Human Participant Ethics Protocol Submission

CONFIDENTIAL

0 - Identification

RIS Human Protocol Number
42284

Protocol Title
Hyperspectral Video Analysis for Skin Health and Beauty

Protocol Type
Investigator Submission

Applicant Information

Applicant Name
Dr Konstantinos Plataniotis

Rank / Position
Professor

Department / Faculty
Dept of Electrical & Computer Eng - Faculty of App

Business Telephone
4169465605

Extension

Email Address
kostas@comm.utoronto.ca

Collaborators/Co-Investigators

Name	Department	Email	Phone	Designation	Alt Contact
Pai Ng	University of Toronto	pc.ng@utoronto.ca	4169786845	Alternate Contact	X

Projected Project Dates

Estimated Start Date
1-Mar-22

Estimated End Date
30-Jul-22

2 - Location

Location of the Research: ☒ University of Toronto ☐ Other Locations

Administrative Approval/Consent

Administrative Approval/Consent Needed: ○ Yes ◉ No

Community Based Particatory Research Project? ○ Yes ◉ No

Other Ethic Boards Approval(s)

Another Institution or Site involved? ○ Yes ◉ No

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3 - Agreements and Reviews

Funding

Project Funded? (•) Yes ( ) No

External Funds Administered by U of T

App No.	Fund No.	Sponsor/Program	Status	Fund End Date	Peer Reviewed
216440	513208	Huawei Technologies Canada Co., Ltd	Awarded	2023-03-31	

Agreements

Funding/non-funding Agreement in Place? (•) Yes ( ) No

Document Title	Document Date
Signed Research Agreement	2021-09-30

Any Team Member Declared Conflict of Interest? ( ) Yes (•) No

Reviews

☐ This research has gone under scholarly review by thesis committee, departmental review committee, peer review committee, or some other equivalent

☐ This research will go under scholarly review prior to funding

☒ This review will not go under a scholarly review

4 - Potential Conflicts

Conflict of Interest

Will researchers, research team members, or immediate family members receive any personal benefit? ( ) Yes (•) No

Restrictions on Information

Are there any restrictions regarding access to, or disclosure of information (during or after closure)? ( ) Yes (•) No

Researcher Relationships

Are there any pre-existing relationships between the researchers and the researched? ( ) Yes (•) No

Collaborative Decision Making

Is this a community based project - i.e.: a collaboration between the university and a community group? ( ) Yes (•) No

5 - Project Details

Summary

Rationale

Describe the purpose and scholarly rationale for the project

(Purpose) The purpose of this project are to 1) reconstruct the hyperspectral images from RGB image captured by consumer grade smartphones or any end-user devices; and 2) apply the advanced hyperspectral imaging (HIS) analysis techniques to predict users' skin information, such as hemoglobin, oxygen saturation, melanin, skin hydration, skin sebum.
(Rationale) Many skin analysis solutions rely on expensive clinical and laboratory equipment, which are not readily available to the end users. Specifically, a skin camera enabled by spectroscopic technology is used under a control environment to extract users' skin information. Through spectroscopic technology, hyperspectral images can be acquired, these images are capable of unveiling richer information of a skin image through different wavelengths beyond the

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visible spectrum. However, capturing hyperspectral images needed to be conducted in a controlled environment as the skin analysis is very sensitive to illumination and environmental (ambient light) changes.
On the other hand, capturing selfie image has become a common activity for many people through their smartphone's camera. Smartphone-based skin analysis can benefit many people who want to get a quick overview of their current skin condition before researching useful skin products that can improve their skin condition. The lack of hyperspectral imaging capabilities on current smartphones is the bottleneck to realizing pervasive skin analysis through everyday smartphone. Rather than embedding expensive hardware components to realize the hyperspectral imaging capabilities on the smartphone, this project explores the possibility of using AI technology to reconstruct the hyperspectral images given the standard RGB images captured by the normal smartphone's camera. Based on the reconstructed images, this project further applies advanced HIS techniques to extract skin information.
In summary, this project aims to develop the skin analysis with consumer-grade devices (e.g., smartphone and smartwatches). To that end, a hyperspectral image reconstruction solution needs to be developed and implemented in consumer-grade device, while applying the advanced HIS analysis to predict the user's skin information. Large-scale hyperspectral and RGB images describing various skin conditions are needed to facilitate the development of this project.
Please note the following:
a) The outcome will be used for user-driven cosmetic purposes.
b) There are no medical or well-being results sought or obtained as the result of the process.
c) There is no direct physical contact with the participant during the data collection.
References:
1. Lou Gevaiux, et al, Real time Skin Chromophore Estimation from Hyperspectral Imaging using a Neural Network, Wiley Skin Research Technology, 2021, 27: 163-177, DOI: 10.1111/srt.12927.
2. E. Zherebtsov, et al, Hyperspectral Imaging of Human Skin aided by Artificial Neural Networks, Biomedical Optical Express, 2019, 10-3545.

Methods

Describe formal/informal procedures to be used

The data collection campaign attempts to collect large-scale dataset consisting of the hyperspectral and RGB images of various skin conditions from approximately 50 volunteers. Three types of cameras will be used to capture the skin images:
1. A hyperspectral camera that can capture the hyperspectral image at different wavelengths (350-2000nm) via snapshot exposure. The data collected from this camera will be used to facilitate the development of 1) hyperspectral image reconstruction and 2) skin analysis (for comparative study)
2. A smartphone camera to capture standard RGB images. The data collected from this camera will be used to facilitate the development of 1) hyperspectral image reconstruction. And the reconstructed image will be used for 2) skin analysis (for experimental study and mobile application development)
3. A skin camera (e.g., VisioScope-PC35) that provides cosmetic information of a skin. The data collected from this camera will be used as ground truth facilitating the 2) skin analysis (for ground truth labelling).
Both the hyperspectral and smartphone camera will be mounted on a tripod. The tripod will be placed at certain distances from the participant, sitting on a chair with a fixed head/chin. Both cameras will be pre-calibrated so that they focus on the participant's face. The investigator will signal the image acquisition process verbally before triggering the acquisition button for both cameras simultaneously. The acquisition buttons are available through a remote control that can be operated from a distance. The distance between the investigator and the participant should be at least 2m. For the skin camera, the user is required to operate the skin camera by themselves to capture the skin information. A short briefing will be provided by the investigator to explain the operation of the skin camera and the skin spot required by our project. A diagram that illustrates the camera positions, and further elaboration regarding the imaging instruments and experimental setups are provided in the attached document. All users are required to understand and sign the consent form prior to the data collection.
While this step cannot be completed online via remote acquisition, our team will work carefully to ensure the compliance with the Covid-19 preventive measures. All the Covid-19 protocols, including the entrance screening, vaccination requirements, masking, sanitization, and disinfection will be observed carefully by our investigators. Specifically, these steps will be followed before allowing a user to participate in the data collection campaign:
1 - COVID-19 screening process and precautions (e.g. screening questions and wearing facial mask/shield, hands/desk sanitization)
2 - The participants (who are mainly UofT grad/undergrad students) will be asked to perform self-assessment (UCheck) before coming to the Uoft premises.
3 - Collection of personal contact information, as required by public health and the University (e.g. Name, phone, address) for contact tracing.

Copies of questionnaires, interview guided and/or other instruments used

Document Title	Document Date
Example of online questionnaire to be filled by the participant	2022-01-10
This document describes the instruments to be used for data collection campaign and the related setup	2022-03-11

Clinical Trials

Is this a clinical trial? ○ Yes ◉ No

6 - Participants and Data

Participants and/or Data

What is the anticipated sample size of number of participants in the study? 50

Describe the participants to be recruited, or the individuals about whom personally identifiable information will be collected. List the inclusion and exclusion criteria. Where the research involves extraction or collection personally identifiable information, please describe where the information will be obtained, what it will include, and how permission to access said information is being sought.

The data collection campaign targets to recruit 40-60 participants, with 50 participants under ideal recruiting conditions. The participants will be recruited either through email invitations or advertisements posted at the University of Toronto forums and advertisement board. The desired sample size will vary depending on the number of experimental conditions while the expected sample size of 50 is set based on budgetary considerations. While there are no specific criteria for

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inclusion/exclusion, healthy participants who are fully vaccinated and are able to show their proof of vaccination will be recruited for this data collection campaign.
Participation in this study will be strictly voluntary. The participant will be briefed about the purpose of the data collection campaign, both in writing and orally. Besides the consent form, the participant is expected to provide their demographic data by filling out an online questionnaire aiming to collect the following personal information:

1. Age
2. Biological Sex
3. Ethnicity
4. Skin type

The online questionnaire will be designed using a secure Microsoft Forms survey form provided by EASI, University of Toronto (link: https://easi.its.utoronto.ca/shared-services/office365/forms/). The outcomes of the survey will be stored privately using the password-encrypted Microsoft One-drive storage available through the MS platform empowered by UofT. A sample draft of the survey questions designed through MS Forms is attached to this application as an appendix. A list of private files with anonymous IDs linking to participants and their contact information will be stored privately in case a participant needs to be contacted later for any reason, or if they request to withdraw from the study. The access to these private files is strictly restricted to the authorized personnel (i.e., the supervisor of this project and the investigators). These files will not be distributed for any research purposes including experiment reproduction or competition. Participants will need to sign a consent form to approve the collection of these personal data. Also, the collection of personal information will be used for contact tracing purposes in case of a positive Covid-19 case following the current public health measures.
Please note that the reason is that this personal information is importance to skin analysis as each individual skin varies in terms of age, gender, ethnicity, and skin type. A comprehensive analysis of diverse skin types from diverse group of people is desirable to provide richer data enabling the development of a more generalized skin detection system.

Is there any group or individual-level vulnerability related to the research that needs to be mitigated (for example, difficulty understanding consent, history of exploitation by researchers, or power differential between the researcher and the potential participant)? ○ Yes ◉ No

Recruitment

Is there recruitment of participant? ◉ Yes ○ No

Recruitment details including how, from where, and by whom

The recruitment process started by circulating a poster via email list servers to those those at the University of Toronto (students), and posted on online forums. An example of the poster is attached in this application as an appendix in the document section. There will be mass recruitment mailings sent either directly by the researchers, or sent on behalf of the researchers through another organization or department.

Is participant observation used? ○ Yes ◉ No

Will translation materials be used/required? ○ Yes ◉ No

Attach copies of all recruitment posters, flyers, letters, email text, or telephone scripts

Document Title	Document Date
Example of poster type advertisement	2022-01-13
Example of poster type advertisement - Updated	2022-05-16

Compensation

Will the participants receive compensation? ◉ Yes ○ No

Type of Compensation

☒ Financial
☐ In-kind
☐ Other

Compensation Justification Details

Each participant will be engaged for approximately 0.5 hour (15min for each part). Participants will be compensated at the rate of $20/hr, plus $10 bonus for good performance. Hence, the maximum compensation is $20 per participant for a data collection that last 30min. If a withdrawal should occur, participant will be compensated on a pro-rated basis at $20 per hour, for the participant's involvement to that point. Compensation will be prorated to the next 15-minute increment. Participants will not receive the $10 good performance bonus if decide to withdraw before the session is completed.

Is there a withdrawal clause in the research procedure? ◉ Yes ○ No

Is compensation affected when a participant withdraws?

Compensation will be pro-rated at $20 per hour. If a withdrawal occur compensation will be prorated to the next 15-minutes. Participants will not receive the

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$10 good performance bonus if decide to withdraw before the session is completed.

7 - Investigator Experience

Investigator Experience with this type of research

Please provide a brief description of the previous experience for this type of research by the applicant, the research team, and any persons who will have direct contact with the applicants. If there is no previous experience, how will the applicant and research team be prepared?

The PI for this application, Professor K.N. Plataniotis, is a signal and image processing expert and an internationally recognized authority on color image processing with pioneering contributions to color image processing, face detection and recognition. He has more than 25 years of experience in the area of image processing, including hyperspectral/multispectral imaging for geoscience and defense related applications.
Under the guidance and direction advised by Professor K.N. Plataniotis, the research team from the internal and external groups will work collaboratively to setup the equipment for data collection, disinfect the equipment, and train the participant on using the skin camera. Prior to that, the research team will work closely on the camera's calibration and remote setup so that the camera can be operated from a distance through a remote control. The research team had previous experience in projects that involved high-end imaging devices and large-scale data collection. Hence, the research team only require minimal self-training to get familiar with the operation of the cameras, including the skin camera. The research team will also be equipped with all the Covid-19 prevention measures so that they can facilitate the data collection in a Covid-free environment.

Are community members collecting and/or analyzing data? ○ Yes ◉ No

8 - Possible Risks and Benefits

Possible Risks

Potential Risk Details:

Physical Risks	○ Yes	◉ No
Psychological/emotional Risks	○ Yes	◉ No
Social Risk	○ Yes	◉ No
Legal Risk	○ Yes	◉ No

Potential Benefits

Benefit Description

Participants will be made aware that the data collected from the trial may benefit the scientific community and that the knowledge gained from their data will be used to develop skin analysis application on consumer-grade smartphone, bringing skin analysis into every day activities.

9 - Consent

Consent Process Details

Participants will receive both written and verbal instructions describing the experimental setup to capture the skin image. The skin image is a visual data that contains the participant's facial and skin information. We acknowledge that the facial data may expose participant's identifiable information, and this will be communicated to the participant so that he/she is aware that the collected data may render them identifiable. To protect the participant's right and ensure the confidentiality, the following steps will be taken:
1. The periocular area will be obfuscated by blurring out the participant's periocular area.
2. The participant can also use "sunglasses" during data collection to cover the eye area.
It will be explained to the participants that the visual data will not leave the University of Toronto's research repository without obfuscating periocular area. Our research team will work to ensure all participants' privacy and identifiable information are protected.
Besides the briefing about the data collection process including the type of data that will be collected and how this data will be protected, our research team will also answer any questions the participants may have. We will ensure the participants are well-informed about the experimental setup, the data, the privacy protection before getting them to sign the consent form. The proposed form is included in this application as an appendix.

Uploaded letter/consent form(s)

Document Title	Document Date
Example of consent form that needs to be signed by the participant	2022-01-10

Is there additional documentation regarding consent such as screening materials, introductory letters etc.: ○ Yes ◉ No

Uploaded letter/consent form(s)

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Will any information collected in the screening process - prior to full informed consent to participate in the study - be retained for those who are later excluded or refuse to participate in the study? ○ Yes ◉ No

Is the research taking place within a community or organization which requires formal consent be sought prior to the involvement of the individual participants ○ Yes ◉ No

Are any participants not capable (e.g.: children) of giving competent consent? ○ Yes ◉ No

10 - Debriefing and Dissemination

DeBrief

Will deception or intentional non disclosure be used? ○ Yes ◉ No

Will a written debrief be used? ○ Yes ◉ No

Do participants/communities have the right to withdraw their data following the debrief? ○ Yes ◉ No

Information Feed Back Details following completion of a participants participation in the project

Participants will be informed about the completion of the experiment and re-assured that their data will be treated confidentially as per the agreed upon procedure.

Procedural details which allow participants to withdraw from the project

The participants can withdraw from the project by giving a written or verbal notice either through email or phone conversation. At least one day (24hrs) notice should be given to allow the research team to reschedule the data collection for the next participant.

☐ Not Applicable

What happens to a participants data and any known consequences related to the removal of said participant

The participant's data will be disposed and removed from our repository permanently, if they withdraw by giving one day notice. If the participant withdraw on-the-spot, their information will be kept for the next 21 days for contact tracing purposes. After 21 days, the information will be removed permanently.

☐ Not Applicable

List reasons why a participant can not withdraw from the project (either at all or after a certain period of time)

☒ Not Applicable

11 - Confidentiality and Privacy

Confidentiality

Is the data confidential? ◉ Yes ○ No

Will the confidentiality of the participants and/or informants be protected? ◉ Yes ○ No

List confidentiality protection procedures

The privacy and confidentiality of the participant's personal information and study data will be protected by assigning a non-descriptive alias to each of them. The alias will be used to match the participant to the participant's questionnaire, data, and interview (prior to consent). The mapping between the participant's identity and alias will not be made available to other participants or appear in any publication. As it was previously stated the image data recording will render the participants identifiable. To protect the identity of participants, the visual data will not leave the University of Toronto's research facilities without obfuscating the participant's periocular area so that to protect their identity.

Are there any limitations on the protection of participant confidentiality? ○ Yes ◉ No

Is participant anonymity/confidentiality not applicable to this research project? ○ Yes ◉ No

Data Protection

Describe how the data (including written records, video/audio recordings, artifacts and questionnaires) will be protected during the conduct of the research and subsequent dissemination of results

All digital data will be stored in a password protected computer system and physical records will be kept under lock-and-key in the Multimedia Laboratory directed by the PI. Digital data will be transferred to a secure server hosted by the ECE department. The transfer or data from the equipment used to the

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password protected desktop computers and servers will be used using encrypted storage devices consistent with UofT's encryption guidelines. UofT's standard cryptographic network protocol for network data transfers will be observed.
Information Technology support staff at the ECE department administer the Multimedia Laboratory's servers and computers. They will oversee compliance with the university's policies and procedures. The mapping key between participant's identities and aliases will be stored in a separate, password protected folder, from the data. Only the principal investigator and the con-investigator listed in this ethics protocol application will have access to the identity keys. During the analysis stage, the data containing aliases will also be transferred to researchers' work computers that are password protected and their security is monitored by the ECE department's IT staff. It should be noted that the participation/consent agreement explicitly states that all collected personal identifiers information shall remain confidential.

Explain for how long, where and what format (identifiable, de-identified) data will be retained. Provide details of their destruction and/or continued storage. Provide a justification if you intend to store identifiable data for an indefinite length of time. If regulatory requirements for data retention exists, please explain.

The data will retained for five (5) years as per standard practice in the discipline of computer research with human subjects. All data on paper will be converted to digital format. All data will be stored in a programmable storage device which will automatically which will automatically delete the data after five (5) years.

Will the data be shared with other researchers or users? (•) Yes ( ) No

Please describe how and where the data will be stored and any restrictions that will be made regarding access.How will participant consent be obtained? If data is to be made open access, please describe how and where they will be maintained.

Hyperspectral and visual images, with obfuscated periocular area so that to protect the participant's identity, will become available to the research community at large for research purposes (open access). No other information or data pertinent to participants will be released. The participation / consent form states the facts. Potential participants will be given the opportunity to discuss the process with the recruiter during the interview process. Researchers interested to access the dataset for their research studies will have to submit an End-User-Licence-agreement (EULA), standard practice in the discipline, and get approved by the principal investigator. Data will be stored, maintained, and curated at the Multimedia Laboratory, ECE Department, University of Toronto.

12 - Level of Risk and Research Ethics Board

Level of Risk for the Project

Group Vulnerability: Low

Research Risk: Low

Risk Level: 1

Explanation/Justification

Explanation/Justification detail for the group vulnerabilty and research risk listed above

Participants are familiar, through their every day activities, with cameras, and there is no risk of physical injury during the data acquisition campaign.
Participants will be provided with a disposable towel to clean their skin after the completion of the experiment. There will not be any hygienic issues since image acquisition is done at a distance and each participants ground truth data will be obtained using disposable tips, a standard industry practice. During the experiment, participants will be asked to notify investigators if they feel discomfort for any reason.
The experimental site is located inside the Multimedia Laboratory, Department of Electrical and Computer Engineering. Each participant is required to complete the UCheck and show their proof of vaccination before entering to the experimental site. Only one participant is allowed in the experimental site at each time slot. The maximum number of investigators on-site is limited to 2. All the equipment will be disinfected before and after the experiment.

Research Ethics Board

REB Associated with this project: Health Sciences

13 - Application Documents Summary

Uploaded Documents

Document Title	Document Date
Response to REB Comment 1	2022-05-16
Response to REB Comment 2	2022-05-16
Response to REB Comment 3	2022-05-16
Response to REB Comment 4	2022-05-16

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Document Title	Document Date
Response to REB Comment 5	2022-05-16
Response to REB comments - comprehensive	2022-05-16
Revised Consent Document - Section 9	2022-05-16
Revised Poster Document	2022-05-16
Demographic questionnaire	2022-05-16
Signed Research Agreement	2021-09-30
Example of online questionnaire to be filled by the participant	2022-01-10
This document describes the instruments to be used for data collection campaign and the related setup	2022-03-11
Example of poster type advertisement	2022-01-13
Example of poster type advertisement - Updated	2022-05-16
Example of consent form that needs to be signed by the participant	2022-01-10
Our input to the risk assessment form	2022-03-14

14 - Applicant Undertaking

I confirm that I am aware of, understand, and will comply with all relevant laws governing the collection and use of personal identifiable information is research. I understand that for research involving extraction or collection of personally identifiable information, provincial, federal, and/or international laws may apply and that any apparent mishandling of said personally identifiable information, must be reported to the office of research ethics.

As the Principal Investigator of the project, I confirm that I will ensure that all procedures performed in accordance with all relevant university, provincial, national, and/or international policies and regulations that govern research with human participants. I understand that if there is any significant deviation in the project as originally approved, I must submit an amendment to the Research Ethics Board for approval prior to implementing any change.

☒ I have read and agree to the above conditions

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RIS Protocol Number: 42284

Approval Date: 20-May-22

PI Name: Dr Konstantinos Plataniotis

Division Name:

Dear Dr Konstantinos Plataniotis:

Re: Your research protocol application entitled, "Hyperspectral Video Analysis for Skin Health and Beauty"

The Health Sciences REB has conducted a Delegated review of your application and has granted approval to the attached protocol for the period 2022-05-20 to 2023-05-19.

This approval covers the ethical acceptability of the human research activity; please ensure that all other approvals required to conduct your research are obtained prior to commencing the activity.

Please be reminded of the following points:

- An **Amendment** must be submitted to the REB for any proposed changes to the approved protocol. The amended protocol must be reviewed and approved by the REB prior to implementation of the changes.
- An annual **Renewal** must be submitted for ongoing research. Renewals should be submitted between 15 and 30 days prior to the current expiry date.
- A **Protocol Deviation Report** (PDR) should be submitted when there is any departure from the REB-approved ethics review application form that has occurred without prior approval from the REB (e.g., changes to the study procedures, consent process, data protection measures). The submission of this form does not necessarily indicate wrong-doing; however follow-up procedures may be required.
- An **Adverse Events Report (AER)** must be submitted when adverse or unanticipated events occur to participants in the course of the research process.
- A **Protocol Completion Report** (PCR) is required when research using the protocol has been completed.
- If your research is funded by a third party, please contact the assigned Research Funding Officer in Research Services to ensure that your funds are released.

Best wishes for the successful completion of your research.

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