STANFORD UNIVERSITY Research Consent Form

Protocol Director: Dr. Nielsen Fernandez-Becker

IRB Use Only
Approval Date: June 25, 2026
Expiration Date: February 10, 2027

Protocol Title: A first-in-patient study to evaluate the safety and tolerability of HB-2121 as a diagnostic for celiac disease

V2.0

Are you participating in any other research studies? _____ Yes _____ No

KEY INFORMATION ABOUT THIS RESEARCH STUDY

You are being invited to take part in a research study funded by the National Institutes of Health (NIH). This summary provides a brief overview of the study to help you decide whether or not to participate. A more detailed explanation follows this section.

- **Voluntary Participation:** You can choose not to take part, or you can change your mind and leave the study at any time without any penalty or loss of medical benefits.
- **Study Purpose:** The purpose is to evaluate if HB-2121 is safe and feasible for helping doctors diagnose celiac disease.
- **Study Drug:** HB-2121 is investigational, meaning it is not approved by the U.S. Food and Drug Administration (FDA) for this use. This is an open-label study, so everyone will receive HB-2121 and both you and the study team will know you are receiving it.
- **Dosing:** You will drink a single dose of HB-2121 dissolved in 16.9 fluid ounces of drinking water 2-4 hours before your scheduled endoscopy.
- **Study Duration:** 30 days
- **Visits:** 6 total visits
  - **4 in-person clinic visits:** Screening, Day 1 (study treatment), Day 2, and Day 7 follow-up
  - **2 remote visits:** Day 15 and Day 30
- **Key Risks and Discomforts:**
  - 21 people have received HB-2121 in a previous study: 9 people who did not have celiac disease and 12 people who did have celiac disease.
  - Expected risks are mild to moderate and temporary.
  - The most common side effect is temporary blue or green discoloration of the mouth, teeth, urine, or stool, which is not harmful and resolves on its own.

Participant ID:
Name:
MRN:
DOB:

STUDY

  - Other study-related burdens include blood draws and time spent completing study visits.
  - Because HB-2121 is still being studied, unknown side effects are possible.
- **Potential Benefits:**
  - You may or may not benefit directly from participating in this study.
  - Information from this study may help improve the diagnosis of celiac disease for future patients.
- **Alternative Option:** You do not have to be in this study to receive your diagnostic testing. If you choose not to participate, your alternative is to simply continue with the standard of care diagnostic process for celiac disease, including your scheduled endoscopy, without taking HB-2121. Choosing not to participate in this study will not affect the clinical care you receive.
- **Compensation:** You may receive up to $400 in gift cards for completing study activities.

Please read the full consent document carefully before making your final decision.

PURPOSE OF RESEARCH

You are invited to participate in a research study to determine the safety and tolerability of HB-2121 in subjects with suspected celiac disease.

HB-2121 is an investigational drug being developed by Stanford University. It is not approved by the Food and Drug Administration. Twenty one people have received HB-2121 in a previous study: 9 people who did not have celiac disease and 12 people who did have celiac disease. This study is the first time that HB-2121 will be tested in people with suspected celiac disease.

HB-2121 is under development by Stanford University as a tool to assist doctors in diagnosing patients with celiac disease. Celiac disease is a condition in which the immune system reacts to gluten, a component of wheat, barely, and rye. The immune response can cause gastrointestinal symptoms, damage the intestine, and

prevent people from absorbing nutrients in food. The only known effective treatment is exclusion of dietary gluten by following a gluten free diet. Patients must eat gluten to be accurately diagnosed with celiac disease. The team studying HB-2121 would like to understand if HB-2121 can help diagnose celiac disease without requiring patients already on a gluten free diet to consume gluten.

You were selected as a possible participant in this study because your doctor suspects that you may have celiac disease and has recommended that you have an esophagogastroduodenoscopy (EGD). HB-2121 binds to a protein, transglutaminase 2, which may act differently in people who do not have celiac disease and people with celiac disease. HB-2121 binds to the protein without changing how the intestine functions. HB-2121 contains a blue dye that will enable doctors to see the protein in the intestine. Researchers want to know whether HB-2121 can help diagnose celiac disease by studying HB-2121 in people who may or may not have celiac disease.

This research study is looking for up to 20 total participants with suspected celiac disease throughout the United States. Stanford University expects to enroll all 20 research study participants at Stanford University.

VOLUNTARY PARTICIPATION

Your participation in this study is entirely voluntary. Your decision not to participate will not have any negative effect on you or your medical care. You can decide to participate now, but withdraw your consent later and stop being in the study without any loss of benefits or medical care to which you are entitled. If you decide to terminate your participation in this study, you should notify the Protocol Director, Dr. Nielsen Fernandez-Becker, at 650-736-5555.

DURATION OF STUDY INVOLVEMENT

Your participation in the research study is expected to take approximately 30 days. Your participation requires four (4) in-person study visits at Stanford and two (2) remote phone or video conference visits. Visit 1 is a longer visit of up to 7 hours because you will be observed after dosing. Visit 1 and 5 require that you visit a lab of your choosing for blood draws and urine collection. What will happen during the visits and estimated times are in the "Procedures" section of

this consent form. If you or the study staff raise concerns during the remote visits, we may request that you come to Stanford for an in-person evaluation if clinically indicated.

PROCEDURES

In this study, the safety and tolerability of HB-2121 will be studied in participants with suspected celiac disease.

If you choose to participate, the Protocol Director, Dr. Nielsen Fernandez-Becker, and her research study staff will ask you to participate in all study visits and assessments. The research study team will perform the following:

Schedule of Assessments

	Screening (Within 30 Days of visit 1)	Visit 1 (Day 1)	Visit 2 (Day 2 am)	Visit 3 (Day 7 ± 3)	Visit 4 Day 15 ± 3)	Visit 5 (Day 30 ± 5)
Informed Consent	X					
Demographics	X					
Medical History	X					
Physical Exam	X	X	X	X		
Vital Signs	X	X	X	X		
Electrocardiogram	X	X	X	X		
Safety Blood Draw	X	X	X	X		X
Pregnancy Test (Urine or Blood)	X	X				X
Urine Test	X	X	X	X		
Research Urine Sample		X	X	X		
Research Blood Draw		X				
Celiac auto-antibodies tests		X				
Genetic test (HLA-DQ2 and HLA-DQ8)	X					
Administration of Study Drug		X				
Duodenal endoscopy with tissue sample collection		X				
Safety Assessments	X----------X					
Pregnancy Avoidance and Contraception Counseling	X	X	X	X	X	X
Daily Diary		X----------X (DAY 1-7)				

Participant ID:
Name:
MRN:
DOB:

STUDY

Consent and Eligibility

The research staff will provide you with the consent form and be available to answer any questions. You must sign the form if you agree to participate in the study. You will be asked several questions to confirm your eligibility to participate in the study.

The total volume of blood collected for this study is approximately 157 mL (33 teaspoons) over a 30 day period. This amount is less than one-third of the volume typically collected during a standard blood donation.

Visit 0-Screening and Eligibility (1-2 hours):

During the screening visit, the study staff will determine if you are eligible to participate.

During the visit, study staff will perform the following to determine your eligibility to participate:

- Vital signs (blood pressure, heart rate, respiratory rate, temperature, oxygen saturation)
- Height, weight, and BMI
- Review medical history
- Review of the current medications you are taking.
- Physical exam: A study physician will examine your body (such as your heart, lungs, abdomen, skin, and reflexes) to assess your overall health
- Pregnancy avoidance and contraception counseling
- Electrocardiogram: Small stickers (electrodes) will be placed on your chest, arms, and legs to check your heart's electrical activity. This test is painless and takes only a few minutes.
- Safety Blood draw for:
  - Hematology and chemistry panels (approximately 2 teaspoons)
  - Genetic test for celiac disease-related genes; if you already have this in your history, it will not be re-tested (approximately 2 teaspoons)
- Urine collection for:
  - Urinalysis: A panel that measures the chemicals and cells in your urine
  - Urine pregnancy test for persons who could become pregnant

Visit 1, Day 1 – HB-2121 administration (7 hours)::

During the first visit of the study, you will receive an oral dose of HB-2121 four hours before you are scheduled to undergo an esophagogastroduodenoscopy (EGD) as part of your standard medical care.

Pre-Visit Preparations:

Within 52 hours before dosing, you will complete a blood draw (approximately 2 teaspoons) and urine will be collected for baseline urinalysis, hematology, and chemistry tests. While it is preferable to have these labs drawn at a Stanford lab location, the study team can also help you find a lab nearby that is convenient for you. Visiting the lab may take between 15 to 30 minutes.

You are required to fast the night before your appointment, consuming only clear liquids until four (4) hours before dosing. Four hours prior to dosing, no food or drink is permitted.

This is the longest study visit. Plan to do a quiet activity, such as reading or working on a computer, when you are not interacting with the study staff.

During the visit and before HB-2121 administration, study staff will perform:

- Vital signs (blood pressure, heart rate, respiratory rate, temperature, oxygen saturation)
- Weight
- Review of the current medications you are taking.
- Physical exam
- Pregnancy avoidance and contraception counseling
- Electrocardiogram
- Place a small tube called an IV in your arm to collect blood for:
  - Celiac disease-related blood protein measurement (approximately 2 teaspoons)
  - Immune cell analysis (approximately 2 teaspoons)
- Urine collection for:
  - Urine research sample
  - Urine pregnancy test for persons who could become pregnant

Administration of HB-2121:

- Stanford Investigative Pharmacy will dispense the a 250mg dose of HB-2121 into a plastic bottle.
- The study staff will add 500 mL (16.9 fluid ounces) of sterile distilled water to HB-2121.
- The study staff will invert the bottle several times to dissolve the HB-2121.
- You will then drink 500 mL of HB-2121 dissolved in water.

After the administration of the study drug, the study staff will perform the following over the next 6 hours:

- Post-dose observation for 6 hours
- Duodenal endoscopy with sample collection at least 120 minutes post-dose. This procedure is part of your standard of care to determine whether you have celiac disease. Biopsies are collected as part of the standard of care to diagnose celiac disease. Additional biopsies are collected for the purpose of this research study
- Vital signs following HB-2121 administration at 60 (± 5), 120 (± 5), 180 (± 30), and 360 (± 30) minutes post-dose
- Blood sample collection at different times after you receive HB-2121 for:
  - Hematology and chemistry panel 60 (± 5) and 360 (± 30) minutes post-dose (approximately 4 teaspoons total)
  - Immune cell analysis at 60 (± 5) and 360 (± 30) minutes post-dose (approximately 8 teaspoons)
- Electrocardiogram 60-80 minutes post-dose
- Urine collection for:
  - Urinalysis
  - Each time you urinate after receiving HB-2121 until the end of the study visit, you will collect all urine each time you urinate using a jug provided by the study team. Urine collected during this period, may be combined into one sample (called a pooled sample) for testing.
- Questionnaire- Participant Diary
  - You will be asked to answer 5-6 questions about how you are feeling and whether you have noticed any changes or possible side effects in the past 24 hours (for example, changes in how you feel overall, stool or urine discoloration, or other symptoms that concern you).
- Review any possible any possible side effects
- Review of the current medications you are taking.

Visit 2, Day 2 (23-26 hours post-dose) – Safety follow-up (1 hour):

The morning after receiving the study drug, you will return to the clinic for study staff to perform the following assessments:

- Vital signs (blood pressure, heart rate, respiratory rate, temperature, oxygen saturation)
- Weight
- Review of the current medications you are taking.
- Physical exam
- Pregnancy avoidance and contraception counseling
- Electrocardiogram
- Safety Blood draw for:
  - Hematology and chemistry panels (approximately 2 teaspoons)
- Urine collection for:
  - Urinalysis
  - Urine research sample
- Questionnaire – Participant Diary
- Review any possible any possible side effects

Visit 3, Day 7 (±3 days) – Safety Follow-up Visit (1 hour):

On your third visit, 6 days after receiving HB-2121, you will return to Stanford for the following assessments:

- Vital signs (blood pressure, heart rate, respiratory rate, temperature, oxygen saturation)
- Weight
- Review of the current medications you are taking.
- Physical exam
- Pregnancy avoidance and contraception counseling
- Electrocardiogram
- Safety Blood draw for hematology and chemistry panels (approximately 2 teaspoons)
- Urine collection for:
  - Urinalysis

- Urine research sample
- Questionnaire- Participant diary
- Review any possible side effects

Visit 4, Day 15 (±3 days) - Remote Visit (30 minutes):

The study team will schedule a time with you for this remote visit. During the visit, the study staff will call you for:

- Review of the current medications you are taking.
- Pregnancy avoidance and contraception counseling
- Review any possible side effects

Visit 5, Day 30 (±5 days) - Remote Visit and Labs (30 minutes):

The study team will schedule a time with you for this remote visit. During the visit, the study staff will call you for:

- Review of the current medications you are taking.
- Safety Blood draw for hematology and chemistry panels at a lab convenient for you (approximately 2 teaspoons)
- Pregnancy test
- Pregnancy avoidance and contraception counseling
- Review any possible side effects

Potential for Additional Visits

Participating in this study may require additional in-person study visits if medically indicated.

If any medical concerns arise during the remote study visits or you contact the study team with concerns, the study team may ask you to return for an in-person visit. This visit may include, but is not limited to, the following:

- Vital signs (blood pressure, heart rate, respiratory rate, temperature, oxygen saturation)
- Physical exam
- A safety blood draw for:
  - Hematology and chemistry panel (approximately 2 teaspoons)

  - HB-2121 blood levels (approximately 2 teaspoons)
- Urine collection for:
  - Urinalysis
  - Urine research sample
- Electrocardiogram
- Pregnancy test
- Review any possible side effects
- Review of the current medications you are taking.

Future Use of Private Information and/or Specimens

Research using private information and/or specimens is an important way to try to understand human disease. You are being given this information because the investigators want to save private information and/or specimens for future research.

Identifiers will be removed from identifiable private information and/or identifiable specimens and, after such removal, the information and/or specimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

Any specimens that are stored will have a unique specimen ID and will not include any identifying information. You may contact the Protocol Director to revoke your consent to the use of your specimens. However, once specimens have been analyzed, they cannot be destroyed.

Any of your specimens which are used in research may result in new products, tests or discoveries. In some instances, these may have potential commercial value and may be developed and owned by the Investigators, Stanford University and/or others. However, donors of specimens do not retain any property rights to the materials. Therefore, you would not share in any financial benefits from these products, tests or discoveries. Your de-identified data will be shared with Stanford University, to assist in the further development of HB-2121. This

research will not include whole genome sequencing. Genetic testing is part of this study. The samples will not be used for future genetic testing

You will be told the results of tests that are part of your clinical care, but you will not be told the results of the research tests, including any future research tests.

Your specimens will be sent outside of Stanford for analysis.

By signing this ICF, you agree to the future use of your private information and/or specimens.

Genetic Testing and Future Research

As part of the analysis on your specimens, the investigators may do genetic testing. Genetic research is research that studies genes, including gene characteristics and gene versions that are transmitted by parents to children. Genetic research may include looking at information, such as personal appearance and biochemistry, gene sequences, genetic landmarks, individual and family medical histories, reactions to medications and responses to treatment. Genetic research raises certain questions about informing you of any results. Possible risks of knowing results include: anxiety; other psychological distress; and the possibility of insurance and job discrimination. A possible risk of not knowing includes being unaware of the need for treatment. These risks can change depending on the results of the research and whether there is a treatment or cure for a particular disease.

Sometimes patients have been required to furnish information from genetic testing for health insurance, life insurance, and/or a job. A Federal law, the Genetic Information Nondiscrimination Act of 2008 (GINA), generally makes it illegal for health insurance companies, group health plans, and employers with 15 or more employees to discriminate against you based on your genetic information.

The process of determining all or nearly all of your DNA sequence is called whole genome sequencing. It is different from genetic testing that does not

involve whole genome sequencing because it provides a much more detailed snapshot of your genome. This research will not include whole genome sequencing.

The results of the study of your data and/or specimens from this project will be used for research purposes only, and you may be told the results of the tests if you request them from the study team.
Regarding informing you of the test results, you should understand the following:

- The information may be too limited to give you particular details or consequences;
- You may be determined to carry a gene for a particular disease that can be treated;
- You may be determined to carry a gene for a particular disease for which there is no current treatment;

You may be determined to carry a gene for a disease and might consider informing relatives that they, too, might carry the gene.

Persons Who Could Become Pregnant

If you are a person who is able to become pregnant, it is expected that you will use an effective method of birth control to prevent exposing a fetus to an agent with unknown risk to the fetus. If you are pregnant or currently breastfeeding, you may not participate in this study. You understand that if you are pregnant, if you become pregnant, or if you are breastfeeding during this study, you or your child may be exposed to an unknown risk.

To confirm to the extent medically possible that you are not pregnant, you agree to have a pregnancy test done before beginning this research study. You must agree to avoid sexual intercourse or use a birth control method judged to be effective by the investigator and which will not interfere with the proposed investigation. You must accept the risk that pregnancy could still result despite the responsible use of a reliable method of birth control. You agree to notify the investigator as soon as possible of any failure of proper use of your birth control method, or if you become pregnant, either of which may result in your being withdrawn from the study.

If you are participating in this study and you could cause your partner to become pregnant, if not surgically sterilized, and if engaging in sexual intercourse with a

partner of childbearing potential, must be willing to use highly effective contraception from screening through 30 days post-dose and agree not to donate semen during this waiting period.

Your doctor will discuss with you what methods of birth control are considered adequate. You should inform your study doctor if your partner becomes pregnant.

Diagnosis of a Gastrointestinal Disorder

You may be diagnosed with celiac disease or another gastrointestinal disorder as a result of findings obtained during your EGD procedure or otherwise. The diagnosis of celiac disease or another gastrointestinal disorder, or a lack thereof, and any resulting follow-ups, treatments, or complications are unrelated to the study drug. If you are diagnosed with a gastrointestinal disorder as a result of findings obtained during your EGD procedure or otherwise, the Protocol Director may follow-up with recommendations on how to proceed. Participation in this trial will not impact treatment for your diagnosis.

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the Protocol Director and study staff.
- Keep your study appointments. If it is necessary to miss an appointment, please contact the Protocol Director or research study staff to reschedule as soon as you know you will miss the appointment.
- Remote study visits require that you have a private space to discuss your health with the study staff. You need access to a phone or computer with internet connection for the remote visits.
- Tell the Protocol Director or research study staff about any side effects, doctor visits, or hospitalizations that you may have.
- Tell the Protocol Director or research staff if you believe you might be pregnant or have gotten your partner pregnant.
- Ask questions as you think of them.
- Tell the Protocol Director or research staff if you change your mind about staying in the study.

WITHDRAWAL FROM STUDY

If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care for your disease and you will not lose any benefits to which you would otherwise be entitled.

If you decide to withdraw your consent to participate in this study, you should notify Dr. Nielsen Fernandez-Becker at 650-736-5555.

Subjects are free to withdraw consent and discontinue participation in a study at any time without prejudice to further treatment. The investigator may discontinue a subject from treatment intervention or the entire study for medical or administrative reasons. The following reasons may lead to discontinuation from the study intervention or the entire study.

- There is a need for any treatment not allowed by the protocol
- If the study treatment causes serious side effects, making it unsafe to continue the study treatment.
- Withdrawal of consent
- Study non-compliance
- Participant becomes pregnant
- Investigator discretion
- Failure to follow the instructions of the Protocol Director and study staff.
- The Protocol Director decides that continuing your participation could be harmful to you.
- You need treatment not allowed in the study.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

If you elect to withdraw consent from further treatment with the study intervention, or is withdrawn by the investigator, it will be confirmed and documented if the subject will consent to continue to be followed per protocol, if applicable. The rationale for the investigator's decision to discontinue treatment will be clearly documented.

Data collected on you to the point of withdrawal remains part of the study database and may not be removed per the Food and Drug administration.

POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES

There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. You should talk with the Protocol Director if you have any questions.

You are required to travel to Stanford for four (4) in-person visits and two (2) remote or phone call visits. Visits 1 and 2 are 24 hours apart. Visit 3 is 7 (±3 days) days after you receive HB-2121. The two (2) remote visits via phone or video are 15 (±3 days) and 30 days (±5 days) after you receive HB-2121.

As a participant in this study, you will receive one (1) oral dose of HB-2121, an experimental product that is not approved by the FDA.

Known Potential Risks of Study Drug HB-2121

Twenty one people have received HB-2121 in a previous study: 9 people who did not have celiac disease and 12 people who did have celiac disease. This study is the first time that HB-2121 will be tested in people with suspected celiac disease. The expected risks of HB-2121 are mild to moderate and temporary. People who received HB-2121 previously did not experience side effects caused by HB-2121. Additionally, the researchers completed safety testing in animals with HB-2121 before giving HB-2121 to people. These animal tests did not identify safety risks. There may be unknown risks from taking this drug.

HB-2121 contains a blue dye. People who received HB-2121 experienced blue and/or green urine and/or stool (feces). Animals in the safety tests experienced blue and/or green urine and/or stool (feces). The color was temporary and resolved within 2-5 days of taking HB-2121. Based on the previous data with people and animal studies, we expect that participants will experience the following:

- Blue or green urine and stool following administration of HB-2121
- Blue mouth and/or teeth after drinking HB-2121 dissolved in water

Urine and stool discoloration is expected to be temporary and resolve within 2-5 days of drinking HB-2121. The discoloration of the mouth and teeth is temporary and resolves a few hours of consuming HB-2121. Brushing and flossing may help remove the dye from your mouth and teeth. If you are concerned about the discoloration of your teeth, the study team will provide you with a straw to minimize discoloration.

Known Potential Risks of Study Procedures

Blood Draw
Taking your blood sample may cause some pain, redness, or bruising at the site where blood was drawn. In addition, lightheadedness, fainting, or an infection (rare) is possible.

Blood Draw Using venipuncture

To collect blood during Visit 1, a small tube (called a catheter) will be placed into a vein in your arm. You may feel brief pain, discomfort, or anxiety when the needle goes in. Some people may also have mild bruising, swelling, or tenderness at the site. In rare cases, there can be infection or irritation of the vein. If the tube stays in for a longer time, there is a small chance of a blood clot forming. To minimize these risks, trained professionals will do all blood draws using standard hospital procedures.

Electrocardiogram
You may develop a mild rash or skin irritation where the electrodes were attached. If any paste or gel is used to attach the electrodes, you may have an allergic reaction to it. This irritation usually goes away once the patches are removed, without requiring treatment.

Esophagogastroduodenoscopy (EGD)
Risks from EGD are rare. Side effects include a sore throat and gas or bloating. Serious complications are bleeding or a tear in the digestive tract. Participants may feel off-balance, dizzy, or drowsy from the sedation.

Sedation

Participants will receive a sedative prior to the EGD as standard of care. Participants may feel off-balance, dizzy, or drowsy from the sedation.

Participation in this research study may involve risks which are currently unforeseeable.

POTENTIAL BENEFITS

This study may help improve the diagnosis of suspected celiac disease and the evaluation of persistent symptoms in patients who follow a gluten-free diet. However, participants should not expect to receive any direct benefits from their involvement in this study. We cannot and do not guarantee or promise that you will receive any benefits from this study.

ALTERNATIVES

The alternative is not to participate. Choosing not to participate in this study will not affect the clinical care you receive.

PARTICIPANT'S RIGHTS

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction. If you decide not to participate, tell the Protocol Director, Dr. Nielsen Fernandez-Becker.

You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

You have the right to refuse to answer particular questions.

ClinicalTrials.gov

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.

CONFIDENTIALITY

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed except as authorized by you or as required by law**.** However, there is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by NIH, which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical

care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law such as child abuse and neglect, or harm to self or others.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document such as including research data in the medical records.

The purpose of this research study is to obtain information on the safety of HB-2121. The results will be provided to the study team, the Food and Drug Administration and other federal and regulatory agencies as required.

Authorization To Use Your Health Information For Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?

The purpose of the research is to determine the safety and tolerability of HB-2121 in subjects with suspected celiac disease.

Health information you provide to the study team and information in your medical records will determine whether you are eligible to participate in the study. Any side effects of HB-2121 will be used to determine whether HB-2121 is a safe diagnostic agent for the identification of celiac disease.

Your study data will be shared with Stanford University to assist in the further development of HB-2121.

Partial data and information will be shared with the Food and Drug Administration to assist in the further development of HB-2121.

Do I have to sign this authorization form?

You do not have to sign this authorization form. If you do not sign this authorization form, you will not be able to participate in this research study. Including receiving any research-related treatment. Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later?

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to: Dr. Nielsen Fernandez-Becker, email: nfernan1@stanford.edu , office address: 420 Broadway St Pav D 2nd Fl Pod 2 and 3 Redwood City, CA 94063.

What Personal Information Will Be Obtained, Used or Disclosed?

Your health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to, your full name, date of birth, medical record number, lab or test results, demographics, dates of medical care (e.g Date of study visit), place of birth, mailing address, email address, provider notes, medications, telephone number, sex at birth, ethnicity, and medical history.

Who May Use or Disclose the Information?

The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director Dr. Nielsen Fernandez-Becker.
- Research Staff

Who May Receive or Use the Information?

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- Stanford University
- Stanford Innovative Medicines Accelerator
- The Food and Drug Administration
- Stanford's Data Safety Monitoring Board
- External safety lab(s)
- National Institutes of Health (NIH)

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?

Your authorization for the use and/or disclosure of your health information will end on December 31, 2090 or when the research project ends, whichever is earlier.

Will access to my medical record be limited during the study?

To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until

it is completed. At that point, you would have access to such health information if it was used to make a medical or billing decision about you (e.g., if included in your official medical record).

_____ _____

Signature of Adult Participant Date

_____

Print Name of Adult Participant

FINANCIAL CONSIDERATIONS

Payment

You will receive up to $400 in gift cards for completing the study as appreciation for your time and effort. You will receive $25 for the screening visit, $175 for Visit 1, $75 each for Visits 2 and 3, and $25 each for Visits 4 and 5 for a total possible reimbursement of $400.

Payments may only be made to U.S. citizens, resident non-citizens, and those who are in a status that allows them to receive a taxable payment from a U.S. payer.

As a participant in this study, you will be offered hotel accommodations for the night before dosing and the night of dosing to help make your visit comfortable.

Costs

If you participate in this study, the study will pay for those services, supplies, procedures, and care associated with the study that are not a part of your routine medical care. However, there may be additional costs to you. These include basic expenses like transportation and the personal time it will take to come to the study visits. You and/or your health insurance must pay for services, supplies, procedures, and care that are required during this study for routine medical care. **You will also be responsible for any co-payments and/or deductibles as required by your insurance.** Participation in this study is not a substitute for health insurance.

Sponsor

The Stanford Innovative Medicines Accelerator and the National Institutes of Health (NIH) are providing financial support for this study.

Stanford University is providing the study agent, HB-2121, for this study.

COMPENSATION for Research-Related Injury

All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist you in obtaining appropriate medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits program. **You will be responsible for any associated co-payments or deductibles as required by your insurance.**

If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs. If you are unable to pay for such costs, the Protocol Director will assist you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital.

You do not waive any liability rights for personal injury by signing this form.

CONTACT INFORMATION

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Dr. Nielsen Fernandez-Becker, you may contact her now or later at 650-736-5555. You should contact her at any time if you feel you have been hurt by being a part of this study.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at 650-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB at irbeducation@stanford.edu.

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form; and
- be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

May we contact you about future studies that may be of interest to you? _____ Yes _____ No

Signing your name means you agree to be in this study and that you will receive a copy of this signed and dated consent form.

_____ _____

Signature of Adult Participant Date

Participant ID:
Name:
MRN:
DOB:



_____
Print Name of Adult Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Print Name of Person Obtaining Consent

The following witness line is to be signed only if the consent is provided as a summary form and accompanied by a short form foreign language consent.

_____ _____
Signature of Witness Date

_____
Print Name of Witness

(e.g., staff, translator/interpreter, family member)

- *Translated short form must be signed and dated by both the participant (or their LAR) AND the witness.*
- *The English consent form (referred to as the "Summary Form" in the regulations):*
  - *Must be signed by the witness AND the person obtaining consent (POC).*

- *The non-English speaking participant/LAR does not sign the English consent.*
- *The non-English speaking participant/LAR should not sign the HIPAA participant line*
- *If the participant or the LAR is non-English speaking, the person obtaining consent (POC) must ensure that 1) the LAR's Description of Authority is completed and 2) that any questions or options presented by the consent form are documented and initialed by the POC on the Summary Form, per the participant's wishes, as they are understood during the consent process.*