SUBJECT INFORMATION SHEET AND INFORMED CONSENT FORM

Sponsor:	Gan & Lee Pharmaceuticals USA
Protocol No:	GL-GLAT1-3001
Protocol Title:	**AN OPEN-LABEL, RANDOMIZED, MULTICENTER, PHASE III STUDY TO COMPARE THE IMMUNOGENICITY, EFFICACY, AND SAFETY OF GAN & LEE PHARMACEUTICALS INSULIN GLARGINE INJECTION TO LANTUS® (INSULIN GLARGINE INJECTION) IN ADULT SUBJECTS WITH TYPE 1 DIABETES MELLITUS**
Investigator:	
Address:	
Phone:	

You are being invited to participate in a research study. It is up to you to decide if you wish to participate. Before you decide if you want to take part in this study it is important for you to understand why the research is being done, how your information will be used, what the study will involve, and the possible benefits, risks and discomforts. Please take time to read the following information carefully and discuss it with your doctor.

This study is sponsored by Gan & Lee Pharmaceuticals, USA (the "Sponsor").

Why is this study being done?

The purpose of this study is to investigate immunogenicity (capacity to cause reaction of the immune system), safety, and effectiveness of the Sponsor's Insulin Glargine in comparison with Lantus® insulin glargine for treatment of patients with Type 1 Diabetes Mellitus. This is an equivalence research study, meaning that the study will investigate whether the Sponsor's Insulin Glargine is biosimilar to Lantus®, for treatment in patients with Type 1 Diabetes Mellitus. A biosimilar medicine is a biological medicine that is similar to an already approved biological medicine. Insulin Glargine is a biosynthetic insulin analog with a longer duration of action than human insulin. The Sponsor's Insulin Glargine is a proposed biosimilar to the reference drug Lantus® Insulin Glargine. The Sponsor's Insulin Glargine is an investigational drug, meaning that it has not been approved by the regulatory authorities in (insert country).

Approximately 550 subjects will participate in this research study.

Do I have to take part?

It is up to you to decide whether or not to take part. If you decide not to participate in the clinical study, your decision will not affect the medical treatment and care you are entitled to receive. After reading this Informed Consent Form ("ICF"), if you do decide to take part, you will be asked to indicate your consent to participate in this study by signing this ICF. If you do not sign this form, you will not be allowed to participate.

If you decide to take part you are still free to withdraw from study assessments and/or study treatment at any time. This option is described in more detail in a later section of this document.

Who can be in the study?

Subjects in this study must be between the ages of 18 and 75 years with a confirmed diagnosis of Type 1 Diabetes Mellitus.

How long will I be in the study?

Your participation in this study will last 26 weeks with a follow up phone call 4 weeks after completion.

What will happen to me if I take part?

In this study, you will be put into a group to receive either the Sponsor's insulin glargine or Lantus®. The chances of you receiving the investigational drug is 50/50 (like flipping a coin).

To participate in this study, there are several examinations, tests, and/or procedures as described below, that will be performed at different times before, during, and after your treatment with the Sponsor's Insulin Glargine or Lantus® and you will be asked to visit your Study Doctor's office at various times during the study.

Visit 1: Screening Visit

During this visit, you will undergo a series of screening tests to determine if you are eligible to participate in the study. The Screening Visit can occur up to 2 weeks before receiving the first dose of study medication. The following screening examinations, tests, or procedures will be performed after you have given consent to participate in this study:

- You will be asked about your general health and any new side effects, new symptoms or change in existing symptom(s) or complaints you experience
- Your medical history (including diabetes mellitus and thyroid disease history), the medicines (including insulin) that you are taking or have taken will be recorded
- A physical examination will be done which will include vital signs, height, body weight and body mass index (BMI)
- A 12-lead electrocardiogram (ECG), which records the electrical activity of your heart, will be performed
- Blood samples will be taken to check your blood counts (numbers of different types of cells in your blood), chemistries (elements and minerals in your body, including thyroid-stimulating hormone [TSH] and free thyroxine [T4]), your fasting glucose (the amount of sugar in your blood), and to check how your immune system reacts to insulin
- Urine samples will be collected for urinalysis
- If you are a woman who is able to become pregnant, you will have a urine pregnancy test
- You will have a CGM sensor (continuous glucose monitoring device) attached to your arm that you will have to wear for 8 days. During this period, it will record the amount of glucose in your tissue every 15 minutes throughout the day. You are not required to do anything for this to happen, you just need to wear the sensor. Applying the sensor may cause bruising or bleeding. If there is bleeding that does not stop, remove the sensor, and apply a new one at a different site. After wearing the sensor for 8 days, you can collect it from your arm and place it in the provided

biohazard bag and bring it with you at your next site visit. If the 8 days coincides with your next site visit (randomization visit), then you can simply leave it on your arm and it will be removed by study staff at your randomization visit. If the sensor falls off at any time during the 8-day period, you should place it in the biohazard bag and bring it back at the next site visit

- If you need to measure your glucose using a finger prick test at any time you can do this as well, as information recorded by the sensor on your arm will not be available to you. You will be given a capillary blood glucometer, test strips, and other supplies and the study staff will provide instructions on how to use the glucometer.
- During this period, you will also be asked to complete a Mealtime & Insulin Dose Record for 8 days to record your meal times and the amount and times of day you take medicines for your diabetes.
- You will also be given a Hypoglycemic Events Record in which you will be asked to record information about any hypoglycemic (low blood sugar) events, such as headache, dizziness, palpitations, nervousness, confusion, weakness, sweating, etc., that you experience while you are participating in the study. If the screening procedures and results indicate that you are eligible to participate in the study, your Study Doctor will schedule the Randomization Visit.
- Prior to your next visit your study doctor will adjust the dose of your insulin to ensure that you are receiving the optimal dose for you.

Visit 2: Randomization (Day 1)

During this visit, you will be randomly assigned to one of the two study groups. You will have a 50/50 chance to receive either the Sponsor's Insulin Glargine or the reference drug Lantus®.

The following information will be collected or procedures performed:

- You will be asked about your general health and any new side effects, new symptoms or change in existing symptom(s) or complaints you experience
- You will be asked about any medicines you are taking, and how long you have been taking them
- Your insulin use and glucose results since the previous visit will be recorded and the Hypoglycemic Events Record will be reviewed
- The CGM sensor attached to your arm will be collected (either you will provide it in a biohazard bag, or if the end of the 8-day period coincides with the date of the randomization visit, the study staff will collect it during the visit)
- The Mealtime & Insulin Dose Record will be collected and reviewed
- Vital signs, body weight and body mass index (BMI) will be collected
- Blood samples will be taken to check your fasting glucose, the average glucose level (the amount of sugar) in your blood and how your body processes insulin.
- If you decide to participate in the optional blood draw to measure the amount of study drug in your blood before the next dose, blood should be collected before administration of your regular insulin dose,
- Urine samples will be collected for urinalysis
- If you are a woman who is able to become pregnant, you will have a urine pregnancy test
- You will be given the study medication
- You will be instructed on all study procedures, proper dose administration and be asked to bring all used pen devices to each clinic visit

Visit 3 and 4: Weeks 2 and 4 (+/- 3 days)

The following information will be collected or procedures performed:

- You will be asked about your general health and any new side effects, new symptoms or change in existing symptom(s) or complaints you experience
- You will be asked about any medicines you are taking, and how long you have been taking them
- Your study drug and bolus insulin use and glucose results will be collected and the Hypoglycemic Events Record will be reviewed
- Vital signs, body weight and body mass index (BMI) will be collected
- Blood samples will be taken to check your fasting glucose, the average glucose level (the amount of sugar) in your blood and how your body processes insulin.
- Optional blood draw to measure the amount of study drug in your blood before the next dose (blood should be collected before administration of your regular insulin dose),
- Urine samples will be collected for urinalysis
- If you are a woman who is able to become pregnant, you will have a urine pregnancy test
- If needed, you will receive additional study medication and other supplies
- Any used insulin pens will be collected from you to check how much insulin you have used since your last clinic visit

Telephone Contacts: Weeks 6, 10, 14, 18, and 22 (+/- 3 days)

At these weeks, your Study Doctor will call you and will collect information about:

- Any medications you are taking, and how long you have been taking them
- Your general health and any new side effects, new symptoms or change in existing symptom(s) or complaints you experience.
- The study medication and bolus insulin use.
- The glucose levels that you have recorded
- You will be asked about any hypoglycemic events you may have experienced and ensure that they have been recorded in the Hypoglycemic Events Record

Visit 5: Week 8 (+/- 3 days)

In addition to the assessments performed during Visits 3 and 4, the following information will be collected or procedures performed:

- Blood samples will be taken to check the average glucose level (the amount of sugar) in your blood

Weeks 11, and 25

You will attend a brief visit to have the CGM sensor attached to your arm as during the Screening Visit. This visit should take place between 8 and 10 days before the scheduled visits at Weeks 12, and 26 respectively. You will also be asked to complete the Mealtime and Insulin Dose to record your meal times and the amount and times you take the medicines for your diabetes.

Visit 6: Week 12 (+/- 3 days)

In addition to the assessments performed during Visits 3 and 4, the following information will be collected or procedures performed:

- Blood samples will be taken to check your blood counts, chemistries and to check how your immune system reacts to insulin
- Your Study Doctor will collect the CGM sensor device
- The Mealtime & Insulin Dose Record will be collected and reviewed

If you terminate the study early prior to Visit 6 (Week 12 +/- 1 week), you will be encouraged to attend this visit as well as your actual Visit 9 (Week 26) to have blood draws to check how your immune system reacts to insulin as well as average glucose level (the amount of sugar) in your blood

Visit 7: Week 16 (+/- 3 days)

In addition to the assessments performed during Visits 3 and 4, the following information will be collected or procedures performed:

- Blood samples will be taken to check the average glucose level (the amount of sugar) in your blood

Visit 8: Week 20 (+/- 3 days)

The assessments will be the same as those performed during Visits 3 and 4.

Visit 9: Week 26 (+/- 3 days)

This visit is the end-of-study visit and the early withdrawal visit for any subject who withdraws from the study before Week 26. In addition to the assessments performed during Visits 3 and 4, the following information will be collected or procedures performed:

- You will have a physical examination
- Blood samples will be taken to check your blood counts, chemistries, the average glucose level in your blood, and to check how your immune system reacts to insulin
- A 12-lead electrocardiogram (ECG), which records the electrical activity of your heart, will be performed
- Your Study Doctor will collect the CGM sensor device
- The Mealtime & Insulin Dose Record will be collected and reviewed
- All remaining IP kits will be collected for accountability

If you terminate the study early you will be encouraged to attend your actual Visit 9 (Week 26 +/- 4 weeks) to have blood draws to check how your immune system reacts to insulin as well as average glucose level (the amount of sugar) in your blood

Follow Up Visit – Telephone Contact (Week 30)

- Your study doctor will call you to enquire about any side effects, new symptoms or change in existing symptom(s) or complaints you experience.

What do I have to do?

As a participant in this study, you have certain responsibilities to help ensure your safety. You must be willing to:

- Provide accurate and complete information about your medical history and your present condition.
- Come for all scheduled visits as requested by the Study Doctor or staff.
- Take the study medication as instructed by your Study Doctor.

- Tell your Study Doctor about any new side effect, injury, new symptom(s) or change in existing symptom(s) or complaint you experience.
- Tell your Study doctor if you experience any symptoms of hypoglycemia (low blood sugar) or if you are recording glucose levels which are above the target range. Your study doctor will review the symptoms of hypoglycemia and target glucose levels.
- Report if you (or your partner, if you are a man) become pregnant.
- Complete all the Mealtime and Insulin Dose Record and Hypoglycemic Events Record cards that are given to you.
- Inform the Study Doctor or staff if you decide you no longer wish to participate in the study. You will be required to complete a close out visit.

What if new information becomes available?

During the research study, you will be notified of newly discovered significant findings that may affect your willingness to participate in this study. In this case, you may be asked to sign a new consent form that shows that you have been informed of new information relating to this research study and you still agree to continued participation.

What are the potential benefits to taking part in the study

There is no guarantee that you will benefit from study participation. The study treatment may result in lowering your fasting glucose concentration or you may have no improvement at all. It is possible that your diabetes may worsen during the study. The information we get from this study may help improve the treatment of people with Type 1 Diabetes Mellitus.

What are the possible side effects, risks and discomforts of taking part?

While on the study, you are at risk of side effects. You should discuss any side effects that you have with the Study Doctor. The Study Doctor may suggest treatment to help make side effects less serious and uncomfortable. Ask the Study Doctor what treatments you may receive for side effects (and any risks these medications may have).

Many side effects are mild or moderate and go away shortly after the study medication is stopped, but in some cases, side effects can be serious, long-lasting or permanent, and in rare cases, fatal (causing death).

You may experience none, some or all of the side effects listed below. There may be risks involved in taking these drugs that have not been identified (unknown risks).

Many studies have been conducted using the Sponsor's Insulin Glargine and given the similarity of the clinical safety profiles between both study medications, the side effects from the Sponsor's insulin glargine are not expected to be different from the ones of Lantus®.

The most common side effect is hypoglycemia (low blood sugar), which may be serious and life threatening. It may cause harm to your heart or brain. Symptoms of serious low blood sugar may include shaking, sweating, fast heartbeat, and blurred vision, but you may discuss the entire list of symptoms of hypoglycemia with your Study Doctor. Low blood sugar may not cause any symptoms at all, this is why it is essential to monitor your blood glucose.

Lantus® may cause serious side effects that can lead to death, such as severe allergic reactions. Get medical help immediately if you have:

- A rash over your whole body

- Trouble breathing
- A fast heartbeat
- Sweating
- Swelling of your face, tongue, or throat
- Shortness of breath
- Extreme drowsiness, dizziness, or confusion

Other possible serious side effects may include:

- Low Potassium Levels (Hypokalemia)
- Certain medicines such as Thiazolidinediones (TZDs, eg. Avandia) when used in combination with insulin can cause fluid retention, which can lead to or worsen heart failure
- High Blood Sugar (Hyperglycemia)
- Prolonged use of subcutaneous insulin (injected under your skin) may lead to needing a longer time to recover from hypoglycemia (low blood sugar)

Other possible side effects may include swelling, weight gain, injection site reactions, including changes in fat tissue at the injection site, and allergic reactions.

Potential Risks and Discomforts

There are potential risks and discomforts with some of the study tests you will need to take; these are listed in the following section. Your Study Doctor will talk to you about these risks and answer any questions you may have.

Blood Samples

Your Study Doctor or study staff will take your blood by sticking a needle into a vein in your arm. You will give between approximately X to X tablespoons (2 to 7 mL) of blood during each study visit. There may be side effects of having blood drawn such as:

- Fainting (temporary loss of conscious)
- Dizziness
- Pain
- Bruising
- Bleeding
- Infection

Electrocardiogram (ECG)

The ECG test is harmless. The sticky pads used may sometimes cause some discomfort such as redness or itching. If the skin under the patches needs to be shaved, irritation from shaving also could occur.

CGM Sensor (Continuous Glucose Monitoring Device)

You may experience mild pain as the device is fitted, just like the finger prick when you test your blood yourself to monitor the glucose in your blood.

Gan & Lee Insulin pen and Lantus® Solostar®:

You may experience mild pain when injecting insulin.

Effects on ability to drive and use machines

Your ability to concentrate and react may be impaired as a result of too low (hypoglycemia) or too high (hyperglycemia) glucose level in your blood for example, or as a result of your vision becoming blurry. This may constitute a risk in situations where these abilities are of special importance like driving a car or using machines. You should take precautions to avoid hypoglycemia while driving.

Pregnancy and Birth Control (Female Participants)

Although a large amount of data on pregnant women (more than 1000 pregnancy outcomes) indicate no specific adverse effects of insulin glargine on pregnancy and no specific malformation or toxicity on unborn babies, you cannot be in this study if you are:

- Pregnant
- Planning to become pregnant during the study
- Nursing a child

If you become pregnant during the study, you should report immediately to your Study Doctor, who will guide you to discontinue the study medication and begin a non-study insulin regimen.

Male Reproduction and Birth Control

Although there is no evidence of specific adverse effects of insulin glargine on male reproduction, if the female partner of a male subject becomes pregnant, the subject may continue in the study but the pregnancy should be reported to the Study Doctor. Any congenital anomaly or birth defect in the newborn baby of the subject will be reported as a serious adverse event.

What are the costs of taking part in this study?

There are no anticipated costs for you to participate in the study. The study medication will be provided to you free of charge. You will not be charged for any procedure performed for the purpose of this study. You will not be paid for your participation in the study, but you will be reimbursed for any reasonable travel expenses incurred such as travel to and from the study site for your visits and/or parking at the hospital.

What other alternative treatments are available?

If you do not wish to participate in this study, you will continue to be treated by your normal doctor and your care will not be affected in any way. If you do not wish to participate, your doctor will help you decide if another drug may be appropriate. Other insulin treatments are available including long lasting ones and their combination in one pen. There are benefits and risks associated with these medications, which your doctor will discuss with you.

Will my medical information be kept private?

In the context of the clinical trial, the Sponsor will be responsible for all the personal data collected during the study from each participant.

[EU COUNTRIES ONLY. DELETE IF THE INFORMED CONSENT IS FOR US. This responsibility is as the data controller. The data controller must ensure that all those working on the study abide by the EU Directive on Data Protection and any additional requirements in your country law for the collection, use and processing of personal information obtained for this study.]

The sponsor is responsible for deciding what personal data is collected from you and how it will be used. The sponsor will also make sure all those working on the study comply with any data protection requirement for the collection. Your personal data will be relevant to the study. Along with medical data, other information may include your sex, age, or date of birth, race, ethnicity (according to FDA guidance), body weight and height. The personal data will be documented in coded form (without using your name but only your allocated patient number).

If you feel any of your rights related to the collection or use of your personal data have been violated, you should contact the Sponsor. If your concerns cannot be resolved to your satisfaction you can lodge a complaint with your country's data protection supervisory authority.

In order to verify that the study is being conducted correctly and for safety reasons the Contract Research Organisation (CRO) working for the Sponsor, the Ethics Committee and where required, the regulatory authorities will be allowed to inspect your personal records held by the Study Doctor. In exceptional circumstances and in accordance with the law, the regulatory authorities may also require that personal data be made available to them. Other authorised representatives may also have direct access such as a central laboratory responsible for testing your samples and study auditors. The Sponsor will use and disclose study data (but not identify individuals) when applying to market the study drug.

Those authorized representatives to whom personal data are disclosed are obliged to maintain confidentiality and are only allowed to pass on your personal data in coded form.

[EU COUNTRIES ONLY. DELETE IF THE INFORMED CONSENT IS FOR US. The personal data may be transferred within Europe and/or outside Europe, including to the USA. The laws about the protection of personal data in other countries may be not as strict as in this country.]

Your personal data may be transferred with Europe and/or outside Europe including to the USA. The laws on protecting your personal data in other countries may not be as strict as in this country. Your personal data will be stored in databases until the end of the study and for a period of time as required by law including letting you know what safeguards are taken to keep your personal data safe. Some ways in which your personal data is kept safe includes having study sites put the appropriate arrangements for the security of your personal data, removing some direct identifiers of your personal data or key-coding it so that it is not identifiable and collecting only the personal data needed. You can request this information about safeguards through your study doctor..

[EU COUNTRIES ONLY. DELETE IF THE INFORMED CONSENT IS FOR US The purpose of the transfer by Sponsor is to support regulatory submissions made by Sponsor for the study. The Sponsor and its representatives will take all reasonable steps to protect your privacy as is required by country law.]

You may refuse to sign the consent relating to the collection and processing of personal information. However, this will prevent you from participating in the study. If you withdraw your consent to participate or for processing personal information after commencing the study, the data collected cannot be deleted due to the legal requirement to store all study data for a period of at least 25 years and because it is necessary to preserve the integrity of the research being conducted. [EU COUNTRIES ONLY. DELETE IF THE INFORMED CONSENT IS FOR US Your right of access to the personal information collected and held and the right to correct any information that is incorrect remain and any enquiry by you in writing will be coordinated by the Sponsor as data controller.]

If the results of the study are published, the absolute confidentiality of the personal data of the patients' remains guaranteed.

Your general practitioner may be informed about your participation in this study.

US ONLY. DELETE IF THE INFORMED CONSENT IS FOR EU COUNTRIES. All reasonable measures to protect the confidentiality of your study records and your identity will be taken to the extent permitted by the applicable laws and/or regulations, and will not be made publicly available. HIPAA Regulations or applicable state law requires that you authorize the release of any health information that may reveal your identity. The persons and entities that you are authorizing to use or disclose your individually identifiable health information may include the Study Doctor, the study staff, the Institution, the Sponsor and (list all applicable parties). In order to analyze the data collected during this research study, all of the health information generated or collected about you during the study may be inspected by the study Sponsor or the authorized agents of the Sponsor, the FDA, the Department of Health and Human Services (DHHS) other government regulatory agencies from other countries, the study center ethics committee, (insert name of board) as well by representatives of the Sponsor, its affiliates or their designee (list other parties as appropriate, e.g., CRO, lab, vendor).]

The results of this study may be presented at meetings or in publications; however, your identity will not be disclosed in these presentations. By signing this informed consent form, you are authorizing such access to your medical records. This authorization will not have an expiration date.

You have a right of access to information about you and a right to correct information which is not correct, but you cannot be given information about which study medication you are receiving and/or results from study procedures while the study is being conducted.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Website will not include information that can identify you. At most, the Website will include a summary of the results. You can search this website at any time. Information on this study will also be posted in a similar format on the European Website at www.clinicaltrialsregister.eu.

What will happen to my biological samples?

Your samples will be shipped to, temporarily stored and analysed by Eurofins Global Central Laboratory, 2430 New Holland Pike, Suite D100, Lancaster, PA 17601, USA OR Bergschot 71 4817 PA Breda, The Netherlands. Samples will be sent to WuXi AppTec/XenoBiotic Laboratories Inc., (107 Morgan Lane, Plainsboro, NJ 08536, USA) for additional analysis to test how your immune system reacts to insulin and then to BioRepository Resources Inc. (755 Central Ave., Unit 3, New Providence, NJ 07974 USA) for long term storage. All testing samples will be destroyed at the end of the study, which is estimated to take approximately five years after the study. Your privacy is kept as the laboratory will only receive your study patient number

Can I stop being in the study?

At any time after joining the study and for any reason, you can withdraw from the study without any penalty or loss of benefits to which you are otherwise entitled. Your decision to leave the study will have no effect on your future care or treatment by physicians or by this institution. If you leave the study early, you will be asked to undergo a final evaluation visit. If you wish to withdraw from the study, you should contact:

(*Insert name of Study Doctor*) or study personnel at (*insert phone no*).

You may also revoke the authorization

to use or disclose personal information about your health. If you choose to withdraw your authorization, you must notify the Study Doctor in writing. The Study Doctor's mailing address is:

(Insert Principal Investigator's name and mailing address)

The Study Doctor will still be able to use the information collected about you prior to your withdrawal from the study. Information that has already been collected by the Study Doctor prior to your withdrawal cannot be deleted or removed from the databases immediately due to the legal requirement to store all study data for a period of at least 25 years after collection and because it forms part of the study being conducted. Your right to access your personal information collected and held and the right to correct any information that is incorrect remains. You may exercise these rights by applying in writing to the Sponsor.

Your participation in this study may be discontinued without your consent by the investigator or the sponsoring company if you fail to follow the investigator's instructions, such as repeatedly failing to return for protocol-required visits or repeatedly failing to follow dosing instructions, you are unable to comply with procedures required by the study, if you no longer meet the eligibility criteria for continuing in the study, or if the site withdraws from the study. You may also be withdrawn from the study if, in the investigator's opinion, the study medication is ineffective, harmful, or has medically unacceptable side effects, or for other reasons at the discretion of the Sponsor or investigator. If you are withdrawn from the study, you will be asked to have the appropriate medical tests and follow-up to evaluate your health and safety.

What happens if I have an injury resulting from this study?

Before participating you should consider if this will affect any insurance you have and seek advice if necessary.

If you suffer from an illness or injury that is determined to be directly related to the administration of study medication or the properly-performed study procedures, the Sponsor will pay all reasonable and necessary medical expenses to treat such illness or injury provided that you have followed the directions of the Study Doctor, and that you have not otherwise been reimbursed by your personal insurance, a government program, or other third-party coverage for such medical expenses. No other compensation will be offered by the Sponsor or the institution. Financial compensation for such things as lost wages, disability, or discomfort due to any research-related injury has not been made available. By signing this form, you are not waiving any legal right to seek additional compensation through the courts.

Who can I contact if I have questions about the study?

If you have any questions concerning your participation in this study, or if you feel you have experienced a research-related injury or a reaction to the study medication, you should contact:

Dr. (insert Principal Investigator's Name), at (insert phone number)

If you feel that there has been a breach of your confidential information, you should contact the principal investigator for this study:

Dr. (insert Principal Investigator's Name), at (insert phone number)

This research project has been reviewed by the (insert name of board or institutional review board (IRB)/ independent ethic committee (IEC)). This committee or board is a group of individuals from the community responsible for the review and approval of research proposed to be conducted. If you have questions about your rights as a research subject, you may contact:

The (person to contact), at (insert phone number).

Subject Consent Form

Sponsor:	Gan & Lee Pharmaceuticals, USA
Protocol No:	GL-GLAT1-3001
Protocol Title:	**AN OPEN-LABEL, RANDOMIZED, MULTICENTER, PHASE III STUDY TO COMPARE THE IMMUNOGENICITY, EFFICACY, AND SAFETY OF GAN & LEE PHARMACEUTICALS INSULIN GLARGINE INJECTION TO LANTUS® (INSULIN GLARGINE INJECTION) IN ADULT SUBJECTS WITH TYPE 1 DIABETES MELLITUS**
Investigator:	
Address:	
Phone / Fax:	

By signing this consent form, I confirm that:

- I have read the above information, have been given the opportunity to ask questions, and my questions have been answered to my satisfaction.
- I voluntarily consent to participate in the research study and that I am free to withdraw at any time, without giving a reason, without my medical care or legal rights being affected.
- I understand that by signing this informed consent I am not waiving any legal rights that I otherwise have.
- I am authorizing the use and disclosure of my personal health information. I cannot participate in this research study without this authorization. If I refuse to give my authorization, my medical care will not be affected.
- I agree that my general practitioner or treating specialist may be informed about my participation in this study.
- I hereby agree to participate in this research study

☐ I agree to participate in the optional blood draw to measure the amount of study drug in your blood before the next dose.

☐ I do not agree to participate in the optional blood draw to measure the amount of study drug in your blood before the next dose1

☐ If I end the study prior to the scheduled end of study, I agree to return to the site for the Week 26 (+/- 4 weeks) visit (and Week 12 +/- 1 weeks, if applicable) for blood draws to check how my immune system reacts to insulin as well as average glucose level (the amount of sugar) in my blood.

Signature of subject | Date of signature

Printed name of subject (BLOCK CAPITALS)

Signature of person conducting informed consent discussion | Date of signature

Printed name of person conducting informed consent discussion (BLOCK CAPITALS)

The legally acceptable representative signature should be added if the subject is unable to sign. The relationship between the subject and the legally acceptable representative should be stated.

Signature of legally acceptable representative | Date of signature

Printed name of legally acceptable representative (BLOCK CAPITALS)

Relationship of legally acceptable representative to subject (BLOCK CAPITALS)

Signature of person conducting informed consent discussion | Date of signature

Printed name of person conducting informed consent discussion (BLOCK CAPITALS)

The impartial witness signature should be added if the subject is unable to read or write

Signature of impartial witness | Date of signature

Printed name of impartial witness (BLOCK CAPITALS)