TMU-Joint Institutional Review Board
INFORMED CONSENT FORM

English Version V8, dated February 12, 2025

Study Title: Investigation of the treatment of infertility patients with mitochondrial defects by artificial reproductive technology

Study Site: Taipei Fertility Center

Telephone: (02) 2725-2333 ext. 8630

Sponsor/Pharmaceutical Company: None

Principal Investigator: Dr. Chii-Ruey Tzeng, Attending Physician / Chief Executive Officer

Contact Telephone: (02) 2725-2333 ext. 8630

Co-Investigator: Professor Shu-Huei Kao, Department of Medical Laboratory Science and Biotechnology, Taipei Medical University; Professor; (02) 2736-1661 ext. 3317

Co-Investigator: Dr. Yun-Ting Kuo, Department of Pediatrics, Shuang Ho Hospital, Ministry of Health and Welfare; Department Director; 02-2249-0088 ext. 2951

Co-Investigator: Dr. Heng-Kien Au, Division of Obstetrics, Department of Obstetrics and Gynecology, Taipei Medical University Hospital; Director; 0970-405-153

Co-Investigator: Dr. Ching-Wen Chang, Division of Gynecology, Department of Obstetrics and Gynecology, Taipei Medical University Hospital; Attending Physician; (02) 2737-2181

Co-Investigator: Dr. Chih-Ping Chen, Department of Obstetrics and Gynecology / Department of Reproductive Health, MacKay Memorial Hospital; Attending Physician; (02) 2543-3535

24-Hour Emergency Contact: Dr. Chii-Ruey Tzeng, Attending Physician / Chief Executive Officer; Mobile: 0933-897-698

Participant Name: _____ Sex: _____ Age: _____

Medical Record No.: _____

Mailing Address: _____

Telephone: _____

Emergency Contact Name / Relationship to Participant: _____

Mailing Address: _____

Telephone: _____

1. Background of the Trial/Research and Current Status of the Study Drug/Medical Device/Product

You have agreed to consider participation in a clinical trial using assisted reproductive technology to remove ooplasm containing pathogenic mitochondrial DNA. This trial has been reviewed by the Ministry of Health

and Welfare and approved for conduct at Taipei Fertility Center. You are being asked here whether you are willing to participate. Six participants will be enrolled: three recipients who require mitochondrial replacement therapy and three healthy oocyte donors.

Mitochondria are maternally inherited. Mutations in mitochondrial DNA in oocytes may cause disease or even death in offspring. Assisted reproductive technology may be used to remove ooplasm containing pathogenic mitochondrial DNA. However, formal reports worldwide concerning offspring of patients undergoing this type of treatment remain very limited. To further determine the proportion of mutant mitochondrial genes carried after mitochondrial replacement therapy in patients with mitochondrial defects, this study will further examine genetic mutations in germ cells from patients with mitochondrial defects, with the aim of refining the testing and operating procedures for this therapy.

The study will be funded using surplus funds from the clinic. At present, the only countries worldwide that have approved implementation of this therapy are the United Kingdom and Australia; legislation permitting implementation of this trial has not yet been enacted domestically. Domestic expert meetings have discussed the safety and concerns of this therapy on more than two occasions. Based on the conclusions of those meetings, the assisted reproduction procedures in this trial will be modified to improve safety and success rates.

2. Purpose of the Trial

The purpose of this study is to determine whether mitochondrial mutations in oocytes can be addressed through assisted reproductive technology by removing ooplasm containing pathogenic mitochondrial DNA. Formal reports worldwide concerning offspring of patients with this condition remain very limited. Through this study, the validity and operating procedures of this therapy will be further refined.

3. Participant Inclusion and Exclusion Criteria

Inclusion criteria (one of the following):

Oocyte recipients: (a) female recipient participants aged 20-45 years with mitochondrial genetic defects or mutations; or (b) female recipient participants aged 20-45 years who have had a delivery or miscarriage involving mitochondrial genetic defects, or offspring with a mitochondrial mutation.

Healthy oocyte donors: healthy female oocyte-donor participants aged 20-40 years.

Exclusion criteria:
(a) History of uterine cancer; (b) participants found to carry other genetic defects that are unfavorable for preimplantation embryo screening; (c) pregnant women; (d) persons infected with human immunodeficiency virus (HIV).

4. Trial Procedures and Related Examinations

Your role in this trial is:
☐ Oocyte recipient requiring mitochondrial replacement therapy
☐ Healthy oocyte donor

Steps required of you in this trial:

Whether you are a healthy oocyte donor or an oocyte recipient, after the Principal Investigator explains the purpose and significance of this study to you and you sign this consent form, you will be asked to undergo an oocyte retrieval cycle using assisted reproductive technology. The following specimens will be collected: (1) cumulus cells surrounding the oocyte obtained during oocyte retrieval; (2) ooplasm from the oocyte; (3) medically discarded polar bodies removed from your oocytes; and (4) a small blood sample (3 mL, approximately half a teaspoon) for extraction of mitochondrial DNA. Next-generation sequencing (NGS) or Sanger sequencing will be used to analyze mitochondrial DNA heteroplasmy. You will need to provide the above specimens only once. The blood sample will be collected from your arm. Genetic material will be obtained from the blood and used for mitochondrial DNA analysis.

Because persons infected with human immunodeficiency virus (HIV) must be excluded from this trial, you will undergo a confidential, identified HIV test. Only participants with a negative test result may participate. If the result is positive (including a false-positive result), the study will provide referral for follow-up medical care or counseling. Once confirmed, the case must be reported to the competent authority in accordance with the Human Immunodeficiency Virus Infection Control and Patient Rights Protection Act.

I agree to undergo the above testing and, when necessary, related medical referral, counseling, and legally required reporting to the competent authority.

Signature: _____ Date: _____ (YYYY/MM/DD)

If you are an oocyte recipient requiring mitochondrial replacement therapy, you will undergo an additional approximately 12-week fertilization and embryo-transfer treatment course. This includes: (1) thawing the recipient's oocytes, removing the spindle, and transferring it into a donor oocyte; (2) sperm injection followed by incubation to observe fertilization and development; (3) trophectoderm (TE) biopsy of blastocysts produced through mitochondrial replacement; and (4) PGT-A to determine whether the blastocyst has a normal chromosome complement (euploidy or aneuploidy). To determine the proportion of mutant mitochondrial DNA carried, polar bodies and cumulus cells from the participant's oocytes and non-developing embryos after mitochondrial replacement will be compared for mutant mitochondrial DNA. These tests are intended to address concerns regarding the unknown genetic background of donor oocytes and to improve the precision and clinical applicability of mitochondrial replacement therapy.

If you qualify as an oocyte recipient requiring mitochondrial replacement therapy, the following steps will be performed after transfer of an appropriate embryo:

An embryo found to have a normal chromosome complement will be transferred into the recipient participant's uterus. An hCG pregnancy test will be performed two weeks later, followed by examination of the gestational sac and fetal heartbeat every two weeks. At 16-20 weeks of pregnancy, amniocentesis will be performed to obtain amniotic-fluid cells for chromosomal karyotyping and mitochondrial DNA sequencing. If there are concerns, please discuss with the Principal Investigator and your attending physician whether an amniotic-fluid microarray is necessary.

After successful delivery following embryo transfer, neonatal umbilical cord blood will be collected to examine whether defective mitochondrial DNA remains. Within 48 hours after birth, routine newborn screening for congenital metabolic disorders and routine hematocrit (HCT) testing will be performed to assess anemia and thrombocytopenia commonly seen in Pearson syndrome. Thereafter, growth and development will be monitored together with the routine 21-item publicly funded newborn screening program and routine newborn vaccinations. Because late manifestations of mitochondrial DNA defects may include type 1 diabetes and lipid accumulation, the child will undergo blood glucose testing, blood cell and platelet measurements, and Oil Red staining of blood smears every six months. Health monitoring will continue until six years of age. The study will also continue annual follow-up of the child's health from 6 through 15 years of age.

Please carefully consider whether you agree to cooperate with the above examinations for follow-up of fetal and neonatal health:

☐ I agree to cooperate with examinations arranged by the Principal Investigator and attending physician during pregnancy and after delivery, including regular follow-up of the newborn (the participant is responsible for the costs of this portion).

☐ I do not agree to examinations during pregnancy and after delivery.

5. Possible Side Effects, Risks, and Management

You may experience physical, psychological, and social side effects as a result of participating in this study.

1. Physical aspects

Whether you are a healthy oocyte donor or an oocyte recipient requiring mitochondrial replacement therapy, participation in this trial includes a routine oocyte retrieval cycle. Sedation will be administered. Under transvaginal ultrasound guidance, an oocyte retrieval needle will puncture the follicles and aspirate their contents. You may experience the following common side effects of this procedure:

(1) Common: postoperative drowsiness, fatigue, and generalized weakness; nausea and vomiting within 24 hours after the procedure (20-30%). In most patients with mild nausea and vomiting, symptoms can be relieved with a small amount of antiemetic medication.
(2) Common: ovarian hyperstimulation syndrome (OHSS), with rapid abdominal distension and pain accompanied by nausea, vomiting, reduced urine output, and shortness of breath (3.1-8%).
(3) Uncommon: severe intra-abdominal bleeding, including severe abdominal pain and distension accompanied by tachycardia, hypotension, and bleeding.
(4) Pelvic infection causing abdominal pain accompanied by unexplained fatigue, fever, and increased vaginal discharge (0.03-1%).
(5) Rare: postoperative difficulty urinating due to urinary tract injury.

During the trial, the study physician and other clinical staff will regularly monitor you for side effects. Additional visits and examinations will be arranged when necessary. If you experience side effects, please inform the study physician and other study staff. The study physician will determine appropriate management based on your condition.

Even when both members of a couple have normal reproductive function, naturally conceived infants have a 4% risk of mental or physical defects and there is a 20% risk of miscarriage. Even after assisted reproductive treatment and embryo transfer, the chances of miscarriage and ectopic pregnancy are the same as those in the general naturally pregnant population. Embryo transfer involves using a speculum to open the vagina and inserting the transfer device through the cervix; a small proportion of patients may experience bleeding, infection, or other occasional complications. Because hormones are used to synchronize endometrial receptivity, minor side effects similar to those described above for oocyte retrieval may occur. After amniotic-fluid testing at 16 weeks, mild pain at the abdominal needle puncture site, temporary abdominal tightening or hardening, and uterine contractions may occur; these are described in the source consent form as normal phenomena. If mitochondrial DNA abnormalities are found after amniocentesis, termination of pregnancy before 24 weeks of gestation will be required under the study plan. If miscarriage or unexpected preterm birth occurs, the Principal Investigator and study team will fulfill their medical responsibilities by providing professional medical care and consultation.

If you experience any of the serious or dangerous side effects described above, you should promptly:
(1) Call the study's 24-hour emergency contact.
(2) Go to the nearest emergency department as needed.

2. Psychological aspects

For recipient participants requiring mitochondrial replacement therapy, participation requires a germ-cell donation treatment process and may cause psychological stress because of uncertainty during treatment. There has not yet been a successful domestic case of this treatment. This uncertainty and psychological stress may affect relationships between you and your family. Research indicates that impaired mitochondrial function in brain cells may cause neurological diseases. Although embryos produced through mitochondrial replacement therapy may compensate for the original mitochondrial functional deficiency, there remain concerns that the procedure may carry greater risks than conventional oocyte donation. You retain the right to choose the lower-risk option of oocyte donation to have a child. If the stress of treatment exceeds what you can tolerate, you may freely decide whether to participate, and you may stop participating at any time. Stopping participation will stop the treatment, and your rights and interests will not be adversely affected.

3. Social aspects

The Principal Investigator will carefully protect the confidentiality of all of your genetic research results. Taipei Fertility Center will store your genetic samples in a confidential and secure location and control access to the samples and all related information. However, it is currently impossible to predict how

disclosure of your genetic information might affect your social rights and interests, such as education, employment, or medical care. In embryos produced by mitochondrial replacement therapy, mitochondrial DNA will be genetic material from the healthy oocyte donor (present only in the ooplasm). Although the nuclear chromosomes of your future child will come from you and your spouse, the source consent form states that limitations may exist in applying current parentage-testing procedures to determine parentage, and future parentage testing may therefore have limitations. The source consent form further states that United Kingdom law removed donor anonymity for sperm and oocyte donors in 2005, allowing children born through such assisted reproductive technology to obtain basic information about the biological donor after reaching 18 years of age. If domestic law is amended in the future to change donor-anonymity rules, the rules then in effect will apply.

6. Expected Effects and Possible Benefits of the Trial; Possible Commercial Benefits

The therapy in this study is currently being discussed only in terms of medical effectiveness. Because the results of genetic research may have commercial value, patent value, or value for academic publication, if you agree to participate in this trial/research, the samples you provide, the trial/research results, and trial/research records may be used and developed by the sponsor, study institution, and/or Principal Investigator. Any potential commercial benefits derived from the research will not belong to the participant; that is, you will not receive any potential commercial benefits as a result of participating in this study.

Expected trial/research benefits

Patients with mitochondrial defects often have hematologic, muscular, or neurological disorders and may not survive to adulthood. The study anticipates that participants receiving mitochondrial replacement therapy may give birth to offspring with normal, healthy mitochondria, which may provide substantial benefit to participants. The genetic test results from this trial will be disclosed to participants before embryo transfer. The Principal Investigator will make the research findings public while protecting participants' names and personal information.

The source consent form states that a mitochondrial DNA defect level greater than 70% will result in pathogenicity. This trial aims to reduce the proportion of defective DNA through mitochondrial replacement. However, unexpected circumstances may prevent the replacement procedure from effectively reducing the proportion of defective DNA. If this occurs, the Principal Investigator will notify you and discuss whether the trial should be discontinued.

7. Other Possible Treatment Options and Explanation

For recipient participants requiring mitochondrial replacement therapy, participation requires a germ-cell donation treatment process. There has not yet been a successful domestic case of this treatment. Although embryos produced through mitochondrial replacement therapy may compensate for the original mitochondrial functional deficiency, there remain concerns that this procedure may carry greater risks than conventional oocyte donation. You retain the right to choose the lower-risk option of oocyte donation to have your own child.

8. Prohibited or Restricted Activities During the Trial

Whether you are a healthy oocyte donor or a recipient, after the Principal Investigator explains the purpose and significance of the study and you sign the consent form, you will be asked to undergo an oocyte retrieval cycle using assisted reproductive technology. During this period, please follow the anesthesia precautions for the oocyte retrieval procedure and use contraception.

9. Confidentiality and Handling of Collected Data and Specimens After the Trial/Research

Principal Investigator Dr. Chii-Ruey Tzeng will treat your information as confidential to the extent required by law. You also understand that the co-investigators, the Ministry of Health and Welfare, and the TMU-Joint Institutional Review Board have the right to inspect your information and will comply with ethical confidentiality requirements.

If this study is regulated by the U.S. FDA, the U.S. FDA may inspect relevant records, and trial-related information may be posted on ClinicalTrials.gov. The ClinicalTrials.gov website will not contain any personally identifiable information and will provide a summary of study results. You may search the website at any time.

Studies conducted in the European Union (EU) or European Economic Area (EEA) may also be required to post trial-related information on the EU clinical trials register. You may search that website at any time.

Your blood and genetic samples will be labeled with your study number. Therefore, the samples will not contain identifying information such as your name, initials, medical record number, national identification number, telephone number, fax number, or address. Researchers and scientists conducting this trial/research will not know your identity. Researchers will carefully protect the confidentiality of all of your genetic test results.

Even if requested by you or any other person, your samples will not undergo any additional testing unrelated to this trial/research.

You may freely decide whether to participate in this trial/research. The results may improve understanding of relevant genes, specific diseases, or medications. If research results are published in the future, publication will not reveal your identity.

The Principal Investigator will securely retain this signed consent form in a protected file, and it will not be attached to your medical record. Your medical record will not contain any genetic trial/research results.

Specimen handling and storage location

Your germ-cell specimens, embryo specimens derived from germ cells, blood samples, and extracted DNA will be stored at the reproductive center of this clinic. The person responsible for DNA specimen storage will retain the specimens until 15 years after completion of the trial, with destruction scheduled for December 31, 2059. Frozen embryos will be stored at the reproductive center for ten years from the date of cryopreservation. Specimens and derivatives will be destroyed once their maximum permitted storage period is exceeded.

Personnel who may use specimens and specimen-related information

In addition to Principal Investigator Dr. Chii-Ruey Tzeng and co-investigators Professor Shu-Huei Kao, Dr. Yun-Ting Kuo, Dr. Heng-Kien Au, and Dr. Ching-Wen Chang, Taipei Fertility Center researcher Wei-Fang Chang and Chief Embryologist Yung-Ling Huang may use the specimens. Your specimens will not be transferred to another institution for use without your consent.

Handling of data and specimens after the end of the study

Data:

☐ I agree to continue providing the data to Principal Investigator Dr. Chii-Ruey Tzeng and co-investigator Professor Shu-Huei Kao for other related research. Any such future research protocol must first be reviewed by the TMU-Joint Institutional Review Board, which will determine whether you must sign another consent form.

☐ I do not agree; Principal Investigator Dr. Chii-Ruey Tzeng will be responsible for destruction.

Specimens:

☐ I agree to continue providing the specimens to Principal Investigator Dr. Chii-Ruey Tzeng and co-investigator Professor Shu-Huei Kao for other related research. Any such future research protocol must first be reviewed by the TMU-Joint Institutional Review Board, which will determine whether you must sign another consent form.

☐ I do not agree; Principal Investigator Dr. Chii-Ruey Tzeng will be responsible for destruction.

10. Withdrawal and Discontinuation of the Trial

You may freely decide whether to participate in this trial/research and may withdraw your consent and leave the trial/research at any time during the study without giving any reason. Doing so will not cause any

disadvantage or affect your future medical care. You also fully understand that the Principal Investigator may discontinue the trial/research when necessary, but this will not affect the medical care provided by your physician.

If, when you decide to withdraw, the study personnel have already obtained information about you and genetic research results from this trial/research, those research data will be retained and analyzed, and Principal Investigator Dr. Chii-Ruey Tzeng will have rights to use and develop those research results. Any use beyond the original scope will require renewed informed consent from you and prior approval by the TMU-Joint Institutional Review Board. The specimens you provided will be handled according to the option you select below:

Specimens:
☐ I am willing to continue allowing the Principal Investigator to use the specimens in this trial/research. Any use beyond the original scope requires renewed informed consent from me and prior approval by the TMU-Joint Institutional Review Board. After completion of the study, the specimens shall be handled or destroyed according to the established schedule.
☐ The Principal Investigator shall destroy the specimens after I notify the study of my withdrawal (whether I decide to withdraw on my own or withdrawal is recommended by the Principal Investigator).

11. Compensation for Trial-Related Injury and Insurance

(1) Trial/research participation involves risk. If adverse reactions, side effects, or injuries occur because of the trial in accordance with the specified use or related circumstances, Taipei Fertility Center will be responsible for the related medical expenses. However, expected adverse reactions or side effects of routine treatment will not be compensated (for example, ovarian hyperstimulation syndrome or local infection caused by oocyte retrieval). If an adverse reaction, side effect, or injury occurs as a result of the study protocol, please immediately notify the Principal Investigator. Taipei Fertility Center and Taipei Medical University, a collaborating study institution, will provide professional medical care and medical consultation. Medical care for adverse reactions and side effects arising from participation in this trial/research will be provided by the relevant medical specialists on this team at each stage.

(2) By signing this consent form, you do not waive any legal rights.

This study: ☐ is insured ☒ is not insured.
If you are unwilling to accept this risk, you may decide not to participate in the study or may withdraw during the study without giving any reason, and none of your rights or interests will be affected.

12. Participant Rights and Responsibilities

All expenses related to this trial/research will be borne by the study.

You will not receive additional compensation for participating in this trial. Procedures required for mitochondrial replacement therapy include oocyte retrieval for the oocyte recipient and healthy oocyte donor, oocyte cryopreservation, mitochondrial replacement, intracytoplasmic sperm injection (ICSI), embryo culture, preimplantation chromosomal screening and embryo cryopreservation, testing the proportion of mutant mitochondrial DNA carried by embryos, and frozen embryo transfer. You will not be required to pay for medications or related surgical expenses used in the above assisted reproductive procedures. Mitochondrial replacement is a new medical technology and will not require an additional fee, and the clinic will also pay the cost of next-generation sequencing of mitochondrial DNA. Follow-up during pregnancy after embryo transfer, fetal ultrasound, amniocentesis, delivery procedures (including miscarriage-related procedures), and newborn screening are observational items in the trial and are also routine pregnancy examinations; therefore, they are not included among the items provided free of charge.

(1) This trial/research:
☐ Provides transportation reimbursement: _____ (specify the amount per visit; if payment differs by participation activity, describe separately)
☐ Provides nutrition allowance: _____ (specify the amount per visit; if payment differs by participation

activity, describe separately)

☐ Provides gifts: _____ (specify type, quantity, or value)

Any support is provided according to your participation progress/proportion and does not need to be returned if you withdraw.

☒ No subsidy or gift is provided; participation is without compensation.

(2) During the trial/research, any important finding related to your health or disease that could affect your willingness to continue participating will be provided to you promptly.

(3) If you have any questions or problems now or during the study, you may contact Dr. Chii-Ruey Tzeng, a researcher at the reproductive center of Taipei Fertility Center, at 0933-897-698.

(4) If you have questions about the nature of the research, comments concerning your rights as a participant, or suspect that you have been harmed by participating in the trial/research, you may contact the TMU-Joint Institutional Review Board at (02) 6620-2589 ext. 15313 or by email at tmujirb@gmail.com.

In addition to the circumstances described above, if the participant or the participant's legal representative, guardian, assistant, or other person authorized to provide consent has any questions or matters requiring discussion concerning current, future, or past research, please contact the TMU-Joint Institutional Review Board. A person independent of the research will be made available to provide information. If needed, contact the TMU-Joint Institutional Review Board at (02) 6620-2589 ext. 15313 or tmujirb@gmail.com.

13. Signatures

Investigator Statement

I certify that I, or a member of my research team who is authorized to perform this step, have explained this trial/research, including its purpose, procedures, possible risks and benefits of participation, and currently available alternative treatments. All questions raised by the participant have been answered.

Researcher Explaining the Consent Form - Printed Name: _____
Signature: _____
Date: _____

Participant Statement

The above information has been explained to me. I have had the opportunity to ask questions about this study. I understand the information and agree to participate in this research study. A copy of the consent form has been provided to me. If I have questions later, I may contact researcher Wei-Fang Chang at the reproductive center of Taipei Fertility Center.

Participant - Printed Name: _____

Date of Birth: _____ / _____ / _____

Signature: _____

Date: _____

Legal Representative / Guardian / Assistant / Person Authorized to Consent - Printed Name:

_____ (if applicable)

Relationship to Participant (circle one): Spouse / Father / Mother / Son / Daughter / Other: _____

Signature: _____

Date: _____

For a participant without legal capacity (a minor under seven years of age or a person under guardianship), the legal representative shall sign; for a person under guardianship, the guardian serves as the legal representative.

For a participant with limited legal capacity (a minor aged seven years or older, or a person who, due to mental disorder or other cognitive impairment, has been declared by a court to require assistance because the person's ability to express intent, receive expressions of intent, or understand the effects of such expressions is clearly insufficient), consent from both the participant and the legal representative or assistant shall be obtained.

Persons authorized to provide consent shall sign in accordance with the laws and regulations applicable to the trial/research. Where the proviso of Article 79, Paragraph 1 of the Medical Care Act or the proviso of Article 12, Paragraph 1 of the Human Subjects Research Act applies, the exercise of consent rights shall be governed respectively by Article 79, Paragraph 2 of the Medical Care Act, Article 5 of the Regulations on Human Trials, or Article 12, Paragraphs 3 and 4 of the Human Subjects Research Act.

I. Human trials involving new drugs, new medical devices, or new medical technologies (Article 5 of the Regulations on Human Trials):
(1) Spouse; (2) parents; (3) adult children living with the participant; (4) grandparents living with the participant; (5) siblings living with the participant; (6) other relatives who have lived with the participant during the most recent year.

II. Human subjects research (Article 12 of the Human Subjects Research Act):
(1) Spouse; (2) adult children; (3) parents; (4) siblings; (5) grandparents.

Written consent by a person in one of the above categories may be provided by one person. If persons in the relevant categories disagree, priority shall follow the order listed above. Among persons at the same level of priority, the closer degree of kinship takes precedence; if the degree of kinship is the same, a cohabiting relative takes precedence; if there is no cohabiting relative, the older person takes precedence.

Witness to Oral Consent

(If the participant cannot read the above information and it is explained orally by the researcher, another witness must be present.)

I hereby certify that the Principal Investigator and researchers have fully explained the contents of this trial/research to the participant.

If the participant, legal representative, guardian, assistant, or person authorized to provide consent cannot read, a witness shall be present for all discussions concerning informed consent. After confirming that consent is given entirely voluntarily, the witness shall sign and date the informed consent form. Trial/research personnel may not serve as witnesses.

Witness - Printed Name: _____ (study personnel may not serve as witness)

National Identification No.: _____

Contact Telephone: _____

Mailing Address: _____

Signature: _____

Date: _____

Principal Investigator Statement

Principal Investigator / Co-Investigator - Printed Name: _____

Signature: _____

Date: _____

Translator's Note

This English document is a faithful translation of the Chinese TMU-JIRB Form050 informed consent form, Version V8 dated February 12, 2025. The study content, participant options, contact information, risk statements, storage periods, and signature fields have been retained. Where the source wording could be interpreted in more than one way, the translation preserves the meaning of the source rather than introducing new study information.