination with radiotherapy regimens for you and patients with similar conditions in terms of life extension.

2） Find out if studying zimberelimab in combination with radiotherapy regimens will help you and patients with similar conditions in terms of quality of life.

3） Understand the safety and adverse effects of study drugs.

The investigational drug zimberelimab has shown initial efficacy and manageable toxicity in the treatment of advanced refractory lymphomas and solid tumors, recurrent or metastatic cervical cancer, and other cancer types, but prospective trials investigating the efficacy and safety of this drug in locally advanced cervical cancer are still lacking.

The drug used in this study, zimberelimab, is the study drug (the drug is already on the market); because of the single-arm trial, a control group and a control risk drug are not required for this study.

Consent for this study was obtained from the Ethics Committee of Zhongshan Hospital, Fudan University.

II. What will happen if I participate in the study?

The study will be conducted at Zhongshan Hospital of Fudan University and is expected to last for 2 years, with 19 subjects to be recruited. The study is a single-arm, single-center, prospective phase II clinical study.

You may be included in this study if you meet the following criteria.

(i) Inclusion criteria .

1) Have reached the age of 18-75 and are open to both men and women
2) You have a pathology report (pathology report such as histology or cytology of the original primary tumor) confirming squamous carcinoma of the cervix, adenocarcinoma of the cervix, or adenosquamous carcinoma of the cervix.
3) You are able to take care of yourself and are physically active; or you are unable to do any physical activity but are awake for about half of the day or more (<50% of the time you are bedridden during the day).
4) You do not have severe bone marrow suppression, coagulation abnormalities, or liver or kidney insufficiency.

(Your blood draw report is subject to the following.

Absolute neutrophil count ≥1.5×10^9 /L

Platelets ≥ 100×10^9 /L

Hemoglobin ≥10g/dL

Bilirubin ≤ 1.5 times ULN

ALT and AST ≤2.5 times ULN (Note: ≤5 times in patients with liver metastases)

Serum creatinine ≤ 1.5 times ULN or creatinine clearance ≥ 50 ml/min

Activated partial thromboplastin time (APTT) and international normalized ratio (INR ≤ 1.5 × ULN))

5) Male or female patients of childbearing potential voluntarily use an effective method of contraception, such as a double barrier method, condoms, oral or injectable contraceptive drugs, or intrauterine devices, during the study period and within 6 months of the last study dose. (Special circumstances: For female subjects, if you are spontaneously menopausal, have undergone artificial menopause or sterilization (e.g., hysterectomy, bilateral adnexal resection, or radiation ovarian irradiation) these conditions cannot be included).

You are not recommended to participate in this study if you have

（二） Exclusion criteria.

1） Abnormal mental status; inability to meet the conditions of informed consent; inability to ensure that the medication is administered at the prescribed dose and regimen.

2） You have had cancer in the past, but for the following: diagnosed 5 years ago and no recurrence of the disease in those 5 years;.

3） You have any active autoimmune disease or a history of autoimmune disease; have an innate or acquired immune deficiency; or are using immunosuppressive drugs and were still using them within 2 weeks prior to enrollment; or require concurrent antitumor therapy outside of the study protocol.

4） Syphilis spirochete infections, hepatitis C virus antibodies, human immunodeficiency virus (HIV) positive individuals.

5） Pregnant or lactating women; or women of childbearing age with a positive blood pregnancy test

6） You have more serious cardiovascular disease (including but not limited to acute myocardial infarction, severe/unstable angina, or coronary artery bypass grafting within 6 months prior to enrollment; congestive heart failure New York Heart Association (NYHA) class >2; ventricular arrhythmia requiring pharmacologic treatment; LVEF (left ventricular ejection fraction) <50%).

7） Have undergone any major surgery or major invasive treatment or operation (except intravenous placement, puncture drainage, etc.) within 4 weeks prior to enrollment.

8） Abnormal coagulation (International Normalized Ratio (INR) > 1.5 or Partially Activated Plasminogen Time (APTT) > 1.5 x ULN) in persons with bleeding tendencies (e.g. active ulcerative lesions in the stomach, black stools and/or vomiting of blood within 3 months, hemoptysis).

10） Urine routine suggesting urine protein ≥ 2+ and 24-hour urine protein amount > 1.0g.

11） ECG-corrected QT interval > 470msec; if you have a pacemaker (and no other cardiac abnormalities), the investigator will determine whether you are a suitable candidate for enrollment in the study.

12） You have a history of severe allergic reactions to monoclonal antibodies and uncontrolled allergic asthma or a known allergy to a drug component.

13） Those who have received a history of allogeneic organ transplantation or allogeneic hematopoietic stem cell transplantation.

14） Prior or current idiopathic pulmonary fibrosis, interstitial pneumonia, pneumoconiosis, radiation pneumonia, mechanized pneumonia, drug pneumonia, or screening CT showing active pneumonia.

15） Hypersensitivity to both non-ionic contrast agents commonly used in CT and to the magnetic resonance contrast agent gadolinium.

16） Any active infection requiring systemic treatment by intravenous drip within 14 days prior to screening.

17） Receipt of live attenuated vaccine within 14 days prior to screening or planned during the study.

18） Other conditions that may result in increased risk associated with study drug use or interfere with the interpretation of study results, affect trial compliance, etc. that the investigator determines to be inappropriate for participation in this trial.

Note: "Single arm" indicates that this study is a single-arm clinical trial and that you and the other subjects included in the study are receiving the same treatment regimen.

III. What is the specific process of the study?

1. [Before you are enrolled in the study, you will undergo the following tests to determine if you can participate in the study, called the screening period

All study procedures were conducted after signing the informed consent form. The

following items were to be completed 1 week prior to the start of the trial for observation and assessment.

- The doctor will ask and record your medical history and demographic information in detail, including your ID, gender, age, mailing address, contact number; hepatitis B, hepatitis C, quality of life, fasting blood sugar, etc.
- A complete physical examination of you: ECOG score, height, weight, vital signs, physical examination of all organs (including dental function); HCG check for female patients of childbearing age except for pregnancy.
- Knowledge of your previous and current medication use.
- Need to collect specimens such as your blood and urine and feces for blood, urine, fecal related tests, etc.
- Complete your cardiac ultrasound, pregnancy test (for women, except for pregnancy), thyroid function, ECG, imaging (including chest (CT), abdomen/pelvis (CT/MRI/Ultrasound), head (CT/MRI)) (with imaging specific items to be completed after evaluation by the investigator and extendable up to 28 days prior to the study).
- **You will be required to provide 5-10 biopsies of previously archived tissues and send them to our pathology department for pathological testing to determine if you are eligible for enrollment in this study; if you are unable to obtain biopsies you will be required to undergo biopsy to reacquire tumor tissue, and the specific procedures include.**

1） After evaluating your basic condition, your doctor will arrange for a biopsy of the lesion if possible.

2） For different subjects, before the biopsy operation, the doctor will inform you of the site, significance, possible complications and risks, and details of the biopsy, and if you have any questions, you will be informed; the biopsy may need to be done with the assistance of an imaging system, and the doctor will also inform you if this is necessary.

3） If there is a need to adjust the procedure, the doctor will inform you again and obtain your consent before proceeding with the procedure.

- In addition to the above items, your doctor may recommend additional tests depending on the needs of your condition.

2. [If you are eligible for the above examination, you will be studied according to the following steps, called the treatment period *(or visiting period)*

Treatment.

You will need to receive the appropriate treatment under the strict guidance of your study doctor or his or her team, and when you have questions about your treatment, please talk to your study doctor.

The test protocol is as follows.

Radiotherapy: completed within 8 weeks; concurrent chemotherapy: every 7 days, administered no more than 5 times; zimberelimab injection: 240 mg/dose, administered intravenously every 14 days, starting in the first week of radiotherapy, for a maximum duration of one year.

Treatment follow-up.

You will need to come to the hospital for regular follow-up visits and continue until the end of the study, which is expected to last two years. The purpose of the follow-up visits is to find out how your treatment is working and whether you are experiencing any adverse effects and to manage them accordingly.

During the follow-up period, your doctor will arrange for you to have the following tests.

- ECOG score and physical examination once on days 7 and 14 of the first cycle, including height, weight, vital signs, physical examination of all organs (including dental function), blood pressure, quality of life, and recording of other adverse events that occur.

- Record adverse reactions during treatment and concomitant medications, including nausea, vomiting, diarrhea and abdominal distension. Observe various clinical manifestations during medication administration and record them.
- Routine blood count and blood biochemistry will be checked every 1 week during each cycle.
- A urine and fecal specimen, thyroid function, coagulation function, and cardiac enzyme profile at the end of each cycle (day 14).
- Electrocardiogram is performed once per cycle. Echocardiogram and troponin should be added if symptoms such as chest pain and palpitations occur.

Your doctor may also recommend additional tests depending on the needs of your condition.

Test flow chart

	Screening Period[1]	Treatment period						Last follow-up visit[2]	Follow-up period	
		Cycle 1 C1			Week 2 C2	Odd numbere	Even cycle C2n+2		Security[3]	Survival period[4]
Visits	**Visits 1**	**Visits 2**	**Visits 3**	**Visit 4**	**Visits 5**	**Visits**	**Visits 2n+2**	**Withdrawal from the study within 7 days**	**28 days (±7 days) after the last dose**	**8 weeks/session**
Evaluation time window (days)	**D-28~-1**	**D1**	**D7 ±3 days**	**D14 ±3**	**D14 ±3 days**	**D14 ±3 days**	**D14 ±3 days**			
Informed Consent	X									
Medical history,	X									
History of Oncology	X									
Experimental drug		X (1 treatment cycle every 14 days)								
Physical Examination	X (within 7		X	X	X	X	X	X	X	
Vital signs	X (within 7	X	X	X	X	X	X	X	X	
ECOG Rating	X (within 7				X		X	X	X	
Virological examination	X (within 14									
Pregnancy test[6]	X (within 7									
Blood routine, blood	X (within 7			X	X	X	X	X	X	
Amylase[7]	X (within 7			X	X	X	X	X		
Coagulation[7]	X (within 7			X	X	X	X	X		
Thyroid function[8]	X (within 7				X		X	X		
Urine Routine[10]	X (within 7			X	X	X	X	X	X	
Convenient routine	X (within 7							X		
12-lead	X (within 7			X	X	X	X	X	X	
Echocardiography	X									
Quality of life score	X				X		X	X		
Adverse Events	X									

Remark.

1. The screening period is 28 days, and protocol-eligible test results are accepted up to the validity of the subject's signed informed consent form. A full physical examination, ECOG score, vital signs, laboratory tests, 12-lead ECG will be accepted up to 7 days prior to the first dose, virology up to 14 days prior to the first dose, bone scan up to 6 months prior to the first dose, and echocardiography and imaging up to 28 days prior to the first dose.
2. Subjects who complete the trial or withdraw early should complete the final follow-up within 7 days of withdrawal and should complete an efficacy assessment before receiving a new treatment regimen, without repeating the test if results are available within 7 days, and accepting results within 28 days.
3. The safety follow-up period is from the completion of the last study visit until 28 days after the last dose of zimberelimab or until the start of other antitumor therapy, whichever occurs first. If an unintended adverse event related to immunogenicity occurs during the safety follow-up period, an additional immunogenic blood collection should be performed as soon as the adverse event is confirmed.
4. After the safety follow-up period, we entered the survival follow-up period with telephone follow-up every 8 weeks to obtain the survival status and follow-up of other anti-tumor treatments.
5. Virological examination: including hepatitis B two-to-half, HCV, HIV, syphilis-related indicators (HBV DNA test for hepatitis B surface antigen positive, HCV RNA test for hepatitis C virus antibody positive).
6. Pregnancy test: urine pregnancy or blood pregnancy tests are available, only for women of childbearing age.
7. Laboratory tests: amylase and coagulation tests were performed once per treatment cycle during the screening and first 8 cycles of the treatment period; after the 8th cycle, every 4 treatment cycles, i.e. C1, C2, ..., C8, C12, C16, C20... ...
8. Laboratory tests: Thyroid function tests are performed every 2 treatment cycles during the screening period, the first 8 cycles of the treatment period; after the 8th cycle, every 4 treatment cycles, i.e. C2, C4, ..., C8, C12, C16, C20... ...
9. Blood routine and blood biochemical examination items are detailed in the appendix.
10. Urine routine: If urine protein is ++ or above, 24-hour urine protein quantification is required.

* Imaging evaluation: The screening period includes at least enhanced CT or MRI of the head, neck, chest, abdomen, and pelvis (except for contrast allergy), and imaging in subsequent cycles is recommended to include enhanced CT or MRI of the chest, abdomen, pelvis, and other sites with lesions (except for contrast allergy), with additional imaging of the corresponding sites if there are suspicious sites during the period. The first imaging examination will be performed before the start of treatment, the second imaging examination will be performed after the end of external radiotherapy and before post-loading radiotherapy; the third imaging examination will be performed 2 months after the completion of all treatments; and every three months thereafter.

3. [After you finish the treatment, we will continue to know whether you have any adverse reactions and follow-up treatment through the following steps, called end-of-treatment visit and long-term follow-up visit].

At the end of the trial, your doctor will schedule you for the following tests.

- Careful and thorough physical examination: ECOG score, height, weight, vital signs, physical examination of all organs (including dental function).
- Perform the appropriate tests as directed by your doctor.

As well, you and the investigator can decide together on the next step of treatment and keep a record of it.

- Treatment and follow-up continued for adverse reactions that had not recovered by the end of the trial until recovery to NCICTCAE version 4.3 classification degree 1 or full recovery.
- You will also need to come to the hospital for regular follow-up after your treatment is completed. You will be seen by your primary care physician at week 6, week 12 and then every 8 weeks after your radiation treatment. The purpose of these follow-up visits is to find out how your treatment is working and whether you are experiencing any adverse effects and to treat them accordingly.

IV. What are the issues that need attention in the study?

- You need to take the medication as directed by your doctor and give feedback to your doctor in case of special circumstances.
- You will need to come to the hospital at the follow-up time your doctor has agreed with you. Your follow-up visits are important because your doctor will determine whether the study measures you are receiving are actually working.

- You should not use other drugs such as antineoplastic drugs or immunosuppressants during the study period. If you require other treatment, please contact your physician in advance.
- The need for you to inform the study doctor of any discomfort or health problems during the study, even if you do not consider them to be important.
- Make sure your doctor or researcher can reach you during the study.
- For female subjects, if you suspect or have a pregnancy during the study, please tell the study doctor or study staff promptly.
- Make sure the study drug is kept in a safe place, away from children, for your use only.
- If you have other special circumstances or do not want to continue to participate in this study, please let the study doctor or staff know in a timely manner.

V. What alternative treatments are available if not participating in the study?

If you decide not to participate in the study, or withdraw from this study, you still have the following treatment options available to you, which you should discuss carefully with your doctor.

- Not participating in the study, using approved or other recommended drugs, treatment regimens: e.g. anti-PD-1 drugs pembrolizumab, nabumab, etc.
- Participation in other studies.
- Receiving symptomatic supportive care, also known as palliative care, is a treatment option that aims to improve your quality of life as much as possible, but has no curative effect on the disease.

VI. What are the possible benefits of participating in this study?

If you agree to participate in this study, it is possible that your disease may go into remission, but it is also possible that you may not achieve the desired results,

have no benefit, and experience disease progression. We hope that the information obtained from your participation in this study will be useful in the future for the treatment of patients with the same condition as yours.

VII. What are the possible risks and inconveniences of participating in this study?

- ●The trial drug was used in this study for a super-indication and was not approved for the cervical cancer indication at this time.
- ●Of the safety information from a total of 374 patients from two previous clinical trials of this study drug, we are aware of the following possible adverse reactions.

I. Thyroid function

1) Hypothyroidism incidence 16.6%

(2) The incidence of hyperthyroidism 4.0%

3） The incidence of elevated blood thyroid hormone is 3.5%.

4) Incidence of hyperglycemia and diabetes mellitus 2.7%

5) Incidence of adrenal insufficiency 0.3%

Second, the incidence of immune-related skin adverse reactions 4.0%

III. Incidence of immune-associated pneumonia 3.2%

IV. Incidence of immune-related hepatitis 1.1%

V. Incidence of immune-related thrombocytopenia 0.8%

VI. Incidence of immune-associated gastroenteritis 0.3%

VII. Incidence of immune-related nephritis 0.3%

VIII. Immune-related myocarditis and other rare immune-related adverse reactions may also occur when receiving anti-PD-1 /PD-L1 antibody therapy, but have not been observed in clinical trials of this product at this time.

Nine, the incidence of infusion reaction 4%

- These are possible risks associated with the use of study drugs and do not necessarily occur. If any of these or other new conditions occur, the study doctor or study staff will inform you of the situation in due course and will do their best to manage the risk for you.
- Risks of radiotherapy.

1) Systemic reactions: malaise, decreased appetite, nausea, vomiting.
2) Hematopoietic system reactions: bone marrow suppression, leukopenia, thrombocytopenia.
3) Heart damage: tachycardia, arrhythmia, myocarditis, heart failure, aggravation of heart disease, increased chance of myocardial infarction.
4) Tracheal damage: cough, coughing up blood, radiation bronchitis, tracheal stenosis, tracheal fistula.
5) Lung damage: radiation pneumonia, pulmonary fibrosis, pulmonary function impairment.
6) Esophageal damage: radiation esophagitis, esophageal perforation, esophage-tracheal fistula, esophageal hemorrhage, ruptured mediastinal vessels hemorrhage.
7) Liver damage: abnormal liver function, radioactive hepatitis, radiation hepatic necrosis.
8) Gastrointestinal damage: gastritis, radiation proctitis, intestinal stricture, intestinal obstruction, gastrointestinal perforation, intestinal bleeding, intestinal adhesions.
9) Urological damage: urethritis, radiation cystitis, abnormal renal function, radiation nephritis, bladder bleeding, perforation, contracture, urethral stricture, obstruction.
10) Bone damage: osteoporosis, radiation osteomyelitis, fractures, radiation

osteonecrosis.

11) Salivary gland and oral reactions: inhibition of salivary gland secretion, acute reactions of oral mucosa, and chronic ulcers.
12) Twelve, skin and muscle damage: acute radiation reaction, post-radiation fibrosis, congestion, swelling, erosion, ulceration and even the formation of sinus tracts, long-lasting, etc.; soft tissue redness, pain, edema, cellulitis, necrosis, muscle atrophy, myospasm, etc.
13) Spinal cord damage: radiation myelitis, paraplegia.
14) Fourteen, brain injury: acute radioactive brain edema, increased intracranial pressure, brain herniation, chronic radioactive brain injury, brain necrosis.
15) Fifteen, growth disorders, endocrine hypofunction, damage to the five senses, radioactive cataracts, fundus damage, optic nerve damage, eye atrophy, blindness, hearing impairment, etc.

- In addition, for biopsies, for women of childbearing age, other supplemental tests or procedures that may be risky the study physician or investigator will inform you in advance and obtain your written consent to perform them.

Unpredictable risks may arise in the study due to the disease itself, as well as other pre-existing comorbidities or the combination of medications. In addition, study interventions may appear ineffective, and the disease may continue to progress or even become life-threatening.

You will need to follow up with the hospital and have some tests done on time during the study period, all of which may also cause you trouble or inconvenience.

In addition, study interventions may appear to be ineffective, as well as continue to progress due to ineffective treatment or due to comorbidities such as other diseases.

VIII. Do I need to pay for participating in this study?

During your participation in this study, the drug zimberelimab provided by Guangzhou Goodwill Biotechnology Co., Ltd. is completely free of charge, and a

subsidy of 500 RMB is provided for examination costs. The rest of the chemotherapy drugs, radiotherapy, and examinations are routine treatment items that have been used in clinical applications for many years, and the costs need to be borne by you.

The cost of drugs and medical tests not related to the study, treatment and tests required for your concurrent co-morbidities, and the cost of switching to other treatments due to ineffective treatment, will be your responsibility.

IX. Will I receive a subsidy for participating in this study?

This study was an investigator-initiated, non-remunerated experiment, and subjects were not paid or otherwise compensated for their work.

X. What will happen if I suffer damage as a result of participating in this study?

If you experience any discomfort, new changes in your condition, or any unforeseen circumstances, whether or not related to the study, during the study, please notify your physician promptly and he/she will make a judgment call and provide medical treatment.

Guangzhou Goodwill Biotechnology Co., Ltd., the company providing the zimberelimab drug, has purchased clinical study insurance for the study. During the insurance period (January 1, 2022 to December 31, 2026), the insurer is responsible for compensation for personal injury or death of a subject due to an adverse event occurring as a result of the use of the investigational drug during a clinical trial of the drug, as agreed in the insurance contract. The main conditions of the insurer's liability: 1) the expected and unintended side effects related to the trial drug are covered; 2) the trial drug includes zimberelimab and other marketed antineoplastic drugs specified in the trial protocol are covered; 3) the adverse events caused by the implementation of laboratory tests or imaging tests specified in the trial protocol are covered; and 4) extended coverage for adverse events due to intravenous blood collection; extended

coverage for adverse events due to intravenous infusion; 5) extended coverage for the subject's own costs of medication abortion or surgical abortion due to an unwanted pregnancy, with a limit of $20,000 per person; the main conditions under which the insurer excludes liability: 1) personal injury or death or deterioration of health that would have occurred despite the original disease or the subject's non-participation in the trial; 2) Damage due to the subject's own cause or bodily injury or death that existed prior to the start date of this insurance (including retroactive period); 3) Failure of the drug used in the trial to achieve the desired effect.

XI. What will happen if I don't participate or choose to withdraw from the study in the middle?

You may withdraw from this study at any time during the study for any reason, and this will not affect your relationship with your doctor or your medical treatment and rights. Your decision will not have any effect on your continued medical treatment.

Data prior to your withdrawal that has been integrated into the research project will continue to be used in this study while protecting your privacy.

If you withdraw from the study for any reason, you will be asked why you withdrew from the study and you may also be asked to undergo relevant laboratory tests and physical examinations if your doctor deems it necessary, which is very beneficial to protect your health.

XII. Under what circumstances will the study be terminated or you be asked to withdraw from the study?

This study may be discontinued at the request of the study physician, ethics committee or government administration for the following reasons

- New research evidence of study drug ineffectiveness.
- Quality problems with investigational drugs.

- This research project may be discontinued if too many people discontinue the trial due to poor adherence, improper administration, etc.

Your doctor may also stop your study medication for the following reasons.

- Progression of disease or development of intolerable adverse effects, complications, etc., where the study physician believes that continued participation in the study would be harmful to you.
- Pregnancy events during the course of the study.
- You develop allergies and hypersensitivity reactions to study medications.
- Poor patient compliance in the opinion of the investigator, requiring the patient to discontinue the trial treatment.
- When you fail to administer medication according to the study protocol or commit a serious violation of the protocol principles after enrollment
- other circumstances that the investigator felt warranted withdrawal from the study.

XIII. Is my personal information confidential?

We will protect your information and medical data in this study as required by law and regulation. Your name, gender, and other personally identifiable information will be replaced with a code name or number and will be kept strictly confidential, and your privacy will be well protected as only the research team knows your personal information. Research results may be published in journals, conferences, but no personally identifiable information about you will be disclosed.

Your medical records (study charts, labs, etc.) will be kept intact at the hospital for a **period of 20 years. The** supervisors and auditors appointed by the sponsor, the ethics committee and the relevant regulatory authority inspectors will be allowed to access your medical records according to the appropriate authority in order to verify the authenticity, accuracy and reliability of the study data. By signing the informed consent form, you are also consenting to the access of your medical records by the

aforementioned personnel.

XIV. How will I get more information?

Your physician will promptly notify you or your guardian if there is any important new information during the course of the study; if the new information may affect your willingness to continue to participate in the study, you will be required to sign a new informed consent form.

If you have any questions related to your rights/interests, or if you would like to reflect difficulties, dissatisfaction and concerns encountered during your participation in this study, or if you would like to provide comments and suggestions related to this study, please contact the Ethics Committee of Zhongshan Hospital, Fudan University, at 021-31587871.

Fifteen, what should I do now?

It is up to you to decide whether or not to participate in this study. You can discuss this decision with your family or friends before making a decision. Before you make a decision to participate in the study, please ask your doctor as many questions as possible until you fully understand the study.

Thank you for reading the above material. If you decide to participate in this study, please let your doctor know and he/she will make all the arrangements for you regarding the study.

You will sign this informed consent form in duplicate, one copy to be retained by the investigator and one copy to be retained by the subject. You are requested to retain this material.

(No text below)

Informed Consent Form - Signature Page

Subjects Affirmation

I have read the above description of this study and have had the opportunity to discuss and ask questions about this study with my doctor, and all of the questions I have asked have been answered to my satisfaction.

I am aware of the possible risks and benefits of participating in this study. I understand that participation in the study is voluntary, I acknowledge that I have had sufficient time to consider it, and I understand that.

- I can always ask the clinicians involved in the study for more information
- I may withdraw from this study at any time without discrimination or retaliation, and my medical treatment and rights will not be affected.
- If I were to withdraw from the study midway through, I might need to complete the appropriate checks, which would be very beneficial to myself and the study as a whole.
- If I need to take any other treatment due to a change in my condition, I will seek the doctor's advice in advance or tell him/her truthfully afterwards.
- I consent to access to my study data by monitors and auditors appointed by the relevant supervisory and regulatory authorities, the ethics committee or the sponsor.
- Informed consent will be given in duplicate and I will receive a signed and dated copy of the informed consent form.

Finally, I decided to agree to participate in this study.

Subject's signature: Contact number._____

Contact address._____

_____ Month _____ Year _____ Day _____

If the subject is incapacitated or restricted, a guardian's signature is required (Subjects with restricted capacity require joint signature of subject and

guardian)

I acknowledge that the investigator has explained the details of the study, including the study protocol, its rights, and possible benefits and risks, to the subjects participating in the study and to me, and that we will be provided with a signed informed consent form, and that I agree to participate in this study on behalf of the subjects.

Guardian's name (in block letters): Relationship._____

Contact number._____

Contact address._____

Guardian's signature: _____ Month of _____ Year _____ Day

If the subject or the subject's guardian lacks the ability to read, the signature of a witness is required

The subject and/or his/her guardian has indicated that he/she is unable to read. One/multiple investigators have read aloud and explained the contents of this informed consent and other written information, including their rights and possible benefits and risks, discussed them with the subject, given the subject an opportunity to ask questions and explain them fully, and will provide the subject with a signed copy of the informed consent form. The subject and/or his or her guardian(s) have given their consent to participate in this clinical study. I have read the informed consent form and other written information and have witnessed the process of signing informed consent.

Name of impartial witness (in block letters): Tel.

ID Name: ID Number.

Contact address._____

Signature of the impartial witness: _____ month of _____ year _____ day

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Researcher affirmation

I have explained to the subject and/or his/her guardian and/or his/her witness who is participating in the study the details of the study, including the contents of the study protocol, his/her rights and possible benefits and risks, and he/she will be provided with a signed informed consent form.

Name of researcher (in block letters): Signature.

Tel: _____ _____ Year _____ Month _____ Day

(No text below)

Appendix List of laboratory test items

Inspection	Assay name (standard abbreviation)
Blood Count	White blood cell count (WBC), neutrophil count (NEUT), lymphocyte count (LYM), eosinophil count (EOS), basophil count (BASO), monocyte count (MONO), red blood cell count (RBC), hemoglobin (HGB), platelet count (PLT)
Urine Routine	Urine pH (PH), urine glucose (GLU), urine protein (PRO), urine occult blood (BLD), urine white blood cells (WBC), urine red blood cells (RBC), when urine protein +++ or above, additional 24-hour urine test is required.
Convenient	Fecal white blood cells (WBC), fecal red blood cells (RBC), fecal occult blood
Blood Biochemistry	alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP), gamma-glutamyl transferase (GGT), lactate dehydrogenase (LDH), total bilirubin (TBIL), direct bilirubin (DBIL), indirect bilirubin (IBIL), total serum protein (TP), serum albumin (ALB), serum globulin (GLOB), total cholesterol (TC), triglycerides (TG), HDL GLOB), total cholesterol (TC), triglycerides (TG), high-density lipoprotein (HDL)
	(HDL), low-density lipoprotein (LDL), urea nitrogen (BUN), creatinine clearance (CCR), and
	Amylase (AMS)

Coagulation	prothrombin time (PT), activated partial thromboplastin time (APTT), prothrombin time
Thyroid function	Triiodothyronine (T3), thyroxine (T4), free triiodothyronine (FT3), free thyroxine (FT4), thyroid stimulating hormone (TSH)
Myocardial	Creatine kinase (CK), creatine kinase isoenzyme MB (CK-MB), troponin T (cTnT)
Pregnancy	Human chorionic gonadotropin (HCG)
Virological examination	Hepatitis B virology: hepatitis B surface antigen (HBsAg), hepatitis B surface antibody (HBsAb), hepatitis B e antigen (HBeAg), hepatitis B e antibody (HBeAb), hepatitis B core antibody (HBcAb), hepatitis B virus deoxyribonucleic acid (HBV-DNA) Hepatitis C virology: hepatitis C antibody (Anti-HCV), hepatitis C virus ribonucleic acid (HCV-RNA) HIV virology: human immunodeficiency virus antibody (Anti-HIV)