University of Pittsburgh
Institutional Review Board
Approval Date: April 03, 2007
Modification Approval Date: May 23, 2007
Renewal Date: April 25, 2008
IRB #: 0506048

CONSENT TO BE A SUBJECT IN A RESEARCH STUDY

TITLE: **University of Pittsburgh: Coordinating Center for Genetic Factors Contributing to Oral Health Disparities in Appalachia**

PRINCIPAL INVESTIGATOR: Mary L. Marazita, Ph.D., F.A.C.M.G.
Professor, Oral/Maxillofacial Surgery; Assoc. Dean of Research
School of Dental Medicine, University of Pittsburgh
Suite 500 Cellomics Building/100 Technology Drive
Pittsburgh, PA 15219 USA
Telephone: 412-648-8380

CO-INVESTIGATORS: Robert J. Weyant, D.M.D., Ph.D.
Head, Division of Pediatric and Developmental Dental Sciences
School of Dental Medicine, University of Pittsburgh
Pittsburgh, PA 15261
Telephone: 412-648-3076

Katherine Neiswanger, Ph.D.
Ph.D. Medical Geneticist
School of Dental Medicine, University of Pittsburgh
Suite 500 Cellomics Building, 100 Technology Drive
Pittsburgh, PA 15219 USA
Telephone: 412-648-8384

[SITE COORDINATOR]
[NAME]
[ADDRESS]
[PHONE]

SOURCE OF SUPPORT: National Institute of Dental and Craniofacial Research, U.S.A.

Why is this research being done?

Dr. Marazita and Dr. Weyant invite you to be in a study to learn more about dental health in families, including behaviors, genes (those factors that determine a person's physical characteristics

Initial & Date

and have been passed to them from their parents), and periodontal (gum tissue) factors. Oral health varies greatly among different people. The purpose of this study is to identify which genes, attitudes, and behaviors play a role in people's oral health, so that risk factors for oral health problems can be better understood.

Who is being asked to take part in this research study?

You are a member of one of approximately 550 families from West Virginia or Western Pennsylvania with at least one child between 1 and 18 years old, who is being asked to participate in this study. Your family is part of a representative sample of similar families in [NAME OF] County.

What procedures are being performed for research purposes?

You and your family will be asked to participate in a 4-part examination process during this visit. You and your family will also be asked to return every two years, for a total of three or four visits over five to seven years. If you agree to participate, you will undergo the following procedures during this visit. You have the right to participate in only one, two, three, or all four parts of the examination:

Part 1) Questionnaires: You will be asked a series of questions about your behaviors, thoughts, and opinions regarding dental health, general health, prevention, family relationships, parenting practices, social relationships, alcohol, drug and tobacco use, and mental health (for example, self esteem and mental illness). Demographic information (for example, age) and general health history (for example, vaccinations and frequency of check ups) also will be recorded. In addition, you will be asked to complete questionnaires that focus on medical symptoms, dental anxiety, and social history. You will be given an opportunity to examine these questionnaires and do not have to answer all the questions. This part of the study will take about 2 hours.

Part 2) Dental, Microbiological and Tobacco Examinations: You will be given a dental screening to document the presence of oral conditions, including dental decay (cavities), gum infections (called gingivitis and periodontitis by dentists), tooth alignment and crowding, dental or oral injury, and a variety of other conditions of the teeth and mouth (for example, thin enamel). The dental exam will be conducted by a licensed dentist or dental hygienist and is similar to a routine checkup visit to a family dentist, except no x-rays will be taken. During this exam, you will be asked questions regarding your dental status, such as history of tooth injury, and brushing and flossing habits. All people have different kinds of bacteria present in their mouth, so the purpose of the oral microbiological exam is to test your saliva ("spit") and the plaque on your teeth for bacteria that could cause cavities or gum infections. For this examination, you will provide a saliva sample by chewing on a wax pellet and then spitting into a vial. You will have a test to check the flow of your saliva. Your saliva will also be used to check if there is any evidence of tobacco use. A plastic strip will be placed on your tongue to collect saliva. The inside of your cheek may also be scraped to collect a sample. Dental instruments and special toothpicks will be used to scrape and collect dental plaque from your teeth and tongue. A long Q-tip will be used to collect a throat swab from the back of your throat.

If any dental problems are found, you will be given referral information and can seek dental care at your own expense. Dental care will not be provided as part of this study. This part of the study will take about 1 hour.

_____
Initial & Date

Part 3) Blood sample for DNA studies: Approximately one and one half teaspoons blood will be used to evaluate your DNA for genes relating to dental health, such as those which affect cavities, tooth development, or wound healing. If you are unwilling to give a blood sample, you have the option of providing a saliva (spit) sample or having the inside of your cheek swabbed with several cotton swabs to collect cells that contain DNA. If necessary, you could also be provided some mouthwash to rinse to collect the DNA. This part of the study will take 5 minutes or less, and will only be done at one visit, unless the sample is insufficient to complete the study.

Part 4) Water Sampling: You have been sent a vial to collect a sample of your drinking water from your home. This water will be tested for fluoride, a mineral in some people's water that can prevent cavities. Please bring this vial with you to your appointment.

What are the possible risks, side effects, and discomforts of participating in this research study?

1) The questions in the interviews and questionnaires may be personal. If any information about child abuse, neglect, or mistreatment is uncovered, then the law requires that it be reported.
2) The dental screening infrequently causes some slight gum bleeding, which usually stops within a few minutes. If you have a serious gum infection, you may be sensitive to the gum examination. There is a rare risk that probing your gums may cause an abscess, or infection, of the gum tissue. Although this is rare and usually goes away within a short period of time, it might be painful and require treatment with antibiotics.
3) The gum examination is usually not a risky procedure for most healthy people. But, if you have had previous bacterial (infective) endocarditis, certain specific and serious congenital (present from birth) heart conditions, or artificial heart valves or have had a knee or hip replaced, this examination could place you at risk for a bacterial infection that would affect your heart and the joints in your bones. You will be asked if you have ever had any of these heart or joint problems, and if so, you will be asked to obtain and take an antibiotic (either amoxicillin or clindamycin, azithromycin, or clarithromycin) at your own expense an hour before the gum examination.
If you have the reduced ability to resist infection, this examination could place you at risk for developing an infection. If you have the reduced ability to form blood clots, you could be at risk for mild, but prolonged bleeding during some of the exam procedures. Prior to the dental exam, you will be asked in detail about having either of these conditions. If you have a reduced ability to resist infection or form blood clots, you will be excused from all parts of the examination that might cause bleeding.
4) Collection of tooth plaque, as well as the tongue and cheek scrapings, is likely to be briefly uncomfortable. The throat swab will likely lead to a brief gagging response.
5) The needle puncture of your vein to obtain the blood sample may infrequently result in pain and soreness, bruising, fainting, and rarely infection. This procedure will be performed by individuals trained and experienced in obtaining blood samples so as to minimize these risks.
6) In the unlikely event of a breach of confidentiality, there is a very remote possibility that the genetic information could affect your ability to be insured, employed, or your family relationships. Such problems are probably rare. You can ask the investigators about the likelihood of the research discovering anything that would lead to these problems.

What are the possible benefits of participating in this research study?

_____
Initial & Date

By participating, you may learn more about your own dental and overall health. You will receive verbal and written feedback about your dental screening. If your dental screening reveals any significant problems, you will also receive names of some dentists or other health professionals who could help with any related dental/medical needs. The information obtained from your participation in this research study may eventually lead to a better understanding and better treatments for oral health problems.

If I agree to take part in this research study, will I be told of any new risks that may be found during the course of this study?

You will be promptly notified if any new information develops during the conduct of this research study, which may cause you to change your mind about continuing to participate.

Will I or my insurance company be charged for the cost of any procedures performed as part of this research study?

If you are required to obtain the prophylactic antibiotic from your family doctor, you or your insurance will be charged the cost of the antibiotic. The study will reimburse any costs that you pay out-of-pocket to obtain the antibiotic.

Will I be paid if I take part in this research study?

You will be paid $5.00 for each procedure of the study that you complete, with an added $5.00 if all four procedures are completed, up to $25.00 for one visit. Each time you return for the study (every 2 years for a total of 3 or 4 visits), you will be paid these same amounts. Over a 5 – 7 year period, you could potentially receive $75 - $100 dollars depending on the total number of visits. You will also be reimbursed for any out-of-pocket expenses, including long distance communication, transportation, parking, one meal, prophylactic antibiotics, and any costs of obtaining a blood sample at a local lab.

Who will pay if I am injured as a result of taking part in this study?

University of Pittsburgh researchers recognize the importance of your voluntary participation in their research studies. These individuals and their staffs will make reasonable efforts to minimize, control, and treat any injuries that may arise as a result of this research. If you believe that you are injured as a result of the research procedures being performed, please contact immediately the Principal Investigator listed on the first page of this form.
Emergency medical treatment of injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. It is possible that UPMC may bill your insurance provider for the costs of this emergency treatment, but none of these costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency, you will be responsible for the costs of this follow-up care unless otherwise specifically stated. There is no plan for monetary compensation. You do not, however, waive any legal rights by signing this form.

Who will know about my participation in this research study?

Any information obtained about you from this research study will be kept as confidential as possible. All information about you or your involvement in this research study will only be accessible to the

Initial & Date

investigators involved in this study and their research staff, and will not be released to anyone without your written permission. Records and information pertaining to your identity and involvement in this research study will be stored in locked file cabinets at the [School of Dentistry of the University of Pittsburgh OR LOCAL SITE]. Computer records will be kept in password protected, secured databases. Your identity on data records, donated blood and dental samples, and DNA will be indicated only by code number. Records linking the codes to your personal identifying information will be stored in a separate, secure location. You will not be identified by name in any publication of the research results unless you sign a separate form giving your permission.

Will this research study involve the use or disclosure of my identifiable medical information?

This research study will NOT involve the use or disclosure of your identifiable medical information from your hospital or physician records, or future medical information that might become available during your participation in this study. This study will record some of your personal health or medical information, which will be kept separate from your medical records, and used only for research purposes.

Who will have access to identifiable information related to my participation in this research study?

The information learned about you during this study will not be released to anyone (for example, relatives, personal physicians, insurance companies, or any other third party) without your prior written permission. However, in the unlikely event that an interviewer identifies someone who is considered to be at immediate risk for harming him or herself or others, they will need to inform the appropriate agencies, as required by Pennsylvania law. Any information about child abuse, neglect, or mistreatment must also be reported. These research records, just like hospital records, may be subpoenaed by court order or may be inspected by federal regulatory authorities.

In addition to the investigators listed on the first page of this consent form and their research staff, the following individuals may have access to identifiable information related to your participation in this research study. Authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office may review your identifiable research information for the purpose of monitoring the appropriate conduct of this research study. In addition, authorized representatives of the University of Pittsburgh may have access to this information for the purpose of making participant payments.

For how long will the investigators be permitted to use identifiable information related to my participation in this research study?

The investigators may continue to use identifiable information related to your participation in this research study for at least 5 years following the completion of the research study.

May I have access to my personal research information resulting from my participation in this research study?

You will be notified if you have any dental problems. You will not be provided with your personal research or genetic information obtained during this study.

Is my participation in this study voluntary?

Your participation in this research study is completely voluntary. Whether or not y
consent for participation in this research study will have no effect on your current c
care at a UPMC Hospital or affiliated health care provider, or your current or fu
with a health care insurance provider or with the University of Pittsburgh. If you tu
course of the study, your parent's permission is no longer valid, and you will be re-contacted to give permission as an adult.

_____
Initial & Date

May I withdraw, at a future date, my consent for participation in this research study?

You do not have to take part in this study and, should you change your mind, you can withdraw from the study at any time by submitting a dated, written request to withdraw to Dr. Marazita, who is listed on page 1 of this form. Any research information recorded before your withdrawal may continue to be used in the research study. Your decision to withdraw from this research study will have no effect on your current or future medical care at a UPMC Hospital or affiliated health care provider, or your current or future relationship with a health care insurance provider or with the University of Pittsburgh. You may be removed from the study by the investigators, if the information you provide is incorrect. If you withdraw or are removed from this research study, your biological samples, blood sample, and DNA will be destroyed.

Will my DNA samples be used for future studies?

Dr. Marazita will control the use of your biological samples and genetic material for this study, and will store your biological samples with codes in freezers at the University of Pittsburgh and West Virginia University. In the future, new research may identify other factors that could be involved in oral health. If this happens, Dr. Marazita would also like to examine them. Thus, if you agree, your biological samples and DNA will be saved for future testing of newly identified factors involved in oral health. When all of her research studies of oral health are completed, any remaining biological samples and DNA will be destroyed at that time. If you do NOT agree, your biological samples and DNA will be discarded at the end of this particular research study. You may also be contacted in the future to be invited to participate in additional research, but that future involvement is voluntary as well. If you turn 18 during the course of the study, your parent's permission is no longer valid, and you will be re-contacted to give permission as an adult regarding the use of your DNA samples.

Your blood sample and its DNA used in this research study may contribute to a new invention or discovery. Sometimes, these inventions or discoveries may be of commercial value and may be sold, patented, or licensed by the investigators and the University of Pittsburgh for use in other research or the development of new products related to oral health**.** If the research investigators are able to develop new products from the use of your biological sample or genetic material, they currently have no plans to share any money or other rewards with you. You retain the right to have your blood sample and its DNA destroyed if you decide to withdraw from this research study.

****

I give my permission for Dr. Marazita to save my biological samples and genetic material, with personal identifiers, for use in other genetic research projects involving the study of oral health.

YES _____ NO _____

I give my permission to be re-contacted to obtain my consent if there is a desi _____
biological sample or genetic material, with personal identifiers, in other rese Initial & Date
involving the study of different diseases or conditions.

YES _____ NO _____

VOLUNTARY CONSENT AND AUTHORIZATION

All of the above has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask additional questions at any time about this research study, and that such future questions will be answered by the researchers listed on the first page of this form. Any questions I have about my rights as a research participant will be answered by the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668).

By signing this form, I agree to participate in this research study. A copy of this consent form will be given to me.

Adults aged 18 and over:

_____ _____
Participant's Signature Date

Children aged 1 – 17:

I understand that, as a minor (age less than 18 years), _____
is not permitted to participate in this research study without my consent. Therefore, by signing this form, I give my consent for their participation in this research study.

_____ _____
Parent's Name Relationship to Participant (Child)

_____ _____
Parent's Signature Date

Children who can sign their name:

This research has been explained to me, and I agree to participate.

_____
Child's Name

_____ _____
Child's Signature Date

Verification of explanation for children who can sign their name:

I certify that I have carefully explained the nature and purpose of this research study to the above-named child in age-appropriate language. They have had an opportunity to discuss it with me in detail. I have answered all their questions, and they have provided assent to participate in this study.

_____ _____
Printed Name of Person Obtaining Consent Role in Research Study

_____ _____
Signature of Person Obtaining Consent Date

All participants:

CERTIFICATION OF INFORMED CONSENT

I certify that the nature and purpose of this research study have been explained to the above-named individual(s), and the potential benefits and possible risks of study participation have been discussed. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____
Investigator's Printed Name

_____ _____
Investigator's Signature Date

University of Pittsburgh

School of Dental Medicine
Department of Oral Biology

Suite 500
Cellomics Building/Bridgeside Point
100 Technology Drive
Pittsburgh, PA 15219
412-648-8381
Fax: 412-648-8779

University of Pittsburgh
Institutional Review Board
Approval Date: 9/12/2007
Renewal Date: 09/13/2008
IRB #: 020773

CONSENT TO BE A SUBJECT IN A RESEARCH STUDY

TITLE: **Genetic Factors Contributing to Oral Health Disparities in Appalachia (Pennsylvania Sites)**

PRINCIPAL INVESTIGATOR: Mary L. Marazita, Ph.D., F.A.C.M.G.
Professor, Oral/Maxillofacial Surgery; Assoc. Dean of Research
School of Dental Medicine, University of Pittsburgh
Suite 500 Cellomics Building/100 Technology Drive
Pittsburgh, PA 15219 USA
Telephone: 412-648-8380

CO-INVESTIGATORS: Robert J. Weyant, D.M.D., Ph.D.
Head, Division of Pediatric and Developmental Dental Sciences
School of Dental Medicine, University of Pittsburgh
Pittsburgh, PA 15261
Telephone: 412-648-3076

Katherine Neiswanger, Ph.D.
Ph.D. Medical Geneticist
Address: Same as for Dr. Marazita, listed above
Telephone: 412-648-8384

Louise Platt-Schulhof, RDH, MHPE, CHES
UPMC Braddock
400 Holland Avenue
Braddock, PA 15104
Telephone: 412-636-5276

SOURCE OF SUPPORT: National Institute of Dental and Craniofacial Research, U.S.A.

Why is this research being done?

Dr. Marazita and Dr. Weyant invite you to be in a study to learn more about dental health in families, including behaviors, genes (those factors that determine a person's physical characteristics and have been passed to them from their parents), and periodontal (gum tissue) factors. Oral health varies greatly among different people. The purpose of this study is to identify which genes, attitudes, and behaviors play a role in people's oral health, so that risk factors for oral health problems can be better understood.

Initial & Date

Who is being asked to take part in this research study?

You are a member of one of approximately 550 families from West Virginia or Western Pennsylvania with at least one child between 1 and 18 years old, who is being asked to participate in this study. Your family is part of a representative sample of similar families in Braddock, Pennsylvania.

What procedures are being performed for research purposes?

You and your family will be asked to participate in a 4-part examination process during this visit. You and your family will also be asked to return every two years, for a total of three or four visits over five to seven years. If you agree to participate, you will undergo the following procedures during this visit. You have the right to participate in only one, two, three, or all four parts of the examination:

Part 1) Questionnaires: You will be asked a series of questions about your behaviors, thoughts, and opinions regarding dental health, general health, prevention, family relationships, parenting practices, social relationships, alcohol, drug and tobacco use, and mental health (for example, self esteem and mental illness). Demographic information (for example, age) and general health history (for example, vaccinations and frequency of check ups) also will be recorded. In addition, you will be asked to complete questionnaires that focus on medical symptoms, dental anxiety, and social history. You will be given an opportunity to examine these questionnaires and do not have to answer all the questions. This part of the study will take about 2 hours.

Part 2) Dental, Microbiological and Tobacco Examinations: You will be given a dental screening to document the presence of oral conditions, including dental decay (cavities), gum infections (called gingivitis and periodontitis by dentists), tooth alignment and crowding, dental or oral injury, and a variety of other conditions of the teeth and mouth (for example, thin enamel). The dental exam will be conducted by a licensed dentist or dental hygienist and is similar to a routine checkup visit to a family dentist, except no x-rays will be taken. During this exam, you will be asked questions regarding your dental status, such as history of tooth injury, and brushing and flossing habits. All people have different kinds of bacteria present in their mouth, so the purpose of the oral microbiological exam is to test your saliva ("spit") and the plaque on your teeth for bacteria that could cause cavities or gum infections. For this examination, you will provide a saliva sample by chewing on a wax pellet and then spitting into a vial. You will have a test to check the flow of your saliva. Your saliva will also be used to check if there is any evidence of tobacco use. A plastic strip will be placed on your tongue to collect saliva. The inside of your cheek may also be scraped to collect a sample. Dental instruments and special toothpicks will be used to scrape and collect dental plaque from your teeth and tongue. A long Q-tip will be used to collect a throat swab from the back of your throat.

If any dental problems are found, you will be given referral information and can seek dental care at your own expense. Dental care will not be provided as part of this study. This part of the study will take about 1 hour.

Part 3) Blood sample for DNA studies: Approximately one and one half teaspoons blood will be used to evaluate your DNA for genes relating to dental health, such as those which affect cavities, tooth development, or wound healing. If you are unwilling to give a blood sample, you will be provided some mouthwash and the rinse will be collected, or the inside of your cheek will be

Initial & Date

swabbed with several brushes to collect cells that contain DNA. If you are unwilling to give a blood sample, you have the option of providing a saliva (spit) sample or having the inside of your cheek swabbed with several cotton swabs to collect cells that contain DNA. If necessary, you could also be provided some mouthwash to rinse to collect the DNA. This part of the study will take 5 minutes or less, and will only be done at one visit, unless the sample is insufficient to complete the study.

Part 4) Water Sampling: You have been sent a vial to collect a sample of your drinking water from your home. This water will be tested for fluoride, a mineral in some people's water that can prevent cavities. Please bring this vial with you to your appointment.

What are the possible risks, side effects, and discomforts of participating in this research study?

1) The questions in the interviews and questionnaires may be personal. If any information about child abuse, neglect, or mistreatment is uncovered, then the law requires that it be reported.
2) The dental screening infrequently causes some slight gum bleeding, which usually stops within a few minutes. If you have a serious gum infection, you may be sensitive to the gum examination. There is a rare risk that probing your gums may cause an abscess, or infection, of the gum tissue. Although this is rare and usually goes away within a short period of time, it might be painful and require treatment with antibiotics.
3) The gum examination is usually not a risky procedure for most healthy people. But, if you have had previous bacterial (infective) endocarditis, certain specific and serious congenital (present from birth) heart conditions, or artificial heart valves or have had a knee or hip replaced, this examination could place you at risk for a bacterial infection that would affect your heart and the joints in your bones. You will be asked if you have ever had any of these heart or joint problems, and if so, you will be asked to obtain and take an antibiotic (either amoxicillin or clindamycin, azithromycin, or clarithromycin) at your own expense an hour before the gum examination.
If you have the reduced ability to resist infection, this examination could place you at risk for developing an infection. If you have the reduced ability to form blood clots, you could be at risk for mild, but prolonged bleeding during some of the exam procedures. Prior to the dental exam, you will be asked in detail about having either of these conditions. If you have a reduced ability to resist infection or form blood clots, you will be excused from all parts of the examination that might cause bleeding.
4) Collection of tooth plaque, as well as the tongue and cheek scrapings, is likely to be briefly uncomfortable. The throat swab will likely lead to a brief gagging response.
5) The needle puncture of your vein to obtain the blood sample may infrequently result in pain and soreness, bruising, fainting, and rarely infection. This procedure will be performed by individuals trained and experienced in obtaining blood samples so as to minimize these risks.
6) In the unlikely event of a breach of confidentiality, there is a very remote possibility that the genetic information could affect your ability to be insured, employed, or your family relationships. Such problems are probably rare. You can ask the investigators about the likelihood of the research discovering anything that would lead to these problems.

What are the possible benefits of participating in this research study?

By participating, you may learn more about your own dental and overall health. You will receive verbal and written feedback about your dental screening. If your dental screening any significant

Initial & Date

problems, you will also receive names of some dentists or other health professionals who could help with any related dental/medical needs. The information obtained from your participation in this research study may eventually lead to a better understanding and better treatments for oral health problems.

If I agree to take part in this research study, will I be told of any new risks that may be found during the course of this study?

You will be promptly notified if any new information develops during the conduct of this research study, which may cause you to change your mind about continuing to participate.

Will I or my insurance company be charged for the cost of any procedures performed as part of this research study?

None of the services and/or procedures (Dental Screening, blood draws, etc.) you receive during this research study will be billed to you or your health insurance. If you get a bill or believe your health insurance has been billed for something that is part of the study, notify a member of the research team or UPMC Patient Billing Services.

You and your health insurance will be charged, in the standard manner, for services and procedures provided for your routine care. If you are required to take the prophylactic oral antibiotic prior to a dental exam, either you or your insurance company will be charged the cost of obtaining the antibiotic. The study will reimburse you for any out-of-pocket costs for the prophylactic antibiotic.

Will I be paid if I take part in this research study?

You will be paid $5.00 for each procedure of the study that you complete, with an added $5.00 if all four procedures are completed, up to $25.00 for one visit. Payment will be in the form of a gift card to your choice of Giant Eagle, Target, or Wal-Mart. Each time you return for the study (every 2 years for a total of 3 or 4 visits), you will be paid these same amounts. Over a 5 – 7 year period, you could potentially receive $75 - $100 dollars worth of gift cards depending on the total number of visits. You will also be reimbursed for any out-of-pocket expenses, including long distance communication, transportation, parking, one meal, and any costs of obtaining a blood sample at a local lab.

Who will pay if I am injured as a result of taking part in this study?

University of Pittsburgh researchers recognize the importance of your voluntary participation in their research studies. These individuals and their staffs will make reasonable efforts to minimize, control, and treat any injuries that may arise as a result of this research. If you believe that you are injured as a result of the research procedures being performed, please contact immediately the Principal Investigator listed on the first page of this form.
Emergency medical treatment of injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. It is possible that UPMC may bill your insurance provider for the costs of this emergency treatment, but none of these costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency, you will be responsible for the costs of this follow-up care unless otherwise specifically stated. There is no plan for monetary compensation. You do not, however, waive any legal rights by signing

Initial & Date

this form.

Who will know about my participation in this research study?

Any information obtained about you from this research study will be kept as confidential as possible. All information about you or your involvement in this research study will only be accessible to the investigators involved in this study and their research staff, and will not be released to anyone without your written permission. Records and information pertaining to your identity and involvement in this research study will be stored in locked file cabinets at the [School of Dentistry of the University of Pittsburgh or at UPMC Braddock. Computer records will be kept in password protected, secured databases. Your identity on data records, donated blood and dental samples, and DNA will be indicated only by code number. Records linking the codes to your personal identifying information will be stored in a separate, secure location. You will not be identified by name in any publication of the research results unless you sign a separate form giving your permission.

Will this research study involve the use or disclosure of my identifiable medical information?

This research study will NOT involve the use or disclosure of your identifiable medical information from your hospital or physician records, or future medical information that might become available during your participation in this study. This study will record some of your personal health or medical information, which will be kept separate from your medical records, and used only for research purposes.

Who will have access to identifiable information related to my participation in this research study?

The information learned about you during this study will not be released to anyone (for example, relatives, personal physicians, insurance companies, or any other third party) without your prior written permission. However, in the unlikely event that an interviewer identifies someone who is considered to be at immediate risk for harming him or herself or others, they will need to inform the appropriate agencies, as required by Pennsylvania law. Any information about child abuse, neglect, or mistreatment must also be reported. These research records, just like hospital records, may be subpoenaed by court order or may be inspected by federal regulatory authorities.
In addition to the investigators listed on the first page of this consent form and their research staff, the following individuals may have access to identifiable information related to your participation in this research study. Authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office may review your identifiable research information for the purpose of monitoring the appropriate conduct of this research study. In addition, authorized representatives of the University of Pittsburgh may have access to this information for the purpose of making participant payments.

For how long will the investigators be permitted to use identifiable information related to my participation in this research study?

The investigators may continue to use identifiable information related to your participation in this research study for at least 5 years following the completion of the research study.

May I have access to my personal research information resulting from my participation in this research study?

_____
Initial & Date

You will be notified if you have any dental problems. You will not be provided with your personal research or genetic information obtained during this study.

Is my participation in this study voluntary?

Your participation in this research study is completely voluntary. Whether or not you provide your consent for participation in this research study will have no effect on your current or future medical care at a UPMC Hospital or affiliated health care provider, or your current or future relationship with a health care insurance provider or with the University of Pittsburgh. If you turn 18 during the course of the study, your parent's permission is no longer valid, and you will be re-contacted to give permission as an adult.

May I withdraw, at a future date, my consent for participation in this research study?

You do not have to take part in this study and, should you change your mind, you can withdraw from the study at any time by submitting a dated, written request to withdraw to Dr. Marazita, who is listed on page 1 of this form. Any research information recorded before your withdrawal may continue to be used in the research study. Your decision to withdraw from this research study will have no effect on your current or future medical care at a UPMC Hospital or affiliated health care provider, or your current or future relationship with a health care insurance provider or with the University of Pittsburgh. You may be removed from the study by the investigators, if the information you provide is incorrect. If you withdraw or are removed from this research study, your biological samples, blood sample, and DNA will be destroyed.

Will my DNA samples be used for future studies?

Dr. Marazita will control the use of your biological samples and genetic material for this study, and will store your biological samples with codes in freezers at the University of Pittsburgh and West Virginia University. In the future, new research may identify other factors that could be involved in oral health. If this happens, Dr. Marazita would also like to examine them. Thus, if you agree, your biological samples and DNA will be saved for future testing of newly identified factors involved in oral health. When all of her research studies of oral health are completed, any remaining biological samples and DNA will be destroyed at that time. If you do NOT agree, your biological samples and DNA will be discarded at the end of this particular research study. You may also be contacted in the future to be invited to participate in additional research, but that future involvement is voluntary as well. If you turn 18 during the course of the study, your parent's permission is no longer valid, and you will be re-contacted to give permission as an adult regarding the use of your DNA samples.

Your blood sample and its DNA used in this research study may contribute to a new invention or discovery. Sometimes, these inventions or discoveries may be of commercial value and may be sold, patented, or licensed by the investigators and the University of Pittsburgh for use in other research or the development of new products related to oral health. If the research investigators are able to develop new products from the use of your biological sample or genetic material, they currently have no plans to share any money or other rewards with you. You retain the right to have your blood sample and its DNA destroyed if you decide to withdraw from this research study.

I give my permission for Dr. Marazita to save my biological samples and genetic material, with personal identifiers, for use in other genetic research projects involving the study of oral health.

_____
Initial & Date

YES _____ NO _____

I give my permission to be re-contacted to obtain my consent if there is a desire to use my biological sample or genetic material, with personal identifiers, in other research projects involving the study of different diseases or conditions.

YES _____ NO _____

VOLUNTARY CONSENT AND AUTHORIZATION

All of the above has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask additional questions at any time about this research study, and that such future questions will be answered by the researchers listed on the first page of this form. Any questions I have about my rights as a research participant will be answered by the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668).

By signing this form, I agree to participate in this research study. A copy of this consent form will be given to me.

Adults aged 18 and over:

_____ _____
Participant's Signature Date

Children aged 1 – 17:

I understand that, as a minor (age less than 18 years), _____ is not permitted to participate in this research study without my consent. Therefore, by signing this form, I give my consent for their participation in this research study.

_____ _____
Parent's Name Relationship to Participant (Child)

_____ _____
Parent's Signature Date

Children who can sign their name:

This research has been explained to me, and I agree to participate.

_____
Child's Name

Child's Signature _____ Date _____

Verification of explanation for children who can sign their name:

I certify that I have carefully explained the nature and purpose of this research study to the above-named child in age-appropriate language. They have had an opportunity to discuss it with me in detail. I have answered all their questions, and they have provided assent to participate in this study.

Printed Name of Person Obtaining Consent _____ Role in Research Study _____

Signature of Person Obtaining Consent _____ Date _____

All participants:

CERTIFICATION OF INFORMED CONSENT

I certify that the nature and purpose of this research study have been explained to the above-named individual(s), and the potential benefits and possible risks of study participation have been discussed. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

Investigator's Printed Name _____

Investigator's Signature _____ Date _____

University of Pittsburgh
Institutional Review Board
Approval Date: 9/12/07
Renewal Date: 9/13/08
IRB #: 020773

CONSENT TO BE A SUBJECT IN A RESEARCH STUDY

TITLE: **Genetic Factors Contributing to Oral Health Disparities in Appalachia (Pennsylvania Sites)**

PRINCIPAL INVESTIGATOR: Mary L. Marazita, Ph.D., F.A.C.M.G.
Professor, Oral/Maxillofacial Surgery; Assoc. Dean of Research
School of Dental Medicine, University of Pittsburgh
Suite 500 Cellomics Building/100 Technology Drive
Pittsburgh, PA 15219 USA
Telephone: 412-648-8380

CO-INVESTIGATORS: Robert J. Weyant, D.M.D., Ph.D.
Head, Division of Pediatric and Developmental Dental Sciences
School of Dental Medicine, University of Pittsburgh
Pittsburgh, PA 15261
Telephone: 412-648-3076

Katherine Neiswanger, Ph.D.
Ph.D. Medical Geneticist
School of Dental Medicine, University of Pittsburgh
Suite 500 Cellomics Building, 100 Technology Drive
Pittsburgh, PA 15219 USA
Telephone: 412-648-8384

Lorraine Ettaro, Ph.D., Director
University of Pittsburgh Center for Rural Health Practice
300 Campus Drive
Bradford, PA 16701
Telephone: 814-362-5050

SITE COORDINATOR: Patricia Demjan, MA /Address same as Lorraine Ettaro, Ph.D.
Telephone: 814-362-5050 or 814-362-5048

SOURCE OF SUPPORT: National Institute of Dental and Craniofacial Research, U.S.A.

Why is this research being done?

Dr. Marazita and Dr. Weyant invite you to be in a study to learn more about dental health in families, including behaviors, genes (those factors that determine a person's physical characteristics and have been passed to them from their parents), and periodontal (gum tissue) factors. Oral health varies greatly among different people. The purpose of this study is to identify which genes, attitudes, and behaviors play a role in people's oral health, so that risk factors for oral health problems can be better understood.

Who is being asked to take part in this research study?

You are a member of one of approximately 550 families from West Virginia or Western Pennsylvania with at least one child between 1 and 18 years old, who is being asked to participate in this study. Your family is part of a representative sample of similar families in Bradford, Pennsylvania.

What procedures are being performed for research purposes?

You and your family will be asked to participate in a 4-part examination process during this visit. You and your family will also be asked to return every two years, for a total of three or four visits over five to seven years. If you agree to participate, you will undergo the following procedures during this visit. You have the right to participate in only one, two, three, or all four parts of the examination:

Part 1) Questionnaires: You will be asked a series of questions about your behaviors, thoughts, and opinions regarding dental health, general health, prevention, family relationships, parenting practices, social relationships, alcohol, drug and tobacco use, and mental health (for example, self esteem and mental illness). Demographic information (for example, age) and general health history (for example, vaccinations and frequency of check ups) also will be recorded. In addition, you will be asked to complete questionnaires that focus on medical symptoms, dental anxiety, and social history. You will be given an opportunity to examine these questionnaires and do not have to answer all the questions. This part of the study will take about 2 hours.

Part 2) Dental, Microbiological and Tobacco Examinations: You will be given a dental screening to document the presence of oral conditions, including dental decay (cavities), gum infections (called gingivitis and periodontitis by dentists), tooth alignment and crowding, dental or oral injury, and a variety of other conditions of the teeth and mouth (for example, thin enamel). The dental exam will be conducted by a licensed dentist or dental hygienist and is similar to a routine checkup visit to a family dentist, except no x-rays will be taken. During this exam, you will be asked questions regarding your dental status, such as history of tooth injury, and brushing and flossing habits. All people have different kinds of bacteria present in their mouth, so the purpose of the oral microbiological exam is to test your saliva ("spit") and the plaque on your teeth for bacteria that could cause cavities or gum infections. For this examination, you will provide a saliva sample by chewing on a wax pellet and then spitting into a vial. You will have a test to check the flow of your saliva. Your saliva will also be used to check if there is any evidence of tobacco use. A plastic strip will be placed on your tongue to collect saliva. The inside of your cheek may also be scraped to collect a sample. Dental instruments and special toothpicks will be used to scrape and collect dental plaque from your teeth and tongue. A long Q-tip will be used to collect a throat swab from the back of your throat.

If any dental problems are found, you will be given referral information and can seek dental

Initial & Date

care at your own expense. Dental care will not be provided as part of this study. This part of the study will take about 1 hour.

Part 3) Blood sample for DNA studies: Approximately one and one half teaspoons blood will be used to evaluate your DNA for genes relating to dental health, such as those which affect cavities, tooth development, or wound healing. If you are unwilling to give a blood sample, you have the option of providing a saliva (spit) sample or having the inside of your cheek swabbed with several cotton swabs to collect cells that contain DNA. If necessary, you could also be provided some mouthwash to rinse to collect the DNA. This part of the study will take 5 minutes or less, and will only be done at one visit, unless the sample is insufficient to complete the study.

Part 4) Water Sampling: You have been sent a vial to collect a sample of your drinking water from your home. This water will be tested for fluoride, a mineral in some people's water that can prevent cavities. Please bring this vial with you to your appointment.

What are the possible risks, side effects, and discomforts of participating in this research study?

1) The questions in the interviews and questionnaires may be personal. If any information about child abuse, neglect, or mistreatment is uncovered, then the law requires that it be reported.
2) The dental screening infrequently causes some slight gum bleeding, which usually stops within a few minutes. If you have a serious gum infection, you may be sensitive to the gum examination. There is a rare risk that probing your gums may cause an abscess, or infection, of the gum tissue. Although this is rare and usually goes away within a short period of time, it might be painful and require treatment with antibiotics.
3) The gum examination is usually not a risky procedure for most healthy people. But, if you have had previous bacterial (infective) endocarditis, certain specific and serious congenital (present from birth) heart conditions, or artificial heart valves or have had a knee or hip replaced, this examination could place you at risk for a bacterial infection that would affect your heart and the joints in your bones. You will be asked if you have ever had any of these heart or joint problems, and if so, you will be asked to obtain and take an antibiotic (either amoxicillin or clindamycin, azithromycin, or clarithromycin) at your own expense an hour before the gum examination.
If you have the reduced ability to resist infection, this examination could place you at risk for developing an infection. If you have the reduced ability to form blood clots, you could be at risk for mild, but prolonged bleeding during some of the exam procedures. Prior to the dental exam, you will be asked in detail about having either of these conditions. If you have a reduced ability to resist infection or form blood clots, you will be excused from all parts of the examination that might cause bleeding.
4) Collection of tooth plaque, as well as the tongue and cheek scrapings, is likely to be briefly uncomfortable. The throat swab will likely lead to a brief gagging response.
5) The needle puncture of your vein to obtain the blood sample may infrequently result in pain and soreness, bruising, fainting, and rarely infection. This procedure will be performed by individuals trained and experienced in obtaining blood samples so as to minimize these risks.
6) In the unlikely event of a breach of confidentiality, there is a very remote possibility that the genetic information could affect your ability to be insured, employed, or your family relationships. Such problems are probably rare. You can ask the investigators about the likelihood of the research discovering anything that would lead to these problems.

_____
Initial & Date

What are the possible benefits of participating in this research study?

By participating, you may learn more about your own dental and overall health. You will receive verbal and written feedback about your dental screening. If your dental screening reveals any significant problems, you will also receive names of some dentists or other health professionals who could help with any related dental/medical needs. The information obtained from your participation in this research study may eventually lead to a better understanding and better treatments for oral health problems.

If I agree to take part in this research study, will I be told of any new risks that may be found during the course of this study?

You will be promptly notified if any new information develops during the conduct of this research study, which may cause you to change your mind about continuing to participate.

Will I or my insurance company be charged for the cost of any procedures performed as part of this research study?

If you are required to take the prophylactic oral antibiotic prior to a dental exam, either you or your insurance company will be charged the cost of obtaining the antibiotic. The study will reimburse you for any out-of-pocket costs for the prophylactic antibiotic.

Will I be paid if I take part in this research study?

You (each participant) will receive a $25 dollar Bradford Area Chamber of Commerce gift certificate (which is good at many area stores) once all study procedures are completed. Each time you return for the study (every 2 years for a total of 3 or 4 visits), you (each participant) will receive the same gift certificate in the same dollar amount. Over a 5 – 7 year period, you (each participant) could potentially receive $75 - $100 dollars in gift certificates, depending on the total number of visits.

Who will pay if I am injured as a result of taking part in this study?

University of Pittsburgh researchers recognize the importance of your voluntary participation in their research studies. These individuals and their staffs will make reasonable efforts to minimize, control, and treat any injuries that may arise as a result of this research. If you believe that you are injured as a result of the research procedures being performed, please contact immediately the Principal Investigator listed on the first page of this form.

Emergency medical treatment of injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. It is possible that UPMC may bill your insurance provider for the costs of this emergency treatment, but none of these costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency, you will be responsible for the costs of this follow-up care unless otherwise specifically stated. There is no plan for monetary compensation. You do not, however, waive any legal rights by signing this form.

Who will know about my participation in this research study?

Any information obtained about you from this research study will be kept as confidential as possible. All information about you or your involvement in this research study will only be accessible to the investigators involved in this study and their research staff, and will not be released to anyone

_____
Initial & Date

without your written permission. Records and information pertaining to your identity and involvement in this research study will be stored in locked file cabinets at the [School of Dentistry of the University of Pittsburgh or at the University of Pittsburgh Center for Rural Health Practice. Computer records will be kept in password protected, secured databases. Your identity on data records, donated blood and dental samples, and DNA will be indicated only by code number. Records linking the codes to your personal identifying information will be stored in a separate, secure location. You will not be identified by name in any publication of the research results unless you sign a separate form giving your permission.

Will this research study involve the use or disclosure of my identifiable medical information?

This research study will NOT involve the use or disclosure of your identifiable medical information from your hospital or physician records, or future medical information that might become available during your participation in this study. This study will record some of your personal health or medical information, which will be kept separate from your medical records, and used only for research purposes.

Who will have access to identifiable information related to my participation in this research study?

The information learned about you during this study will not be released to anyone (for example, relatives, personal physicians, insurance companies, or any other third party) without your prior written permission. However, in the unlikely event that an interviewer identifies someone who is considered to be at immediate risk for harming him or herself or others, they will need to inform the appropriate agencies, as required by Pennsylvania law. Any information about child abuse, neglect, or mistreatment must also be reported. These research records, just like hospital records, may be subpoenaed by court order or may be inspected by federal regulatory authorities.

In addition to the investigators listed on the first page of this consent form and their research staff, the following individuals may have access to identifiable information related to your participation in this research study. Authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office may review your identifiable research information for the purpose of monitoring the appropriate conduct of this research study. In addition, authorized representatives of the University of Pittsburgh may have access to this information for the purpose of making participant payments.

For how long will the investigators be permitted to use identifiable information related to my participation in this research study?

The investigators may continue to use identifiable information related to your participation in this research study for at least 5 years following the completion of the research study.

May I have access to my personal research information resulting from my participation in this research study?

You will be notified if you have any dental problems. You will not be provided with your personal research or genetic information obtained during this study.

Is my participation in this study voluntary?

Your participation in this research study is completely voluntary. Whether or not you provide your consent for participation in this research study will have no effect on your current or future medical

_____
Initial & Date

care at a UPMC Hospital or affiliated health care provider, or your current or future relationship with a health care insurance provider or with the University of Pittsburgh. If you turn 18 during the course of the study, your parent's permission is no longer valid, and you will be re-contacted to give permission as an adult.

May I withdraw, at a future date, my consent for participation in this research study?

You do not have to take part in this study and, should you change your mind, you can withdraw from the study at any time by submitting a dated, written request to withdraw to Dr. Marazita, who is listed on page 1 of this form. Any research information recorded before your withdrawal may continue to be used in the research study. Your decision to withdraw from this research study will have no effect on your current or future medical care at a UPMC Hospital or affiliated health care provider, or your current or future relationship with a health care insurance provider or with the University of Pittsburgh. You may be removed from the study by the investigators, if the information you provide is incorrect. If you withdraw or are removed from this research study, your biological samples, blood sample, and DNA will be destroyed.

Will my DNA samples be used for future studies?

Dr. Marazita will control the use of your biological samples and genetic material for this study, and will store your biological samples with codes in freezers at the University of Pittsburgh and West Virginia University. In the future, new research may identify other factors that could be involved in oral health. If this happens, Dr. Marazita would also like to examine them. Thus, if you agree, your biological samples and DNA will be saved for future testing of newly identified factors involved in oral health. When all of her research studies of oral health are completed, any remaining biological samples and DNA will be destroyed at that time. If you do NOT agree, your biological samples and DNA will be discarded at the end of this particular research study. You may also be contacted in the future to be invited to participate in additional research, but that future involvement is voluntary as well. If you turn 18 during the course of the study, your parent's permission is no longer valid, and you will be re-contacted to give permission as an adult regarding the use of your DNA samples.

Your blood sample and its DNA used in this research study may contribute to a new invention or discovery. Sometimes, these inventions or discoveries may be of commercial value and may be sold, patented, or licensed by the investigators and the University of Pittsburgh for use in other research or the development of new products related to oral health**.** If the research investigators are able to develop new products from the use of your biological sample or genetic material, they currently have no plans to share any money or other rewards with you. You retain the right to have your blood sample and its DNA destroyed if you decide to withdraw from this research study.

****

I give my permission for Dr. Marazita to save my biological samples and genetic material, with personal identifiers, for use in other genetic research projects involving the study of oral health.

YES _____ NO _____

I give my permission to be re-contacted to obtain my consent if there is a desire to use my biological sample or genetic material, with personal identifiers, in other research projects involving the study of different diseases or conditions.

YES _____ NO _____

_____
Initial & Date

VOLUNTARY CONSENT AND AUTHORIZATION

All of the above has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask additional questions at any time about this research study, and that such future questions will be answered by the researchers listed on the first page of this form. Any questions I have about my rights as a research participant will be answered by the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668).

By signing this form, I agree to participate in this research study. A copy of this consent form will be given to me.

Adults aged 18 and over:

_____ _____

Participant's Signature Date

Children aged 1 – 17:

I understand that, as a minor (age less than 18 years), _____ is not permitted to participate in this research study without my consent. Therefore, by signing this form, I give my consent for their participation in this research study.

_____ _____

Parent's Name Relationship to Participant (Child)

_____ _____

Parent's Signature Date

Children who can sign their name:

This research has been explained to me, and I agree to participate.

_____

Child's Name

_____ _____

Child's Signature Date

Verification of explanation for children who can sign their name:

I certify that I have carefully explained the nature and purpose of this research study to the above-

named child in age-appropriate language. They have had an opportunity to discuss it with me in detail. I have answered all their questions, and they have provided assent to participate in this study.

_____	_____
Printed Name of Person Obtaining Consent	Role in Research Study
_____	_____
Signature of Person Obtaining Consent	Date

All participants:

CERTIFICATION OF INFORMED CONSENT

I certify that the nature and purpose of this research study have been explained to the above-named individual(s), and the potential benefits and possible risks of study participation have been discussed. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____	
Investigator's Printed Name	
_____	_____
Investigator's Signature	Date

University of Pittsburgh

School of Dental Medicine
Department of Oral Biology

Suite 500
Cellomics Building/Bridgeside Point
100 Technology Drive
Pittsburgh, PA 15219
412-648-8381
Fax: 412-648-8779

University of Pittsburgh
Institutional Review Board
Approval Date: 9/12/07
Modification Approval Date: 10/12/07
Renewal Date: 9/13/08
IRB #: 020773

CONSENT TO BE A SUBJECT IN A RESEARCH STUDY

TITLE: **Genetic Factors Contributing to Oral Health Disparities in Appalachia (Pennsylvania Sites)**

PRINCIPAL INVESTIGATOR: Mary L. Marazita, Ph.D., F.A.C.M.G.
Professor, Oral/Maxillofacial Surgery; Assoc. Dean of Research
School of Dental Medicine, University of Pittsburgh
Suite 500 Cellomics Building/100 Technology Drive
Pittsburgh, PA 15219 USA
Telephone: 412-648-8380

CO-INVESTIGATORS: Robert J. Weyant, D.M.D., Ph.D.
Head, Division of Pediatric and Developmental Dental Sciences
School of Dental Medicine, University of Pittsburgh
Pittsburgh, PA 15261
Telephone: 412-648-3076

Katherine Neiswanger, Ph.D.
Ph.D. Medical Geneticist
School of Dental Medicine, University of Pittsburgh
Suite 500 Cellomics Building, 100 Technology Drive
Pittsburgh, PA 15219 USA
Telephone: 412-648-8384

Suzann P. McGeary, D.D.S.,
Louise Platt-Schulhof, RDH MHPE CHES,
Jayme Zovko, RDH, BS
Cornerstone Care Community Medicine & Dental Plaza
1227 Smith Township State Road
Burgettstown, PA 15021
Telephone: 724-947-9466 or 412-383-7126

SOURCE OF SUPPORT: National Institute of Dental and Craniofacial Research, U.S.A.

Why is this research being done?

Dr. Marazita and Dr. Weyant invite you to be in a study to learn more about dental health in families, including behaviors, genes (those factors that determine a person's physical characteristics and have

Initial & Date

been passed to them from their parents), and periodontal (gum tissue) factors. Oral health varies greatly among different people. The purpose of this study is to identify which genes, attitudes, and behaviors play a role in people's oral health, so that risk factors for oral health problems can be better understood.

Who is being asked to take part in this research study?

You are a member of one of approximately 550 families from West Virginia or Western Pennsylvania with at least one child between 1 and 18 years old, who is being asked to participate in this study. Your family is part of a representative sample of similar families in Burgettstown, Pennsylvania.

What procedures are being performed for research purposes?

You and your family will be asked to participate in a 4-part examination process during this visit. You and your family will also be asked to return every two years, for a total of three or four visits over five to seven years. If you agree to participate, you will undergo the following procedures during this visit. You have the right to participate in only one, two, three, or all four parts of the examination:

Part 1) Questionnaires: You will be asked a series of questions about your behaviors, thoughts, and opinions regarding dental health, general health, prevention, family relationships, parenting practices, social relationships, alcohol, drug and tobacco use, and mental health (for example, self esteem and mental illness). Demographic information (for example, age) and general health history (for example, vaccinations and frequency of check ups) also will be recorded. In addition, you will be asked to complete questionnaires that focus on medical symptoms, dental anxiety, and social history. You will be given an opportunity to examine these questionnaires and do not have to answer all the questions. This part of the study will take about 2 hours.

Part 2) Dental, Microbiological and Tobacco Examinations: You will be given a dental screening to document the presence of oral conditions, including dental decay (cavities), gum infections (called gingivitis and periodontitis by dentists), tooth alignment and crowding, dental or oral injury, and a variety of other conditions of the teeth and mouth (for example, thin enamel). The dental exam will be conducted by a licensed dentist or dental hygienist and is similar to a routine checkup visit to a family dentist, except no x-rays will be taken. During this exam, you will be asked questions regarding your dental status, such as history of tooth injury, and brushing and flossing habits. All people have different kinds of bacteria present in their mouth, so the purpose of the oral microbiological exam is to test your saliva ("spit") and the plaque on your teeth for bacteria that could cause cavities or gum infections. For this examination, you will provide a saliva sample by chewing on a wax pellet and then spitting into a vial. You will have a test to check the flow of your saliva. Your saliva will also be used to check if there is any evidence of tobacco use. A plastic strip will be placed on your tongue to collect saliva. The inside of your cheek may also be scraped to collect a sample. Dental instruments and special toothpicks will be used to scrape and collect dental plaque from your teeth and tongue. A long Q-tip will be used to collect a throat swab from the back of your throat.

If any dental problems are found, you will be given referral information and can seek dental care at your own expense. Dental care will not be provided as part of this study. This part of the

Initial & Date

study will take about 1 hour.

Part 3) Blood sample for DNA studies: Approximately one and one half teaspoons blood will be used to evaluate your DNA for genes relating to dental health, such as those which affect cavities, tooth development, or wound healing. If you are unwilling to give a blood sample, you will be provided some mouthwash and the rinse will be collected, or the inside of your cheek will be swabbed with several brushes to collect cells that contain DNA. If you are unwilling to give a blood sample, you have the option of providing a saliva (spit) sample or having the inside of your cheek swabbed with several cotton swabs to collect cells that contain DNA. If necessary, you could also be provided some mouthwash to rinse to collect the DNA. This part of the study will take 5 minutes or less, and will only be done at one visit, unless the sample is insufficient to complete the study.

Part 4) Water Sampling: You have been sent a vial to collect a sample of your drinking water from your home. This water will be tested for fluoride, a mineral in some people's water that can prevent cavities. Please bring this vial with you to your appointment.

What are the possible risks, side effects, and discomforts of participating in this research study?

1) The questions in the interviews and questionnaires may be personal. If any information about child abuse, neglect, or mistreatment is uncovered, then the law requires that it be reported.

2) The dental screening infrequently causes some slight gum bleeding, which usually stops within a few minutes. If you have a serious gum infection, you may be sensitive to the gum examination. There is a rare risk that probing your gums may cause an abscess, or infection, of the gum tissue. Although this is rare and usually goes away within a short period of time, it might be painful and require treatment with antibiotics.

3) The gum examination is usually not a risky procedure for most healthy people. But, if you have had previous bacterial (infective) endocarditis, certain specific and serious congenital (present from birth) heart conditions, or artificial heart valves or have had a knee or hip replaced, this examination could place you at risk for a bacterial infection that would affect your heart and the joints in your bones. You will be asked if you have ever had any of these heart or joint problems, and if so, you will be asked to obtain and take an antibiotic (either amoxicillin or clindamycin, azithromycin, or clarithromycin) an hour before the gum examination. You may obtain the antibiotic from the on-site study dentist or your personal physician at your own expense.

If you have the reduced ability to resist infection, this examination could place you at risk for developing an infection. If you have the reduced ability to form blood clots, you could be at risk for mild, but prolonged bleeding during some of the exam procedures. Prior to the dental exam, you will be asked in detail about having either of these conditions. If you have a reduced ability to resist infection or form blood clots, you will be excused from all parts of the examination that might cause bleeding.

4) Collection of tooth plaque, as well as the tongue and cheek scrapings, is likely to be briefly uncomfortable. The throat swab will likely lead to a brief gagging response.

5) The needle puncture of your vein to obtain the blood sample may infrequently result in pain and soreness, bruising, fainting, and rarely infection. This procedure will be performed by individuals trained and experienced in obtaining blood samples so as to minimize these risks.

Initial & Date

6) In the unlikely event of a breach of confidentiality, there is a very remote possibility that the genetic information could affect your ability to be insured, employed, or your family relationships. Such problems are probably rare. You can ask the investigators about the likelihood of the research discovering anything that would lead to these problems.

What are the possible benefits of participating in this research study?

By participating, you may learn more about your own dental and overall health. You will receive verbal and written feedback about your dental screening. If your dental screening reveals any significant problems, you will also receive names of some dentists or other health professionals who could help with any related dental/medical needs. The information obtained from your participation in this research study may eventually lead to a better understanding and better treatments for oral health problems.

If I agree to take part in this research study, will I be told of any new risks that may be found during the course of this study?

You will be promptly notified if any new information develops during the conduct of this research study, which may cause you to change your mind about continuing to participate.

Will I or my insurance company be charged for the cost of any procedures performed as part of this research study?

If you are required to take the prophylactic oral antibiotic prior to a dental exam, either you or your insurance company will be charged the cost of obtaining the antibiotic. The study will reimburse you for any out-of-pocket costs for the prophylactic antibiotic.

Will I be paid if I take part in this research study?

You will be paid $5.00 for each procedure of the study that you complete, with an added $5.00 if all four procedures are completed, up to $25.00 for one visit. Each time you return for the study (every 2 years for a total of 3 or 4 visits), you will be paid these same amounts. Over a 5 – 7 year period, you could potentially receive $75 - $100 dollars depending on the total number of visits. You will also be reimbursed for any out-of-pocket expenses, including long distance communication, transportation, parking, one meal, and any costs of obtaining a blood sample at a local lab.

Who will pay if I am injured as a result of taking part in this study?

University of Pittsburgh researchers recognize the importance of your voluntary participation in their research studies. These individuals and their staffs will make reasonable efforts to minimize, control, and treat any injuries that may arise as a result of this research. If you believe that you are injured as a result of the research procedures being performed, please contact immediately the Principal Investigator listed on the first page of this form.
Emergency medical treatment of injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. It is possible that UPMC may bill your insurance provider for the costs of this emergency treatment, but none of these costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency, you will be responsible for the costs of this follow-up care unless otherwise specifically stated. There is no plan for monetary compensation. You do not, however, waive any legal rights by signing

Initial & Date

this form.

Who will know about my participation in this research study?

Any information obtained about you from this research study will be kept as confidential as possible. All information about you or your involvement in this research study will only be accessible to the investigators involved in this study and their research staff, and will not be released to anyone without your written permission. Records and information pertaining to your identity and involvement in this research study will be stored in locked file cabinets at the School of Dentistry of the University of Pittsburgh or at Cornerstone Care Community Medicine and Dental Plaza. Computer records will be kept in password protected, secured databases. Your identity on data records, donated blood and dental samples, and DNA will be indicated only by code number. Records linking the codes to your personal identifying information will be stored in a separate, secure location. You will not be identified by name in any publication of the research results unless you sign a separate form giving your permission.

Will this research study involve the use or disclosure of my identifiable medical information?

This research study will NOT involve the use or disclosure of your identifiable medical information from your hospital or physician records, or future medical information that might become available during your participation in this study. This study will record some of your personal health or medical information, which will be kept separate from your medical records, and used only for research purposes.

Who will have access to identifiable information related to my participation in this research study?

The information learned about you during this study will not be released to anyone (for example, relatives, personal physicians, insurance companies, or any other third party) without your prior written permission. However, in the unlikely event that an interviewer identifies someone who is considered to be at immediate risk for harming him or herself or others, they will need to inform the appropriate agencies, as required by Pennsylvania law. Any information about child abuse, neglect, or mistreatment must also be reported. These research records, just like hospital records, may be subpoenaed by court order or may be inspected by federal regulatory authorities.

In addition to the investigators listed on the first page of this consent form and their research staff, the following individuals may have access to identifiable information related to your participation in this research study. Authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office may review your identifiable research information for the purpose of monitoring the appropriate conduct of this research study. In addition, authorized representatives of the University of Pittsburgh may have access to this information for the purpose of making participant payments.

For how long will the investigators be permitted to use identifiable information related to my participation in this research study?

The investigators may continue to use identifiable information related to your participation in this research study for at least 5 years following the completion of the research study.

May I have access to my personal research information resulting from my participation in this

Initial & Date

research study?

You will be notified if you have any dental problems. You will not be provided with your personal research or genetic information obtained during this study.

Is my participation in this study voluntary?

Your participation in this research study is completely voluntary. Whether or not you provide your consent for participation in this research study will have no effect on your current or future medical care at a UPMC Hospital or affiliated health care provider, or your current or future relationship with a health care insurance provider or with the University of Pittsburgh. If you turn 18 during the course of the study, your parent's permission is no longer valid, and you will be re-contacted to give permission as an adult.

May I withdraw, at a future date, my consent for participation in this research study?

You do not have to take part in this study and, should you change your mind, you can withdraw from the study at any time by submitting a dated, written request to withdraw to Dr. Marazita, who is listed on page 1 of this form. Any research information recorded before your withdrawal may continue to be used in the research study. Your decision to withdraw from this research study will have no effect on your current or future medical care at a UPMC Hospital or affiliated health care provider, or your current or future relationship with a health care insurance provider or with the University of Pittsburgh. You may be removed from the study by the investigators, if the information you provide is incorrect. If you withdraw or are removed from this research study, your biological samples, blood sample, and DNA will be destroyed.

Will my DNA samples be used for future studies?

Dr. Marazita will control the use of your biological samples and genetic material for this study, and will store your biological samples with codes in freezers at the University of Pittsburgh and West Virginia University. In the future, new research may identify other factors that could be involved in oral health. If this happens, Dr. Marazita would also like to examine them. Thus, if you agree, your biological samples and DNA will be saved for future testing of newly identified factors involved in oral health. When all of her research studies of oral health are completed, any remaining biological samples and DNA will be destroyed at that time. If you do NOT agree, your biological samples and DNA will be discarded at the end of this particular research study. You may also be contacted in the future to be invited to participate in additional research, but that future involvement is voluntary as well. If you turn 18 during the course of the study, your parent's permission is no longer valid, and you will be re-contacted to give permission as an adult regarding the use of your DNA samples.

Your blood sample and its DNA used in this research study may contribute to a new invention or discovery. Sometimes, these inventions or discoveries may be of commercial value and may be sold, patented, or licensed by the investigators and the University of Pittsburgh for use in other research or the development of new products related to oral health. If the research investigators are able to develop new products from the use of your biological sample or genetic material, they currently have no plans to share any money or other rewards with you. You retain the right to have your blood sample and its DNA destroyed if you decide to withdraw from this research study.

I give my permission for Dr. Marazita to save my biological samples and genetic material,

_____
Initial & Date

with personal identifiers, for use in other genetic research projects involving the study of oral health.

YES _____ NO _____

I give my permission to be re-contacted to obtain my consent if there is a desire to use my biological sample or genetic material, with personal identifiers, in other research projects involving the study of different diseases or conditions.

YES _____ NO _____

VOLUNTARY CONSENT AND AUTHORIZATION

All of the above has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask additional questions at any time about this research study, and that such future questions will be answered by the researchers listed on the first page of this form. Any questions I have about my rights as a research participant will be answered by the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668).

By signing this form, I agree to participate in this research study. A copy of this consent form will be given to me.

Adults aged 18 and over:

_____ _____
Participant's Signature Date

Children aged 1 – 17:

I understand that, as a minor (age less than 18 years), _____ is not permitted to participate in this research study without my consent. Therefore, by signing this form, I give my consent for their participation in this research study.

_____ _____
Parent's Name Relationship to Participant (Child)

_____ _____
Parent's Signature Date

Children who can sign their name:

This research has been explained to me, and I agree to participate.

Child's Name

Child's Signature Date

Verification of explanation for children who can sign their name:

I certify that I have carefully explained the nature and purpose of this research study to the above-named child in age-appropriate language. They have had an opportunity to discuss it with me in detail. I have answered all their questions, and they have provided assent to participate in this study.

Printed Name of Person Obtaining Consent Role in Research Study

Signature of Person Obtaining Consent Date

All participants:

CERTIFICATION OF INFORMED CONSENT

I certify that the nature and purpose of this research study have been explained to the above-named individual(s), and the potential benefits and possible risks of study participation have been discussed. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

Investigator's Printed Name

Investigator's Signature Date

West Virginia University
SCHOOL OF DENTISTRY

Institutional Review Board
University of Pittsburgh, PA, USA
IRB Number: 020773

CONSENT and INFORMATION FORM
for PARENTS OR GUARDIANS

TITLE: ***Genetic Factors Contributing to Oral Health Disparities in Appalachia***

PRINCIPAL INVESTIGATOR:

University of Pittsburgh
Mary L. Marazita, Ph.D.
Associate Dean of Research
School of Dental Medicine
Pittsburgh, PA 15261
Telephone: 412-648-8380

CO-INVESTIGATORS:

West Virginia University
Richard Crout, D.M.D., Ph.D.
Associate Dean of Research
School of Dentistry
Morgantown, WV 26506
Telephone: 304-293-6290

Daniel W. McNeil, Ph.D.
Clinical Associate Professor,
Dental Practice and Rural Health
School of Dentistry
Morgantown, WV 26506
Telephone: 304-293-2001 ext. 31622

Marybeth Hummel, M.D.
Clinical Associate Professor, Pediatrics
School of Medicine
Morgantown, WV 26506
Telephone: 304-293-1240

SOURCE OF SUPPORT: National Institute of Dental and Craniofacial Research, U.S.A.

DESCRIPTION: The purpose of this research study between West Virginia University and the University of Pittsburgh is to learn more about dental health in families, including behaviors, genes

Dental Research
Robert C. Byrd Health Sciences Center
PO Box 9448
Morgantown, WV 26506-9448
Phone: 304-293-6133
Fax: 304-293-8561

Genetic Factors Contributing to Oral Health Disparities in Appalachia
(Consent and Information Form for Parents and Guardians)

(those factors that determine a person's physical characteristics and have been passed to them from their parents), and periodontal (gum tissue) factors among children between 1 and 18 years old and their families. The study has been explained to me by _____.

DNA, or the physical material that makes up the genes, will be obtained from blood or cheek swab samples, and will be used to attempt to find genetic factors involved in oral health. I understand that my family volunteered as one of approximately 500 families with at least one child who is between 1 and 17 years old. My family is part of a representative sample of similar families in Webster and Nicholas counties. I understand that my child will be asked to participate in a 4-part examination process during this visit. My child will be asked to return every two years, for a total of three or four visits over five to seven years.

If I agree to allow my child to participate in this research study, my child will go through the following four procedures. I understand that my child has the right to participate in only one, two, three, or all four parts of the study:

Part 1) Questionnaires: My child will be asked a series of questions about their behaviors, thoughts, and opinions regarding dental health, general health, family relationships, social relationships, alcohol, drug and tobacco use, and mental health (for example, self esteem and mental illness). Demographic information (for example, age) and general health history (for example, vaccinations and frequency of check ups) also will be recorded. I understand that only the questions that are appropriate for my child's age will be asked. In addition, my child will be asked to complete paper-and-pencil or computerized questionnaires that focus on medical symptoms, dental anxiety, and social history. If my child is 11 to17 years old, they will answer most of the questions themselves. If my child is 7 to 10 years old, I or one of the researchers will help them answer the questions that are appropriate for their age. If my child is 1 to 6 years old, I will complete their interviews and questionnaires. My child and I will be given an opportunity to examine these questionnaires. I know that my child does not have to answer all the questions. This part of the study will take about 2 hours for children aged 11 to 17, and 1 hour for children aged 1 to 10.

Part 2) Dental, microbiological and tobacco examinations, water sample for fluoride analysis: My child will be given a dental exam to document the presence of oral conditions, including dental decay (cavities), gum infections (called gingivitis and periodontitis by dentists), tooth alignment and crowding, dental or oral injury, and a variety of other conditions of the teeth and mouth (for example, thin enamel). The dental exam will be conducted by a licensed dentist or dental hygienist and is similar to a routine checkup visit to a family dentist, except no x-rays will be taken. During this exam, I or my child will be asked questions regarding my child's dental status, such as history of tooth injury, and brushing and flossing habits.

All people have different kinds of bacteria present in their mouth, so the purpose of the oral microbiological exam is to test my child's saliva ("spit") and the plaque on my child's teeth for bacteria that could cause cavities or gum infections. For this examination, if my child is old enough, they will provide a saliva sample by chewing on a wax pellet and then spitting into a vial. My child will also have a test to check the flow of his/her saliva. The saliva will also be used to check if there is any evidence of tobacco use. For all children aged 1 and older, a plastic strip will be placed on the tongue to collect saliva. The inside of my child's cheek may be scraped to collect a sample.

Dental instruments and special toothpicks will be used to scrape and collect dental plaque from my child's teeth and tongue. A long Q-tip will be used to collect a throat swab from the back of my child's throat.

If any dental problems are found, I will be given referral information and can seek dental care for my child at my own expense. Dental care will not be provided as part of this study. This part of the study will take about 1 hour. My family will be sent a small plastic vial and instructions on providing a water sample for fluoride analysis. This sample will be returned on my family's first visit or a later visit and tested for fluoride content.

Part 3) Medical genetics evaluation: My child will have an evaluation by a trained genetics counselor, who will measure their height, weight, abdominal circumference, blood pressure if my child is age 11-17, assess the shape of his/her face, and check for anything unusual that could possibly be caused by genes, and that might affect how healthy they are and how healthy their teeth and gums are. About two teaspoons of my child's blood in total will be taken by placing a needle in a vein in one of my child's arms with a small needle and glass tubes. My child's blood will be drawn by a person with phlebotomy (blood collecting) experience. One half teaspoon of this blood will be checked to look for specific problems with their chromosomes, which are the biological structures that carry the genes. (The other teaspoon and a half will be added in Part 4).

I will be notified if there is a specific problem with one of my child's chromosomes. I will also be given a referral, and can seek additional clinical information for my child at my own expense. This part of the study will take about 30 minutes.

Part 4) Blood sample for DNA studies: About 1 and one half teaspoons of blood will be used to evaluate my child's DNA for genes relating to dental health, such as those which affect cavities, tooth development, or wound healing. Less blood will be taken from smaller sized children. If my child is unwilling to give a blood sample, my child may be provided some mouthwash and the rinse may be collected or the inside of my child's cheek will be swabbed with up to 6 cotton swabs to collect cells that contain DNA. I understand that my child and I will not be provided with any of my child's personal genetic information from the DNA analyses done during this part of the study. I understand that the DNA can also be harvested from a sample of saliva that I have already given. If there is not enough, my child may be asked to spit into another vial that is used for this test. This part of the study will take 5 minutes or less, and will only be done at one visit, unless the sample is insufficient to complete the study.

I understand that my child's biological samples or DNA may be accidentally lost as a result of equipment failure (for example, refrigerator/freezer) or other unforeseen events. Even under the best conditions, research studies on genes are not perfect and may lead to useless or incorrect results.

Dr. Marazita (the principal investigator of this research project) will control the use of my child's biological samples and genetic material for this research study, and will store my child's biological samples with codes in freezers at the University of Pittsburgh. In the future, new research may identify other factors that could be involved in oral health. If this happens, Dr. Marazita would also like to examine them. Thus, if I agree, my child's biological samples and DNA will be saved for future testing of newly identified factors involved in oral health. When all of her research

studies of oral health are completed, any remaining biological samples and DNA will be destroyed at that time. If I do NOT agree, my child's biological samples and DNA will be discarded at the end of this particular research study.

I give my permission for Dr. Marazita to save my child's biological samples and genetic material, with personal identifiers, for use in other genetic research projects involving the study of oral health.
YES _____ NO ____ Signature _____Date_____

RISKS AND BENEFITS:
Risks:
1) The questions in the interview and questionnaires may be personal to my child. If any information about child abuse, neglect, or mistreatment is uncovered, then the law requires that it be reported.
2) The dental exam infrequently causes some slight gum bleeding that usually stops within a few minutes. If my child has a medical condition that would require that he/she take antibiotics before a dental examination, any part of the dental or microbiological tests that may result in bleeding will not be done. If my child has a serious gum infection, they may be sensitive to the gum examination. There is a rare risk that testing for inflamed gums may cause an abscess, or infection, of the gum tissue. Although this is rare and usually goes away within a short period of time, it might be painful and require treatment with antibiotics.
3) Collection of tooth plaque, as well as the tongue and cheek scrapings, is likely to be briefly uncomfortable for my child. The throat swab will likely lead to a brief gagging response.
4) In rare instances, my child's medical genetics evaluation could possibly reveal that my child might have a genetic condition I am unaware of. Should this rare event occur, Dr. Hummel will discuss the situation with me, and will also provide referral information, so that I can learn more about my child's condition and treatment options.
5) The needle puncture of my child's vein to obtain the blood sample may infrequently result in pain and soreness, bruising, fainting, and rarely infection. This procedure will be performed by individuals trained and experienced in obtaining blood samples in children, so as to minimize these risks.
6) In the unlikely event of a breach of confidentiality, there is a very remote possibility that the genetic information could affect my child's ability to be insured or employed, or their future plans for children or their family relationships.

Benefits: By participating, my child may learn more about their own dental and overall health. My child and I will receive verbal and written feedback if my child's dental exam or medical genetics evaluation reveals any significant problems along with the names of dentist who could help. The information obtained from my child's participation in this research study may eventually lead to a better understanding and better treatments for oral health problems.

NEW INFORMATION: I have already been told I will be notified if my child has any dental

problems, or if there is a problem with one of my child's chromosomes as it pertains to health care. However, my child's personal results from the DNA studies will not be provided to me or my child. I will be promptly notified if any other information about this research develops during the course of the study, which may cause me to change my mind about my child's continuing to participate.

COSTS AND PAYMENTS: I understand that my child will be paid $25.00 for participating . It will be paid to my child in the form of a gift certificate to WalMart in my child's name. If my child does not finish all the parts in one appointment, he/she will be provided another $25.00 gift certificate for coming back a second time to finish. I understand that each time my child returns for the study (every 2 years for a total of 3 or 4 visits, they will be paid these same amounts. Over a 5 – 7 year period, they could potentially receive $75 - $100 dollars in gift certificates depending on the total number of visits.

COMPENSATION FOR INJURY: If my child is injured as a result of this research, treatment will be available. Compensation for my injuries will not be provided voluntarily by the investigator, sponsor, West Virginia University, or other associated affiliates.

CONFIDENTIALITY: I understand that any information obtained as a result of my child's participation in this research will be kept as confidential as legally possible. I understand that all records and information pertaining to my child's identity and involvement in this research study will be stored for five years after the study is completed in locked file cabinets at the School of Dentistry of the West Virginia University. Secure computer databases containing only non-identifying information on my child will be available to investigators at WVU and the University of Pittsburgh. My child's records will only be accessible to the investigators listed on the first page of this informed consent document. I understand that my child's identity on all of the research information (for example, blood and saliva samples, questionnaire responses, dental results) will be coded before the data is sent to the University of Pittsburgh for analysis. My child's name, or any other information from which they might be identified, will not be published without my separate, written consent. If I agreed on page 4, above, to allow Dr. Marazita to retain my child's genetic samples for additional genetic studies of oral health, then my child's biological samples and DNA will be saved for future testing. If I did not agree, my child's biological samples and DNA will be discarded at the end of this research study.

I understand that the information learned about my child during this study will not be released to anyone (for example, relatives, personal physicians, insurance companies, or any other third party) without my prior written permission. However, in the unlikely event that an interviewer identifies someone who is considered to be at immediate risk for harming him or herself or others, an appropriate action will be taken. I also understand that if any information about child abuse, neglect, or mistreatment is uncovered, then the law requires that it be reported. I understand that my child's research records, just like hospital records, may be subpoenaed by court order or may be inspected by federal regulatory authorities. The West Virginia University and the University of Pittsburgh Research Conduct and Compliance Offices may review my child's research records.

Genetic Factors Contributing to Oral Health Disparities in Appalachia
(Consent and Information Form for Parents and Guardians)

ALTERNATIVE: My child does not have to take part in this research study. My child's current and future care and any other benefits will be the same whether they participate in this research study or not.

RIGHT TO WITHDRAW: I understand that my child's participation in this research study is completely voluntary. My child does not have to take part in this research study and, should they change their mind, they can withdraw from the study at any time. I also understand that my child may be removed from the research study by the investigators if it is determined that the information my child has provided is incorrect. If my child withdraws or is removed from participation in this research study, their biological samples, blood sample, and DNA will be destroyed.

My child's blood sample and its DNA used in this research study may contribute to a new invention or discovery. In some instances, these inventions or discoveries may be of commercial value and may be sold, patented, or licensed by the investigators and the University of Pittsburgh for use in other research or the development of new products related to oral health. If the research investigators are able to develop new products from the use of my child's biological sample or genetic material, they currently have no plans to share any money or other rewards with me or my child. I retain the right to have my child's blood sample and its DNA destroyed if either my child or I decide to withdraw from this research study.

VOLUNTARY CONSENT: Participation in this study is voluntary. My child has been given the opportunity to ask questions about the research, and my child has received answers concerning areas they did not understand. My child may withdraw from this study at any time. Refusal to participate or withdrawal will involve no penalty or loss of benefits for my child. I understand that I may be contacted in the future for my child to be invited to participate in additional research, but that future involvement is voluntary as well.

I give my permission to be re-contacted to obtain my consent if other researchers desire to use my child's biological sample or genetic material, with personal identifiers, in other research projects involving the study of different diseases or conditions.

YES ___ NO ___ Signature _____ Date_____

For more information about this research, my child or I may contact any of the individuals listed on the first page of this document. For information regarding my child's rights as a research participant, my child or I may contact the Executive Secretary of the West Virginia Institutional Review Board at (304) 293-7073 or the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh at (412) 578-8570. A copy of this consent form will be given to me.

Genetic Factors Contributing to Oral Health Disparities in Appalachia

(Consent and Information Form for Parents and Guardians)

I understand that, as a minor (age less than 18 years), my child is not permitted to participate in this research study without my consent. By signing this form, I agree to allow my child

_____ to participate in this research study.
(Child's Name)

_____	_____	_____
Parent's Signature	Date	Time
_____	_____	_____
Parent's Signature	Date	Time
_____	_____	_____
Witness' Signature	Date	Time
_____	_____	_____
Signature of Investigator or Investigator's Representative	Date	Time

West Virginia University
SCHOOL OF DENTISTRY

Institutional Review Board
University of Pittsburgh, PA, USA
IRB Number: 020773

ASSENT FORM for CHILDREN AGED 7 to 13

TITLE: ***Genetic Factors Contributing to Oral Health Disparities in Appalachia***

PRINCIPAL INVESTIGATOR:

University of Pittsburgh
Mary L. Marazita, Ph.D.
Associate Dean of Research
School of Dental Medicine
Pittsburgh, PA 15261
Telephone: 412-648-8380

CO-INVESTIGATORS:

West Virginia University
Richard Crout, D.M.D., Ph.D.
Associate Dean of Research
School of Dentistry
Morgantown, WV 26506
Telephone: 304-293-6290

Daniel W. McNeil, Ph.D.
Clinical Associate Professor,
Dental Practice and Rural Health
School of Dentistry
Morgantown, WV 26506
Telephone: 304-293-2001 ext. 31622

Marybeth Hummel, M.D.
Clinical Associate Professor, Pediatrics
School of Medicine
Morgantown, WV 26506
Telephone: 304-293-1240

SOURCE OF SUPPORT: National Institute of Dental and Craniofacial Research, U.S.A.

DESCRIPTION: I have been told by _____ that this study will learn about the health of my teeth, gums, and mouth, as well as my thoughts and feelings about my teeth and mouth. The research people will also ask general questions about me and my family, like how old I am. Some of my blood or cheek cells will be tested for genes, which are physical traits passed on to me from my parents. The research people are especially interested in

Dental Research
Robert C. Byrd Health Sciences Center
PO Box 9448
Morgantown, WV 26506-9448
Phone: 304-293-6133
Fax: 304-293-8561

genes that affect my teeth, like genes that control how thick the enamel on my teeth is, or how easily I get cavities. They will test my spit (saliva) and the white stuff on my teeth (plaque) for germs that cause cavities. All of this information about me and my parents will be tested together using math on computers.

My family is one of about 500 families like mine that live in Webster and Nicholas counties, that have a child between 1 and 18, and that have agreed to be in this study. If I agree to be in this study, I will be asked to do four different things during this visit, and I will come back again in two years. I can do all four parts of the study (listed below) , but if I don't want to do, I can do only one, two, or three parts of the study.

Part 1) Questionnaires: I will be asked some questions about how I feel and act, what I think and know about my teeth and the dentist, my health, my family (for example how they get along), my friends, about drinking, drugs, and tobacco, and about mental health (for example, how I feel about myself). I don't have to answer the questions if I don't want to. I will also be asked to fill out surveys about my past physical health and feelings. If I am 11 to13 years old, I will answer most of the questionnaires myself. If I am 7 to 10 years old, my mom, dad, or one of the researchers will help me answer the questions. I can look at the questions before I answer them, and I do not have to answer all the questions. This part of the study will take about 1 to 2 hours.

Part 2) Dental, microbiological and tobacco exam, water sample for fluoride analysis: I will be given a dental exam by a dentist or dental hygienist. It will be just like a regular checkup at the dentist, except there will be no x-rays. The dentist will ask me questions about my teeth and mouth. If the dentist notices any problems, my parents will be told about it. All people have different kinds of germs in their mouth, so part of the exam is to look for germs in my mouth that might cause cavities. For this part of the exam, I will chew on a wax pellet and then spit into a small glass jar. I will also have a test to check the flow of my saliva. My saliva will also be used to check if there is any evidence of tobacco use. Also, a paper strip will be placed on my tongue to collect more spit. The inside of my cheek may be scraped to collect a sample. Dental instruments and special toothpicks will be used to collect plaque (white stuff) from my teeth and tongue. A long Q-tip will be used to collect a throat swab from the back of my throat. This part of the study will take about 1 hour. My family will be sent a small plastic vial and instructions on giving a water sample for fluoride analysis. This sample will be returned on my family's first visit or at a later visit and tested for fluoride content.

Part 3) Medical genetics evaluation: I will have an exam to measure my height, weight, blood pressure if I am age 11-13, tummy size, the shape of my face, and to see if there is anything unusual that might affect how healthy I am and how healthy my teeth and gums are. About two teaspoons in total of blood will be taken by placing a needle in a vein in one of my arms. One half teaspoon of this blood will be checked for problems with my chromosomes, which are the physical structures that carry my genes. (The other teaspoon and a half will be added in Part 4.) If anything unusual is noticed, my parents will be told about it. This part of the study will take about 30 minutes.

Part 4) Blood sample for gene studies: About 1 and one half teaspoons of blood will be taken for the genetic evaluation. This sample will be collected to see if anything in my genes is affecting my dental health. If I don't want to give a blood sample, I may be provided some mouthwash and the rinse may be collected or the inside of my cheek will be swabbed with up to 6 cotton swabs to collect cells. I understand that the DNA can also be harvested from a sample of saliva that I have already given. If there is not enough, I may be asked to spit into another vial that is used for this test. This part of the study will take 5 minutes or less, and will only be done at one visit, unless it is not enough for the study.

RISKS AND DISCOMFORTS: Some of the questions may be difficult for me to answer, or may be personal, and I may not enjoy trying to answer them. The dental exam may cause my gums to bleed a little, but this is infrequent and usually stops in a few minutes. If I have any medical condition that would require that I take antibiotics before the examination, I will not have any part of the dental or microbiological tests done that may cause bleeding. There is a rare chance that I could get a gum infection, which might be painful and need antibiotics. Collecting the saliva and tooth plaque samples will likely be slightly uncomfortable. The throat swab will likely cause me to gag once. Having the blood drawn will likely be uncomfortable, and can sometimes cause a bruise, bleeding, fainting, or even an infection, although this is rare.

BENEFITS: I will be participating in a research project that may help people have better dental health in the future. By participating, I may learn more about my own dental and overall health. If there is anything wrong with my teeth or mouth, my parents will be told about it and receive a written report of the findings along with the names of some dentists who could help.

COSTS AND PAYMENTS: I will be paid $25.00 for being in the study. It will be given to me as a gift certificate to WalMart. If I do not finish all the parts in one appointment, I will be provided another $25.00 gift certificate for coming back a second time to finish. Each time I return for the study (every 2 years for a total of 3 or 4 visits), I will be paid these same amounts. Over a 5 – 7 year period, I could potentially receive $75 - $100 dollars in gift certificates depending on the total number of visits.

CONFIDENTIALITY: Anything that is learned about me in this study will be kept as secret as possible. If I give a blood or spit sample, they will be sent to West Virginia University in Morgantown or the University of Pittsburgh in Pennsylvania, and will be kept for five years after the study is over and then destroyed.

VOLUNTARY CONSENT: I have been told that I do not have to do this. No one will be mad at me if I refuse to do this or if I decide to quit. I can change my mind whenever I want to. I have been allowed to ask questions about the research, and all of my questions have been answered. If I have any more questions, I may call Dr. Daniel McNeil, at (304) 293-2001 ext.

Genetic Factors Contributing to Oral Health Disparities in Appalachia
(Assent Form for Children Aged 7 to 13)

31622, Dr. Richard Crout at (304) 293-6290, Dr. Marybeth Hummel at (304) 293-1240, or Dr. Mary Marazita in Pennsylvania at (412) 648-8380.

I may contact the Executive Secretary of the West Virginia Institutional Review Board at (304) 293-7073 or the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh at (412) 578-8570. A copy of this assent form will be given to me.

I willingly agree to be in this research.

_____	_____	_____
Subject's Signature	Date	Time

PARENTAL CONSENT:

I understand that, as a minor (age less than 18 years), my child is not permitted to participate in this research study without my consent. A copy of this form will be given to me. By signing this form, I agree to allow my child

_____ to participate in this research study.
(Child's Name)

_____	_____	_____
Parent's Signature	Date	Time
_____	_____	_____
Parent's Signature	Date	Time
_____	_____	_____
Witness' Signature	Date	Time

VERIFICATION OF EXPLANATION: I certify that I have carefully explained the purpose and nature of this research study to the above-named child in age appropriate language. He/she has had an opportunity to discuss it with me in detail. I have answered all his/her questions and he/she has provided affirmative agreement (i.e., assent) to participate in this study.

_____	_____	_____
Signature of Investigator or Investigator's Representative	Date	Time

West Virginia University
SCHOOL OF DENTISTRY

Institutional Review Board
University of Pittsburgh, PA, USA
IRB Number: 020773

ASSENT FORM for CHILDREN AGED 14 to 17

TITLE: ***Genetic Factors Contributing to Oral Health Disparities in Appalachia***

PRINCIPAL INVESTIGATOR:

University of Pittsburgh
Mary L. Marazita, Ph.D.
Associate Dean of Research
School of Dental Medicine
Pittsburgh, PA 15261
Telephone: 412-648-8380

CO-INVESTIGATORS:

West Virginia University
Richard Crout, D.M.D., Ph.D.
Associate Dean of Research
School of Dentistry
Morgantown, WV 26506
Telephone: 304-293-6290

Daniel W. McNeil, Ph.D.
Clinical Associate Professor,
Dental Practice and Rural Health
School of Dentistry
Morgantown, WV 26506
Telephone: 304-293-2001 ext. 31622

Marybeth Hummel, M.D.
Clinical Associate Professor, Pediatrics
School of Medicine
Morgantown, WV 26506
Telephone: 304-293-1240

SOURCE OF SUPPORT: National Institute of Dental and Craniofacial Research, U.S.A.

DESCRIPTION: I have been told by _____ _____ that the purpose of this study between West Virginia University and the University of Pittsburgh is to learn more about the health of my and my parents' teeth, gums, and mouth, as well as my and my parents' thoughts and feelings about dental health. Also, general information about me and my family,

Dental Research
Robert C. Byrd Health Sciences Center
PO Box 9448
Morgantown, WV 26506-9448
Phone: 304-293-6133
Fax: 304-293-6561

like our ages, will be recorded. A sample of my blood or cheek cells will be tested for genes that affect dental health, like the genes that determine how thin or thick the enamel on my teeth might be. My saliva ("spit") and the plaque (white stuff) on my teeth will be tested to look for bacteria that cause cavities. All of this information from me and my parents will be tested together using math on computers.

I understand that my family volunteered as one of approximately 500 families with at least one child who is between 1 and 18 years old. My family is part of a sample of similar families in Webster and Nicholas counties. I know that I will be asked to participate in a 4-part examination process during this visit. My family and I will be asked to return every two years, for a total of three or four visits over five to seven years.

If I agree to be in this research study, I will go through the following four procedures. I have the right to participate in only one, two, three, or all four parts of the study:

Part 1) Questionnaires: I will be asked some questions about my behaviors, thoughts, and opinions about dental health, general health, family relationships, social relationships, alcohol, drug and tobacco) use, and mental health (for example, self-esteem and mental illness). General information about me (for example, my age) and my health history (for example, vaccinations and frequency of check ups) also will be recorded. I don't have to answer the questions if they make me uncomfortable. In addition, I will be asked to complete paper-and-pencil or computerized questionnaires about my medical and social history. I will answer most of the questionnaires myself, but can get help from my parents or the researchers. I will have a chance to look at these questions before I answer them, and I know that I do not have to answer all the questions. This part of the study will take about 2 hours.

Part 2) Dental, microbiological, and tobacco examination, water sample for fluoride analysis: I will be given a dental exam by a dentist or dental hygienist. It will be just like a regular checkup visit to the dentist, except there will be no x-rays. The dentist will ask me questions about my teeth and mouth. If the dentist notices any problems, my parents will be told about it. All people have different kinds of bacteria in their mouth, so the purpose of the oral microbiology exam is to look for bacteria in my mouth that might cause cavities or gum infections. For this exam, I will chew on a wax pellet and then spit into a small glass jar. I will also have a test to check the flow of my saliva. My saliva will also be used to check if there is any evidence of tobacco use. The inside of my cheek may be scraped to collect a sample. Dental instruments and special toothpicks will be used to scrape and collect dental plaque from my teeth and tongue. A long Q-tip will be used to collect a throat swab from the back of my throat. This part of the study will take about 1 hour. My family will be sent a small plastic vile and instructions on providing a water sample for fluoride analysis. This sample will be returned on my family's first visit or a later visit and tested for fluoride content.

Part 3) Medical genetics evaluation: I will have an evaluation to measure my height, weight, abdominal circumference, blood pressure, the shape of my face, and to see if there is anything unusual that might affect how healthy I am and how healthy my teeth and gums are. About two teaspoons in total of blood will be taken by placing a needle in a vein in one of my arms. One half teaspoon of my blood will be checked for problems with my chromosomes, which are the

physical structures that carry my genes (The other teaspoon and a half will be added in Part 4). If anything unusual is noticed, my parents will be told about it. This part of the study will take about 30 minutes.

Part 4) Blood sample for DNA studies: About 1 and one half teaspoons of blood, will be taken for genetic evaluation. This sample will be collected to see if anything in my genes is affecting my dental health. If I don't want to give a blood sample, I may be provided some mouthwash and the rinse may be collected or the inside of my cheek will be swabbed with up to 6 cotton swabs to collect cells that contain DNA. I understand that the DNA can also be harvested from a sample of saliva that I have already given. If there is not enough, I may be asked to spit into another vile that is used for this test. This part of the study will take 5 minutes or less, and will only be done at one visit, unless it is not enough.

RISKS AND DISCOMFORTS: Some of the questions may be difficult for me to answer, or may be personal, and I may not enjoy trying to answer them. The dental exam may cause my gums to bleed a little, but this is infrequent and usually stops in a few minutes. If I have any medical condition that would require that I take antibiotics before the examination, I will not have any part of the dental or microbiological tests done that may cause bleeding. There is a rare chance that I could get a gum infection, which might be painful and need antibiotics. Collecting the saliva and tooth plaque samples will likely be slightly uncomfortable. The throat swab will likely cause me to gag once. Having the blood drawn will likely be uncomfortable, and can sometimes cause a bruise, bleeding, fainting, or even an infection, although this is rare.

BENEFITS: I will be participating in an important research project that may help people have better dental health in the future. By participating, I may learn more about my own dental and overall health. If there is anything wrong with my teeth or mouth, my parents will be told about it and receive a written report of the findings along with the names of some dentists who could help.

COSTS AND PAYMENTS: I will be paid $25.00 for being in the study. It will be given to me as a gift certificate to WalMart. If I do not finish all the parts in one appointment, I will be provided another $25.00 gift certificate for coming back a second time to finish. Each time I return for the study (every 2 years for a total of 3 or 4 visits, I will be paid these same amounts. Over a 5 – 7 year period, I could potentially receive $75 - $100 dollars in gift certificates depending on the total number of visits.

CONFIDENTIALITY: I have been promised that anything that is learned about me in this study will be kept as secret as possible. If I give a blood or saliva sample, they will be sent to West Virginia University in Morgantown or the University of Pittsburgh in Pennsylvania, and will be kept for five years after the study is over and then destroyed.

VOLUNTARY CONSENT: I have been told that I do not have to do this. No one will be mad at me if I refuse to do this or if I decide to quit. I can change my mind whenever I want to. I

have been allowed to ask questions about the research, and all of my questions have been answered. If I have any more questions, I may call Dr. Daniel McNeil, at (304) 293-2001 ext. 31622, Dr. Richard Crout at (304) 293-6290, Dr. Marybeth Hummel at (304) 293-1240, or Dr. Mary Marazita in Pennsylvania at (412) 648-8380. If I want to know my rights as a research participant, I may contact the Executive Secretary of the West Virginia Institutional Review Board at (304) 293-7073 or the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh at (412) 578-8570. A copy of this assent form will be given to me.

I willingly agree to be in this research.

_____	_____	_____
Subject's Signature	Date	Time

PARENTAL CONSENT:

I understand that, as a minor (age less than 18 years), my child is not permitted to participate in this research study without my consent. A copy of this assent form will be given to me. By signing this form, I agree to allow my child

_____ to participate in this research study.
(Child's Name)

_____	_____	_____
Parent's Signature	Date	Time
_____	_____	_____
Parent's Signature	Date	Time
_____	_____	_____
Witness' Signature	Date	Time

VERIFICATION OF EXPLANATION: I certify that I have carefully explained the purpose and nature of this research study to the above-named child in age appropriate language. He/she has had an opportunity to discuss it with me in detail. I have answered all his/her questions and he/she has provided affirmative agreement (i.e., assent) to participate in this study.

_____	_____	_____
Signature of Investigator or Investigator's Representative	Date	Time

West Virginia University
SCHOOL OF DENTISTRY

Institutional Review Board
University of Pittsburgh, PA, USA
IRB Number: 020773

CONSENT and INFORMATION FORM for ADULTS TO ACT AS A SUBJECT IN A RESEARCH STUDY

TITLE: ***Genetic Factors Contributing to Oral Health Disparities in Appalachia***

PRINCIPAL INVESTIGATOR:

University of Pittsburgh
Mary L. Marazita, Ph.D.
Associate Dean of Research
School of Dental Medicine
Pittsburgh, PA 15261
Telephone: 412-648-8380

CO-INVESTIGATORS:

West Virginia University
Richard Crout, D.M.D., Ph.D.
Associate Dean of Research
School of Dentistry
Morgantown, WV 26506
Telephone: 304-293-6290

Daniel W. McNeil, Ph.D.
Clinical Associate Professor,
Dental Practice and Rural Health
School of Dentistry
Morgantown, WV 26506
Telephone: 304-293-2001 ext. 31622

Marybeth Hummel, M.D.
Clinical Associate Professor, Pediatrics
School of Medicine
Morgantown, WV 26506
Telephone: 304-293-1240

SOURCE OF SUPPORT: National Institute of Dental and Craniofacial Research, U.S.A.

DESCRIPTION: The purpose of this research study between West Virginia University and the University of Pittsburgh is to learn more about dental health in families, including behaviors, genes (those factors that determine a person's physical characteristics and have been passed to them from their parents), and periodontal (gum tissue) factors among children between 1 and 18 years old and

Dental Research
Robert C. Byrd Health Sciences Center
PO Box 9448
Morgantown, WV 26506-9448
Phone: 304-293-6133
Fax: 304-293-8561

their families. The study has been explained to me by _____.

DNA, or the physical material that makes up the genes, will be obtained from blood, cheek swab samples, mouthrinse or saliva and will be used to attempt to find genetic factors involved in oral health. I understand that my family volunteered as one of approximately 500 families with at least one child who is between 1 and 18 years old. My family is part of a representative sample of similar families in Webster and Nicholas counties. I understand that my family and I will be asked to participate in a 4-part examination process during this visit. My family and I will be asked to return every two years, for a total of three or four visits over five to seven years.

If I agree to participate in this research study, I will go through the following four procedures. I will be sent a copy of the adult consent form that I can review before my appointment. I understand that I have the right to participate in only one, two, three, or all four parts of the study:

Part 1) Questionnaires: I will be asked a series of questions about my behaviors, thoughts, and opinions regarding; dental health; general health; prevention; family relationships; parenting practices; social relationships; alcohol, drug and tobacco use; and mental health (for example, self-esteem and mental illness). Demographic information (for example, age) and general health history (for example, vaccinations and frequency of check ups) also will be recorded. In addition, I will be asked to complete paper-and-pencil or computerized questionnaires that focus on medical symptoms, dental anxiety, and social history. I will be given an opportunity to examine these questionnaires and know that I do not have to answer all the questions. This part of the study will take about 2 hours.

I also understand that I may be one of a group of up to 100 people who may be asked to evaluate the satisfaction of the computerized versus the paper-and-paper versions of the self report questionnaires. Half of the group will receive the paper-and-pencil version and half will receive the paper-and-pencil version. The time taken to complete the questionnaires will be recorded on a stopwatch. Upon completion of the questionnaires, I will be asked to complete a brief questionnaire evaluating the two approaches which should only take about 20 minutes to fill out.

Part 2) Dental, microbiological and tobacco examinations, water sample for fluoride analysis: I will be given a dental exam to document the presence of oral conditions, including dental decay (cavities), gum infections (called gingivitis and periodontitis by dentists), tooth alignment and crowding, dental or oral injury, and a variety of other conditions of the teeth and mouth (for example, thin enamel). The dental exam will be conducted by a licensed dentist or dental hygienist and is similar to a routine checkup visit to a family dentist, except no x-rays will be taken. During this exam, I will be asked questions regarding my dental status, such as history of tooth injury, and brushing and flossing habits.

All people have different kinds of bacteria present in their mouth, so the purpose of the oral microbiological exam is to test my saliva ("spit") and the plaque on my teeth for bacteria that could cause cavities or gum infections. For this examination, I will provide a saliva sample by chewing on a wax pellet and then spitting into a vial. I will also have a test to check the flow

of my saliva. My saliva will also be used to check if there is any evidence of tobacco use. Also, a plastic strip will be placed on my tongue to collect saliva. The inside of my cheek may also be scraped to collect a sample. Dental instruments and special toothpicks will be used to scrape and collect dental plaque from my teeth and tongue. A long Q-tip will be used to collect a throat swab from the back of my throat.

If any dental problems are found, I will be given referral information and can seek dental care at my own expense. Dental care will not be provided as part of this study. This part of the study will take about 1 hour. My family will be sent a small plastic vile and instructions on providing a water sample for fluoride analysis. This sample will be returned on my family's first visit and tested for fluoride content.

Part 3) Medical genetics evaluation: I will have an evaluation by a trained genetics counselor, who will measure my height, weight, abdominal circumference, blood pressure, assess the shape of my face, and check for anything unusual that could possibly be caused by genes, and that might affect how healthy I am and how healthy my teeth and gums are. About two teaspoons of my blood in total will be taken by venipuncture, which is a standard procedure to take blood from a vein in one of my arms with a small needle and glass tubes. One half teaspoon of this blood will be taken, to look for specific problems with my chromosomes, which are the biological structures that carry the genes. (The other teaspoon and a half will be added in Part 4).

I will be notified if there is a specific problem with one of my chromosomes. I will also be given a referral, and can seek additional clinical information at my own expense.
This part of the study will take about 30 minutes.

Part 4) Blood sample for DNA studies: Approximately one and one half teaspoons will be drawn. This sample will be used to evaluate my DNA for genes relating to dental health, such as those which affect cavities, tooth development, or wound healing. If I am unwilling to give a sample, I may be provided some mouthwash and the rinse will be collected or the inside of my cheek will be swabbed with up to 6 cotton swabs several brushes to collect cells that contain DNA. I understand that I will not be provided with any personal genetic information from the DNA analyses done during this part of the study. I understand that the DNA can also be harvested from a sample of saliva that I have already given. If there is not enough, I may be asked to spit into another vial that is used for this test. This part of the study will take 5 minutes or less, and will only be done at one visit, unless the sample is insufficient to complete the study.

I understand that my biological samples or DNA may be accidentally lost as a result of equipment failure (for example, refrigerator/freezer) or other unforeseen events. Even under the best conditions, research studies on genes are not perfect and may lead to useless or incorrect results.
Dr. Marazita (the principal investigator of this research project) will control the use of my biological samples and genetic material for this research study, and will store my biological samples with codes in freezers at the University of Pittsburgh. In the future, new research may identify other factors that could be involved in oral health. If this

happens, Dr. Marazita would also like to examine them. Thus, if I agree, my biological samples and DNA will be saved for future testing of newly identified factors involved in oral health. When all of her research studies of oral health are completed, any remaining biological samples and DNA will be destroyed at that time. If I do NOT agree, my biological samples and DNA will be discarded at the end of this particular research study. I give my permission for Dr. Marazita to save my biological samples and genetic material, with personal identifiers, for use in other genetic research projects involving the study of oral health.

YES _____ NO _____ Signature _____Date_____

RISKS AND BENEFITS:

Risks:

1) The questions in the interviews and questionnaires may be personal to me. If any information about child abuse, neglect, or mistreatment is uncovered, then the law requires that it be reported.
2) The dental exam infrequently causes some slight gum bleeding, which usually stops within a few minutes. If I have a serious gum infection, I may be sensitive to the gum examination. There is a rare risk that probing my gums may cause an abscess, or infection, of the gum tissue. Although this is rare and usually goes away within a short period of time, it might be painful and require treatment with antibiotics.
3) The gum examination is usually not a risky procedure for most healthy people. But, if I have had rheumatic fever with heart valve complications, certain other heart conditions or have had a knee or hip replaced, this examination could place me at risk for a bacterial infection that would affect my heart and the joints in my bones. I will be asked if I have ever had any of these heart of joint problems, and if so, I will be offered an antibiotic (either amoxicillin or clindamycin) an hour before the gum examination, and the risks of taking the antibiotic will be explained to me.
4) Collection of tooth plaque, as well as the tongue and cheek scrapings, is likely to be briefly uncomfortable. The throat swab will likely lead to a brief gagging response.
5) In rare instances, my medical genetics evaluation could possibly reveal a genetic condition I am unaware of. Should this rare event occur, Dr. Hummel will discuss the situation with me, and will also provide referral information, so that I can learn more about the condition and treatment options.
6) The needle puncture of my vein to obtain the blood sample may infrequently result in pain and soreness, bruising, fainting, and rarely infection. This procedure will be performed by individuals trained and experienced in obtaining blood samples so as to minimize these risks.
7) In the unlikely event of a breach of confidentiality, there is a very remote possibility that the genetic information could affect my ability to be insured, my ability to be employed, my future plans for children, or my family relationships.

Benefits:

By participating, I may learn more about my own dental and overall health. I will receive verbal

and written feedback if my dental exam or medical genetics evaluation reveals any significant problems along with the names of some dentists who could help with any dental needs.

The information obtained from my participation in this research study may eventually lead to a better understanding and better treatments for oral health problems.

NEW INFORMATION: I have already been told that I will be notified if I have any dental problems, or if there is a problem with one of my chromosomes as it pertains to health care, but that my personal results of the DNA studies will not be provided to me. I will be promptly notified if any other information about this research develops during the course of the study, which may cause me to change my mind about continuing to participate.

COSTS AND PAYMENTS: I understand that I will be paid $25.00 for my participation.. I have the option to have this in the form of a check or a WalMart gift certificate. I will check below which one I would like to receive.

$25.00 WalMart gift certificate ____ $25.00 check ____

If I do not finish all the parts in one appointment, I will be provided another $25.00 for coming back a second time to finish. In addition if all members of the household participate in all parts of the study, I understand that there will be an additional $100.00 given to the parent of record or the parent who originated the contact. I understand that each time I return for the study (every 2 years for a total of 3 or 4 visits, I will be paid these same amounts. Over a 5 – 7 year period, I could potentially receive $375 - $400 dollars depending on the total number of visits and if all the household members participate.

COMPENSATION FOR INJURY: If I am injured as a result of this research, treatment will be available. Compensation for my injuries will not be provided voluntarily by the investigator, sponsor, West Virginia University, or other associated affiliates.

CONFIDENTIALITY: I understand that any information obtained as a result of my participation in this research will be kept as confidential as legally possible. I understand that all records and information pertaining to my identity and my involvement in this research study will be stored for five years after the study is completed in locked file cabinets at the School of Dentistry of West Virginia University. Secure computer databases containing only non-identifying information will be available to investigators at WVU and the University of Pittsburgh. My records will only be accessible to the investigators listed on the first page of this informed consent document. I understand that my identity on all of the research information (for example, blood and saliva samples, questionnaire responses, dental results) will be coded before the data is sent to the University of Pittsburgh for analysis. My name, or any other information from which I might be identified, will not be published without my separate, written consent. If I

agreed on page 3, above, to allow Dr. Marazita to retain my genetic samples for additional genetic studies of oral health, then my biological samples and DNA will be saved for future testing. If I did not agree, my biological samples and DNA will be discarded at the end of this research study.

I understand that the information learned about me during this study will not be released to anyone (for example, relatives, personal physicians, insurance companies, or any other third party) without my prior written permission. However, in the unlikely event that an interviewer identifies someone who is considered to be at immediate risk for harming him or herself or others, appropriate action will be taken. I also understand that if any information about child abuse, neglect, or mistreatment is uncovered, then the law requires that it be reported. I understand that these research records, just like hospital records, may be subpoenaed by court order or may be inspected by federal regulatory authorities. West Virginia University and the University of Pittsburgh Research Conduct and Compliance Offices may review my research records.

ALTERNATIVE: I do not have to take part in this research study. My current and future care and any other benefits will be the same whether I participate in this research study or not.

RIGHT TO WITHDRAW: I understand that my participation in this research study is completely voluntary. I do not have to take part in this research study and, should I change my mind, I can withdraw from the study at any time. I also understand that I may be removed from the research study by the investigators if it is determined that the information I have provided is incorrect. If I withdraw or am removed from participation in this research study, my biological samples, blood sample, and DNA will be destroyed.

My blood sample and its DNA used in this research study may contribute to a new invention or discovery. In some instances, these inventions or discoveries may be of commercial value and may be sold, patented, or licensed by the investigators and the University of Pittsburgh for use in other research or the development of new products related to oral health. If the research investigators are able to develop new products from the use of my biological sample or genetic material, they currently have no plans to share any money or other rewards with me. I retain the right to have my blood sample and its DNA destroyed if I decide to withdraw from this research study.

VOLUNTARY CONSENT: Participation in this study is voluntary. I have been given the opportunity to ask questions about the research, and I have received answers concerning areas I did not understand. I may withdraw from this study at any time. Refusal to participate or withdrawal will involve no penalty or loss of benefits for me. I understand that I may be contacted in the future to be invited to participate in additional research, but that future involvement is voluntary as well.

I give my permission to be re-contacted to obtain my consent if other researchers desire to use my biological sample or genetic material, with personal identifiers, in other

research projects involving the study of different diseases or conditions.

YES _____ NO _____

Signature _____Date_____

For more information about this research, I may contact any of the individuals listed on the first page of this document. For information regarding my rights as a research participant, I may contact the Executive Secretary of the West Virginia Institutional Review Board at (304) 293-7073 or the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh at (412) 578-8570. A copy of this consent form will be given to me.

By signing this form, I agree to participate in this research study.

_____	_____	_____
Participant's Signature	Date	Time
_____	_____	_____
Witness' Signature	Date	Time

INVESTIGATOR'S CERTIFICATION

I certify that the nature and purpose, the potential benefits, and possible risks associated with participation in this research study have been explained to the above individual and that any questions about this information have been answered.

_____	_____	_____
Signature of Investigator or Investigator's Representative	Date	Time