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Social Environment and Biomarkers of Aging Study (SEBAS) in Taiwan, 2000 and 2006

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Consent Forms, SEBAS 2006 [Public Use]

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Address: 5F., No.503, Sec. 2, Liming Rd., Nantun District, Taichung City
Telephone number: 04-22591999
Website: www.bhp.doh.gov.tw

Executive Yuan, Department of Health, Bureau of Health Promotion
First Home Visit Proxy Consent Form

INSTRUCTIONS TO INTERVIEWER

This consent form consists of two copies. One is kept by the proxy for the respondent and the other is kept by the Bureau of Health Promotion. The proxy for the respondent must sign the copy kept by the Bureau of Health Promotion.

Please explain to the proxy that s/he needs to help the respondent decide whether to participate in this study. The proxy should read the consent form as if s/he were the respondent.

NAME OF PROJECT: The Social Factor and Biomarker Study of Older Adults' Health – Home Interview and Health Assessment
FIELDWORK PERIOD: July 1,2006 - February 28, 2007
PROJECT DIRECTOR: Dr. Chun-Ming Wu, Director-General, Bureau of Health Promotion
Tel: (04)22591999 ext. 205 Fax: (04)22591728
AFFILIATED DIRECTORS: Dr. Maxine Weinstein of Georgetown University, USA
Dr. Noreen Goldman of Princeton University, USA
The project is a collaboration between the Bureau of Health Promotion, Department of Health and Georgetown University and Princeton University in the USA, and the data will be owned by Taiwan and the cooperating institutions and be held with confidentiality protections (as described below).

INTRODUCTION:
Taking care of older persons is not just an individual's or a family's concern but a society's concern. The purpose of this research is to further our understanding of the health and living situations of older persons in Taiwan in order for our government to design policies related to maintaining and improving health.

First, we would like to thank you for your prior participation in our studies. Your participation has been very important to us. We invite you to continue your participation in this study, "The Social Factor and Biomarker Study of Older Adults' Health." We expect that between 1000 and 1500 persons will participate in this study.

The purpose of this study, possible benefits, risks or discomforts, and other information about the study are discussed below. If you have any questions about this study, please raise them at any time and we will provide you with answers.

PROCEDURE:

We will be asking you to talk with us about your health and living situation. The interview will last about one hour. We will take your blood pressure and measure your grip strength and lung capacity here in your own home. Finally, we will ask you to stand up from a chair and to walk a short distance. Before doing these tests, we will check whether you have certain conditions that might make it difficult or uncomfortable to do these tests. If there is any test that you do not wish to do, you may refuse it or stop it at any time.

BENEFITS AND RISKS:
The information collected during the course of this research will provide a reference for health maintenance and disease prevention of middle-aged and old-aged adults in Taiwan. Based on the information that you and other participants provide, we hope to learn what types of people are more likely to have certain diseases. You need not answer any questions that you think are inconvenient to answer or you do not wish to answer.

COMPENSATION:
The Bureau of Health Promotion has obtained indemnity and liability insurance. We will make every effort to prevent study-related injuries and illnesses. During the study, if you are injured or become ill due to your participation in this study, you will receive necessary medical care at the usual charge. No funds are available from Princeton University, Georgetown University, Georgetown University Hospital, MedStar Research Institute, or their affiliates, the District of Columbia government or the United States government to repay you or compensate you for a study-related injury or illness.

CONFIDENTIALITY:
Every effort will be made to protect the personal information that we gather during this study to the extent allowed by law. Your answers along with the responses of others will be used for analysis. Your name will not be used; it will be replaced by a number for any analyses that are done. Your records will be kept in a locked, secure location. You will not be identified in any reports or publications resulting from this study. Researchers will be unable to identify who you are personally. We will not release information that would allow you to be identified. If needed, individuals from the Institutional Review Board (IRB) will look at research records related to this study to assure quality control of the research and data analysis.

IF I DECIDE TO PARTICIPATE IN THE STUDY, CAN I CHANGE MY MIND?
Yes. Your participation in the study is entirely voluntary. You can withdraw from this study any time for any reason or without giving a reason, and no one will hold it against you. You are free to refuse to answer any of the questions or participate in any of the tests.

WITHDRAWAL:
The investigators or staff may stop the study or take you out of the study at any time should they judge that it is in your best interest to do so or if you do not comply with the study plan; they can do this without your consent.

CONTACT INFORMATION:
If you have any questions about this study, please contact us and we will further explain this study to you. The contact person is Yi-Li Chuang, telephone: (04) 22591999 extension number

500. If you have any questions about the rights and benefits of participating in this study, please contact Mei-Hui Lee, the contact person of the Institutional Review Board of the Bureau of Health Promotion, telephone: (04) 2251728 ext. 401.

★ AFTER THE PROXY READS THE FOLLOWING PARAGRAPH OR THE INTERVIEWER READS IT ALOUD, PLACE AN "X" IN THE BOX NEXT TO THE FOLLOWING TWO ITEMS:

I have carefully read (or listened to Ms _____ about) this consent form.

I understand the content and purpose of the study, procedures, and benefits and risks, and/or I have asked questions about anything I didn't understand and all such questions have been answered to my satisfaction.

I understand that my participation in this study is entirely voluntary and that I may end my participation at any time.

★ IF YOU AGREE TO HAVE THE RESPONDENT PARTICIPATE IN THE HOME INTERVIEW AND HEALTH ASSESSMENT, PLEASE PLACE AN "X" IN THE BOX NEXT TO THE FOLLOWING TWO STATEMENTS AND SIGN/STAMP/FINGERPRINT:

I agree that _____ should participate in the Social Factor and Biomarker Study of Older Adults' Health – Home Interview and Health Assessment.

I understand that I am agreeing to let _____participate in this study. I believe that s/he would make the same decision.

_____ (Signature/Stamp/Fingerprint) Date: ROC 95 Year ____Month ____ Day

★ INTERVIEWER TO COMPLETE THE FOLLOWING:

The relationship of the proxy to the respondent:

Respondent's Guardian
Respondent's Spouse
Adult Child of the Respondent
Adult Sibling of the Respondent
Other Adult Relative of the Respondent _____ (Indicate Relationship)
Close Friend of the Respondent

I have explained this consent form to the proxy.

_____ (Signature/Stamp) Date: ROC 95 Year ____Month ____ Day

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Tel: (04)22591999 ext. 205 Fax: (04)22591728
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The purpose of this study, possible benefits, risks or discomforts, and other information about the study are discussed below. If you have any questions about this study, please raise them at any time and we will provide you with answers.

PROCEDURE:
We will be asking you to talk with us about your health and living situation. The interview will last about one hour. We will take your blood pressure and measure your grip strength and lung capacity here in your own home. Finally, we will ask you to stand up from a chair and to walk a short distance. Before doing these tests, we will check whether you have certain conditions that

might make it difficult or uncomfortable to do these tests. If there is any test that you do not wish to do, you may refuse it or stop it at any time.

BENEFITS AND RISKS:
The information collected during the course of this research will provide a reference for health maintenance and disease prevention of middle-aged and old-aged adults in Taiwan. Based on the information that you and other participants provide, we hope to learn what types of people are more likely to have certain diseases. You need not answer any questions that you think are inconvenient to answer or you do not wish to answer.

COMPENSATION:
The Bureau of Health Promotion has obtained indemnity and liability insurance. We will make every effort to prevent study-related injuries and illnesses. During the study, if you are injured or become ill due to your participation in this study, you will receive necessary medical care at the usual charge. No funds are available from Princeton University, Georgetown University, Georgetown University Hospital, MedStar Research Institute, or their affiliates, the District of Columbia government or the United States government to repay you or compensate you for a study-related injury or illness.

CONFIDENTIALITY:
Every effort will be made to protect the personal information that we gather during this study to the extent allowed by law. Your answers along with the responses of others will be used for analysis. Your name will not be used; it will be replaced by a number for any analyses that are done. Your records will be kept in a locked, secure location. You will not be identified in any reports or publications resulting from this study. Researchers will be unable to identify who you are personally. We will not release information that would allow you to be identified. If needed, individuals from the Institutional Review Board (IRB) will look at research records related to this study to assure quality control of the research and data analysis.

IF I DECIDE TO PARTICIPATE IN THE STUDY, CAN I CHANGE MY MIND?
Yes. Your participation in the study is entirely voluntary. You can withdraw from this study any time for any reason or without giving a reason, and no one will hold it against you. You are free to refuse to answer any of the questions or participate in any of the tests.

WITHDRAWAL:
The investigators or staff may stop the study or take you out of the study at any time should they judge that it is in your best interest to do so or if you do not comply with the study plan; they can do this without your consent.

CONTACT INFORMATION:
If you have any questions about this study, please contact us and we will further explain this study to you. The contact person is Yi-Li Chuang, telephone: (04) 22591999 extension number 500. If you have any questions about the rights and benefits of participating in this study, please contact Mei-Hui Lee, the contact person of the Institutional Review Board of the Bureau of Health Promotion, telephone: (04) 2251728 ext. 401.

★ AFTER THE RESPONDENT READS THE FOLLOWING PARAGRAPH OR THE INTERVIEWER READS IT ALOUD, PLACE AN "X" IN THE BOX NEXT TO THE FOLLOWING TWO ITEMS:

I have carefully read (or listened to Ms _____ about) this consent form.

I understand the content and purpose of the study, procedures, and benefits and risks, and/or I have asked questions about anything I didn't understand and all such questions have been answered to my satisfaction.

I understand that my participation in this study is entirely voluntary and that I may end my participation at any time.

★ IF YOU ARE WILLING TO PARTICIPATE IN THE HOME INTERVIEW AND HEALTH ASSESSMENT, PLEASE SIGN/STAMP/FINGERPRINT THE FOLLOWING STATEMENT:

I agree to participate in the Social Factor and Biomarker Study of Older Adults' Health – Home Interview and Health Assessment.

_____ (Signature/Stamp/Fingerprint) Date: ROC 95 Year ____Month ____ Day

★ INTERVIEWER TO COMPLETE THE FOLLOWING:

I have explained this consent form to the respondent.

_____ (Signature/Stamp) Date: ROC 95 Year ____Month ____ Day

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Website: www.bhp.doh.gov.tw

Executive Yuan, Department of Health, Bureau of Health Promotion
Second Home Visit Proxy Consent Form

INSTRUCTIONS TO INTERVIEWER

This consent form consists of two copies. One is kept by the proxy for the respondent and the other is kept by the Bureau of Health Promotion. The proxy for the respondent must sign the copy kept by the Bureau of Health Promotion.

Only a guardian or relative (of the respondent) may give proxy consent on behalf of the respondent. The respondent's spouse (where applicable) would be the first choice to act as proxy, followed by one of the respondent's adult children or the adult guardian.

Please explain to the proxy that s/he needs to help the respondent decide whether to participate in this study. The proxy should read the consent form as if s/he were the respondent.

NAME OF PROJECT: The Social Factor and Biomarker Study of Older Adults' Health – Health Examination
FIELDWORK PERIOD: July 1,2006 - February 28, 2007
PROJECT DIRECTOR: Dr. Chun-Ming Wu, Director-General, Bureau of Health Promotion
Tel: (04)22591999 ext. 205 Fax: (04)22591728
AFFILIATED DIRECTORS: Dr. Maxine Weinstein of Georgetown University, USA
Dr. Noreen Goldman of Princeton University, USA
The project is a collaboration between the Bureau of Health Promotion, Department of Health and Georgetown University and Princeton University in the USA, and the data will be owned by Taiwan and the cooperating institutions and be held with confidentiality protections (as described below).

INTRODUCTION:

The purpose of this research is to further our understanding of the health and living situations of older persons in Taiwan in order for our government to design policies related to maintaining and improving health.

We thank you for your prior participation in our home interview and health assessment, and invite you to continue your participation in this study. We expect that between 1000 and 1500 persons will participate in this study.

The benefits, risks or discomforts, and other information about the study are discussed below. If you have any questions about this study, please raise them at any time and we will provide you with answers.

PROCEDURE:
We will arrange for you to travel to a nearby hospital to complete a **free comprehensive** health examination. We will work with you to choose a date that will be convenient for you, and we will help arrange transportation to the hospital where your examination will be conducted. Whether you choose to participate or not, you are still eligible for the National Health Insurance Examination. You will not be eligible to participate in this study if you are seriously ill, use a catheter or diaper, or are on kidney dialysis.

You will have the option of doing all the tests ordinarily covered in the National Health Insurance Examination including: a physical exam; medical history; and blood tests. In addition, we will ask to measure your waist and hip circumference, perform an abdominal ultrasound, and collect blood and urine specimens in order to do additional tests of liver and kidney function, cholesterol, and other functions. We will obtain about 25-28 cc. of your blood. These tests are done in hospital and will take about two to three hours.

The night before the hospital visit, we will ask you to collect urine at home; we will provide you with a set of containers to collect urine from 7PM on the night before the health exam to 7AM the next day. You will be asked not to eat anything from midnight (12:00AM) of the night before the hospital visit until we provide you with breakfast after the examination.

BENEFITS AND RISKS:
You will be provided with a report, by mail, on the results of your personal health examination approximately one month after your hospital visit. The results from some of the tests (including the three genetic markers referred to on page 4 and part of blood, urine tests) are for research purposes only and will not be reported back to you. This report will give you some information on your health status and will indicate whether you should see your physician for follow-up. Payment for the cost of any such follow-up or treatment will be your responsibility.

The blood-drawing procedure should not affect your health, but you may feel some pain or discomfort at the place where the blood is drawn. There should not be any infection because all the needles are sterilized and are disposable. The blood-drawing procedure will be conducted by experienced personnel in the hospital.

COMPENSATION:
The Bureau of Health Promotion has obtained indemnity and liability insurance. We will make every effort to prevent study-related injuries and illnesses. During the study, if you are injured or become ill due to your participation in this study, you will receive necessary medical care at the usual charge. No funds are available from Princeton University, Georgetown University, Georgetown University Hospital, MedStar Research Institute, or their affiliates, the District of Columbia government or the United States government to repay you or compensate you for a study-related injury or illness.

CONFIDENTIALITY:
Every effort will be made to protect the personal information that we gather during this study to the extent allowed by law. Your examination results along with others' results will be used for analysis. Your name will not be used; it will be replaced by a number for any analyses that are done. Your records will be kept in a locked, secure location. You and your health exam or test results (including three genetic markers) will not be identified in any reports or publications resulting from this study. Researchers will be unable to identify who you are personally. We will not release information that would allow you to be identified. Although we currently are unable to predict the possible impact on

your social rights and benefits if any genetic data were leaked, the principal investigators and staff will be responsible for keeping your genetic information confidential and will make every effort to avoid the leakage of your genetic information. If needed, individuals from the Institutional Review Board will look at research records related to this study to assure quality control of the research and data analysis.

IF I DECIDE TO PARTICIPATE IN THE STUDY, CAN I CHANGE MY MIND?
Yes. Your participation in the study is entirely voluntary. You can withdraw from this study or refuse to have any of the tests at any time for any reason or without giving a reason, and no one will hold it against you. If you decide to withdraw from the study, the Bureau of Health Promotion will be in charge of destroying the collected data, blood, and urine specimens.

WITHDRAWAL:
The investigators or staff may stop the study or take you out of the study at any time should they judge that it is in your best interest to do so or if you do not comply with the study plan. They may remove you from the study for various other administrative or medical reasons; they can do this without your consent.

CONTACT INFORMATION:
If you have any questions about this study, please contact us and we will further explain this study to you. The contact person is Yi-Li Chuang, telephone: (04) 22591999 extension number 500. If you have any questions about the rights and benefits of participating in this study, please contact Mei-Hui Lee, the contact person of the Institutional Review Board of the Bureau of Health Promotion, telephone: (04) 2251728 ext. 401.

★ AFTER THE PROXY READS THE FOLLOWING PARAGRAPH OR THE INTERVIEWER READS IT ALOUD, PLACE AN "X" IN THE BOX NEXT TO THE FOLLOWING THREE ITEMS AND SIGN/STAMP/FINGERPRINT BELOW:

I have carefully read (or listened to Ms _____ about) this consent form.

> I understand the content and purpose of the study, procedures, and benefits and risks, and/or I have asked questions about anything I didn't understand and all such questions have been answered to my satisfaction.
>
> I understand that my participation in this study is entirely voluntary and that I may end my participation at any time.
>
> I agree to participate in the Health Examination Program of the Social Factor and Biomarker Study of Older Adults' Health

I understand that I am agreeing to let _____participate in this research study. I believe that s/he would make the same decision.

_____ (Signature/Stamp/Fingerprint) Date: ROC 95 Year ____Month ____ Day

We ask for your consent to use a small sample of your blood to study your genes. Genes provide instructions for processes in the body and for traits such as eye color. Everyone's genes are a little different. Information about these differences among people can help researchers identify genetic

markers associated with health. We will use your blood specimen to determine three genetic markers known as APOE, 5HTT, and telomere length. Researchers believe that these markers may be associated with one's health, but further study is needed to understand the function of these markers.

With your permission, we would like to store your blood and urine samples for use in future studies by the Bureau of Health Promotion or for transport to Georgetown or Princeton University for use in future studies. Such studies may involve additional tests of the blood and urine made possible by new technology or identified as important by other researchers. Any such future studies would have to be reviewed and approved by the Institutional Review Board before they can be done. During the study, serum, plasma, extracted DNA and urine samples (both acidified and unacidified) will be stored at the Bureau of Health Promotion (kept by Yi-Li Chuang) and Georgetown University (kept by Dr. Maxine Weinstein). The samples are expected to be in storage for 10 years, after which the remaining specimens will be transported back to the Bureau of Health Promotion.

★ PLEASE TELL US WHETHER YOU WILL ALLOW US TO USE YOUR BLOOD SPECIMEN TO DETERMINE THREE GENETIC MARKERS (KNOWN AS APOE, 5HTT, AND TELOMERE LENGTH). PLEASE PLACE AN "X" IN THE BOX NEXT TO ONE OF THE FOLLOWING CHOICES:

My blood specimen **can** be used to determine these genetic markers.

My blood specimen **cannot** be used to determine these genetic markers.

★ PLEASE TELL US WHETHER YOU WILL ALLOW US TO STORE YOUR SAMPLES. PLEASE PLACE AN "X" IN THE BOX NEXT TO ONE OF THE FOLLOWING TWO CHOICES:

My blood and urine specimens **can** be stored and used for future research beyond the study described here.

My blood and urine specimens **cannot** be stored or used for future research beyond the study described here.

★ PLEASE TELL US WHETHER YOU WILL ALLOW US TO STORE YOUR GENETIC MATERIAL (FROM YOUR BLOOD). PLEASE PLACE AN "X" IN THE BOX NEXT TO ONE OF THE FOLLOWING TWO CHOICES:

My genetic material **can** be stored and used for future research beyond the study described here.

My genetic material **cannot** be stored or used for future research beyond the study described here. It should be destroyed by the BHP.

★ PLEASE SIGN/STAMP/FINGERPRINT THE FOLLOWING WITH REGARD TO USE AND STORAGE OF SPECIMENS:

_____ (Signature/Stamp/Fingerprint) Date: ROC 95 Year ____Month ____ Day

★ INTERVIEWER TO COMPLETE THE FOLLOWING:

The relationship of the proxy [**guardian or relatives only**] to the respondent:

Respondent's Guardian
Respondent's Spouse
Adult Child of the Respondent
Adult Sibling of the Respondent
Other Adult Relative of the Respondent _____ (Indicate Relationship)

I have explained this consent form to the proxy.

_____ (Signature and Stamp) Date: ROC 95 Year ____Month ____ Day

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You will have the option of doing all the tests ordinarily covered in the National Health Insurance Examination including: a physical exam; medical history; and blood tests. In addition, we will ask to

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CONFIDENTIALITY:
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WITHDRAWAL:
The investigators or staff may stop the study or take you out of the study at any time should they judge that it is in your best interest to do so or if you do not comply with the study plan. They may remove you from the study for various other administrative or medical reasons; they can do this without your consent.

CONTACT INFORMATION:
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> I agree to participate in the Health Examination Program of the Social Factor and Biomarker Study of Older Adults' Health

_____ (Signature/Stamp/Fingerprint) Date: ROC 95 Year ____Month ____ Day

We ask for your consent to use a small sample of your blood to study your genes. Genes provide instructions for processes in the body and for traits such as eye color. Everyone's genes are a little different. Information about these differences among people can help researchers identify genetic markers associated with health. We will use your blood specimen to determine three genetic markers known as APOE, 5HTT, and telomere length. Researchers believe that these markers may be associated with one's health, but further study is needed to understand the function of these markers.

With your permission, we would like to store your blood and urine samples for use in future studies by the Bureau of Health Promotion or for transport to Georgetown or Princeton University for use in future studies. Such studies may involve additional tests of the blood and urine made possible by new technology or identified as important by other researchers. Any such future studies would have to be reviewed and approved by the Institutional Review Board before they can be done. During the study,

serum, plasma, extracted DNA and urine samples (both acidified and unacidified) will be stored at the Bureau of Health Promotion (kept by Yi-Li Chuang) and Georgetown University (kept by Dr. Maxine Weinstein). The samples are expected to be in storage for 10 years, after which the remaining specimens will be transported back to the Bureau of Health Promotion.

★ PLEASE TELL US WHETHER YOU WILL ALLOW US TO USE YOUR BLOOD SPECIMEN TO DETERMINE THREE GENETIC MARKERS (KNOWN AS APOE, 5HTT, AND TELOMERE LENGTH). PLEASE PLACE AN "X" IN THE BOX NEXT TO ONE OF THE FOLLOWING TWO CHOICES:

My blood specimen **can** be used to determine these genetic markers.

My blood specimen **cannot** be used to determine these genetic markers.

★ PLEASE TELL US WHETHER YOU WILL ALLOW US TO STORE YOUR SAMPLES. PLEASE PLACE AN "X" IN THE BOX NEXT TO ONE OF THE FOLLOWING TWO CHOICES:

My blood and urine specimens **can** be stored and used for future research beyond the study described here.

My blood and urine specimens **cannot** be stored or used for future research beyond the study described here.

★ PLEASE TELL US WHETHER YOU WILL ALLOW US TO STORE YOUR GENETIC MATERIAL (FROM YOUR BLOOD). PLEASE PLACE AN "X" IN THE BOX NEXT TO ONE OF THE FOLLOWING TWO CHOICES:

My genetic material **can** be stored and used for future research beyond the study described here.

My genetic material **cannot** be stored or used for future research beyond the study described here. It should be destroyed by the BHP.

_____ (Signature/Stamp/Fingerprint) Date: ROC 95 Year ____Month ____ Day

★ INTERVIEWER TO COMPLETE THE FOLLOWING:

I have explained this consent form to the participant.

_____ (Signature and Stamp) Date: ROC 95 Year ____Month ____ Day