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INTEGREVIEW IRB
OCTOBER 22, 2018

INFORMED CONSENT DOCUMENT

STUDY TITLE:	"Observational Study: Image Collection of Infant/Toddler Stools for Danone Software Development"
PROTOCOL NUMBER:	OBVIO-DAN-002
SPONSOR:	Danone Nutricia
PRINCIPAL INVESTIGATOR/STUDY DOCTOR:	Parth Shah, M.D.
TELEPHONE NUMBER(S), DAYTIME & AFTER HOURS:	(877) 620-6023
E-MAIL:	Parth.shah@sprim.com

INTRODUCTION
You and your child may be eligible to take part in this study, Observational Study: Image Collection of Infant/Toddler Stools for Danone Software Development. You have been asked to take part in this study because you have shown interest in providing images of your child's stool for collection and use for research purposes. This document gives you important information about this study. It describes the purpose, procedures, benefits, and risks of this study. It also describes your right to withdraw from the study at any time. Taking part in this study is entirely voluntary. If you decide to participate, you must sign this form to show that you want to take part in this study.

Based on your answers on the initial questionnaire, the study team has determined that you and your child meet the initial requirements for participation. Before agreeing to participate in this study, it is important that you read and understand the following explanation of the proposed procedures. In order to decide whether or not you agree to be part of this research study, you should know enough about its possible risks and benefits. Please read this document carefully. We urge you to discuss any questions about this study with the study team. The study team will explain any words or information you do not clearly understand. You may choose to talk to your doctor, family and friends about the study. Please take your time to make your decision. If you decide to take part in this trial and provide your consent, a signed and dated copy will be provided to you for your reference.

This study is sponsored by Danone Nutricia (Sponsor). The Sponsor is paying the study Investigator and ObvioHealth (Contract Research Organization) for the services they provide in the conduct of this study.

An Institutional Review Board (IRB) is an independent committee established to help protect the rights of research subjects. IntegReview (IRB) has reviewed and approved this study. You must think about the information in this consent document for yourself, and then decide if you want to be part of the study.

PURPOSE OF THE RESEARCH
The purpose of this study is to create a variety of images of infant/toddler stool, and score them on the Brussels Infant and Toddler Stool Scale (BITSS), which ranges from "Score 1" (hard) to "Score 7" (liquid). The BITSS, based off a scale used for classifying adult stool consistency called the Bristol Stool Scale, was recently developed to be used for the classification of infant and toddler stool. The goal of this study is to collect at least 200 images of each consistency score of the BITSS and 200 images of empty diapers without stools.

Approximately 100 mothers and children will take part in this research study in the United States.

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STUDY DESCRIPTION AND PROCEDURES
You have been recruited for this study based on the answers you provided via electronic questionnaire during prescreening. If you decide to participate in this study and sign this consent form, you will be asked to complete another questionnaire. If you and your child successfully meet the criteria of that questionnaire, the Investigator will enroll you into the study.

Subject Responsibilities
While participating in this research study, you will need to:

- Be willing and able to follow the study directions and procedures
- Tell the study staff about any problems
- Ask questions as you think of them
- Tell the investigator or the study staff if you change your mind about staying in the study
- Upload quality images of your child's stool daily

Study Procedures:
The study consists of four periods: Prescreening, Screening, Observation and End of Observation.

You will be expected to be compliant with all the tasks described below under each of the study periods.

Prescreening Period:
If you are reading the informed consent form, you have already passed this period by successful completion of the initial, prescreening questionnaire.

If you wish to participate in this study, you will be asked to read, ask questions and, if appropriate, sign this informed consent document before any study-specific tests or procedures are performed, as outlined below.

Screening period:
Screening will begin after you voluntarily sign the informed consent form and will include the following:

- You will complete a detailed screening questionnaire via the ClaimIt app
- You will be asked to upload three (3) test images and their corresponding stool score via the ClaimIt app
- The Investigator will review this information to determine if you meet all the criteria prior to study enrollment
- If you and your child meet the criteria for the study, you will be enrolled into the study by the Investigator

Observation period:
You will use the following application during this portion of the study:

- ClaimIt application: You will be responsible for completing daily uploads and providing a corresponding stool score using this application

To complete these tasks, you will need a reliable internet connection and a suitable device like a tablet or smartphone. Access to the internet may be required at various times during the 24-hour day.

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You will carry out the following tasks during this study:

- **Submit empty (without stool) disposable diaper images at the beginning and end of the study**
  - These images should be taken using the type of disposable diaper you use most frequently with your child
  - Additional empty (without stool) disposable diaper images may only be submitted if the brand/type of diaper is changed; if the diaper size changes, no additional images need to be uploaded
- **Take and upload stool images daily**
  - You should upload one image of every bowel movement
  - You will be given instructions on how to take high quality, standardized images with proper lighting
  - If you do not submit images in a timely manner, you will be sent daily reminders via the ClaimIt app
- **Rate the uploaded stool images on the BITSS based only on consistency and not color**
  - The BITSS will be accessible within the ClaimIt app while you are storing the stool image
  - A laminated form will be mailed to you with both the BITSS and detailed instructions on how to take high quality, standardized images

The above cycles will be followed for 30 consecutive days. In addition to providing guidelines on image quality, the ClaimIt app will also provide you with access to the study team if you have any questions or concerns throughout the duration of the trial.

End of study period:
After completion of the study period, you will be asked to complete a questionnaire to assess and comment on your experience with the ClaimIt app and the scoring process. You may be contacted by the study team if anything else is required.

Duration of study
If you agree to take part in this study, your involvement will last approximately 30 days. If you upload a low number of quality images due to your child's constipation and infrequency of stool, you may be asked if you want to continue in the study for an additional 30 days. You will be asked to upload images daily. Each image upload and scoring will take less than 5 minutes.

ClaimIt Application
If, based on the results of the screening period, you qualify to participate in the study, you will be provided access to the ClaimIt application and instructions on how to use it. You will also be provided a study information sheet, which will be shipped to your provided address. This sheet will include the BITSS and directions on how to take a proper image.

Concomitant Medications, Supplements and Diet
Your child should continue with the same medications, supplements and diet which were started prior to the trial as medically necessary or desired.

POSSIBLE DISCOMFORTS AND RISKS
While in the study, it is unlikely that you or your child would experience any study-related events. However, if any study-related event is experienced, such as a cut from the laminated copy of the BITSS sheet, it should be reported to your doctor and the study Investigator.

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POSSIBLE BENEFITS
You and your child may not benefit from taking part in this research study; however, data collected in this study may be used for research and development purposes.

ALTERNATIVES TO PARTICIPATING IN THE STUDY
Since this study is for research only, the only other choice would be not to be in the study.

PRIVACY AND DATA – HIPAA DISCLOSURE
Your records of being in this study will be kept private except when ordered by law. The following people will have access to your study records:

- The investigator
- Danone Nutricia
- ObvioHealth study personnel
- The United States Food and Drug Administration (FDA)
- Other country, state or federal regulatory agencies
- IntegReview IRB

Some of these records could contain information that personally identifies you. Reasonable efforts will be made to keep the personal information in your research record private and confidential but absolute confidentiality cannot be guaranteed when disclosure is required by law.

The Sponsor must store, process and analyze the images and data collected for this study. To this end, images, medical data and other data such as date of birth or gender will be transmitted to the company or people or companies acting on their behalf. All data will remain anonymous and only identified by a code number. You and your child's personal information (name, address, and other similar personal data) will remain confidential and will not be transferred to the Sponsor. The Sponsor may store the images and study data indefinitely. The personal data collected for the study will be stored on an anonymous basis as long as such information is relevant for the purpose of research.

This data (subject-level data and other study information) may also be shared after anonymization for the purposes of scientific and medical research (e.g., with researchers, to allow public access to study information, for sharing results with subjects who participate in this or another study, or in publications). To safeguard your privacy, all information that could re-identify you or the child will be removed before the data is released.

Records of your participation in this study will be held confidential to the extent permitted by the applicable laws and regulations, and consistent with the Health Insurance Portability and Accountability Act ("HIPAA") authorization that you will also be asked to sign. The study Investigator and under certain circumstances, the United States Food and Drug Administration (FDA), as well as governmental agencies in other countries where the study is conducted will be able to inspect and copy confidential study specific records which identify you and the child by name. Therefore, absolute confidentiality cannot be guaranteed. If the results of this study are published or presented at meetings, you and the child will not be identified.

By signing this form, you consent to the Study Doctor and Study Staff collecting and using personal data about you for the study, as permitted by the applicable laws and regulations. This includes the images and other study data collected. Your consent to the use of your study data does not expire unless required by

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state law. You may withdraw your consent at any time by notifying the Investigator in writing at the address: 3452 Lake Lynda Drive, Building 100 Suite 151, Orlando, FL 32817. If you withdraw your consent, the Investigator will no longer collect new information or study data. However, study data and information collected before you withdraw consent will be used as described in this form.

You have the right to request to see your study data held by the Investigator and the Sponsor. However, you may not see your study data in its entirety until after the study has been completed, to help preserve the scientific integrity of the research. You also have the right to request that any inaccuracies in your data be corrected. If you wish to make a request, then please contact the Investigator.

A description of this clinical trial will be available on https://clinicaltrials.gov/, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the study and the results. You can search the website at any time.

COST AND COMPENSATION FOR PARTICIPATION
There is no charge to you for your participation in this study.

If you believe that you have been injured as a direct result of participating in any procedures required under the study protocol (written study plan), necessary medical care will be made available to you. It is highly unlikely that the procedures within this study would result in any injuries. All reasonable medical expenses to treat such illness or injury will be paid if you have followed the directions of the study Investigator and staff. You will not lose any of your legal rights or release the Sponsor, the study Investigator, the study staff or the study site from liability for mistakes or intentional misconduct by signing this consent document.

For fully completing this study, you will be given a total amount of $100.00 to compensate you for your time and expenses. If you withdraw or are withdrawn prior to completion of the study, you will be compensated with a prorated amount as follows: $50.00 for successful screening and completion of the first 15 days of image uploads. Your total amount will be delivered to your home address following the study completion.

VOLUNTARY PARTICIPATION AND STUDY WITHDRAWAL
Taking part in this research study is voluntary. You do not have to participate in this study. If you choose to take part, you have the right to stop at any time. While you take part in this study, you have the right to ask your study doctor or the study staff questions concerning the study at any time. If you decide not to participate or if you decide to stop taking part in the research at a later date, there will be no penalty or loss of benefits to which you are otherwise entitled. Your decision whether or not to participate in this study will not interfere with your future care.

It is also possible that your participation in this study may be terminated. This might happen if:

- You do not follow the study procedures
- In the opinion of the study doctor, it is in your best interest to stop participating in the study
- If it is discovered that you do not meet the study requirements
- You need treatment(s) that may interfere with the study
- The study Sponsor, FDA, or IRB ends the study for any reason

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CONTACT INFORMATION FOR QUESTIONS OR CONCERNS

You have the right to ask any questions you may have about this research. If you have questions, complaints, or concerns, contact Parth Shah at (877) 620-6023 or parth.shah@sprim.com.

If you do not want to talk to the Investigator or study staff, if you have concerns or complaints about the research, or to ask questions about your rights as a study subject, you may contact IntegReview.

IntegReview's policy indicates that all concerns/complaints are to be submitted in writing for review at a convened IRB meeting to:

Mailing Address:	OR	Email Address:
Chairperson IntegReview IRB 3815 S. Capital of Texas Highway Suite 320 Austin, Texas 78704		integreview@integreview.com

If you are unable to provide your concerns/complaints in writing, contact our office at:

512-326-3001 or
Toll-free at 1-877-562-1589
between 8 a.m. and 5 p.m. Central Time

If this is an emergency situation regarding your or your child's safety, please call 911.

EXPERIMENTAL BILL OF RIGHTS

For residents of California, only

California law, under Health & Safety Code Section 24172, requires that any person asked to take part as a subject in research involving a medical experiment, or any person asked to consent to such participation on behalf of another, is entitled to receive the following list of rights written in a language in which the person is fluent.

For the list, please click https://oag.ca.gov/sites/all/files/agweb/pdfs/research/bill_of_rights.pdf.

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SIGNATURE AND CONSENT/PERMISSION TO BE IN THE RESEARCH
Before making the decision about enrolling in this research study, please read and answer the statements below.

Please answer YES or NO to the following statements:

A. This document is in a language I understand. _____

B. I understood the information in this document. _____

C. I was given enough time to review the document and ask questions. _____

D. All of my questions were answered by the study team to my satisfaction. _____

E. I received enough information about the study. _____

F. I volunteer my child and I to be in this study of our own free will without being pressured by the investigator or study staff. _____

G. I know that my child and I can leave the study at any time without giving a reason and without it affecting our healthcare. _____

H. I know that my and my child's health records from this study may be reviewed by the sponsor company and by government authorities. _____

IF YOU ANSWERED "NO" TO ANY OF THE ABOVE QUESTIONS,
OR YOU ARE UNABLE TO ANSWER ANY OF THE ABOVE QUESTIONS,
YOU SHOULD NOT SIGN THIS CONSENT FORM.

IntegReview approves the use of electronic signatures.

My electronic signature below indicates that I have read the information contained within this consent form and my child and I voluntarily chose to take part in this study.

_____	_____	_____	_____
Signature of Participant	Date	Time	Printed Name

You will receive a signed and dated copy of this consent form to keep.