The University of British Columbia
Office of Research Ethics
Clinical Research Ethics Board – Room 210, 828 West 10th Avenue, Vancouver, BC V5Z 1L8

ACKNOWLEDGEMENT LETTER

PRINCIPAL INVESTIGATOR:	INSTITUTION / DEPARTMENT:	UBC CREB NUMBER:
Bruce A. Vallance	UBC/Medicine, Faculty of/Paediatrics	H17-00303

SPONSORING AGENCIES:
- BC Children's Hospital Research Institute - "UVB influences the human microbiota, a pilot study"
- Natural Sciences and Engineering Research Council of Canada (NSERC) - "Vitamin D - A regulator of host-microbe interactions in the mammalian GI tract?"

PROJECT TITLE:
Intestinal Microbiota Changes after Ultraviolet Radiation B Exposure

This letter will acknowledge receipt of the study closure.

There are no items to display

The following is a simplified summary of complex privacy and security requirements at UBC. For further information please consult: http://it.ubc.ca/services/security/ubc-information-security-office & http://universitycounsel.ubc.ca/access-and-privacy/

a. Make appropriate plans for archiving your project data to meet UBC policy requirements for study data to be retained for at least 5 years after presentation or publication within a UBC facility.

b. Ensure plans for final data destruction comply with the minimum standards set out in Clearing and Declassifying Electronic Data Storage Devices (ITSG-06).

c. Track and log disposal of all University-owned devices and electronic information.

d. Be prepared to provide a data destruction certificate upon request to a data steward.

Research Data Management

UBC Library has implemented robust research data management software – Abacus Dataverse (http://dvn.library.ubc.ca/dvn/)Dataverse is an open source repository designed to assist researchers in the creation, management and dissemination of their data. The Dataverse platform allows management of datasets, metadata, and digital objects and offers support for disposition of sensitive data, which has been collected under ethics approval. The system is opened to UBC researchers, labs and institutes.

DMP Assistant (https://assistant.portagenetwork.ca/ software – is a bilingual tool for preparing data management plans (DMPs). The tool follows best practices in data stewardship and walks researchers step-by-step through key questions about data management including data storage, ethics and legislative requirements, data archiving, and future uses. Hosted by the national Portage (https://portagenetwork.ca/ initiative, DMP Assistant is designed to meet the anticipated Data Management Plan requirements (in English or French) of most major Canadian funders.

DATE OF ACKNOWLEDGEMENT:	*Acknowledged on behalf of the Clinical Research Ethics Board by:*
February 12, 2019	Pia Ganz, Manager, Clinical Ethics

Date: 5/22/2019, 3:08:53 PM	Print	Close

The University of British Columbia
Office of Research Services
Clinical Research Ethics Board
Room 210, 828 West 10th Avenue
Vancouver, BC V5Z 1L8

H17-00303 **UVB: skin to gut study (Version 3.0)**

Principal Investigator: Bruce A. Vallance

1. Principal Investigator & Study Team - Human Ethics [View Form]

1.1. Principal Investigator Please select the Principal Investigator (PI) for the study. Once you hit Select, you can enter the PI's name, or enter the first few letters of his or her name and hit Go. You can sort the returned list alphabetically by First name, Last name, or Organization by clicking the appropriate heading.

Last Name	First Name	Employer.Name	Email
Vallance	Bruce A.	Paediatrics	bvallance@cw.bc.ca

Enter Principal Investigator Primary Department and also the primary location of the PI's Institution:

Pediatics, BCCHR

1.2. Primary Contact Provide the name of ONE primary contact person in addition to the PI who will receive ALL correspondence, certificates of approval and notifications from the REB for this study. This primary contact will have online access to read, amend, and track the application.

Last Name	First Name	Rank
Bosman	Else Susan	Graduate Student

1.3. Co-Investigators List all the Co-Investigators of the study. These members WILL have online access which will allow them to read, amend and track the application. These members will be listed on the certificate of approval (except BC Cancer Agency Research Ethics Board certificates). If this research application is for a graduate degree, enter the graduate student's name in this section.

Last Name	First Name	Institution/Department	Rank
Lui	Harvey	UBC/Medicine, Faculty of/Dermatology & Skin Science	Professor
Bosman	Else Susan	UBC/Medicine, Faculty of/Paediatrics	Graduate Student
Dutz	Jan P.	UBC/Medicine, Faculty of/Dermatology & Skin Science	Professor

Role in Study: Describe each co-

I's role in study, e.g. statistician, supervisor, adviser, student etc.	
1.4. Additional Study Team Members - Online Access List the additional study team members who WILL have online access to read, amend, and track the application but WILL NOT be listed on the certificate of approval.	**Last Name First Name Institution/Department Rank**
Role in Study:	
1.5. Additional Study Team Members - No Online Access Click Add to list study team members who WILL NOT have online access to the application and will NOT be listed on the certificate of approval.	**Last Name / First Name / Institution / Department / Rank / Job Title / Email Address** Stintzi / Alain / Faculty of Medicine, University of Ottawa / Vice-Dean / astintzi@uottawa.ca
Role in Study:	
Tri Council Policy Statement2 (TCPS2) Tutorial All study team members (including but not limited to faculty, undergraduate and graduate students, medical residents and research staff) are required to complete the TCPS2 Tutorial (CORE) before submission. Indicate completion of the TCPS2 (CORE) tutorial below: 1.6.A. All Faculty, including hospital appointment equivalents deemed a PI by an affiliated institution or by a Dean:	Yes
1.6.B. All Other Study Team members:	Yes
Comments:	
1.7. Project Title Enter the title of this research study as it will appear on the certificate. If applicable, include the protocol number in brackets at the end of the title. If this is a class-based project, see guidance on the right. Title given must match the title on all study documents.	Intestinal Microbiota Changes after Ultraviolet Radiation B Exposure
1.8. Project Nickname Enter a nickname for this study. What would you like this study to be	UVB: skin to gut study

known as to the Principal Investigator and study team?	
2. Study Dates and Funding - Human Ethics [View Form]	
You plan to start collecting data immediately after obtaining ethics and any other required approvals (the start date on the ethics certificate will reflect the approval date),	yes
You plan to start data collection at a later date i.e., 2 months or more after approvals are obtained. Click the calendar icon below to select the dates (Internet Explorer) or enter the dates manually using the format yyyy-mm-dd. Estimated start date:	
2.1. B. Estimated end date:	8/31/2018
2.2.A. Types of Funds Please select the applicable box(es) below to indicate the type(s) of funding you are receiving to conduct this research. You must then complete section 2.3 and/or section 2.4 for the name of the source of the funds to be listed on the certificate of approval.	Grant
2.2.B. For Industry Sponsored studies, please provide a sponsor contact.	
2.2.C. Please enter any applicable information about your funding which is not already shown in Box 2.3 or 2.4 (including funding applied for but not yet received).	
2.3. Research Funding Application/Award Associated with the Study that was Submitted to the UBC Office of Research Services Please click Add to identify the research funding application/award associated with this study. Selecting Add will list the sources of all research funding applications that have been submitted by the PI (and the person completing this application if different from the	**UBC Number** / **Title** / **Sponsor** F12-04845 / Vitamin D - A regulator of host-microbe interactions in the mammalian GI tract? / Natural Sciences and Engineering Research Council of Canada (NSERC) F17-05461 / UVB influences the human microbiota, a pilot study / BC Children's Hospital Research Institute

PI). If the research funding application/award associated with this study is not listed below, please enter those details in question 2.4.	
2.4. Research Funding Application/Award Associated with the Study not listed in question 2.3. Please click Add to enter the details for the research funding application/award associated with this study that is not listed in question 2.3. When you press Add you can do a search for your funding award by doing a search in the Sponsor box - over 7000 options are listed	**UBC Number Title Sponsor**
2.5.A. Is this a DHHS grant? (To view a list of DHHS funding agencies click on add in 2.5.B below)	no
2.5.B. If yes, please select the appropriate DHHS funding agency from the selection box, and attach the grant to box 9.8. of the application.	**DHHS Sponsor List: Order: Active:**
Attach DHHS Grant Application for each sponsor listed above	
2.6. Conflict of Interest Conflicts of Interest (COIs) can arise naturally from an Investigator's engagement inside and outside the University, and the mere existence of a COI or the perception of a COI does not necessarily imply wrongdoing on anyone's part. Nonetheless, real and perceived COI must be recognized, disclosed, and assessed. This question asks Investigators to disclose COIs that may relate to the research study that is the subject of the REB application. Do the Principal Investigator, Co-Investigators and/or their related parties (defined at s.8.12 UBC Policy 97) have any personal interest(s) that could compromise or reasonably be perceived to compromise the	no

objective conduct of the research or the integrity of the data generated by the study? Personal interests may include business, commercial or financial interests, as well as personal matters and career interests.	
4. Study Type - Human Ethics Application [View Form]	
4.1. UBC Research Ethics Board Indicate which UBC Research Ethics Board you are applying to and the type of study you are applying for:	UBC Clinical Research Ethics Board
N/A	no
4.2.A. Institutions and Sites for Study	**Institution** / **Site** Vancouver Coastal Health (VCHRI/VCHA) / Vancouver General Hospital Children's and Women's Health Centre of BC (incl. Sunny Hill) / BC Children's Hospital (includes Research Institute)
4.2.B. Please enter any other locations where the research will be conducted under this Research Ethics Approval (e.g., Name of privately owned clinic, community centre, school, classroom, participant's home, in the field - provide details).	The data will be collected in The Skin Care Center, located at Vancouver General Hospital and data analysis will be done by Life Labs and by the University of Ottawa in collaboration with professor Stintzi. Data storage will be done in the BCCHR institute.
4* Clinical Study Review Type [View Form]	
4.3. Relationship with other proposals 4.3.A. If this proposal is closely linked to any other proposal previously/simultaneously submitted, enter the Research Ethics Board number of that proposal.	No
4.3.B. If applicable, please describe the relationship between this proposal and the previously/simultaneously submitted proposal listed above.	
4.3.C. Have you received any information or are you aware of any rejection of this study by any Research Ethics Board? If yes, please provide known details	no

and attach any available relevant documentation in question 9.7.	
4.3.D. Will biological materials be collected or analyzed by UBC researchers or a UBC research lab? If yes, please provide the UBC Biosafety Permit Number:	No
4.3.E. Will radioisotopes be used in this project? If yes, provide the UBC Radiation Permit Number:	N/A
4.4. Level of Risk After reviewing the minimal risk guidance notes and the criteria for minimal risk, does this study qualify for minimal risk review? Note that all studies which do not fall into the minimal risk category will undergo full board review.	no
Peer Review If this research proposal has received any independent scientific/methodological peer review, please include the names of committees or individuals involved in the review. State whether the peer review process is ongoing or completed. All above minimal risk studies generally require a peer review. 4.5.A. External peer review details:	NO
4.5.B. Internal (UBC or hospital) peer review details:	Yes: dr. Vincent Ho, MD, FRCPC, FRCP. completed
4.5.C. If this research proposal has NOT received any independent scientific/methodological peer review, explain why no review has taken place.	N/A
4.6. Multi-jurisdictional studies Please read and review the guidance note on the right prior to completing this question. Is this study a multi-jurisdictional study that will also require review by one or more REB with which the University of British Columbia has a collaborative review agreement? (See the guidance to the right for details about the harmonized process.)	no

Simon Fraser University University of Alberta University of Northern British Columbia Northern Health Authority University of Saskatchewan University of Victoria Island Health Authority Fraser Health Authority Interior Health Authority Note: If submitting an amendment for an already approved study, you must respond "No" to this question)	
4* Clinical Study Review Type (Q 4.7, 4.8) [View Form]	
4.7.A Creation of a Registry (Data or Tissue Bank) Does this study involve the creation of a registry (data or tissue bank) for future use in other research? [if no, skip to 4.8]	no
4.7.B Is the purpose of this application exclusively to obtain approval for the creation of a research database, registry or tissue bank? [Note if the creation of the database or registry or tissue repository is part of a bigger project also included in this application, you must answer no below.]	no
Clinical Chart Review 4.8.A. Is this an application for research requiring access to clinical charts OR data from registries or databases such as PopData BC or Pharmanet?	no
4.8.B. Insert the date range of the charts/data to be included in this research. (e.g. 7 September 2005 – 6 September 2011)	
4.8.C. Is this study exclusively a retrospective chart review where the only source of data will be medical charts/records that are currently in existence? (i.e., will pre-date the date of your initial ethics approval?)	
4.8.D. Are you collecting and retaining personally identifiable information to be a part of the data set?	
4.8.E. Is this a retrospective	

chart review study for which participant consent will be obtained?	
5. Summary of Study and Recruitment - Clinical Study [View Form]	
5.1. Study Summary 5.1.A Provide a short summary of the project written in lay language suitable for non-scientific REB members. DO NOT exceed 100 words and do not cut and paste directly from the study protocol.	This research will explore the potential effects of Narrow-Band Ultra Violet B (NB-UVB) radiation on the intestinal microbiota composition and confirm a regulatory skin-to-gut axis during baseline conditions. Changes in the intestinal microbiota composition caused by NB-UVB phototherapy could be beneficial for patients with chronic/auto-inflammatory diseases like IBD by removing dangerous bacteria, increasing beneficial bacteria, and ultimately modulating immune responses.
5.1.B Summarize the research proposal: Purpose, Hypothesis , Justification, Objectives, Research Design and Statistical Analysis	Purpose: To explore the potential effects of Narrow-Band Ultra Violet B (NB-UVB) radiation on the intestinal microbiota composition in humans and confirm a regulatory skin-to-gut axis during baseline conditions. Hypothesis: Humans exposed to UVB-NB light will show changes in the intestinal microbiota composition with selection of certain phyla of bacteria. Justification: To date, there is no data that describes a biological response to UVB light in the body that affects the intestinal microbiota. Changes in the intestinal microbiota composition caused by NB-UVB phototherapy could be beneficial for patients with chronic/auto-inflammatory diseases like IBD by removing dangerous bacteria, increasing beneficial bacteria, and ultimately modulating immune responses. Objectives: 1. Establish if there is an skin regulatory response towards NB-UVB light in humans. 2. Examine what changes in the microbiota composition can be observed on bacterial phyla and class level. 3. Determine if this research is worth pursuing in a larger cohort. Research design: During the first visit, the skin type will be assessed by using the Fitzpatrick skin type questionnaire. Subsequently, subjects will be exposed three times within one week to full body NB-UVB light in The Skin Care Centre to a sub erythemic dose (cause slight redness of the skin but not burning). The exposures will happen during the winter months to prevent UVB exposure from the sun during daily activities to interfere with our observations. Stool samples will be collected before the first exposure (2x) and after the last exposure (2x) to analyse the

	microbiota composition. Also serum vitamin D (25-hydroxy vitamin D) will be measured before and after the UVB exposure as a marker of previous UVB exposure before the experiment. Subjects will be healthy Caucasian females between 19-40 years of age with a Fitzpatrick skin type I, II or III to minimise the variability in skin responses towards the UVB-NB light since fair skin colour is less adapted to absorb the UVB radiation than dark coloured skin. The microbiota composition will be analysed with 16S rRNA Illumina sequencing and calculated for differential abundance on phylum level. Statistical analysis: The statistical analysis will focus the personal microbiota composition variation after NB-UVB light exposure in comparison to before the UVB light exposure. Because we collect two samples before and two samples after the UVB exposures, each individual can serve as her own internal control.
5.2. Inclusion Criteria Inclusion Criteria. Describe the participants being selected for this study, and list the criteria for their inclusion. For research involving human pluripotent stem cells, provide a detailed description of the stem cells being used in the research.	Healthy Caucasian females between 19-40 years of age. Fitzpatrick skin type I, II or III (see box 9.8A for Fitzpatrick skin type assessment).
5.3. Exclusion Criteria Exclusion Criteria. Describe which potential participants will be excluded from participation, and list the criteria for their exclusion.	The participants will be excluded if they have skin photo sensitivity or taking medication that promotes photo sensitivity of their skin. Also participants that have been on vacation to a sunny destination since October 2017 or visit tanning beds on a regular basis will be excluded because they have been exposed to UVB radiation.
5.4. Recruitment Provide a detailed description of the method of recruitment. Include where applicable A) Who will contact prospective participants B) by what means this will be done. C) How prospective participants will be identified D) Ensure that any letters of initial contact or other recruitment materials are attached to this submission on Page 9.	The recruitment will be done via social media with Facebook (UVBstudy page). The recruitment advertisement is included in the submission. The researcher will contact prospective participants after they voluntarily contacted the study email address: UVBstudy@alumni.ubc.ca Initial contact will be through email conversation until the potential participant expresses interest participating by email. Once the participant has signed the consent form, a study identifier will be assigned to the participant to protect the individuals identity.
5.5. Recruitment of Normal/Control Participants Describe how prospective normal/control participants will	Each participant will serve as her own control. All participants will be recruited the same way.

be identified, contacted, and recruited, if the method differs from the above.	
5.6. Use of Records If existing records (e.g. health records, clinical lists or other records/databases) will be used to IDENTIFY potential participants or COLLECT DATA, please describe how permission to access this information, and to collect and use this information will be obtained.	No existing records will be used for this study.
5.7. Summary of Study Procedures	Participants will contact the study coordinator and will be invited to participate by and email that will be sent along with the consent form. A first meeting will be set up between the research coordinator and the participant at the Skin Care Center to explain the protocol and to sign consent forms. Also four stool collection kits will be handed to the participant. After signing the consent form, the Fitzpatrick skin type will be assessed with the hand of a questionnaire about the sun exposure habits. The participant is responsible to collect two stool samples during the week prior to the first light exposure and store it in her freezer at home. On the Monday of the first NB-UVB exposure, the research coordinator will confirm that a stool sample is collected by the participant. The participant will be referred to the lab at Life Labs to collect one blood sample (one tube of 15 ml, approximately one table spoon full) and will later go to The Skin Care Centre at VGH where the participants will be assessed under supervision of dr. Harvey Lui MD, for their first full body NB-UVB exposure. The participants will wear specialised goggles to protect the eyes from the UVB rays, and wear broad spectrum sunscreen on face and hands to protect these areas from the light. The NB-UVB light exposure will happen in a full body cabin, like an upright tanning bed, and will take no longer than 5 minutes. A time will be scheduled for the next two sessions with the participants. On Wednesday and Friday, the participant will receive a NB-UVB dose that is 10% higher than the fisrt visit, if tolerated well. Description of blood collection procedure at Life Labs: A blood sample will be taken by first applying a tourniquet to the upper arm. The skin on the inner side of the elbow will be sterilised and a small, sterile needle will be inserted into the vein. Two blood collection tubes will then be attached to the needle which will fill with blood. When the tube is full, the needle will be removed. A plaster or small bandage will be applied to cover the site where the needle

	was removed. Blood samples will be marked with their study identifiers and analysed in Life labs for of serum 25-hydroxy vitamin D3 according to Standards Council of Canada's Good Laboratory Practice (GLP) principles and Good Clinical Practice (GCP). The participant is responsible to collect tw stool samples the week after the three NB-UVB light exposures and store it in the freezer. The research coordinator will contact the participant when and where to pick up the stool samples, or participant can drop them off at their own convenience at the Skin Care Centre during on Monday, Wednesday and Friday nights. The stool samples that are collected from the participant will be stored in the BCCHR in a -80C freezer, in a locked lab until all samples from all participants are collected. Once all stool samples are collected, they will be send off to the Stintzi Lab at the University of Ottawa for 16S rRNA sequencing. The results will be analysed and stored on the BCCHR password-secured computer.
6. Participant Information and Consent Process - Clinical Study [View Form]	
6.1. Time to Participate How much time will a participant be asked to dedicate to the project beyond that needed for normal care?	The first visit to sign the consent form and do the Skin type assessment will take approximately 20 minutes. The visit for the first UVB exposure will take approx 20 minutes to review the exposure methods. The next two visits will take approximately 10-12 minutes each. The visits for the blood draws will take about 30 minutes, depending on the amount of waiting time of the Life Labs location. The total time the participant will spend to this study will be 2 hours minutes.
6.2. Time to Participate – Normal/Control Participants If applicable, how much time will a normal/control volunteer be asked to dedicate to the project?	Each participant will be treated similarly.
6.3. Risks/Harms Describe what is known about the risks (harms) of the proposed research.	The exposure to NB-UVB light will turn the skin slightly pink for 1-2 days. NB-UVB is ultraviolet radiation and could cause long term effects after excessive exposure, like skin ageing and skin cancer. The exposure from this study is equivalent to 5 min sun exposure during a summer's day, per visit and is unlikely to have any long-term effects. Short-term side effects may include skin redness, skin dryness, triggering of a cold sore. All of these effects are minor and

	will resolve, usually within a week. In rare cases the skin might turn red and gives a sun burn-like sensation. In this case, the sensation will fade away over the next days. The participant should contact the researcher in this case. Although minimal, there is a 0.5% risk of bleeding from the needle site. If this occurs the subject can be given a pressure bandage. The risks of blood draw also includes pain and/or discomfort, bruising, fainting and/or light headed sensation, and the rare possibility of infection.
6.4. Benefits Describe any potential benefits to the participant that could arise from his or her participation in the proposed research.	Exposure to NB-UVB will produce vitamin D in your skin that helps against seasonal affective disorder (SAD) and is important for your general health.
6.5. Reimbursement Describe any reimbursement for expenses (e.g. meals, parking, medications) or payments/incentives/gifts-in-kind (e.g. honoraria, gifts, prizes, credits) to be offered to the participants. Provide full details of the amounts, payment schedules, and value of gifts-in-kind.	There is a $750 budget for this study for the 30 test participants. Each participant will be given a $25 gift-certificate when the stool samples are collected and the participant is done with the study requirements.
6.6. Obtaining Consent Specify A) who will explain the consent form B) who will consent participants C) Include details of where the consent will be obtained and under what circumstances and D) the relationship of the person obtaining consent and participant.	Once the potential participants agree to participate to the study by email, the consent form will be explained in person by the research coordinator. The research coordinator will be able to answer all questions about possible concerns and about the procedure. The consent form will be discussed in person with the participant in an office setting in the Skin Care Center. Once the participants sign the consent form, they agree to be a part of the study. The participants will get the stool collection kits at that time and will come back for the further procedures one week later. The participant is free to withdraw from the study at any given time for the duration of the study. The physicians at the Skin Care Centre will go through the procedures with the participant and is able to answer any questions regarding the UVB exposure.
6.7.A. Waiver/Alteration of Consent If you are asking for a waiver or an alteration of the requirement for participant informed consent, please justify the waiver or alteration and explain how the study meets all the criteria on the right. Please click Guidance Notes on right and ensure that you address	There will be no waiver

each criteria individually. Include the corresponding letter (A, B, C, D, E) before each answer.	
6.7.B. Waiver of Consent in Individual Medical Emergencies If you are asking for a waiver or an alteration of the requirement for participant informed consent in individual medical emergencies, please justify the waiver or alteration and explain how the study meets all the criteria on the right. Please click Guidance Notes on right and ensure that you address each criteria individually. Include the corresponding letter (A, B, C, D, E) before each answer.	N/A
6.8. Time to Consent How long after being provided with detailed information/consent form about the study will the participant have to decide whether or not to participate? Provide your rationale for the amount of time given.	Once the participant contacts the study by email the consent form will be sent to them by email to read through before the first meeting. The research coordinator will discuss the contents of the consent form with the participant one week prior to the UVB light exposure protocol. Thus, participants will have 1-2 weeks to review the consent form before making a decision about participation.
6.9. Capacity to Consent Will every participant have the capacity to give fully informed consent on his/her own behalf? Please click Select to complete the question and view further details.	**Will the participant have the capacity to give fully informed consent?** / **Details of the nature of the incapacity** / **If not, who will consent on his/her behalf?** / **If not, will he/she be able to give assent to participate?** / **If Yes, explain how assent will be sought.** Yes [Details]
6.10. Renewal of Consent Describe any situation in which the renewal of consent for this research might be appropriate, and how this would take place.	There are no plans for renewal of consent. No further contact is required after obtaining the samples. All samples and data will be de-identified on collection and cannot be tracked back to the subjects.
6.11. Provisions for Consent What provisions are planned for participants, or those consenting on a participant's behalf, to have special assistance, if needed, during the consent process (e.g. consent forms in Braille, or in languages other than English).	Participants have to be able bodied to be able to participate in order to receive the UVB exposure. Subjects with no understanding of the English language will not be approached for involvement in the study unless a translator is present who can converse in the first language of the subject.
6.12. Restrictions on Disclosure Describe any restrictions	There are no restrictions on disclosure of information.

regarding the disclosure of information to research participants (during or at the end of the study) that the sponsor has placed on investigators, including those related to the publication of results. Also, indicate any plans for communicating study results to participants.	
7. Number of Participants and Study Drugs - Clinical Study [View Form]	
7.1. Multi-Centre Studies 7.1.A. Is this a multi-centre study (involves centres outside of those applied for under this Approval?)	no
If known, please list the other sites below:	
7.1.B. Is this study being submitted for ethical approval to any other Research Ethics Board?	**Description:** No
If yes, please provide the name of the REB(s) and if available, contact information:	
7.2. Number of Participants 7.2.A. How many participants (including controls) will be enrolled in the entire study? (i.e. the entire study, world-wide)	30
7.2.B. How many participants (including controls) will be enrolled at institutions covered by this Research Ethics Approval? (i.e. only at the institutions covered by this approval)	30
7.2.C. Of these, how many are controls?	0
7.2.D. Please enter any additional comments:	
7.3. Drug approvals Enter the generic name of any investigational drug(s) not yet approved or any marketed drug(s) used outside of its approved indication.	N/A
7.4. Marketed Drugs Enter the name of any marketed drug(s)	N/A

used within its approved indication.	
7.5. Natural Health Products Enter the name of any Natural Health Products used:	N/A
7.6. Experimental Devices Enter the name of any new investigational devices, or marketed devices used in experimental mode, that will be used outside of their approved indication.	A whole body stand-up photo-unit with Phillips UVB-NB fluorescent light bulbs as used in The Skin Care Center at Vancouver General Hospital.
7.7. PERs Enter the name of any positron-emitting radiopharmaceuticals (PERs).	N/A
7.8. Health Canada Regulatory Approvals 7.8.A. Health Canada Regulatory Approvals Is this study a clinical trial or investigational test requiring Health Canada regulatory approval (If this study does not require Health Canada approval, skip to 7.10)	no
7.8.B. If Yes, check all that apply from the list below.	**Description Regulatory Approval:**
7.8.C. Name the sponsor/institution/investigator responsible for filing a Clinical Trial Application (CTA) or Investigational Testing Authorization (ITA) with Health Canada or Other.	
7.9. Details of Health Canada Regulatory Approvals If regulatory approval from a Health Canada directorate is required for this study, your certificate of ethical approval will not be released until the regulatory approval certificate, approval date and control number are received by REB administration. Click Add to enter the name of the regulatory agency, the date of the application (if pending) or the date of the approval, and the control number and the date of approval, for either the initial application or subsequent	**Name of Agency** **Date of Approval** **Date of Pending Application:**

amendments. A copy of the approval (NOL, ITA, NOA) must also be attached in question 9.1.			
Health Canada NOL Control Number	**Health Canada NOL Control Number**	**Date of Approval**	
7.10. Stem Cell Research Does this research fall within the categories of pluripotent stem cell research that need to be submitted to the CIHR Stem Cell Oversight Committee (SCOC)?	no		
7.11. Registration for Publication of Clinical Trials 7.11.A. Does this clinical study fall within the definition stated on the right (in the guidelines)?	no		
7.11.B. If Yes, click Add to enter the following information. (Please note that registration by UBC ORS administration requires the prior ethical approval of the study. In that case, registration information should be added when it becomes available.)	**Has it been registered?**	**Indicate the Authorized Registry used:**	**Enter your Clinical Trial unique identifier:**
7.12. US Regulatory Requirements 7.12.A. Is there a requirement for this research to comply with United States regulations for research ethics?	no		
7.12.B. If yes, please indicate whether or not FDA (Investigational New Drug) number (drug studies) or an FDA Investigational Device Exception (IDE) is required for the research and provide documentation from the Sponsor or the FDA verifying the IND/IDE number, or explaining the study exemption status, in Question 9.1.C.			
8. Data Monitoring and Storage - Clinical Study [View Form]			
8.1. Unblinding in an Emergency Describe the provisions made to break the code of a double-blind study in an emergency situation, and indicate who has the code.	N/A		
8.2. Data Monitoring Procedures Describe data monitoring procedures while research is	N/A		

ongoing. Include details of planned interim analyses, Data and Safety Monitoring Board, or other monitoring systems.	
8.3. Study Stoppage Describe the circumstances under which the ENTIRE study could be stopped early. Should this occur, describe what provisions would be put in place to ensure that the participants are fully informed of the reasons for stopping the study.	Circumstances under which the entire study could be stopped would be very unlikely because the study includes healthy participants and the photo therapy irradiance dosages have been established by dermatologists. In case more than 50% of the included participants will have adverse side effects (lasting burning sensation and redness of the skin) from the UVB exposure(s), the study will be stopped early. The participants will be contacted by email about the situation and will be given the option to withdraw the biological samples, in case they are already collected, the samples will be discarded in the bio hazard waste disposal.
8.4. Personal Identifiers 8.4.A. Describe how the identity of the participants will be protected both during and after the research study, including how the participants will be identified on data collection forms.	The blood and stool samples will be marked with a study identifier (A,B,C,...) in executive letters to keep track what samples belong to which participant. This identifier will also be written on a master list that will be kept separately from the other participant information. The master list will be stored on a password protected computer in the BCCHR. There wont be any other personal details written on the samples to protect the identity of the participant.
8.4.B. Will any personal health information or personal identifiers be collected?	no
If yes, please describe what personal identifying information will be collected, and justify the need for it to be collected.	N/A
8.5. Data Access and Storage 8.5.A. A) Explain who will have access to the data at each stage of processing and analysis, B) indicate whether a current list of the names of study personnel (including co-investigators and research staff) and their delegated tasks will be maintained in the study file. C) If a list will not be maintained, please explain.	A list of enrolled participants and their consent forms will be available to the research coordinator. These files will be stored in a locked cabinet at the BC Children's Hospital Research Institute (Room 201, 950 West 28th Ave Vancouver, BC Canada V5Z 4H4). All data is de-identified by study identifier at the point of sample collection. The PI and students as listed on this application will have access to the data during process and analysis which will be stored on an analysis node which is hosted by the BC Children's Hospital research institutes network. The code number ensures the data cannot be traced back to a subject's ID number, by the PI, co-PIs, and students during processing and analysis. A list of names of study personnel and their delegated tasks will be maintained in the study file.
8.5.B. Describe how the data will be stored (e.g., computerized	The hard copy files from this study will be kept in a locked file cabinet in a locked office in the BC Children's Hospital

files, hard copy, video-recording, audio recording, personal electronic device, other).	Research Institute (Room 201, 950 West 28th Ave Vancouver, BC Canada V5Z 4H4). The de-identified data is gathered on paper clinical records forms and will be transferred to an electronic spreadsheet. The data that will be collected from the microbiota analysis will be stored and analysed on an analysis node which is hosted by the BC Children's Hospital Research institute's network. The data can be accessed on a password protected computer.
8.5.C. Describe the safeguards in place to protect the confidentiality and security of the data.	The hard copy files will be kept in a facility that has restrictive access, ID badge only for employees. The files are kept in a locked file cabinet in an locked office. The electronic data will be saved on a password accessible computer in the same room and is connected to a BCCHR hosted network that can not be accessed from outside the BCCHR.
8.5.D. If any data or images are to be kept on the Web, what precautions have you taken to prevent it from being copied?	No data or images will be kept on the web.
8.6. Disposition of Study Data and Biospecmens 8.6.A. Describe A) what will happen to the data at the end of the study including B) how long the study data will be retained, C) when and how the data will be destroyed, and D) what plans there are for future use of the data, including E) who will have access to the data in the future and for what purpose. If this study involves the creation of a research database or registry for the purpose of future research, please refer to the Guidance note linked on the right and provide the requisite information.	The raw and analysed data will be stored for 5 years on the BCCHR computing hard drive. This data is only accessible to people with a password to the computing node. The data will be removed from the computing node after passing 5 years after publication of the study results. Once the study is completed, the data will not be used for future research. Hard copies of the consent forms will be kept in the BCCHR and is only accessible to the principle researchers. The hard copies will be destroyed by a shredder once the 5 year term has ended.
8.6.B. If applicable, A) describe what will happen to the study samples/ biospecimens at the end of the study, including B) how long the study samples will be retained and C) where, when and how the samples will be destroyed, and D) what plans there are for future use of the samples, including who will have access to the sample in the future and for what purpose.	The serum samples will be analysed by Life Labs in Vancouver and will be discarded in the biological hazard waste upon analysis. The DNA from the stool samples will be collected with a commercial kit and shipped to the University of Ottawa for analysis. The remainder of the DNA will be stored in a -80C freezer in the BCCHR until quality of the sequencing analysis is confirmed. DNA samples will be discarded in the biological hazard waste afterwards quality control of the sequencing run. Neither of the labs get any personal information about the participants.
8.7. Data Transfer to Other	yes

Institutions 8.7.A Will data be sent outside of the Institution where it is being collected?:	
8.7.B. If yes, please describe A) the type of data to be transferred, B) who the data will be transferred to, C) where the data will be transferred, and D) how the data will be sent.	The stool samples will be send to the University of Ottawa for sequencing for bacterial composition analysis. The samples will be send, labelled with a study identifier to our collaborator in the Stintzi lab. The data for further analysis will be send back electronically and encrypted to the BCCHR researchers to store on password-protected computers.
8.8. Data Transfer to Institution 8.8.A Will the researchers be receiving data from other sites?:	no
8.8.B If yes, please describe A) the type of data to be received, B) who the data will be received from, C) where it will be received from, and D) how the data will be received.	
8.9. Data Linkage 8.9.A. Will the data be linked to any other data source (including a biorepository)?	no
8.9.B. A) Identify the data set, B) how the linkage will occur, and C) explain how confidentiality regarding the shared information will be preserved.	

9. Documentation - Clinical Study [View Form]

9.1.A. Protocol Examples of types of protocols are listed on the right. Click Add to enter the required information and attach the documents.	**Document Name**	**Version**	**Date**	**Password (if applicable)**
	Ethics proposal	5	January 23, 2018	[View]
9.1.B. Health Canada regulatory approval (receipt will be acknowledged)	**Document Name**	**Version**	**Date**	**Password (if applicable)**
9.1.C. FDA IND or IDE letters (receipt will be acknowledged)	**Document Name**	**Version**	**Date**	**Password (if applicable)**
9.2. Consent Forms Examples of types of consent forms are listed on the right. Click Add to enter the required information and attach the forms.	**Document Name**	**Version**	**Date**	**Password (if applicable)**
	Consent Form UVB study	5.2	February 13, 2018	[View]
9.3. Assent Forms Examples of types of assent forms are listed	**Document Name**	**Version**	**Date**	**Password (if applicable)**

on the right. Click Add to enter the required information and attach the forms.	
9.4. Investigator Brochures/Product Monographs Please click Add to enter the required information and attach the documents.	**Document Name** **Version** **Date** **Password (if applicable)**
9.5. Advertisement to Recruit Participants Examples are listed on the right. Click Add to enter the required information and attach the documents.	**Document Name** **Version** **Date** **Password (if applicable)** Recruitment Poster UVB study 5 January 23, 2018 [View] facebook page UVB study 1 May 15, 2017 [View]
9.6. Questionnaire, Questionnaire Cover Letter, Tests, Interview Scripts, etc. Please attach each separately. Please click Add to enter the required information and attach the documents.	**Document Name** **Version** **Date** **Password (if applicable)**
9.7. Letter of Initial Contact Please click Add to enter the required information and attach the forms.	**Document Name** **Version** **Date** **Password (if applicable)** Letter of initial contact research participant 3 May 4, 2017 [View]
9.8. Data collection forms and Other Documents 9.8.A. Please attach Data collection Forms, Chart extraction forms, CRF or other documents. Examples of other types of documents are listed on the right.	**Document Name** **Version** **Date** **Password (if applicable)** Response to REB review 3 May 12, 2017 [View] Fitzpartick scale 3 May 4, 2017 [View] UVBstudy peer review 1 February 1, 2017 [View]
9.8.B. If a Web site is part of this study, enter the URL below. Since URL's may change over time or become non-existent, you must also attach a copy of the documentation contained on the web site to this section or provide an explanation.	
10. Fee for Service - Clinical Study [View Form]	
Please indicate which of the following methods of payment	N/A (Not funded by an Industry For-Profit Sponsors)

will be used for this application.	
Enter information stating when the fee will be sent:	
11. UBC Children's and Women's Research Ethics Board [View Form]	
11.1. In order for a research project to be undertaken at C&W, either an employee or a member of the medical staff (as legally defined) needs to be designated as the Principal Investigator. This individual must have actual responsibility with respect to the project. Select the Principal Investigator for the Children's and Women's Health Centre.	**Last Name** / **First Name** / **Rank** Vallance / Bruce A. / Associate Professor
11.2. Does the Children's and Women's Principal Investigator in question 1.1 (and 11.1, if different) have a UBC academic or clinical appointment?	yes
Select Browse to attach the declaration form.	[View]
11.3. Select which hospital form(s) are required for this application.	Not Applicable
If you selected Other Resource/Service Utilization, please specify below.	
11. Hospital Information - Vancouver Coastal Health [View Form]	
11.1 Have you already received approval from VCHA to conduct this study?	no
If Yes, please provide the VCHA/VCHRI approval number (e.g. V06-0000)	
11.2. A. Does the Principal Investigator in question 1.1 have a medical appointment with VCHRI/VCHA and a UBC faculty appointment?	no
11.2.B. Does the Principal Investigator in question 1.1 have a medical appointment with VCHRI/VCHA (but not a faculty appointment at UBC), or is the Principal Investigator an employee of VCHA?	no
Select the Browse button to attach the declaration form.	[View]

11.2. C. Does the Principal Investigator in question 1.1 have a UBC appointment?	yes	
Select the Site Investigator at VCHA if different from the Principal Investigator in question 1.1.	**lastName** Dutz	**firstName** Jan P.
11.3. Select the VCHA Health Service Delivery Area(s) that will be involved in this study.	Vancouver Acute (Vancouver Acute encompasses the following sites: Vancouver General Hospital, UBC Hospital, GF Strong Rehabilitation Centre, Arthritis Research Centre of Canada, Mary Pack Arthritis Centre, Djavad Mowafaghian Centre for Brain Health)	
12. Save Application - Human Ethics [View Form]		
	Print	Close