Informed Consent Form (ICF)

Precision Biotechnology

Protocol Version: PB-2018-V12 **Protocol Date:** 2021-03-12

Clinical Trial Protocol

Phase I, open-label study to evaluate safety and tolerability of PB101 in combination with standard treatment, EGFR-TKI, in EGFR-mutated advanced non-small cell lung cancer

Investigational Product Name: PB101 Autologous Immune Cell Therapy

Indication: Patients with histologically confirmed EGFR-mutated stage III/IV NSCLC

Study Type: Phase I, single-center, single-arm, open-label study

Protocol ID: PB-2018

Planned Study Start Date: September 2018
Planned Study Early Termination Date: August 2019
Study Completion Date: December 2023

Principal Investigator:
Dr. Kuan-Der Lee, Department of Hematology and Oncology, Taipei Medical University Hospital

Co-Investigators:
Dr. Chen-Liang Tsai, Division of Pulmonary and Critical Care Medicine, Department of Internal Medicine, Tri-Service General Hospital, Taipei, Taiwan.

Sponsor: Precision Biotechnology Co., Ltd.
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24-Hour Emergency Contact Persons [18]

Role	**Telephone (Mobile Phone Number)**
Principal Investigator: (Required) Kuan-Der Lee	0987-710-470
Co-Investigator: (Optional)	【Mobile Phone Number】
Sub-Investigator: (Optional)	【Mobile Phone Number】
Study Nurse or Assistant: (Optional)	【Mobile Phone Number】

Subject Information

Subject Name: 【Subject Name】 [23]**Gender:** ☐Male ☐Female [24]**Date of Birth:** 【Year】 Year 【Month】 Month [25]**Contact Phone Number:** 【Phone Number】 [26]

☐**Legal Agent** ☐**Assisted Person or** ☐**Person with Consent Authority Name:** 【Name】 [27]**Relationship to Subject:** ☐Spouse ☐Father ☐Mother ☐Son ☐Daughter ☐Other: 【Other Relationship】 [28]**Gender:** ☐Male ☐Female [29]**Date of Birth:** 【Year】 Year 【Month】 Month [30]**Contact Phone Number:** 【Phone Number】 [31]

I. Invitation to Participate

You are invited to participate in this human trial/research[32]. This consent form provides you with information related to this study[33]. The Principal Investigator or authorized research personnel will explain it to you in detail and answer any questions you may have. After careful consideration, you will be asked to sign[34]. You can only participate in this trial/study after you have signed this consent form[35].

II. Brief Summary of the Study

This trial is funded by **【Company Name】** and commissioned to **【CRO Company Name, if applicable】**. It is a **【Multi-center/Taiwan Single Center/Taiwan Multi-center】** clinical trial[36]. It is projected to enroll **【XX】** participants globally, **【XX】** participants in Taiwan, and **【XX】** participants at our hospital and **【XXX】** hospital[37].

Product Information: Drug name, brief mechanism of action, route of administration, indication under development, current phase of development, and experience of use (e.g., number of people used)38. (If there are other non-study indications under development, they may also be explained) 39.

Product Market Status: Not yet marketed globally or approved countries, approved indications; current status in Taiwan40.

Status of same-class products: (Optional) 41

The therapeutic effect of the (Research Drug Name) used in this trial for your disease is not yet confirmed[42].

Please state the approximate duration of the entire study: **【Number】** months or years, and the location(s) of enrollment[43].

III. Study Objective

【The description in this section must convey the meaning of Article 22, Paragraphs 1 and 2 of the Good Clinical Practice Regulations. It should primarily introduce to the subject what you are going to do, describe the correlation between the study product, medical technology, or other research and the trial subject. The content does not need to be overly detailed or use professional terminology, as general subjects may find it confusing if they cannot understand it.】 [44]

This trial is the first human use of (Drug Name). (Use **bold** text if applicable) [45]

IV. Eligibility Criteria for Study Subjects

The physician or relevant research personnel executing this research protocol at OO Hospital will discuss the necessary conditions for your participation in this study[46]. You must cooperate and truthfully inform us of your past health conditions[47]. If you have conditions that do not meet the criteria for participation, you will not be able to join this research protocol[48].

※ Inclusion and exclusion criteria must be the same as those in the protocol and application form. [49]

Inclusion Criteria for participating in this research protocol: [50]**※ If there is a control group, please describe the inclusion criteria for different groups in separate paragraphs.** [51]

Exclusion Criteria: You will not be able to participate in this research protocol if you have any of the following conditions: 52※ Examples of not meeting inclusion criteria: not suffering from or suffering from OO disease, or having consumed alcohol or taken OO medication within O months... 53

【Inform the subject of the inclusion and exclusion criteria in plain language. Contents considered contraindications or that might influence participation must be listed using language the subject can understand, avoiding difficult medical jargon. Conditions determined by medical professionals for screening subjects do not necessarily need to be listed.】 54

Example: The physician or research personnel for this research protocol will discuss the necessary conditions for your participation in this study. You must cooperate and truthfully inform us of your past health conditions. If you have conditions that do not meet the criteria for participation, you cannot participate in this research protocol. [55]

Inclusion Criteria: [56]

- You must be 20 years of age or older. (Adulthood in Taiwan is 20 years old) [57]* You must not have donated more than 500cc of blood in the past 3 months. [58]* You must be able to return for visits at certain specific times during the 24 months of the trial. [59]

Exclusion Criteria: If you have any of the following conditions, you will not be

able to participate in this protocol: [60]* You have participated in other research protocols within the previous month. [61]* You have a history of drug dependency or heavy alcohol consumption. [62]* You are currently pregnant or planning to become pregnant. [63]

V. Study Methods, Procedures, and Related Examinations/Tests

(I) Study Methods and Procedures

【Explain the steps of the protocol implementation: how often you need to return for visits, how many milliliters (cc) of blood will be drawn, what examinations will be performed (e.g., what kind of specimen is collected, frequency and quantity of blood draw; site of specimen collection, size of tissue collected, interval between collection times, and frequency of collection), and the duration of the trial. Explain the probability of random assignment to each treatment group and the approximate number of subjects. It is recommended to present this information primarily with **tables (flowchart or study schedule)** and supplement with text.】 [64]

【If the trial uses methods other than drug trials or specimen collection, please specify the trial methods and procedures. For example, if subjects are asked to perform certain exercises to observe the results, the required exercise items, time, location, number of repetitions, etc., must be stated.】 [65]

【If subjects are required to fill out questionnaires, this section should explain the expected content of the questionnaire, the time required, the location of completion, and whether it is anonymous.】 [66]

【Explain terms like randomization, double-blind, and placebo using simple, easy-to-understand language (junior high school/9th grade level). For example: "Placebo" looks the same as the investigational drug but contains no active ingredient. "Randomization" means who is assigned to take the investigational drug or "placebo" is decided by chance, like flipping a coin. "Double-blind" means neither you nor the study physician knows which one you are taking. "Open-label" means the physician will tell you which group you are assigned to

and which drug you are using.】 [67]

【Clearly describe the special examination procedures and associated risks. Content that might influence the subject's willingness to participate, once known, must be included. Avoid professional jargon as much as possible.】 [68]

(II) Study Related Examinations/Tests (Specimen Collection and Management)

【If specimen collection is required, please explain the method, type, quantity, and collection site of the specimen, the custodian of the specimen, and the user of the specimen. Other important matters related to specimen collection, medical record review, follow-up examinations, tests, or condition information should be included as required by each research protocol.】 69【Handling of remaining specimens (simpler handling, e.g., specimens are only used for this study and destroyed after the study ends).】 70

【For gene studies, please use the "Informed Consent Form for Gene Research" template. Gene research must comply with the "Human Biobank Management Act." If the research involves human specimen collection, it must comply with the "Human Subjects Research Act."】 71

(III) How Data/Specimens in the Study Will be Handled and Storage Location

【If the research protocol does not involve specimens, please note "No specimens used" after items (III) and (IV) below.】 [72]

Unit and personnel responsible for using and preserving data: 【Unit and Personnel Name/Title】 [73]**Data processing steps and storage method and location:** 【Processing Steps and Location】 [74]

(IV) Specimen Handling and Storage Location

Unit and personnel responsible for using and preserving specimens: 【Unit and Personnel Name/Title】 [75]**Specimen processing steps and storage method and location:** 【Processing Steps and Location】 [76]

【In addition to stating the personnel authorized to use the specimens in accordance with the law, the PI must also explain whether other relevant

academic researchers will be legally authorized to use them. If so, the research collaborative relationship between them and the role they will play in this project, the institution, research unit, and personnel's names and locations must be described. Ethical hours and a signed statement must be provided as required by the Review Board.】 [77]

VI. Possible Side Effects, Risks, Discomforts, Incidence Rates, and Management Methods

※ (Please write according to the protocol content) [78]

(I) Risks Related to the Investigational Drug (Side Effects of the Drug Used in This Trial)

All investigational drugs may cause side effects, and you may or may not experience the side effects listed below[79].

- **Very Common (Incidence $\geq 1/10$):** 【List side effects】 [80]
- **Common (Incidence $1/100 \leq \text{rate} < 1/10$):** 【List side effects】 [81]
- **Uncommon (Incidence $1/1000 \leq \text{rate} < 1/100$):** 【List side effects】 [82]
- **Rare (Incidence $1/10000 \leq \text{rate} < 1/1000$):** 【List side effects】 [83]
- **Very Rare (Incidence $< 1/10000$):** 【List side effects】 [84]
- **Observed Serious Side Effects and Management:** 【Description and Management】 [85]

During the trial, the study physician and other study personnel will regularly monitor you for the occurrence of side effects[86]. If necessary, you will be scheduled for additional visits and tests[87]. If you experience side effects, please inform your study physician and other study personnel[88]. The study physician will decide on appropriate treatment based on your condition[89].

(II) Risks Related to the Trial Procedure

During the process of the trial, you may feel uncomfortable[90]. Some tests may carry risks, such as: collecting blood samples, ECG testing, liver biopsy, etc. [91]

Example:

* Collecting blood samples: Drawing blood from the arm may cause local pain, bruising, dizziness, and in very rare cases, infection92. The management is to press the venipuncture site for at least 5 minutes after blood draw; bruising can be relieved by warm compress; dizziness requires resting quietly or lying flat93. If the blood draw site becomes infected, please contact the Principal Investigator, Dr. 【PI Name】, immediately94. Tri-Service General Hospital will provide you with necessary medical care95.

* Fasting: May cause dizziness, headache, stomach discomfort, or fainting96. The management is to rest quietly and eat as soon as possible after the blood draw97.

* ECG patches: May cause skin redness or itching and mild discomfort, requiring no treatment98.

* Liver biopsy: Potential risks include abdominal hemorrhage, liver hematoma, bile duct bleeding, bacteremia, biliary peritonitis, pleurisy, or injury to adjacent organs, with an incidence of 0.06% to 0.32%99. In the worst case, it may lead to death, but the chance is low (below $1/10000$ to $1/12000$)100. Medical staff will monitor your condition at all times after the examination and provide immediate treatment101.

If you experience any of the above serious or dangerous side effects, you should promptly: [102]

1. Call the 24-hour emergency contact person[103].
2. Go to the nearest emergency room as needed[104].

【The description in this section must convey the meaning of Article 22, Paragraph 18 of the Good Clinical Practice Regulations. Clearly explain the probability of side effects based on past data, and how high the risk is for

participating in the study. Therefore, the incidence rate of side effects from past data must be clearly explained, preferably described with numbers. It must not be concealed to increase subject participation. If the subject participates and later finds out the study physician concealed or deceived, the consequences may be severe.】 [105]

【If there is a possibility of death, infertility, or causing major harm, or if there is an expected risk or inconvenience to the subject, embryo, infant, or nursing child, it must be clearly stated. This includes: Physiological aspects—blood draw may cause minor effects such as short-term discomfort, bruising, bleeding, swelling, or infection at the venipuncture site; whether collecting tissue specimens will cause discomfort, infection, bleeding, etc. Of course, the methods for managing risks or emergencies and contact information must also be clearly explained, along with reassuring words that the physician will do their best to treat. In addition, the possible anticipated conditions and reasons for the subject's termination of participation in the trial must also be explained to protect the subject's rights.】 [106]

VII. Other Possible Treatments and Explanations

【The description in this section must convey the meaning of Article 22, Paragraph 9 of the Good Clinical Practice Regulations. Let the subject know that participation is not mandatory. If the subject chooses not to participate, what are the current standard treatment methods, and the advantages and disadvantages of each method.】 [107]

【Other important matters related to specimen collection, medical record review, follow-up examinations, tests, or condition information should be included as required by each research protocol.】 [108]

【It is not appropriate to only write "Your physician will tell you about other possible treatment methods in detail." Drug names and surgical names must be listed, though detailed treatment content can be omitted. If there are no alternative therapies, the limitations of standard care must still be explained.】 [109]

Example 1: Your participation is not mandatory. If you choose not to participate in the study, the standard treatments or other possible treatment methods available to you are 【**Drug Name(s)**】 and/or 【**Surgical Name(s)**】, which have shown 【**Past human use experience/results**】 in past human use experience[110].

Example 2: There is no alternative therapy. Currently, for the 【**Disease Name**】 disease, standard treatment is limited to only slightly delaying the time of death and cannot treat the cause[111].

VIII. Expected Benefits of the Study

Example 1 (With Human Use Experience): Past human use experience has shown 【**Past human use experience/results**】[112]. Even with the above information, there is no guarantee that your condition will definitely improve or that you will receive other direct personal benefits by participating in this trial[113]. However, the results of the trial may be helpful to the sponsor and/or the Principal Investigator, and may benefit other patients with the same disease in the future[114].

Example 2 (No Human Use Experience): There is currently no experience with using **(Investigational Drug)** in humans[115]. However, animal trials have observed 【**Animal trial results**】 response, and it is speculated that **(Investigational Drug)** may 【**Hypothesized effect**】[116]. Even with the above information, there is no guarantee that your condition will definitely improve or that you will receive other direct personal benefits by participating in this trial[117]. However, the results of the trial may be helpful to the sponsor and/or the Principal Investigator, and may benefit other patients with the same disease in the future[118].

【The description in this section must convey the meaning of Article 22, Paragraph 8 of the Good Clinical Practice Regulations. Explain the benefits of participating in the study, or the expected effects based on past data, and the scientific contribution value of the research. Describe the trial results of the study product, medical technology, or other domestic/international research, preferably described with numbers. The content must be well-founded and must

not exaggerate the efficacy. If the subject cannot obtain clinical benefit, they should also be informed.】 [119]

IX. Prohibitions, Restrictions, and Necessary Subject Cooperation During the Study

※ (Please write according to the protocol content) [120]

Example: While you are participating in this trial/research, for your safety, please cooperate with the following: 121* You should not participate in other clinical research122.

* Provide accurate information regarding your past medical history, medical records, and current condition123.

* Use the investigational drug correctly as instructed124.

* Do not give the investigational drug to others125.

* Store the investigational drug at 【Storage Method: Room temperature, refrigerated, etc.】, and ensure children cannot access it126.

* Return any unused investigational drug and empty drug packaging (as per protocol)127.

* For your safety, please return for your appointments as scheduled128. If you cannot come at the originally scheduled time, please contact the study personnel129.

* Fill out the diary/log truthfully to record your condition (as per protocol)130.

* For your safety, please inform the study physician of any uncomfortable symptoms you experience131.

* Do not take other medications without permission, including over-the-counter drugs, traditional Chinese medicine/herbal remedies, health foods, etc.132. If you need to use other medications, please discuss it with your study physician (as per protocol)133.

* Drug-related information (whether to fast, timing of administration, restricted

medications, and drug interactions, etc.) (Specific items, such as CYP Inhibitor, Inducer, etc., can be listed) (as per protocol)134.

* If other physicians prescribe new drugs or change your current medications, even for illnesses unrelated to the trial, please inform the study physician135.

* If you have any questions, please do not hesitate to raise them directly with your study personnel (PI, Nurse)136.

* Do not become pregnant or cause pregnancy137. If there is a possibility that you or your partner can become pregnant or cause pregnancy, please use highly effective contraception during the trial, such as IUDs, hormonal contraceptives (as per protocol)138.

* Animal studies show that the investigational drug may affect fertility139. Animal studies show that the use of the investigational drug during the trial may cause abnormal fetal growth and development (depending on whether there is reproductive toxicity or teratogenicity data)140.

* Please carry your Trial Card with you141. It contains your trial-related information, and you need to show this card to any healthcare personnel, including personnel at other medical institutions, so they know you are participating in this trial (if applicable)142.

* If you seek temporary medical care at another medical institution, please inform the medical personnel that you are using an investigational drug143.

* If you have been hospitalized or your medical condition has changed between two visits, or if you wish to stop using the investigational drug (or have already stopped), please notify your study physician144.

【The description in this section must convey the meaning of Article 22, Paragraphs 5 and 7 of the Good Clinical Practice Regulations. Explain the prohibitions or restrictions on activities that the subject needs to cooperate with during the trial, such as what foods or medications are prohibited, the need for contraception, not driving, not drinking alcohol, etc.】 [145]【Matters requiring cooperation, such as when to take the medication, how often to return for visits, when and how much blood to draw, what specimens to collect, what

examinations to perform, etc.】 [146]

X. Costs to be Borne by the Subject

You do not need to bear any costs for participating in this research protocol[147].

XI. Subsidies for Participating in the Research Protocol

【Explain the transportation fees or nutritional fees the subject can receive. A detailed explanation of the method of proportional distribution of payment, payment progress, and amount must be provided.】 [148]【According to Article 39, Paragraph 7 of the National Health Insurance Act, the cost of "human trials" is not covered by National Health Insurance.】 [149]【If it is a gift or voucher, please state the price of the gift (voucher), explain the timing of the provision, and whether it will be provided or other subsidies if the subject fails to complete the trial.】 [150]

XII. Subject Rights

If new information is discovered during the research process that may affect your willingness to continue participating in the clinical trial research protocol, any significant finding will be provided to you immediately[151].

If you experience any discomfort or have questions due to your participation in this study, you may contact the Principal Investigator at any time152.

Principal Investigator: 【PI Name】 153Telephone: 【Phone Number】 15424-Hour Contact Phone Number: 【24-Hour Phone Number】 155

If you have concerns about your personal rights related to participating in the research, you may contact the Tri-Service General Hospital Institutional Review Board (IRB)156:

Telephone: 02-8792-3311 ext. 17763 157Hotline: 02-2793-6995 158E-mail: tsghirb@ndmctsgh.edu.tw 159Mailing Address: IRB, Room 5113, 5th Floor,

Medical Building, Tri-Service General Hospital, No. 325, Section 2, Chenggong Rd., Neihu Dist., Taipei City 114202, Taiwan 160

【Article 10 of Chapter 1 of the Good Clinical Practice Regulations: The trial sponsor shall not coerce or improperly influence the subject regarding the subsidy and payment method the subject can receive. The subsidy for the subject shall be paid proportionally based on the progress of the clinical trial and shall not be paid only upon completion of the trial. However, this restriction does not apply to small amounts.】 [161]

XIII. Protection of Privacy

【Please inform the subject about the data processing method, e.g., who (title/name) processes and stores the data you provide, where the data is stored, on whose (title/name) computer, that the computer files are encrypted, where the related documents are stored in a locked cabinet, and who (title/name) keeps the key.】 [162]

The Principal Investigator will maintain confidentiality regarding your test results and physician's diagnosis[163]. A study number will replace your name[164]. Except for legal investigations by relevant agencies, the Principal Investigator will carefully maintain your privacy[165].

【If the information obtained from the research specimens may affect the specimen provider and their relatives or ethnic group, it needs to be emphasized.】 [166]

The data obtained from the trial research may be published in academic journals, but your name will not be disclosed, and the Principal Investigator will cautiously maintain your privacy[167]. If the results of the trial are published, the subject's identity will remain confidential[168].

The health authorities, the trial sponsor, and the IRB of this hospital have the right to inspect your data according to the law without compromising your privacy[169].

Because this trial requires the exclusion of individuals infected with Human

Immunodeficiency Virus (HIV), you will undergo Human Immunodeficiency Virus (HIV) testing[170]. You can only participate in this trial if the test result is negative[171]. If the test result is positive (including false positives), this trial will provide subsequent medical referral or consultation, and upon confirmation, the case needs to be reported to the competent authority in accordance with the law (Act for the Prevention and Control of Infectious Diseases and the Protection of the Rights of HIV-Infected People)[172].

☐ I agree to undergo the testing173.

☐ I disagree to undergo the testing174.

Subject Signature: 【Subject Signature】 [175]**Date:** 【Year】 Year 【Month】 Month 【Day】 Day [176]

※ (Applicable only if HIV testing is required. Please delete item (II) if not applicable.) [177]

XIV. Withdrawal and Termination of the Research Protocol

You are free to decide whether to participate in this trial[178]. You may also withdraw or terminate your consent and withdraw from the trial at any time during the trial process without giving any reason, and this will not cause any unpleasantness or affect the medical care provided to you by the physician in the future[179].

For your safety, you must withdraw from the trial if the following circumstances occur: [180]**Withdrawal Conditions:** 【List withdrawal conditions】 [181]

If significant new information (meaning information related to your rights or affecting your willingness to continue participating) arises during the execution of the trial, you will be notified and further explanation will be provided[182]. You are free to decide whether to continue participating after reconsideration, and this will not cause any unpleasantness or affect the medical care provided to you by the physician in the future[183].

The Principal Investigator or the sponsor may also terminate the entire trial when

necessary[184].

When you withdraw from this trial or the PI determines that you are unsuitable to continue participating, the data obtained before withdrawal will be retained and will not be removed[185]. After withdrawal, you can choose how to handle the specimens you previously provided and whether to agree to the Principal Investigator or sponsor continuing to collect your data[186].

Regarding the specimens I previously provided: 187☐ I agree to continue authorizing the use for research related to the disease of this trial188. If the use exceeds the scope of the original written consent, I will be required to give my consent again189.

☐ I disagree to continue authorizing the use for this trial190. However, to ensure the accuracy of the completed tests, I agree that the trial-related specimens can be re-confirmed by the laboratory before being destroyed191.

☐ I disagree to continue authorizing the use for this trial192. Please destroy my previous trial-related specimens starting from the date of my withdrawal193.

Allowing the Principal Investigator or sponsor to continue collecting my data after withdrawal, such as obtaining subsequent medical processes and laboratory test results from my medical records194. The confidentiality of your privacy and personal data will still be maintained during the period of continued data collection195.

☐ I agree to data collection196.

☐ I disagree to the continued collection or review of my data for this trial197.

XV. Compensation for Injury and Insurance

If damage is caused by an adverse reaction according to the clinical trial protocol set for this study, the **【Sponsor/PI's Hospital: Please specifically state the responsible sponsor; if there is no sponsor, please fill in the hospital to which the PI belongs; if the sponsor is a foreign company or institution, the domestic agency or the institution responsible for the**

domestic execution of the trial shall be jointly responsible with the foreign sponsor】 shall be responsible for compensation for the damage[198]. However, foreseeable adverse reactions documented in this Informed Consent Form are not eligible for compensation[199].

If an adverse reaction or damage occurs according to the clinical trial protocol set for this study, this hospital is willing to provide professional medical care and consultation[200]. You do not need to bear the necessary medical expenses for treating the adverse reaction or damage[201].

Other than the compensation and medical care in the preceding two paragraphs, this study does not provide any other form of compensation[202]. If you are unwilling to accept such risks, please do not participate in the trial[203].

You will not waive any legal rights by signing this consent form[204].

This study **has (or has not)** purchased human trial liability insurance[205]. *(Note: Whether to include insurance-related matters is decided by the trial sponsor and the trial institution.)* [206]

XVI. Data Handling Method After Study Completion

(I) Nature of the preserved data: 【Nature of data】 [207]**(II) Preserver:** 【Preserver Name/Title】 [208]**(III) Storage location:** 【Storage Location】 [209]**(IV) Method of maintaining confidentiality:** 【Confidentiality Method】 [210]**(V) Data retention period:** 【Retention Period and Handling/Confidentiality Method Upon Expiration】 [211]

XVII. Specimen Handling Method After Study Completion

※ Please choose one of the following explanations based on the trial protocol. Please delete the instructional and inapplicable examples after understanding. [212]

※ If this study does not retain remaining specimens after the trial ends, please only state that this trial does not retain remaining specimens, and all

specimens will be destroyed after the trial ends (in which case, no options need to be provided). [213]

Example: This trial does not retain remaining specimens[214]. Your remaining specimens will be destroyed by the PI, Dr. OOO, of Tri-Service General Hospital after the trial ends[215].

※ If retention is required, please provide the following three $\Box$ options for the subject to choose the storage method. [216]**※ If it is a multi-national, multi-center trial, please state the country of storage, laboratory name and address, retention period, and who is responsible for destruction after the trial ends.** [217]

Example: Please select one of the following options: [218]

☐ **I agree** to the preservation of my remaining specimens[219]. After the trial ends, they will be stored in the **【Laboratory Name】** laboratory of Dr. **【Physician Name】** for **【Number】** years[220]. The PI, Dr. OOO, of Tri-Service General Hospital will be responsible for their destruction upon expiration of the retention period[221].

☐ **I disagree** to the preservation of my remaining specimens[222]. They will be destroyed by the PI, Dr. OOO, of Tri-Service General Hospital after the trial ends[223].

☐ **I agree** to the preservation of my remaining specimens in accordance with the law by the Tri-Service General Hospital Human Biobank after the trial ends[224]. (You will be asked to sign the Human Biobank Participant Consent Form simultaneously with this consent form) [225]*(If the PI provides this option to the subject, please contact the "Human Biobank Administration Center 02-8792-3311 ext. 16744" in advance.)* [226]

XVIII. Potential Commercial Interests Derived from the Study

Example 1: The information obtained from this trial may lead to discoveries, inventions, or the development of commercial products[227]. All these rights belong to the trial sponsor[228]. You and your family will not receive any financial

benefit or monetary compensation, or possess the ownership of the aforementioned inventive results due to the research results, inventions, or other discoveries from this information[229].

Example 2: The information obtained from this trial may lead to discoveries, inventions, or the development of commercial products[230]. You and your family may receive financial benefit or monetary compensation, or possess the ownership of the aforementioned inventive results due to the research results, inventions, or other discoveries from this information[231].

Example 3: This study is not expected to generate patent rights or other commercial interests[232].

XIX. Signature of Personnel Explaining the Consent Form

(The research personnel authorized by the PI to explain the consent form) [233]The research personnel has explained in detail the nature and purpose of the research methods, as well as the possible risks and benefits in this protocol, and has answered the subject's questions[234].

Signature: 【Signature of Explainer】 [235]**Date:** 【Year】 Year 【Month】 Month 【Day】 Day [236]

XX. Signature of Principal Investigator/Co-Investigator/Sub-Investigator

(If the person explaining the consent form is the PI, Co-Investigator, or Sub-Investigator, only sign in the PI column) [237]

☐Principal Investigator / ☐Co-Investigator / ☐Sub-Investigator [238]**Signature:** 【Signature of PI/Co-I/Sub-I】 [239]**Date:** 【Year】 Year 【Month】 Month 【Day】 Day [240]

XXI. Signature of Subject

After the explanation, I have thoroughly understood the research methods and

the possible risks and benefits mentioned above[241]. My questions regarding this trial have also been explained in detail[242]. After sufficient time for consideration and reading the consent form, I agree and voluntarily participate in this trial/research protocol, and I will keep a copy of the consent form[243].

Signature: 【Subject Signature】 [244]**Date:** 【Year】 Year 【Month】 Month 【Day】 Day [245]

XXII. Signature of Legal Agent/Assisted Person/Person with Consent Authority

※ Items (IV) to (V) below can be adjusted and deleted if the study will not enroll subjects who are legally incompetent (limited/no legal capacity), confused, or have mental/intellectual disabilities, or if the subject, legal agent, assisted person, or person with consent authority are all unable to read. [246]

☐Legal Agent ☐Assisted Person ☐Person with Consent Authority [247]**Signature:** 【Signature of Legal Agent/etc.】 [248]**Date:** 【Year】 Year 【Month】 Month 【Day】 Day [249]

Relationship to Subject: ☐Spouse ☐Father ☐Mother ☐Son ☐Daughter ☐Other: 【Other Relationship】 [250]

(The consent of a subject who is legally incompetent (minor under 7 years old or person under guardianship) shall be given by the legal agent; the guardian shall act as the legal agent for a person under guardianship. The consent of a subject with limited legal capacity (minor aged 7 or above, or a person who has received assistance declaration due to mental illness or other mental defects that significantly impair their ability to express or receive intention, or discern the effects of their intention) shall be obtained from both the subject and the legal agent or assisted person. For subjects aged 7 or above but under 12, a separate children's consent form must be added, and their assent obtained. The consent of a subject who is not legally incompetent or with limited legal capacity but is confused or has mental/intellectual disabilities and cannot communicate and

make judgments effectively shall be given by the person with consent authority.) [251]

(Order of the person with consent authority: (1) Spouse. (2) Adult children. (3) Parents. (4) Siblings. (5) Grandparents. Written consent given by a relative in the preceding paragraph may be given by one person; if the relatives' expressions of intent are inconsistent, their priority shall be determined according to the preceding order. For persons of the same priority, the closer kin shall prevail; if the kinship is the same, the cohabiting relative shall prevail; if there is no cohabiting relative, the elder shall prevail.) [252]

XXIII. Witness

Witness 1 Printed Name: 【Witness 1 Name】 [253]**Date:** 【Year】 Year 【Month】 Month 【Day】 Day [254]**Contact Phone Number:** 【Witness 1 Phone Number】 [255]

Witness 2 Printed Name: 【Witness 2 Name】 [256]**Date:** 【Year】 Year 【Month】 Month 【Day】 Day [257]**Contact Phone Number:** 【Witness 2 Phone Number】 [258]

- ※ **Required if the subject, legal agent, or person with consent authority are all unable to read (e.g., foreign nationals, elderly persons, etc.).** The witness must be present during all discussions regarding the informed consent form and confirm that the consent of the subject, legal agent, or person with consent authority is entirely voluntary[259]. The witness should sign the informed consent form and record the date[260].
- ※ **If the subject is conscious but unable to sign in person and no relatives or associates are present, a fingerprint may be used as a substitute for a signature, but two witnesses are required.** [261]
- ※ **Foreign caregivers, colleagues from the same department as the executing unit, and trial/research personnel shall not serve as witnesses.** [262]

XXIV. Other Matters

The person explaining the consent form may write down other relevant matters to remind the subject during the explanation263.

【Other matters to be filled in】