RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE:	Evaluating the Safety and Effectiveness of the Omnipod Horizon™ Automated Glucose Control System in Children with Type 1 Diabetes Aged 2.0-5.9 years: Preschool Cohort
FDA IDE NO.:	G190270
PROTOCOL NO.:	G190270 Preschool Cohort WIRB® Protocol #20201517
CONSENT VERSION NO.:	3.1
SPONSOR:	Insulet Corporation
INVESTIGATOR:	Name Address City, State, Zip Country
STUDY-RELATED PHONE NUMBER(S):	Phone Number Phone Number 24 hours) [24-hour number is required]

A person who takes part in a research study is called a research or study subject. In this consent form "you" always refers to the research subject. If you are the parent/guardian of a minor, please remember that "you" means the research subject.

You are being asked to be in a research study. Your participation in this research study is strictly voluntary, meaning that you may or may not choose to take part. The purpose of this consent form is to help you decide if you want to be in the study. This consent form describes the purpose, procedures, possible benefits, and risks of the study so that you can make an informed decision. This form also explains how your medical information will be used and who may see it. This process is known as informed consent.

You are being asked to take part in this research study because the study doctor feels that you may meet the qualifications of the study. If you have any questions, please ask the study staff that gave you this form. You should not join this study until all your questions are answered. If you would like to participate, you will be asked to sign this form. You will be given a copy of your consent form to keep for your records so you can refer to it while you are in this study.

WHY AM I BEING ASKED TO BE IN THIS STUDY?

You are invited to take part in this study because you have Type I diabetes and are currently using an

insulin pump or receiving basal and bolus insulin using multiple daily injections (MDI) in order to treat and manage your insulin-dependent diabetes. It is important to maintain normal blood glucose (BG) levels (also referred to as blood sugar) in order to reduce episodes of severe hyperglycemic (high blood glucose) and hypoglycemic (low blood glucose) events and also long-term complications related to these episodes.

The sponsor of this research study, Insulet Corporation, is testing the Omnipod Horizon™ Automated Glucose Control System (AGC) (also referred to as the Horizon™ System). The Horizon™ System is a single-hormone automated insulin delivery device. The system is designed to automate the process of maintaining normal blood glucose values or ranges set by health care providers. The system has not been approved for commercial use in the United States by the U.S. Food and Drug Administration (FDA) and therefore its use in this study is investigational. This study is organized and financed by Insulet Corporation.

The purpose of this study is to evaluate the safety and effectiveness of the Omnipod Horizon™ Automated Glucose Control System in patients with type 1 diabetes.

The Omnipod Horizon™ System includes the Omnipod Horizon™ patch pump ("Pod"), the Omnipod Horizon™ Personal Diabetes Manager (PDM), and the Dexcom G6 Continuous Glucose Monitoring System® (CGM). The Pod is placed on the skin and a cannula, within the Pod, is inserted under the skin to deliver insulin. The Dexcom G6 CGM is used to monitor your blood glucose levels with a sensor inserted under the skin. Some of the Dexcom G6 features available in the commercial system may not be available when used as part of the Horizon™ System. The Horizon™ System Algorithm is designed to automate the process of maintaining blood glucose concentrations by applying a set of rules or computations based on blood glucose levels. The CGM will communicate estimated glucose values directly to the Pod every five minutes. The algorithm within the Pod will run the data and adjust insulin delivery accordingly. The information will also be sent to the Omnipod Horizon™ app on the PDM. The hand-held PDM will also provide the ability to calculate a suggested bolus dose using the bolus calculator. If you use your CGM value to bolus, your CGM value and trend will be used to calculate your suggested bolus amount. In general, if your CGM values are trending up or down, the calculator will add or subtract insulin from your suggested bolus amount to help keep your blood glucose within target range.

The Horizon™ System has two modes: Automated Mode (also called hybrid closed-loop) and Manual Mode. In Automated Mode, the system automatically adjusts your basal insulin delivery to drive your blood glucose to your target blood glucose value. In Manual Mode, insulin delivery occurs according to your input basal rates. In each mode you will need to enter (or import from the CGM) a blood glucose value and the number of carbohydrates you eat so the system can calculate and deliver a bolus.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to be in this study, including the hybrid closed-loop extension Phase 3, you may be in this study for approximately 80-weeks. Standard therapy Phase 1 will last approximately 2 weeks, hybrid closed-loop Phase 2 will last approximately 13 weeks, and hybrid closed-loop extension Phase 3 will last approximately 15 months. This study is expected to last for about 33-months.

HOW MANY OTHER PEOPLE WILL BE IN THIS STUDY?

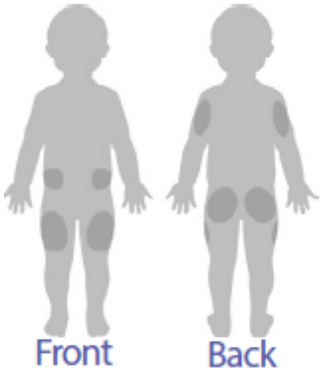
Up to eighty (80) people will participate in this study overall. About forty (40) people participating in the study will also participate in meal and exercise challenges.

WHAT WILL HAPPEN IF I AGREE TO BE IN THIS STUDY?

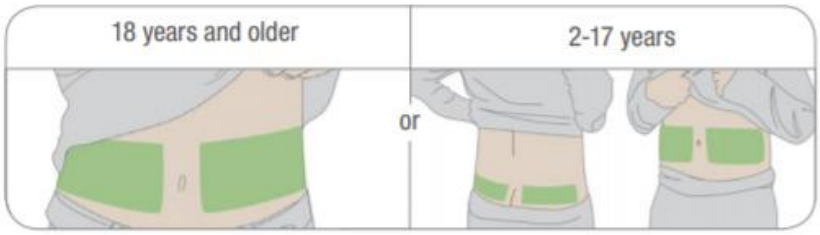
This study does not control the type of medical care that you receive for the treatment of your diabetes. You will receive the same treatment for your diabetes as you would receive even if you were not part of this study. However, this study will control the type of insulin delivery and blood glucose monitoring that is used as part of your medical care.

Listed below is what you can expect to happen if you agree to be in this study.

- Your parent/guardian, will be asked to sign this consent form to document that you agree to be in this study.
- Data will be collected about you.
    - This data includes basic information about you such as your age, gender, ethnicity, and race.
    - Your vital signs will be taken throughout the study and include your heart rate, blood pressure, temperature, respiratory rate, height, and weight.
    - Information about your health history will be recorded.
    - Results of blood tests will be collected.
- You will be trained on the use of all the study devices. You will also be trained how to use the bolus calculator and how to use the Horizon™ System in both Automated and Manual modes.
    - The bolus calculator can suggest a bolus dose based on your individual settings.
    - In Automated Mode, basal insulin dosing is increased or decreased based on CGM values.
    - In Manual Mode, regular insulin delivery occurs according to your defined basal rate(s), and the CGM does not inform insulin dosing.
- The Pod will be placed and the Dexcom G6 CGM sensor will be inserted under your skin. If you have questions about these procedures, please ask the study staff.
    - Recommendations for Pod placement are listed below.
        - Place Pod at least 3 inches from your CGM infusion site or injection site.
        - Ideal sites have a layer of fatty tissue.
        - Ideal sites offer easy access and viewing.
        - The site should be at least 1 inch (2.5 cm) away from the previous site to avoid skin irritation.
        - The site should be at least two inches (5 cm) away from your navel.
        - Avoid sites where belts, waistbands, or tight clothing may rub against or dislodge the Pod.
        - Avoid sites where the Pod will be affected by folds of skin.
        - Avoid placing the Pod over a mole, tattoo, or scar, where insulin absorption may be reduced.
        - Avoid areas of the skin with an active infection.



- Recommendations for the Dexcom G6 CGM placement are listed below.
  - All patients can use their bellies (abdomen). Patients 2 to 5.9 years old can also choose their upper buttocks. Look for a place on your belly or upper buttocks where you have some padding.



- Information will be collected from your study doctor about the use of the devices supplied for the study, including the Horizon System.
  - This will include information about how the device was used, including settings, measurements, and readings.
  - This will include device component information, including inventory number(s).
  - This will include device data uploads recorded during standard therapy and hybrid closed-loop (from the PDM, CGM, BG meter, and ketone meter).
    - During standard therapy, the study staff will manually record information from your personal pump and upload your CGM, BG meter and ketone meter.
    - During hybrid closed-loop, the study staff will manually upload the BG meter and the ketone meter, however, the PDM and CGM will upload automatically to the cloud.
  - This will include information about any problems or complications that may have occurred and that are related to the AGC System or any of its components
- Information will be collected from your study doctor about your health status throughout your participation in this study.
  - This will include information about how you are feeling and the effectiveness of the device.
  - This will include information about any problems or complications that may have occurred while the device is in place.
  - This will include information about your estimated average daily activity level, the type of activity and carbohydrate consumption.

- Your caregiver will be asked to complete questionnaires related to your diabetes and experience in the study. Below are the names and descriptions of the questionnaires you will be given during the study. **Table 1** indicates when each will be given.
    - The Clarke Questionnaire assesses awareness of hypoglycemia.
    - The WHO-5 questionnaire measures current mental well-being.
    - The DTSQs and DTSQc Parent questionnaire measures satisfaction with diabetes treatment regimens.
    - The P-PAID-Child questionnaire measures diabetes-related burden.
    - The Hypoglycemia Confidence Scale measures hypoglycemia unawareness, hypoglycemia frequency, severity, and impact.
    - The PSQI questionnaire measures sleep disturbance and usual sleep habits.
    - The IDSS (T1) questionnaire measures patient satisfaction with their devices and impact on quality of life
    - The SUS questionnaire measures usability of a system.
    - The INSPIRE-Parent questionnaire measures a caregiver's experience of the support they receive.
    - The Human Factors (HF) questionnaire measures trust in the Horizon System.

Table 1: Questionnaires

Visit	Caregiver of Subject*
Visit 1 (Screening)	Clarke Questionnaire
Visit 2	WHO-5 DTSQs Parent P-PAID-Child Hypoglycemia Confidence Scale PSQI IDSS (T1) SUS
Visit 13 (End of Phase 2 or Phase 2 Early Withdrawal)	WHO-5 DTSQc Parent P-PAID-Child Hypoglycemia Confidence Scale PSQI IDSS (T1) SUS INSPIRE-Parent Clarke Questionnaire Human Factors

WHAT ARE THE STUDY PROCEDURES?

If you choose to participate in the study, you are responsible to be available and agree to have all the required tests and activities done during study visits (as described in more detail below).

Your parent/guardian will first be asked to read and sign this Consent Form before any study related procedures can be performed on you. The research staff will ask about your medical history. There is

no guarantee that you will be able to participate in this study. If you do not meet the eligibility requirements, you will not receive the study device and will not be enrolled. Instead your doctor will treat you based upon what is best for you.

This study will consist of three study phases:

1) 14-day outpatient standard therapy phase (Phase 1)
2) 13-week outpatient hybrid closed-loop phase (Phase 2)
3) Hybrid closed-loop extension phase through commercialization (Phase 3)

Standard therapy Phase 1 is a 14-day period where you will use the study CGM at home but continue to manage your diabetes using your own insulin pump or current MDI therapy per your usual routine.

During hybrid closed-loop Phase 2, you will use the Horizon™ System at home and be followed by the study doctor for approximately 13 weeks (94 days) while using the system. You will attend several follow-up visits throughout the study, which will be conducted in person at the clinical study site or over the telephone.

After completing Phase 2, you may continue to hybrid closed-loop extension Phase 3. Hybrid closed-loop extension Phase 3 will last approximately 15-months. During this time you may choose to continue using the Horizon System at home and be followed by the study doctor. You will attend several follow-up visits throughout extension Phase 3 which will be conducted over the telephone or in person at the clinical study site.

If you are participating in the meal and exercise challenges, these challenges will occur 2-days in a row during the hybrid closed-loop phase of the study while in Automated Mode. You will not have to go to the clinical site for these visits.

Visit 1 - Screening (Clinical Study Site)

After this Consent Form is signed, you will continue to the Screening Visit (up to 30 days before the start of hybrid closed-loop Phase 2). This visit will be performed at the clinical study site. At the Screening Visit your vital signs will be taken. Information such as your age, gender, race, blood pressure, height, and weight will be recorded. Your daily insulin totals over the past 7-days will be reviewed. You will be asked to provide the names of the medications that you are taking at the time of screening and throughout the study. A blood test will be performed to obtain A1C values. Once it has been confirmed that you meet all the eligibility criteria, you will proceed to the rest of the study visits.

You will be asked to complete a questionnaire about your awareness of hypoglycemia.

If you are a current Dexcom G6 user, you may submit data from your CGM to complete standard therapy Phase 1. To determine if you do not need to complete the full standard therapy Phase 1, you must be willing to provide CGM data from a 14-day period within the last 30-days that meets the requirements of 80% CGM usage during any consecutive 14-days and have at least 2,016 CGM values. If you meet the requirements you will move straight on to the hybrid closed-loop phase at **Visit 4**.

Visit 2 - Standard Therapy Phase 1 (Clinical Study Site)

Visit 2 may be done on the same day as the Screening Visit and will be the start of the standard therapy phase. It will take place approximately 14-days before the hybrid closed-loop phase. At this visit, the study staff will review any medications you are taking. They will also review your total daily insulin totals over the past 7 days and your pump settings or MDI dosing. The study staff will also ask you for your estimated average daily activity level, the type of activity and carbohydrate consumption over the last week. You will be trained on delivering Glucagon and will be given information on treating hypoglycemia (low blood sugar) and hyperglycemia (high blood sugar).

The study staff will provide you with supplies including a Dexcom transmitter, receiver (which will be blinded so you cannot see the values), sensors, a study blood glucose meter, a study blood ketone meter, test strips, control solutions, and lancets. The study staff will be sure you and/or your caregivers are trained on the use of these devices and CGM sensor insertion. The sensor will be inserted under your skin and you will be started on the CGM. You will then manage your diabetes at home based on your usual routine using either your personal insulin pump or MDI. If you are using MDI, you will also need to maintain a written or electronic record of insulin therapy during this phase.

If you are new to pump therapy, you will have the option to participate in a saline trial during the standard therapy phase. This means that you would be given the Omnipod® DASH System, which is currently on the market, to use to familiarize yourself with pump therapy before the start of the hybrid closed-loop phase. The Pod will be filled with saline and worn just as it would be if it were filled with insulin.

At this visit you will be asked to complete several questionnaires. Please refer to above section “WHAT WILL HAPPEN IF I AGREE TO BE IN THIS STUDY?” and **Table 1** for a complete list of questionnaires and description of each one.

Visit 3 – Standard Therapy Phase 1 (Clinical Study Site)

Visit 3 will be conducted at the clinical study site up to one (1) day before the start of the hybrid closed-loop phase. At this visit, the clinical study staff will ask how you are feeling and review your CGM usage over the last 14-days to make sure you have met the minimum usage requirements to continue to the next phase. If you have not met the requirement the study staff may ask you to continue in the standard therapy phase until you meet the requirements to proceed.

Visit 4 – Hybrid Closed-Loop Phase 2 (Clinical Study Site)

Visit 4 will occur upon completion of the standard therapy phase. The clinical staff will review any medications you are taking and ask how you have been feeling and if you have had any questions or issues with the devices since your last visit. They will also review your total daily insulin needs over the past 7-days and your pump settings or MDI dosing.

You will be trained on the use of the Dexcom G6 CGM System when used as part of the Horizon™ System. This includes setting alerts and entering transmitter serial numbers into the Horizon™ app to

set up the system. The Dexcom Follow app will be available to use on your personal cell phone for the duration of the study.

Your personal insulin pump will be removed (if applicable) and the Horizon™ System will be dispensed to you. You will be trained on first time setup procedures and instructed on how to use the system in both Automated and Manual Modes. Your insulin settings will be entered into the system at this time. For the entire study, you may choose a target BG to any of the available system settings (110 mg/dL, 120 mg/dL, 130 mg/dL, 140 mg/dL, or 150 mg/dL). Once the PDM is set up, a Pod will be filled with your own U-100 rapid-acting insulin and it will be placed on your body. Once you have activated a Pod, have a CGM paired with the Pod, and waited at least 20 minutes, you will be able to enter hybrid closed-loop (Automated Mode).

Meal and Exercise Challenge Visits (2 days in a row)

To test the system, you may be asked to participate in meal and exercise challenges. It will not be required for everyone, but you must be willing to participate if you are part of the selected group. These challenges will occur 2-days in a row during the hybrid closed-loop phase of the study while in Automated Mode. You will not have to go to the clinical site for these visits.

Participation will include a minimum of 3 hours of activity per day along with a dietary challenge. Examples of activities include playing, walking, hiking, running, gymnastics, kicking a ball, throwing a ball, or riding a bike or trike. For the dietary challenge, you will under-bolus for one meal on each challenge day. This is done by reducing the number of carbohydrates entered into the bolus calculator by 50% (you will enter only half of the actual carbohydrate estimate). For example, if a meal is estimated to be 50 grams of carbohydrates, you will enter only 25 grams of carbohydrates into the bolus calculator.

Please make note of the following so you can report this back to the study staff:

- Meal Start and Stop times
- Actual number of carbohydrates and number of carbohydrates entered into the bolus calculator
- Exercise Start and Stop times
- Type of Exercise Activity

You will be encouraged to follow your usual pre-exercise routine such as insulin reduction for meal boluses, having a snack, or adjusting your insulin settings. If your CGM value is less than 70 or greater than 300 mg/dL, you will be encouraged to test your BG level using the study BG meter. You will treat yourself per your usual routine if you experience low or high blood sugar during the exercise challenge.

During the challenges, the study staff will be monitoring your glucose levels using a data portal. Once the study staff confirm you have had 2 CGM checks between 70-300 mg/dL and your BG trend is stable, they will no longer monitor you through the portal. Your participation in the challenges each day will end when you receive a safety follow-up phone call from the study staff a few hours later.

Visits 5, 6, 7, 8, 9, 10, 11, and 12 – Hybrid Closed-Loop Phase 2 (Telephone, Clinical Study Site, Email,

Text)

Visits 5, 6, 7, 8, 9, 10, 11, and 12 may be conducted at the clinical study site or by telephone, email, or text. These visits will occur approximately on Day 2, Day 3, Day 10, Day 24, Day 38, Day 52, Day 66, and Day 80 during hybrid closed-loop Phase 2.

At these visits, the clinical staff will review your current medications, ask how you have been feeling, and check to see if you have had any device issues or questions since your last visit. They will also review the data from your device uploads. The devices will upload to a cloud automatically or be uploaded during an office visit.

If **Visit 7** and **Visit 9** are conducted in the office, your vital signs will also be taken.

At **Visits 9** and **Visit 11,** the study staff will ask you for your estimated average daily activity level, the type of activity and carbohydrate consumption over the last week.

Visit 13– End of Phase 2 / Beginning of Hybrid Closed-Loop First Extension Phase 3 (Telephone, Clinical Study Site, Email, Text)

Visit 13 marks the end of hybrid closed-loop Phase 2, and if you agree to continue, the beginning of hybrid closed-loop extension Phase 3. This visit may be conducted at the clinical study site or by telephone, email, or text and will occur on approximately Day 94 after starting hybrid closed-loop Phase 2.

At this visit, the study staff will review your current medications, ask how you have been feeling, and check to see if you have had any device issues or questions since your last visit. They will also review the data from your device uploads. The devices will upload to a cloud automatically or be uploaded during an office visit. The study staff will ask you for your estimated average daily activity level, the type of activity and carbohydrate consumption over the last week.

Visit 13 also includes a blood test to obtain A1C values. If this visit occurs over the telephone, the study staff will either provide you with a home blood collection kit or instruct you on where to go for the blood test.

At this visit you will be asked to complete several questionnaires. Please refer to above section “WHAT WILL HAPPEN IF I AGREE TO BE IN THIS STUDY?” and **Table 1** for a complete list of questionnaires and a description of each one.

If this visit takes place at the clinical study site, the study staff will also take your vital signs, height, and weight.

If you choose to participate in hybrid closed- loop extension Phase 3, we ask that you review and sign this informed consent form. You may also have the opportunity to sign this consent form at an earlier visit.

As part of your continued participation in the hybrid closed loop extension Phase 3, you will continue to use the Horizon™ System at home and participate in several follow-up visits over the telephone or at the clinical study site.

If you choose not to participate in hybrid closed-loop extension Phase 3, you will return all devices and supplies at this visit and your participation in the study will end.

Visits 14, 15, 16, 17, and 18 – Hybrid Closed-Loop Extension Phase 3 Follow-up (Telephone, Clinical Study Site, Email, Text)

Visits 14, 15, 16, 17, and 18 may be conducted at the clinical study site or by telephone, email, or text. The visits will occur approximately on Day 120, Day 150, Day 180, Day 210, and Day 240 during the hybrid closed-loop extension Phase 3. At these visits, the clinical staff will review your current medications, ask how you have been feeling, and check to see if you have had any device issues or questions since your last visit. They will also review the data from your device uploads. The devices will upload to a cloud automatically or be uploaded during an office visit.

Visit 16 also includes a blood test to obtain A1C values. If this visit occurs over the telephone, the study staff will either provide you with a home blood collection kit or instruct you on where to go for the blood test.

Visit 19 – End of Study (Telephone, Clinical Study Site, Email, Text)

Visit 19 marks the end of the first extension of Hybrid Closed-Loop of Phase 3. This visit may be conducted at the clinical study site or over the telephone and will occur on approximately Day 270. If you agree to participate in the second extension of Phase 3, you will be provided with an informed consent form (this document) to review and sign. You may also have the opportunity to sign this consent form at an earlier visit. The staff will take your height and weight, review any medications you are taking, ask how you have been feeling, and if you have had any device issues since your last visit. They will collect and upload the data from the BG meter and ketone meter. A blood test will also be performed to obtain A1C values.

If you choose not to participate in the hybrid closed-loop second extension of Phase 3, you will return all devices and supplies at Visit 19 and your participation in the study will end.

Visits 20, 21, 22, and 23 – Hybrid Closed-Loop Second Extension Phase 3 Follow-up (Telephone, Clinical Study Site, Email, Text)

Visits 20, 21, 22, and 23 may be conducted at the clinical study site or over the telephone. The visits will take on approximately Day 315, Day 360, Day 405 and Day 450 during the hybrid closed-loop extension Phase 3. At these visits, the clinical staff will review your current medications, ask how you have been feeling, and check to see if you have had any device issues or questions since your last visit. They will also review the data from your device uploads. The devices will upload to a cloud automatically or be uploaded during an office visit.

Visit 21 and Visit 23 also include a blood test to obtain A1C values. If these visits occurs over the

telephone, the study staff will either provide you with a home blood collection kit or instruct you on where to go for the blood test.

At **Visit 23**, you be given the opportunity to continue in the study until the device is commercially available (Extension Through Commercialization). If you choose to continue in the study, you will be given a consent form to review and sign (this document).

If you choose not to extend your participation until the device is commercially available, you will return all devices and supplies at this visit and your participation in the study will end.

Extension Through Commercialization Visits

These visits may be conducted at the clinical site (required for final visit) or over the telephone. The visits will occur approximately every 45 days or sooner if the device becomes commercially available. At these visits, the clinical staff will review your current medications, ask how you have been feeling, and check to see if you have had any device issues or questions since your last visit. They will also review the data from your device uploads. The devices will upload to a cloud automatically or be uploaded during an office visit.

Once the device becomes commercially available, the study will end. Your final study visit will be conducted in person at the clinical study site. The staff will review any medications you are taking, ask how you have been feeling and if you have had any device issues since your last visit. They will collect and upload the data from the BG meter and ketone meter. At the end of the visit, you will return all devices and supplies and your participation in the study will end.

Unscheduled Visit (Telephone, Clinical Study Site, Email, Text)

Aside from scheduled visits, you may require an unscheduled visit either in person at the clinical study site or by telephone, email, or text.

At these visits, the clinical staff will review your current medications, ask how you have been feeling, and check to see if you have had any device issues or questions since your last visit. They will also review the data from your device uploads. The devices will upload to a cloud automatically or be uploaded during an office visit. You will not have to upload any of your devices.

Early Withdrawal (Clinical Study Site)

If you withdraw early from the study, either during Phase 2 or Phase 3, you will be asked to come into the clinical study site for a final visit. At this visit, the study staff will take your height and weight, review your current medications, ask how you have been feeling, and check to see if you have had any device issues or questions since your last visit. They will also review the data from your device uploads. The devices will upload to a cloud automatically or be uploaded during an office visit. The study staff will ask you for your estimated average daily activity level, the type of activity and carbohydrate consumption over the last week. A blood test will be performed to obtain A1C values.

If you are withdrawing from the study during hybrid closed-loop Phase 2, you will also have your vital signs assessed and be asked to complete several questionnaires. Please refer to above section “WHAT WILL HAPPEN IF I AGREE TO BE IN THIS STUDY?” and **Table 1** for a complete list of questionnaires and a

description of each one.

You will return all devices and supplies at this visit and your participation in the study will end.

Reasons for Early Discontinuation from Study

Your participation in the study will be discontinued early if any of the following conditions are met:

- You request that the treatment be stopped.
- If you experience one episode of severe hypoglycemia defined as an event requiring assistance of another person due to altered consciousness, and required another person to actively administer carbohydrate, glucagon, or other resuscitative actions.
- If you experience one episode of diabetic ketoacidosis (DKA) defined as an event meeting all of the following criteria: symptoms such as polyuria, polydipsia, nausea, or vomiting; serum ketones greater than 1.5 mmol/L or large/moderate urine ketones; either arterial blood pH less than 7.30 or venous pH less than 7.24 or serum bicarbonate less than 15 mmol/L; and treatment provided in a health care facility.

The study doctor may also end your participation in the study if they believe your continued participation would harm you or it is not in your best interest. If this occurs, you will be asked to complete the procedures listed under **Early Withdrawal** above.

WHAT ARE THE POSSIBLE RISKS OF BEING IN THIS STUDY?

There may be risks or complications associated with participation in this study including those that might reasonably be expected to occur in association with the study device. Risks may include, but may not be limited to the following:

- Hypoglycemia and/or hyperglycemia as a result of change in diet, activity, diabetes management or insulin regimen during the study.
- Hypoglycemia, hyperglycemia, diabetic ketoacidosis, seizure, coma, or death related to insulin administration, pump use or misuse, or Horizon™ System use or misuse.
- Use of the Pod (Omnipod® tubeless, insulin delivery pump) - Because the Pod uses only rapid-acting insulin, users are at increased risk for developing hyperglycemia if insulin delivery is interrupted. If it is untreated, prolonged hyperglycemia can quickly lead to diabetic ketoacidosis (DKA). DKA can cause symptoms such as breathing difficulties, shock, coma, or death. Further, occlusions can interrupt insulin delivery and lead to hyperglycemia or DKA. Other potential risks associated with using the Pod are:
    - Anaphylaxis (allergic shock)
    - Bruising at the Pod site
    - Bleeding at the Pod site
    - Erythema (redness at the Pod site)
    - Excoriation (raw skin at Pod site)
    - Pruritus (itching)
    - Induration (hardening of the skin at the Pod site)
    - Infection (can include heat, redness, swelling, pain, and drainage)
    - Inflammation (redness, swelling)
    - Skin reaction to adhesive at the Pod site
    - Papule (small, solid raised area on the skin like a pimple)

  - Pain or discomfort
  - Ulceration (skin sores)
  - Vesicles (blisters)
- Use of the CGM - risk of bruising, infection, pain and/or bleeding at the site of insertion, and skin site reaction to adhesive.
- On rare occasions, the CGM sensor may break and leave a small portion of the sensor under the skin that may cause redness, swelling, or pain at the insertion site, and may require surgical removal.
- In rare instances, when the PDM has been used for several weeks or months and has recorded a significant number of boluses, if carbs are entered very quickly into the bolus calculator, the calculations may use only the first digit of the grams of carbs entered (e.g. if 50g of carbs are entered, the calculation may be completed for only 5g of carbs) and result in less insulin than expected for a full meal bolus. This could result in a temporary elevation of blood glucose levels if you do not recognize the reduced meal bolus amount. In order to make sure this does not happen to you, it is important to check the meal bolus before delivering the bolus. Insulet will also keep track of the number of boluses recorded by each PDM and once it reaches an amount where this problem might occur, the clinical site will provide a new PDM to replace your current PDM.
- Blood sampling with fingerstick - minor discomfort and risk of infection at site of fingerstick.

There may be risks which are unknown at this time.

WHAT ARE THE POSSIBLE BENEFITS OF BEING IN THIS STUDY?

You may or may not get any benefit from participating in this study. However, medical science and future patients may benefit from your participation.

WHAT IF NEW INFORMATION BECOMES AVAILABLE ABOUT THIS STUDY?

You will be told about any new information that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.

WHAT ARE MY COSTS FOR PARTICIPATING IN THIS STUDY?

Insulet Corporation will provide the Horizon™ System (including the Pod, the PDM, and the Dexcom G6 CGM) free of charge but they must be returned at the end of your study participation. Insulet Corporation will also provide the study blood glucose meter, ketone meter and test strips to be used during this study. These meters must also be returned at the end of your participation.

You will be required to use your own U-100 rapid-acting insulin during this study.

There will be no cost to you for the study visits and tests done as part of this study. All other medical care provided to you for the treatment of your diabetes, including standard of care visits, procedures, and medications, will be billed to your insurance company or Medicare. If you do not have an insurance policy or Medicare coverage, these costs will be billed directly to you.

You may want to talk with your insurance company or Medicare about its payment policy for standard medical care given during a research study. If your insurance company, or Medicare, does not pay, you may be billed for those charges.

If you have questions about the costs related to this study, please ask your study doctor.

WHAT HAPPENS IF I AM INJURED DURING THIS STUDY?

If you are hurt by this research, we will give you medical care. Medical treatment will be provided at no cost to you or your insurance company for a research-related injury. The sponsor and the study doctor will determine if your injury or illness is research-related. The term "research-related injury" means physical injury caused by drugs, devices or procedures required by the study which are different from the medical treatment you would have received if you had not participated in the study.

By agreeing to the above, you do not give up any of your legal rights which you otherwise would have as a patient.

Your study doctor will treat you according to their standard practice. During the study, if you have any symptoms, are seen by any other doctor, or are hospitalized it is important that you call the study doctor as soon as possible after you have received treatment so that important information can be collected.

WILL I BE PAID FOR MY PARTICIPATION IN THIS STUDY?

You will receive compensation for participation in this study as follows:

- $[Amount] for completing Standard Therapy Phase 1 - Visit 1
- $[Amount] for completing Standard Therapy Phase 1 - Visit 2
- $[Amount] for completing Standard Therapy Phase 1 - Visit 3
- $[Amount] for completing Hybrid Closed-Loop Phase 2 - Visit 4
- $[Amount] for completing Hybrid Closed-Loop Phase 2 - Visit 5
- $[Amount] for completing Hybrid Closed-Loop Phase 2 - Visit 6
- $[Amount] for completing Hybrid Closed-Loop Phase 2 - Visit 7
- $[Amount] for completing Hybrid Closed-Loop Phase 2 - Visit 8
- $[Amount] for completing Hybrid Closed-Loop Phase 2 - Visit 9
- $[Amount] for completing Hybrid Closed-Loop Phase 2 - Visit 10
- $[Amount] for completing Hybrid Closed-Loop Phase 2 - Visit 11
- $[Amount] for completing Hybrid Closed-Loop Phase 2 - Visit 12
- $[Amount] for completing Hybrid Closed-Loop Phase 2 - Visit 13
- $[Amount] for completing Hybrid Closed-Loop Extension Phase 3 - Visit 14
- $[Amount] for completing Hybrid Closed-Loop Extension Phase 3 - Visit 15
- $[Amount] for completing Hybrid Closed-Loop Extension Phase 3 - Visit 16
- $[Amount] for completing Hybrid Closed-Loop Extension Phase 3 - Visit 17
- $[Amount] for completing Hybrid Closed-Loop Extension Phase 3 - Visit 18

- $[Amount] for completing Hybrid Closed-Loop Extension Phase 3 - Visit 19
- $[Amount] for completing Hybrid Closed-Loop Extension Phase 3 - Visit 20
- $[Amount] for completing Hybrid Closed-Loop Extension Phase 3 - Visit 21
- $[Amount] for completing Hybrid Closed-Loop Extension Phase 3 - Visit 22
- $[Amount] for completing Hybrid Closed-Loop Extension Phase 3 - Visit 23
- $[Amount] for each completed Hybrid Closed-Loop Extension Phase 3 visit after Visit 23

Payment will be received after the completion of each study phase.

WHAT IS MY ALTERNATIVE TO PARTICIPATION IN THIS STUDY?

You do not have to participate in this research study to be treated for your diabetes. There are currently other approved commercially available insulin pumps, continuous glucose monitoring devices and automated insulin delivery systems. Your doctor can describe these other treatments and their associated risks and benefits to you in a manner that you can understand. Your decision not to participate in this research study will have no effect on your current treatment or any other future treatment you require.

DO I HAVE THE RIGHT TO LEAVE THIS STUDY?

Your participation in this study is voluntary. You may decide not to participate, or you may leave the study at any time. However, if you decide to leave the study during the hybrid closed-loop phase of the study, your doctor may have additional instructions on how to safely leave the study, such as if you are hypoglycemic or hyperglycemic. You will also be asked to complete the procedures listed under **Early Withdrawal** above. Deciding not to take part or leaving the study will not result in any penalty or loss of benefits to which you are otherwise entitled. Your regular medical care and your relationship with your doctors and the clinical study site will not be affected. All study supplies must be returned.

You may leave the study at any time. We ask that you write to the study doctor at the address at the top of this form. There are no consequences and no specific tests that are required prior to you leaving the study.

Your participation in this study may be stopped at any time by the study doctor or the Sponsor without your consent for any of the following reasons:

- if it is in your best interest
- you do not consent to continue in the study
- your medical condition no longer allows for participation
- if the study is stopped for any reason

HOW WILL INSULET CORPORATION USE THE STUDY INFORMATION?

If you decide to participate in this study, Insulet Corporation (including its agents and contractors) and others who work with the study will see health information about you. This section of the consent form and the section called Authorization to Use and Disclose Health Information will determine how your health information is shared and used.

Insulet Corporation may use your health information to conduct this study as well as for additional purposes. These purposes include overseeing and improving the performance of its devices, new medical research, proposals for developing new medical products or procedures and other business purposes. Any reports or publications about this study or any other research will not include your name or a description of you. In addition, information received during this study will not be used to market you. Your name will not be placed on any mailing lists or sold to anyone for marketing purposes. On occasion, representatives of Insulet may be present during study procedures, with the supervision of the investigator.

Health information may be shared with Dexcom by using the Clarity application during the study. Dexcom will keep your health information confidential in accordance with all applicable laws and regulations.

Insulet Corporation will keep your health information confidential in accordance with all applicable laws and regulations. The U.S. Food and Drug Administration's (FDA) regulations, as well as other applicable laws, control Insulet Corporation's work in developing and determining the safety and quality performance of its medical devices. You agree to allow Insulet Corporation to disclose your health information to the FDA as well as to other U.S. and foreign government authorities and the Institutional Review Boards responsible for watching over the safety and effectiveness of medical products and therapies and the conduct of research studies.

Information from the study may also be given to the Institutional Review Boards and investigators at other sites participating in the study. People from the sponsor, the FDA as well as other regulatory authorities and the Institutional Review Board may visit the clinical study site and review your information there to verify the procedures and data, to the extent permitted by the applicable laws and regulations.

By signing this consent form, you are authorizing such direct access to your health information and you agree to allow Insulet Corporation to use study data in these ways.

CONFIDENTIAL INFORMATION

You are being asked to participate in a clinical study that includes the use of an investigational device. The device is not yet commercially available therefore we ask that you refrain from discussing the details of the study and device with anyone other than the study staff and your caregivers. Please refrain from discussing the details of your study participation on social media sites. Photographs of the device are not allowed during your participation.

AUTHORIZATION TO USE AND DISCLOSE HEALTH INFORMATION

By signing this consent and authorization form, you agree to permit the hospital and/or clinic and their staff(s), your doctors, and your other health care providers (together "Providers") and the study doctor and study staff (together "Researchers"), to use and disclose health information about you, including health information in your medical records, as described below.

The health and personal information that may be collected, used and disclosed includes:

- all information collected related to the study as described in this consent form;
- health information in my medical records that is relevant to the study; and
- personal information such as your name, address, age, gender, race, height, and weight, date of study visits, and other information in my medical record.

The Providers may disclose health and personal information:

- to the Researchers and to the Sponsor of the Research, Insulet Corporation and its agents and contractors (together "Sponsor"); and
- as required by law and to representatives of government organizations, such as the U.S. Federal Food & Drug Administration, review boards, and other persons who are required to watch over the safety and effectiveness of medical products and therapies and the conduct of research.

The Researchers may:

- use and share my health and personal information among themselves and with other participating researchers to conduct the study;
- disclose my health and personal information to the Sponsor for this study; and
- disclose my health and personal information as required by law and to representatives of government organizations, such as the U.S. Federal Food & Drug Administration, review boards, and other persons who are required to watch over the safety and effectiveness of medical products and therapies and the conduct of research.

The Sponsor may:

- Use and share my health and personal information as described in the consent form.
- Disclose my health and personal information as required by law and to representatives of government organizations, such as the U.S. Federal Food & Drug Administration, review boards, and other persons who are required to watch over the safety and effectiveness of medical products and therapies and the conduct of research.

Once my health and personal information has been disclosed to a third party:

- It may be subject to further disclosure by recipients, and federal privacy laws may no longer protect it from further disclosure.

Please note that:

- You do not have to sign this consent form, but if you do not, you will not be allowed to participate in the study.
- You may change your mind and revoke this consent at any time. To revoke your consent, you must write to [name and contact information]. However, if you revoke your consent, you will no longer be allowed to participate in the study. Also, even if you revoke your consent, the information already obtained by the Providers, Researcher, and the Sponsor may be used and disclosed as permitted by this consent form.
- During the course of the study, you may be denied access to (or the right to inspect or copy) some or all of the study-related health information. You are entitled to access this study-related health information once the study is completed.

By signing this consent, you are authorizing the disclosure of your health information for the purposes specified in this consent. This authorization does not have an expiration (ending) date unless you withdraw it.

WHO CAN I CALL WITH QUESTIONS, COMPLAINTS OR CONCERNS ABOUT THIS STUDY?

If you have any questions, concerns, or complaints about this study or your participation, your rights as a study subject, or if you feel that a study related injury has occurred, you should contact [Name] at [Number] (24 hours).

If you have any questions, complaints, or concerns about the conduct of this study, or if you have questions about your rights as a research participant, you may also contact the Institutional Review Board (IRB) that oversees this study at Telephone: 1-800-562-4789 or 360-252-2500, E-mail: help@wirb.com.

IRB is a group of people who perform independent review of research. IRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact IRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers.

If you agree to be in this study, you will receive a signed and dated copy of this consent form for your records.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

CONSENT

My signature below means that:

1. I have read this consent form, or it has been read to me, and I acknowledge the information provided.
2. I have been given time to consider the study requirements and all my questions were answered to my satisfaction.
3. I understand that my participation in the study is voluntary and my refusal to participate will not compromise my medical treatment. I can withdraw my consent at any time prior to and during the study, without any legal consequences and without any penalty or loss of benefits to which I am entitled. I know who to contact in the future if I decide to withdraw or if I require additional information.
4. I agree to comply with the requirements of the study, follow the study staff's instructions, and to inform the study staff about my medical background, medication or other medical matters and about all medical events that occur during the course of this study.

5. My consent does not release the Sponsor from its obligations, and my legal rights will not be affected.
6. I agree that my relevant personal data may be used and transferred for the purpose of this study.
7. I agree that the Sponsor's representatives, regulatory authorities and Institutional Review Board representatives will be granted direct access to my original medical records.
8. I will be given a signed and dated copy of this document for my records.
9. I understand that my personal doctor may be informed about my participation in this study.

Consent and Assent Instructions: Consent is provided by the parent or guardian. Assent of children is not required.

- **Phase 3 Extension (Through Commercialization)**
  Initial below to indicate your choice for hybrid closed-loop extension Phase 3.

  _____**Yes**, I want to participate in the extension of Phase 3 through commercialization
  Parent or Guardian (Initials)

  _____**No**, I do not want to participate in the extension of Phase 3 through commercialization
  Parent or Guardian (Initials)

Your signature documents your permission for the individual named below, to take part in this research.

_____
Printed Name of Subject

_____
Printed Name of Parent or Guardian

_____ _____
Signature of Parent or Guardian Date

_____
Printed Name of Person Conducting the Informed Consent Discussion

_____ _____
Signature of Person Conducting the Informed Consent Discussion Date

****For Sites in California****

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

What information may be used and given to others?
The study doctor will get your personal and medical information. For example:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits.

Who may use and give out information about you?
The study doctor and the study staff. [They may also share the research information with [enter SMO company name], an agent for the study doctor. delete if the site does not have an SMO]

Who might get this information?
The sponsor of this research. "Sponsor" means any persons or companies that are:

- working for or with the sponsor, or
- owned by the sponsor.

Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA),
- Department of Health and Human Services (DHHS) agencies,
- Governmental agencies in other countries,
- The institution where the research is being done,
- Governmental agencies to whom certain diseases (reportable diseases) must be reported, and
- Institutional Review Board (IRB)

Why will this information be used and/or given to others?

- to do the research,
- to study the results, and
- to make sure that the research was done right.

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health

information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

May I withdraw or revoke (cancel) my permission?
This permission will be good until December 31, 2070.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
There is a risk that your information will be given to others without your permission.

Authorization:
I have been given the information about the use and disclosure of my health information for this research study. My questions have been answered.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

AUTHORIZATION SIGNATURE:

_____ _____
Signature of Parent/Guardian **Date**