UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG
Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Ms Venesa Pillay et al

CLEARANCE CERTIFICATE	**M120647**
PROJECT	Identification of Genetic Markers of Obesity Risk and Body Composition in a South African Black Population
INVESTIGATORS	Ms Venesa Pillay et al.
DEPARTMENT	School of Pathology/Div. of Human Genetics
DATE CONSIDERED	29/06/2012
DECISION OF THE COMMITTEE*	Approved unconditionally

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.

DATE 29/06/2012 **CHAIRPERSON** ..... (Professor PE Cleaton-Jones)

*Guidelines for written 'informed consent' attached where applicable
cc: Supervisor : Dr Zane Lombard

DECLARATION OF INVESTIGATOR(S)
To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10004, 10th Floor, Senate House, University.
I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. **I agree to a completion of a yearly progress report.**

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES...

Human Research Ethics Committee (Medical)

Research Office Secretariat: Senate House Room SH 10005, 10th floor. Tel +27 (0)11-717-1252
Medical School Secretariat: Medical School Room 10M07, 10th Floor. Tel +27 (0)11-717-2700
Private Bag 3, Wits 2050, www.wits.ac.za. Fax +27 (0)11-717-1265

25 November 2013

Ms Venesa Pillay et al
School of pathology
Division of Human Genetics
University of the Witwatersrand

Sent by email to: venesap@gmail.com

Dear Ms Pillay

Protocol no: M120647
Protocol Title: Identification of Genetic Markers of Obesity Risk and Body Composition in South African Black Population
Principal Investigator: Ms Venesa Pillay et al
Protocol Amendment

This letter serves to confirm that the Chairman of the Human Research Ethics Committee (Medical) has approved the following amendments as detailed in your letter dated 16 November 2013:

- Extension of the research to include 1260 additional samples from study no M010556

Thank you for keeping us informed and updated,

Yours Sincerely,

.....
Ms Zanele Ndlovu
Administrative Officer
Human Research Ethics Committee (Medical)

health

Department:
Health
REPUBLIC OF SOUTH AFRICA

Private Bag X828, PRETORIA, 0001
Civitas Building Corner Andries and Struben Street, PRETORIA, 0001
Tel (012) 395 0922 • Fax (012) _____

Tel (012) 395-8366/9197 Ms Lineo Motopi

Fax 086 632 6815/2606 J1/2/4/2 No ' '13

Prof Michele Ramsay
Medical Technologist
NHLS and Wits University
Division of Human Genetics
P O Box 1038
JOHANNESBURG
2000

Dear Prof Ramsay

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Attached please receive one export permit as requested by your fax dated 30 April 2013.

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Kind regards

DIRECTOR-GENERAL: HEALTH
Date:
Ms P Netshidzivhani

health

Department:
Health
REPUBLIC OF SOUTH AFRICA

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Civitas Building Corner Andries and Struben Street, PRETORIA, 0001
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Reference : J1/2/4/14 No1/1
Enquiry : Ms Lineo Motopi
Tel : (012) 395-8366/0197
Fax : (086) 632 6815/0306

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In terms of Section 68 of the National Health Act 2003 (Act No. 61 of 2003) –

Prof Michele Ramsay
Medical Scientist
NHLS and Wits University
Division of Human Genetics
P O Box 1038
JOHANNESBURG
2000
Tel. No.: (011) 489 9214 Fax. No.: (011) 489 9226

is hereby authorised to export from the Republic of South Africa –
12 x PCR plates (1034 samples) Human genomic DNA samples

to –

Dr Vanessa
DNA Technologies Core,
University of Crlifornia
Davis 4212A GBSF
475 Health Sciences Drive
Davis, CA, 95616
UNITED STATES OF AMERICA
Tel:. No: 530-754-5821 Fax. 530-754-9658

for – Research.

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4. **This export permit shall expire on 31 May 2014.**

DIRECTOR-GENERAL: HEALTH
Date:
Ms P Netshidzivhani

Human Materials Transfer Agreement
Wits-INDEPTH partnership – AWI-Gen Study
NIH - H3Africa funded research

In agreement between the RECIPIENT and the PROVIDER this is a request to transfer MATERIAL:

MATERIAL: Human Genomic DNA

Definitions:

PROVIDER: Principal Investigator responsible for the project from which the material originates

RECIPIENT: Principal Investigator responsible for the project where the research data will be generated

RECIPIENT SCIENTISTS: Scientists working in the group of the RECIPIENT to generate the data for the specified project

MATERIAL: Refers to the specific biological samples as detailed in Appendix A to this agreement which describes the nature of the project

The PROVIDER asks that the RECIPIENT and the RECIPIENT SCIENTISTS agree to the following before the RECIPIENT receives the MATERIAL:

1. The above MATERIAL is the property of the PROVIDER and is made available for a specific purpose (Generating CardioMetabochip data on the samples provided).

2. THIS MATERIAL IS NOT FOR USE IN HUMAN SUBJECTS.

3. The MATERIAL will be used for the stated purpose only.

4. The MATERIAL will be used as described in Appendix A only. Any other use of the MATERIAL requires the PROVIDER's written consent and an amendment from the relevant Research Ethics Committee.

5. The data generated by the MATERIAL, once it has been used as described in Appendix A, shall be retained by the RECIPIENT for a limited time only AND will be sent to the PROVIDER for use in the public domain according to a stipulated process of the Wits-INEPTH H3Africa funded partnership program. The RECIPIENT will refer requests for access to the data to the appropriate Wits-INDEPTH partnership committee on which the PROVIDER will have representation.

6. The MATERIAL will not be further distributed to others. Any MATERIAL left over after the stipulated experiments have been concluded will be kept until completion of the project and will then be destroyed, as agreed between the parties.

7. The RECIPIENT will not publish any of the data generated.

8. Any MATERIAL delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. The MATERIAL is of human origin and may pose unknown and unrecognized health or safety risks. The RECIPIENT will handle the MATERIAL using appropriate procedures for human-source materials. THE PROVIDER MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIAL WILL NOT INFRINGE ANY

PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS. Unless prohibited by law, RECIPIENT assumes all liability for claims for damages against it by third parties which may arise from the use, storage or disposal of the MATERIAL except that, to the extent permitted by law, the PROVIDER shall be liable to the RECIPIENT when the damage is caused by the gross negligence or willful misconduct of the PROVIDER.

9. The Material provided by the PROVIDER Institution will be de-identified. The RECIPIENT Institution will not be provided with any information that could be used to identify the subjects from whom the MATERIAL was collected, although the PROVIDER Institution may retain a confidential link to the subject's identity. Neither RECIPIENT Institution nor RECIPIENT Scientists shall make any attempts to determine the identity of those subjects, or to contact the subjects. Should a human subject from whom MATERIAL was collected object to the use set forth herein, then the RECIPIENT Institution agrees to promptly comply with PROVIDER Institution's request to return or destroy any such sample.

10. RECIPIENT agrees to use the MATERIAL in a safe manner and in compliance with all applicable laws and regulations. PROVIDER warrants that it has obtained any Institutional Review Board or Ethics Committee approval required for the transfer of this MATERIAL.

11. The RECIPIENT and PROVIDER take responsibility to the authenticity of the ethics approval certificates (Appendix B) and export, import certificates (Appendix C) as required by and in accordance with the laws of their respective countries.

12. This Agreement will terminate upon completion of RECIPIENT Institution's use of the Material. The Parties agree that the provisions of this Agreement are intended to be interpreted and implemented so as to comply with all applicable laws, governmental rules and regulations; however, if it is determined that any provision of this Agreement is not in such compliance, or if an Institutional Review Board or other comparable body objects to the terms of this Agreement or the provision or use of the Materials, then the Parties agree to modify that provision, or this Agreement so as to be in compliance or to be acceptable to such Institutional Review Board. If such modification is not possible, or practical, or if the Parties are unable to agree upon the modification to be made, then either Party may immediately terminate this Agreement. PROVIDER Institution shall have the right to terminate this Agreement for any reason including RECIPIENT Institution's breach of any of its obligations or responsibilities under this Agreement, and such breach is not cured within thirty days of receipt of written notice from PROVIDER Institution. Upon termination for any reason the RECIPIENT Institution will, at PROVIDER Institution's discretion, either store, or return or destroy any remaining Material in accordance with applicable laws and regulations.

The PROVIDER and RECIPIENT must sign both copies of this letter and return one signed copy to the PROVIDER. The PROVIDER will then send the MATERIAL.

PROVIDER INFORMATION and AUTHORIZED SIGNATURE

Provider: Prof. Michèle Ramsay
Provider contact details: Michele.ramsay@nhls.ac.za, 0114899214
Provider Organisation: National Health Laboratory Services
Provider Address: Department of Human Genetics, Room 109 Watkins Pitchford Building, National Health Laboratory Services, Braamfontein, 2000, South Africa

M. Ramsay

29 April 2013

Signature of Provider Date

Name of Authorised Official:
Title of Authorised Official:

03/05/2013

Signature of Authorised Official Date

Chair Human Research Ethics Committee (Medical)

RECIPIENT INFORMATION and AUTHORIZED SIGNATURE

Recipient: Dr Vanessa Rashbrook
Recipient contact details: tel: 530-754-5281, vkrashbrook@ucdavis.edu, fax: 530-754-9658
Recipient Organisation: University of California, Davis
Recipient Address: DNA Technologies Core
4212A GBSF
451 Health Sciences Drive
University of California - Davis
Davis, CA 95616

Vanessa Rashbrook 9 May 2013

Signature of Recipient Date

Name of Authorised Official:
Title of Authorised Official:

9 May 2013

Signature of Authorised Official Date

Appendix A

Aim and objectives of the project

Title of the Research Project: Identification of Genetic Markers of Obesity Risk and Body Composition in a South African Black Population.

The overall aim of the proposed research is to identify genetic markers of obesity risk in a South African Black population (caregivers of the Bt20 cohort)

To achieve this, we will study the genetic population contributions of the Bt20 caregiver cohort, to aid optimal design of the association studies. We will then perform an association study, focusing on loci associated with obesity measures (e.g. Body mass index (BMI), body fat %, waist to hip circumference) in Europeans, to confirm if these loci are similarly associated with obesity risk in Africans, using the Human CardioMetabochip (Illumina).

AIM: Fine map loci previously associated with body composition to assess the association in an African population, and identify the candidate regions at these loci using the data obtained from the cardioMetabochip.

Brief description of the project

Obesity is a considerable risk factor for the development of several chronic, non-communicable diseases (CNDC), and is becoming more prevalent in developing countries such a South Africa. Although environmental factors have a considerable impact on obesity risk it also has a genetic component (Bodurtha et al., 1990; Wardle et al., 2008). The study of syndromic obesity has provided some insight into the genetic causes of obesity and genome-wide association studies (GWAS) have provided further evidence for common obesity risk loci. All current GWAS for body composition and obesity are based on non-African populations, with an explicit deficit of African-centric research. Also the identification of causal variants in genetic association studies in African groups is more efficient, because linkage disequilibrium (LD) exists over a shorter genomic distance. Furthermore, the metabolic consequences of obesity are highly dependant on body fat distribution and ethnic differences in body composition are well documented (Crowther and Ferris, 2010). The factors underlying these differences are not fully understood and there is an explicit shortfall in African-focused research into genetic factors for obesity and body composition. Although

variation within and around numerous genetic loci has been associated with obesity, heritability is not fully explained by our current knowledge of genetic variation. This study will utilize available longitudinal data to search for molecular obesity risk factors across the life-course and will be the first study of its kind focusing on a black South African cohort (Bt20).

Participants in the project
Ethnicity: SE Bantu (South African Black)
Relevant phenotype data: Body mass index (BMI), body fat %, waist to hip circumference

Precise Description of the Material (could be in table format):
Number of samples: 1034
Quantity of material per sample: 25-50µl of 50ng/µl DNA samples in 11 Deep well- round bottom PCR plates.

Ethics approval (Institutional code and number): Clearance certificate for WITS_INDEPTH partnership: Genomic and Environment Risk Factors for Cardiometabolic Disease in Africans (Certificate number; M1210209).
Clearance certificate for research project: "Identification of Genetic Markers of Obesity Risk and Body Composition in a South African Black population." (Certificate number; M120647).
Both certificates attached.

Data analysis and data sharing strategy: To be decided once data is received, data will be analysed using PLINK (Harvard University freeware).

Ownership of data and IP: Letter of intent to publish attached.

Intent to publish (in accordance with Wits-INDEPTH H3Africa funded research protocols): refer above

Financial implications – Provider will pay for services rendered by DNA Technologies Core

Appendix B

Copy of ethics approval certificates

1. From provider:
    a. Approval to collect the samples
    b. Approval for their use in this project
2. From recipient:
    a. Not required (Recipient is a Service Provider – all data generated will be returned to Provider and after an agreed time period the data will be removed from the recipient database)

Appendix C

Legal documents as required from the DONOR and RECIPIENT countries
e.g. Export permit from the South African National Department of Health

health

Department:
Health
REPUBLIC OF SOUTH AFRICA

Private Bag X828, PRETORIA, 0001
Civitas Building Corner Andries and Struben Street, PRETORIA, 0001
Tel (012) 395 0922 • Fax (012) _____

Tel (012) 395-8366/9197 Ms Lineo Motopi

Fax 086 632 6815/2606 J1/2/4/2 No ' '13

Prof Michele Ramsay
Medical Technologist
NHLS and Wits University
Division of Human Genetics
P O Box 1038
JOHANNESBURG
2000

Dear Prof Ramsay

EXPORT PERMIT

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Kind regards

DIRECTOR-GENERAL: HEALTH
Date:
Ms P Netshidzivhani

health

Department:
Health
REPUBLIC OF SOUTH AFRICA

Private Bag X828, PRETORIA, 0001
Civitas Building Corner Andries and Struben Street, PRETORIA, 0001
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Reference : J1/2/4/14 No1/1
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Fax : (086) 632 6815/0306

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DIRECTOR-GENERAL: HEALTH
Date:
Ms P Netshidzivhani

University
of the Witwatersrand,
Johannesburg

Human Research Ethics Committee (Medical)
(formerly Committee for Research on Human Subjects (Medical)

Secretariat: Research Office, Room SH10005, 10th floor, Senate House • Telephone: +27 11 717-1234 • Fax: +27 11 339-5708
Private Bag 3, Wits 2050, South Africa

01 August 2011

Professor Shane Norris
Director
MRC/Wits Developmental
Pathways for Health Research Unit
Department of Paediatrics
School of Clinical Medicine
Faculty of Health Sciences
University

Dear Professor Norris

RE: Re-Consenting Birth to Twenty Cohort Participants around historical blood and DNA Samples

This letter serves to confirm that the Human Research Ethics Committee (Medical) at its meeting on 29 August 2011 discussed your request to "Re-consenting Birth to Twenty Cohort Participants around historical blood and DNA samples" as detailed in your letter dated 17 July 2011.

I am happy to inform you that the Committee unanimously approved your request to "Re-consenting the Birth to Twenty Cohort" and included in this approval are the Information Sheet and Consent Form.

Thank you for keeping us informed and updated.

Yours sincerely,

Professor PE Cleaton-Jones
Chairman
Human Research Ethics Committee (Medical)

INFORMATION SHEET
Birth to Twenty participants
Re-consenting around historical blood and DNA samples

Historical blood samples

You have been a part of the Birth to Twenty cohort since 1990, now over 20 years. We have collected data on the Birth to Twenty participants at 16 time points. At some of these time points you provided consent for us to collect blood samples from you to test for health indicators such as blood sugar (glucose), cholesterol, vitamin D, calcium, etc. These blood samples are stored at the University of the Witwatersrand with only a unique number identifier so your name is not attached to the sample. The information linking you name to the unique number identifier is locked away in the study offices with strict access control and is not made available to the people working on your blood sample.

In the future we may run additional tests on the stored blood samples, but we will not do so without the approval of the Human Research Ethics Committee of the University of the Witwatersrand.

Historical DNA samples

From the blood samples we collected from you in 2003/2004 you consented to us extracting DNA (the inherited material in your cells) so that this DNA could be used for studies that look for genes/changes in DNA that are involved in causing diabetes, obesity and cardiovascular diseases, and for studies to understand how the DNA works (we call this epigenetic studies). DNA studies give us information about how your body works and also whether you are more likely to get certain conditions or diseases. It will also tell us about your ancestry (your family) and about the way that your body uses medications (we call this pharmacogenetics).

Just as for the blood samples, all DNA samples are stored in a safe place at the University of the Witwatersrand and strict control access. If at some future date we realize there are other studies that we would like to carry out on your DNA samples, such tests would only be performed if permission is given to us by the Human Research Ethics Committee of the University of the Witwatersrand. Your identity will be anonymous as your sample will be identified by a number (as described above).

Blood and DNA sample management

The scientists who do the research will generate information (data) which will be placed in databases. Some of the information in the databases will be shared with other scientists, possibly around the world. These scientists will not have access to your name and therefore the data will not be linked back to you. It is possible that we may send small amounts of the DNA out of the country where tests will be done that we cannot easily do in South Africa, but that would give us valuable information for our studies.

Benefits

The discoveries that come from the studies on your DNA will not be of direct benefit to you and will not be communicated back to you. The discoveries may lead to information that will help us in the future to diagnoses disease, understand who is most likely to get ill and how different people behave when they are given medication. The DNA belongs to you and we are the keepers of the DNA. You may withdraw your sample at any time.

Risks

Since the DNA of every person is different, it is possible that if someone tested your blood and compared it to the data in the databases, they could conclude that the two samples come from the same person. However, this is unlikely given the procedures in place that protect your samples.

CONSENT SHEET

The information around the blood and DNA samples taken from me in the past is clear and that the purpose is for me to inform the study what they can or cannot do with these samples.

I acknowledge that all procedure/tests on the stored blood and DNA samples have been or will be approved by the Human Research Ethics Committee of the University of the Witwatersrand.

YES ☐ NO ☐

I am in agreement that my DNA may be stored and used for the purposes described above.

YES ☐ NO ☐

I am in agreement that the data generated from my DNA may be made available in a public domain without any identifiers.

YES ☐ NO ☐

I agree that a small bit of my DNA may be sent out of the country if the research cannot easily be done in South Africa.

YES ☐ NO ☐

I understand that every time a new study is done on my DNA, permission will be obtained from the ethics committee for the study to make sure that it is used only for the purposes stated above.

YES ☐ NO ☐

I understand that I will not benefit directly from the research done on my DNA.

YES ☐ NO ☐

I understand that I may withdraw from the study at any time.

YES ☐ NO ☐

RESEARCH ASSISTANT:

Printed Name Signature/Mark or Thumbprint
Date and Time

PARTICIPANTS

Printed name Signature/Mark or Thumbprint
Date and Time

WITNESS: (If applicable)

Printed Name Signature/Mark or Thumbprint
Date and Time

MRC/Wits Developmental Pathways for Health Research Unit
Department of Paediatrics
School of Clinical Medicine
Faculty of Health Sciences
University of the Witwatersrand, Johannesburg
17th July 2011

The Chair
Human Ethics Research Committee
University of the Witwatersrand, Johannesburg

Dear Professor Cleaton-Jones,

Re-consenting Birth to Twenty cohort participants around historical blood and DNA samples

When Birth to Ten transitioned to Birth to Twenty and the Bt20 cohort and the Bone Health sub-cohort was formed, the HERC approved protocols that entailed the collection of blood and DNA samples for the analyses linked to non-communicable disease (obesity, bone health, diabetes, etc). The participants are now 21 years of age and we wish to re-consent them around the management and use of biological samples collected.

Below are the information and consent sheets. We are asking the participants to consent to the following:

- I acknowledge that all procedure/tests on the stored blood and DNA samples have been or will be approved by the Human Research Ethics Committee of the University of the Witwatersrand.
- I understand that every time a new study is done on my DNA, permission will be obtained from the ethics committee for the study to make sure that it is used appropriately.
- I am in agreement that my DNA may be stored and used for the purposes described.
- I am in agreement that the data generated from my DNA may be made available in a public domain without any identifiers.
- I agree that a small bit of my DNA may be sent out of the country if the research cannot easily be done in South Africa.
- I understand that I will not benefit directly from the research done on my DNA.
- I understand that I may withdraw from the study at any time.

We piloted the re-consent procedure with 10 biological parents of the Bt20 cohort. The re-consent procedure included:

- Power-Point on genetics and core concepts presented by a masters-level research assistant in both English and Zulu.
- Question & Answer session.
- Information sheet distributed and discussed as a group.
- Question & Answer session.
- Individual consent in private with a trained research assistant.

The response from the pilot study was extremely positive. The participants understood and appreciated the presentation; they understood the information sheet and 100% consented to all of the points above. I seek permission from the HERC to approve the re-consent documents and procedure.

Shane Norris

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Title of your dissertation / thesis	The Identification of Genetic Markers of Obesity Risk in African Black population
Expected completion date	Jul 2016
Estimated size(pages)	274
Requestor Location	Venesa Pillay Honeyridge Estate During Street Johannesburg, Gauteng 1724 South Africa Attn: Venesa Pillay
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Publisher of your work	n/a
Expected publication date	Jul 2016
Permissions cost	0.00 USD
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To the Postgraduate Committee Chair

29 March 2016

REPORT OF TURNITIN ASSESSMENT FOR PLAGIARISM

Student: Venesa Pillay (Student nr. 9504731W)
Degree: PhD (Human Genetics)
Title: The Identification of Genetic Markers Of Obesity Risk in a South African Black Population

I wish to confirm that the PhD thesis has been sent through Turnitin. The student and I went through the report very carefully. There was little of note, and the software only picked up usual phrases and word strings common in our field - this did not occur often, and was deemed acceptable. For Chapter 2, a slightly higher level was detected – this is due to this chapter being based on an original research article, written by the student, solely contributing towards the research for this PhD study. Therefore, this too was deemed acceptable.

I am content that there is no plagiarism in the thesis handed in by Ms Pillay. Please do not hesitate to contact me should you require any further information.

Kind Regards

--
Zané Lombard, PhD
PhD Supervisor

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