STUDY PROTOCOL

Anthropometric Survey of Respirator Users

by

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1. Project Overview

1.1 Title

The title for this study is AAnthropometric Survey of Respirator Users.@

1.2 Protocol Summary

The two-fold objective of this study is to: 1) develop an anthropometric database detailing the face-size distributions of respirator users using both traditional measurement methods and three-dimensional (3-D) scanning systems; and 2) use the database to establish fit-test panels to be incorporated into the National Institute for Occupational Safety and Health=s (NIOSH) respirator certification program.

The subjects will be recruited from various industries in which workers rely on respirators to prevent work-related respiratory illnesses, injuries, and death (e.g., manufacturing, construction, mining, and health care). The project will also address the respiratory protection concerns of first responders of chemical and biological terrorism and other crisis situations. Thus, subjects will also include law enforcement officers, firefighters, and health care workers. Height and weight plus 18 facial dimensions will be measured with traditional methods. Each subject=s gender, race, and age will be recorded. A total of 4,000 subjects will be measured using traditional methods, and 1,000 of them will be scanned using a 3-D head scanner (Cyberware Model 3030/RGB).

Three-dimensional anthropometry has only been available recently, and there is no track record of applying scan data to respirators. This study will provide preliminary data on which to develop methods for sizing and designing respirators and protective eyewear using 3-D scan data. The source population for this study will be the nationwide worker population. A specific sub-segment of the population is being targeted for this study.

1.3 Investigators/Collaborator/Funding

Ziqing Zhuang, Ph.D., NPPTL/NIOSH
Bruce Bradtmiller, Ph.D., Anthrotech
Hongwei Hsiao, Ph.D., PTB/DSR/NIOSH
John Odencrantz, Ph.D., FSB/DRDS/NIOSH
Christopher C. Coffey, Ph.D., LRB/DRDS/NIOSH
Donald L. Campbell, Ph.D., LRB/DRDS/NIOSH
Paul A. Jensen, Ph.D., LRB/DRDS/NIOSH

Ziqing Zhuang, Ph.D. B Dr. Zhuang is the project officer for this study and is responsible for developing this protocol, managing data collection, and reporting study results. His major areas of expertise are occupational health and safety engineering and industrial engineering. He has been performing respirator research for the past 12 years. Dr. Zhuang has conducted a series of workplace protection factor studies at foundry, paint-spraying, and steel-manufacturing operations.

He conducted qualitative and quantitative fit tests of various half- and full-facepieces. He also participated in various studies to compare fit factors of six quantitative fit test methods with exposure dose of Freon-113, to measure laboratory performance of N95 respirators, and to determine the adequacy of Bitrex and N95 Companion fit test methods.

Bruce Bradtmiller, Ph.D. B Dr. Bradtmiller is the president of Anthrotech. He is widely recognized in the area of applied anthropometry and has successfully bridged the gap between data collection and the application of data to design problems. He managed the 1988 ANSUR survey that led to the creation of anthropometric techniques and methodology that have become standards in the field. Dr. Bradtmiller designed and directed several specialized anthropometric surveys, including the measuring and scanning of school children=s heads, a survey of school bus drivers, and a survey of luxury car buyers. Through experience with various military and commercial programs, he has developed the techniques to translate anthropometric variability into garment patterns and grading systems. In addition, he has fit tested a variety of products and understands the relationship of anthropometry to personal products. He works well with designers and pattern-makers to make sure that all the required body sizes can be accommodated in the product.

Hongwei Hsiao, Ph.D. B Dr. Hsiao is the Chief of the Protective Technology Branch of DSR, NIOSH. He received a B.S.E. degree from National Cheng Kung University (1977), an M.A. degree from Cornell University, and M.S.E & Ph.D. degrees from the University of Michigan. He joined NIOSH in 1991 to establish the Human Factors and Safety Engineering Program. His major research interests include the development of instrumentation for hazard exposure assessment, anthropometry and human modeling, occupational fall prevention, and virtual reality simulation for safety research.

John Odencrantz, Ph.D. B Dr. John Odencrantz is a statistician in the Field Studies Branch of DRDS, NIOSH.

Christopher C. Coffey, Ph.D. B Dr. Coffey's major area of education and training is chemistry and industrial hygiene. He has extensive experience in testing of air-purifying respirators including qualitative and quantitative fit-testing. In addition, he has participated in a number of workplace protection factor studies involving both powered air-purifying and negative pressure respirators. He has been involved with the testing and certification of air-purifying respirators for 18 years. He was the project officer of the studies entitled ADetermination Of An Assigned Protection Factor For Negative-Pressure Half-mask High-Efficiency Respirators Using A Simulated Health-Care Workplace Test (HSRB 94-DSR-05)@ and AComparison of Six Quantitative Fit-Test Methods to an Actual Measurement of Exposure Using Negative-pressure Full Facepiece Respirators (HSRB 97-DRDS-02)@.

Donald L. Campbell, Ph.D. B Dr. Campbell is a senior scientist in the Laboratory Research Branch of DRDS, NIOSH.

Paul Jensen, Ph.D. B Dr. Paul Jensen is the Chief of the Laboratory Research Branch of DRDS, NIOSH.

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2. Introduction

2.1 Objectives

The goal of this project is to establish fit-test panels to be incorporated into the NIOSH certification program. The two-fold objective of this study is to: 1) develop an anthropometric database detailing the face-size distributions of respirator users using both traditional measurement methods and three-dimensional (3-D) scanning systems; and 2) use the database to establish fit-test panels that accurately represent today=s workers.

2.2 Literature Review/Current State of Knowledge about Project Topics

Sizing data generated by the military for use in fitting respirators has been the normative basis for commercial respirator sizing. Anthropometric data developed for males of military age in the 1950's and 1960's is still in use today and forms the only comprehensive body of information available on this subject.

While there have been many comprehensive anthropometric surveys of military populations over the years, surveys of civilians have been rare. Military personnel have to meet strict entry and fitness criteria and also tend to be younger than the general civilian workforce.

In the United States, the last comprehensive survey of civilian adults was a survey of women by the Department of Agriculture in 1939 (O=Brien and Shelton 1941). The measurements in that survey were for clothing applications, but did not include facial measurements. Also, a handful of measurements were taken in the Health and Nutritional Examination Studies done by the National Center for Health Statistics (Anonymous, 1994). With the exception of the 1960-1962 study (Stoudt et al. 1965) these have focused on providing health related data and not design data. Indeed, even the Stoudt et al. study had only a handful of measures and these focused on workstation or vehicle type applications, rather than measures that would be useful in respirator design.

Military populations cannot represent the worker population because of relatively strict anthropometric armed forces entry requirements and height/weight guidelines for troop retention. Personal protective equipment designed and sized for a military population may not provide the same level of protection to civilian workers because of the greater diversity in body size and shape seen in civilian populations.

The respirator fit-test panels currently used are 25-subject panels, developed by Los Alamos National Laboratory (LANL). The half-mask panel is based on face length and lip length and the

full-facepiece panel is based on face length and face width. These panels were established to represent the working population. The fit of respirators on these subject panels is assumed to be representative of the fit of the respirator user populations. Respirators designed to fit these panels are also expected to accommodate at least 95% of the wearers. The LANL panels are based on data from the 1967-1968 survey of U.S. Air Force men and women. Military data may not represent the greater diversity in face size and shape seen in civilian populations. In addition, the demographics of the U.S. population have changed over the last 30 years. Thus, it is necessary to assess and refine the LANL fit-test panels.

A recent study attempted to revise the current respirator fit-test panels (Zhuang *et al.*, 2001a). Data from the 1987-1988 anthropometric survey of U.S. Army men and women were obtained for that study. As a partner in the project titled ACivilian American and European Surface Anthropometry Resource (CAESAR),@ NIOSH received the manual measurements of 2391 civilian subjects (only two facial dimensions, *i.e.*, face length and face width, were measured). The CAESAR data were used to determine if the military data were appropriate for civilian workers. Two fit-test panels were developed using the LANL approach based on the Army data: a panel with cells based on face length and face width (for full-facepiece respirators), and a panel with cells based on face length and lip length (for half-mask respirators). Respirators designed to fit these panels based on military data are usually assumed to accommodate more than 95% of U.S. workers. However, the LANL and revised panels for full-facepiece respirators were shown to accommodate only 84% and 83% of the CAESAR subjects, respectively.

2.3 Study Design

The study design has two main parts: traditional anthropometry and 3-D scanning. The following sections will describe them in detail. There are several reasons for collecting traditional data. First, some traditional types cannot be captured in a surface scan such as weight (mass), and skinfold thickness. Second, some commonly used measures, while similar to measures extracted from scans, would not be exactly the same. Circumferences and other measurements taken with a tape measure fall into this category. Tape measures span the nooks and crannies of the body, but the scanner measurements do not. Also, when scanning there are often surfaces that are obscured from view when a person is standing or sitting in a normal position, such as the areas behind the ear, or under the nose on some individuals.

2.3.1 Briefing/Consent/Questionnaire

An information sheet will be posted and/or provided to potential subjects (Appendix A). Potential subjects will be briefed on all the procedures to be used in the study. After briefing, there will be an opportunity for questions. When all questions have been answered, the subject will be asked to sign the informed consent document (Appendix B). At this time also, the subject will fill out a brief questionnaire (Appendix C) containing certain demographic information needed to assess achievement of our sampling goals.

2.3.2 Traditional Anthropometry

This portion of the study involves taking measurements on the test subjects using traditional

measuring devices. These devices are: anthropometer, beam caliper (rearranged pieces of the anthropometer), tape measure and scale. The anthropometer is manufactured by GPM in Switzerland, the tape by Lufkin in the United States and the scale by Health-O-Meter in the U.S. Each of these instruments has a long history of clinical and research use and has been proven to be very safe.

Each subject will be measured in his or her normal work clothes. We will identify the following landmarks on the subject: alare (right and left), cheilion (right and left), chin, ectocanthus, frontotemporale (right and left), glabella, gonion (right and left), infraorbitale (right and left), menton, pronasale, sellion, subnasale, top of head, tragion (right and left), and zygofrontale (right and left). We will mark these landmarks using adhesive dots and placing them on the skin. The landmarks and their descriptions are listed in Appendix D.

After landmarking, 20 anthropometric dimensions will be measured using traditional methods and entered into a laptop computer running the data entry and editing software. This proprietary software checks entered values for reasonableness, allowing measurements to be repeated if an error is suspected. This portion of data collection (including completing the questionnaire and landmarking) is expected to take approximately 15 minutes per subject. A complete listing of these measurements accompanied by descriptions is provided in Appendix D.

2.3.3 3-D Scanning

Following the traditional measurements, some subjects will be scanned using a Cyberware head scanner. This is a red light laser scanner whose lasers are about the same intensity as a supermarket checkout scanner. Eye safety regulations for laser based equipment are administered by the Food & Drug Administration (FDA) and are published in 21 CFR Parts 1000 and 1040, Laser Products. Cyberware's Head & Face Color 3D Scanner is registered with the FDA as a Class I device (no known hazards). The equipment is considered so safe that no warning label is required. The system is comparable to a supermarket price or library book scanner. The low level of light used allows the subject being scanned to leave their eyes open and will not even create an after image as one gets from a typical photo flash. This model scanner has been safely used on several studies of approximately 2,000 U.S. Marines, and has been used in the CAESAR survey, where the total sample was approximately 4,000 individuals. No incidents involving problems with the eyes were reported during or after these surveys. About 1,000 test participants will be scanned from selected survey locations. This portion of data collection is expected to take approximately 5 minutes per subject.

2.4 Locale

The study will be conducted at five locations nationwide. Although test sites have yet to be determined, we anticipate collecting data at two facilities in the western U.S., one in the central portion of the country, and at two locations in the east.

2.5 Expected Number of Subjects

The number of subjects used in this study will be about 4,000. The first subject group will be recruited from individuals who are required to do annual respirator fit tests and training conducted by consulting companies. Three consulting companies are willing to help recruit subjects for this survey. They are Vallen Occupational Health Services (VOHS) in Houston, Texas, Occupational Pulmonary Services (OPS) in Cincinnati, OH, and BRC in Santee, CA. VOHS normally conducts fit-tests for about 250,000 workers per year in various industries (such as manufacturing, construction, health care, and law enforcement) and at different locations (Texas, California, Alabama, Illinois, and Louisiana). If 4,000 subjects cannot be recruited from this population, a second group of subjects will be recruited from workers whose fit test and training are administered by company safety and health professionals. If the sampling goal is still not met, then the remainder of the subjects will be recruited from the workers in industries where a respiratory protection program exists. All subjects will be provided with the announcement in Appendix A to make their decision about participation.

2.6 Justification for Study

Respiratory protection is one vital part of NIOSH=s mission to prevent work-related respiratory illnesses, injuries, and death. The NIOSH respirator certification program is responsible for ensuring that the more than six million workers, who rely on respirators for protection, have safe and effective devices. A recent simulated workplace performance test of N95 respirators by NIOSH found that the 5^{th} percentile of simulated workplace protection factors (reciprocal of total penetration through face seal and the filtering facepiece) for each of 21 respirator models ranged from 1.1 to 17 and it was 3 for all 21 respirators combined (Coffey *et al.*, 1999). The 5^{th} percentile is a value that is exceeded by 95% of the simulated workplace protection factors. The NIOSH assigned protection factor (APF) for this class of respirators is 10. In that study, only 4 of the 21 models tested provided a level of performance commensurate with their class APF. In another recent laboratory performance study of hooded/helmeted, powered, air-purifying respirators and supplied air respirators by the Organization Resources Counselors, Inc. (ORC, the trade group representing Fortune 500 companies), one model performed below even the level expected based on the conservative NIOSH APF of 25 (Cohen *et al.*, 1999). Respirators that provide less than expected levels of protection compromise worker safety. Thus, it is necessary for the NIOSH certification to assess performance characteristics of respirators.

To introduce performance tests as a condition of certification for all respirator classes, such tests must be validated in laboratory settings and/or actual workplace conditions. Recent NIOSH research has compared six respirator fit-test methods with a biological measurement of exposure using Freon-113 while subjects were wearing negative-pressure, air-purifying, half-facepiece respirators (APF=10) (Coffey *et al.*, 1998a and 1998b). Fit factors of the corn oil and ambient aerosol fit-test methods were found to be correlated with the wearers= measured exposure doses. Another recent NIOSH study has demonstrated that protection factors measured under actual workplace environment is significantly correlated with quantitative fit factors (Zhuang *et al.*, 2001b). These research findings support incorporating performance tests into the NIOSH

certification program. Currently, NIOSH is advancing its capability to test and validate the level of protection provided by respirators as an inherent part of the respirator certification process.

Performance tests should require each respirator to be worn on a panel of people and the fit factors are used to calculate a 5^{th} percentile to decide if the respirator passes or fails the certification test. A respirator will pass the performance test if the 5^{th} percentile is equal to or greater than the respirator=s class APF value. The fit of this subject panel is assumed to be representative of the fit of the respirator user populations. Respirators designed to fit this panel are also expected to accommodate at least 95% of current U.S. workers. The only panel currently available is a 25-subject panel developed by Los Alamos National Laboratory (LANL) in the early 1970's (Hack *at al*., 1973; Hack and McConville, 1978). The LANL panel is based on data from a 1967-1968 survey of young Air Force men and women. A recent study found that fit-test panels developed from military data, expected to accommodate more than 95% of the civilian population, only accommodate 84% of civilian population (Zhuang *et al.*, 2001a). Face length and lip length, which were used to define the LANL half-mask fit-test panel, have not been found to be consistently associated with respirator fit; and other facial dimensions such as inter-pupillary distance, nose breath, and nose protrusion have been found to correlate with respirator fit (Oestenstad *at al*., 1990a; Oestenstad *at al*., 1990b; Oestenstad and Perkins, 1992; and Brazile *et al*., 1998). New approaches such as employing more than two facial dimensions may be more appropriate to develop fit-test panels. Thus, it is necessary to assess and refine the current LANL fit-test panel so that NIOSH=s assessment of performance characteristics can be as accurate as possible.

To establish fit-test panels representative of today=s workers, it is necessary for the National Personal Protective Technology Laboratory (NPPTL) of NIOSH to establish a database containing anthropometric measures that are representative of nationwide populations who rely on respirators to prevent work-related respiratory illnesses, injuries, and death. The measures will be obtained through the use of traditional measurement techniques and a state-of-the-art 3-D laser scanning system. The data will be used to establish respirator fit-test panels representative of today=s workers. The data can also be used for design and sizing of respirators and other personal protective devices such as eyewear.

The reason the state-of-the-art 3-D laser scanning system is to be used in this project is that today=s automated surface anthropometry has many advantages over the traditional technologies. It provides detail about the surface shape as well as 3-D locations of measures relative to each other. The scan result is independent of the measurer, which makes it easier to standardize. The 3-D anthropometry may best capture the variability in human faces and may have better association with respirator fit than the traditional dimensions. Additionally, it enables easy transfer to Computer Aided Design (CAD) or Manufacturing (CAM) tools and the scan data can be used to develop 3-D human face forms.

The new facial dimension data and state-of-the-art 3-D scanner can be used for evaluating face shape characteristics and designing respirators with improved face-fitting characteristics. The effectiveness of respirators as a safety product for workers would be enhanced by an

anthropometric approach to fit and sizing. It is well known that workers are less likely to wear personal protection systems of any kind if the systems are uncomfortable or do not fit well.

This project is responsive to an identified research priority area in the National Occupational Research Agenda (NORA) B Control Technology and Personal Protective Equipment. If certification tests that realistically predict workplace performance can be developed, and such tests are incorporated into the NIOSH certification program, respiratory protection available to U.S. workers can be greatly improved. Thus, the health and safety of the working men and women will also be improved. The development of fit-test panels is one step in the process of developing such performance tests.

Information generated by this research project will also benefit: (1) the participants by providing a better understanding of respirator size they are supposed to wear; (2) workers exposed to various gases and aerosols by providing fit-test panels that accurately represent today=s workers; and (3) those involved in testing, certifying, and manufacturing respirators to be used in industry by providing them with fit-test panels for evaluating air-purifying respirator facepiece fit characteristics. The long-term potential benefits are improved air-purifying respirator quality and performance and increased worker protection.

2.7 Intended/Potential Use of Study Findings

Results from this study will provide information regarding the facial dimensions of civilian respirator users and 3-D scan data for design and sizing applications. This study will lay the groundwork for many other studies. These parameters are critical to the design and sizing of respirators. Since the 3-D parameters that will be measured in this study have never been measured before, we will also study the population variation of these 3-D parameters.

There are many benefits to obtaining this type of 3-D data. This database can be viewed as a normative database characterizing the variability of people for the cost effective design of just about anything people wear or operate.

The National Institute for Occupational Safety and Health has initiated a project titled ADevelopment of Computer-Aided Face-Fit Evaluation Methods.@ The goal of this project is to establish fit test panels and face-fit evaluation methods to be incorporated into the NIOSH certification program. These data can be used to determine if mask design and face fit can be improved by using three-dimensional (3-D) data. A computer model (database based) for evaluating the fit of a respirator model on respirator-wearer populations can also be developed.

Incorporation of performance tests into the NIOSH respirator certification program will require every certified respirator to demonstrate a level of protection consistent with its class APF value. Respirators with poor face-fitting characteristics will be kept out of the U.S. market. This will result in better performance of NIOSH certified respirators in the workplace, and thus the health and safety of working men and women will be improved.

3. Methods

3.1 Design

3.1.1 How Study Design or Surveillance System Addresses Hypotheses and Meets Objectives

The primary purpose of the study is to build an anthropometric database that can be representative of the nation=s workers who wear, or have the potential to wear, respirators. The most critical demographic parameters that affect head and face size and shape are gender, race and age. Our sampling strategy takes into account all three of these demographic variables, so that variability will be represented in the resulting database. There will be two types of data collected - traditional anthropometry and 3-D scanning. Traditional anthropometric data has known relationships with respirator fit and protection. We believe the 3-D scan data will provide a better description of human facial shape that will be more effective at predicting respirator fit and protection levels.

The first step in our analysis is to compute univariate summary statistics. We will compute these for the traditional dimensions, as well as from any dimensions that are extracted from the scan data. The univariate statistics prepared for the final report will be weighted so the sample accurately reflects the U.S. population of respirator wearers. Since the main goal of this research is to build a database that can be used for the development of test panels in the future, further statistical work is not proposed as a part of this project.

3.2 Study Population

Subjects for this study will be recruited using the announcement contained in Appendix A. No one will be excluded form this study because of race, gender, or odd facial characteristics, however, individual subjects may be excluded if they fall into a race/gender/age sampling cell that has already been filled. Prior to inclusion in this study, all participants will have signed the informed consent documents (Appendix B). An estimate of the race and age distribution of the U.S. population aged 18-65 for the year 2000 will be also obtained from the Census Bureau. The distribution will be used for weighting the subjects from this survey when developing fit-test panels.

The populations will be sampled by age, race and gender. A stratified sampling plan is being used with equal sample size in each cell. The sample size per cell was determined using the procedures outlined in ISO 15535 - *General Requirements for Establishing an Anthropometric Database,* 2001. This international standard estimates the sample needed based on the variability in the dimension of interest (*CV*), the level of precision desired (*a*), and the level of confidence desired in the resulting database [$n = (1.96 \times CV/a)^2 \times 1.534$]. In this case, we based the calculations on the dimension menton-sellion length. It is one of the important bony dimensions for respirator design, and is one of the most variable. Thus it presents a worst-case sample size. If we meet the target for menton-sellion length, then the other dimensions will be sampled adequately also. The best

estimator for facial dimensions in the U.S. currently is the Army=s 1988 anthropometric survey (Gordon *et al.*, 1989). Using the ISO formula, the specific parameters we used in the calculation were: 95% confidence and 1.2 mm (1% of the mean, *a*) as precision. Based on the Army report (Gordon *et al.*, 1989), the mean and standard deviation for menton-sellion length were 121.9 mm and 6.5 mm and the coefficient of variation (*CV*) was 5.3%.

Data from the present project will be used for both testing and design of respirators. As a result, it is important that we not only know the mean value with some certainty. We also need to have good confidence that the tails of the distribution are estimated with 95% confidence, and the same 1.2 mm precision. Therefore, we used version of the ISO formula (with the constant of 1.534) specifically for estimating with confidence at the tails of the distribution. This means that the sample size will be sufficient to calculate the 5^{th} and 95^{th} percentiles with 95% confidence, within plus or minus 1.2 mm. The calculated sample size using these parameters is 166 [$(1.96 \times CV/a)^2 \times 1.534 = (1.96 \times 5.3/1)^2 \times 1.534 = 166$].

The population will be sampled by age, race and gender. A stratified sampling plan is being used with equal sample size in each cell, and each cell will be statistically independent, with a sample of 166 (Table 1). The strata consist of:

3 Age Strata: groups 18-29, 30-44, 45-65 years
2 Gender Strata: male and female
4 Ethnic Group Strata: White, Black, Hispanic, and Others
Total 3*2*4 = 24. Total sample size is 3,984.

The age division points are somewhat arbitrary, but will serve to ensure that we have subjects of a broad age span. We will check on age of consent in the states where recruiting will take place. The matrix will be filled by sampling at five geographic locations, but these are not specific sampling strata. This will satisfy those who may be concerned that a nation-wide survey is conducted. However, geographic sites are not specific sampling strata because there is no a priori or theoretical reason to show that face size or shape varies by geographic area within the U.S. once race, age, and gender are accounted for. Thus, the race by age by gender cells will be statistically sufficient, in terms of sample size, but they should not be broken down by geographic group in data analysis.

Table 1. Minimum Numbers of Subjects

	Male				Female			
Age Group	18 - 29	30-44	45-65	Sum	18-29	30-44	45-65	Sum
White	166	166	166	498	166	166	166	498
Black	166	166	166	498	166	166	166	498

Hispanic	166	166	166	498	166	166	166	498
Others	166	166	166	498	166	166	166	498
Sum	664	664	664	**1992**	664	664	664	**1992**

3.2.1 Description and Source of Study Population and Catchment Area

We will sample the target population in five locations nationwide based on gender, race, and age criteria. We will sample workers from a variety of occupations that require respirator use on the job.

3.2.2 Participant Inclusion Criteria

We will accept any applicant meeting our sampling criteria. They met the criteria specified in Title 29, Code of Federal Regulations, 1910.134 for respirator wearers, such as exclusion of beards, sideburns, etc.

3.2.3 Participant Exclusion Criteria

We will exclude only those individuals who do not meet our sampling criteria.

3.2.4 Justification of Exclusion of Any Sub-segment of the Population

Since we are using a stratified sample, workers will be present in the population in different proportions than they are needed in our database. It will therefore be necessary to exclude some workers who are in the cells with the highest frequency in the target population, since those sampling cells will be filled early in data collection. However, no sub-segment of the population will be excluded - only the individuals in those sub-segments that exceed the sampling goals.

3.2.5 Sampling, Including Sample Size and Statistical Power

The matrix in Table 1 will be filled by sampling at five different locations. This results in a total sample size of 3,984, in which each of the sampling cells is statistically independent. Since this is a large scale study, it is very difficult to collect data for exactly 3,984 subjects. Thus, the term Athe number of subjects is about 4,000" is also used in this protocol.

The purpose of this study is simply to build a database of anthropometry for people who wear respirators; there are no specific hypotheses in mind. The observations will be weighted at the end of the study to represent the U.S. respirator-user population. It can also be re-weighted, as necessary to reflect the demographics of a particular worker group, such as those working in

manufacturing. Because the database will be weighted, according to the Central Limit Theorem, the sample mean and variance for any variable should approach the true population mean and variance.

Although automated surface anthropometry (3-D scan data) has many advantages over the traditional measurement methods, the applications of the 3-D data are still in early exploratory stages. The most promising use of the 3-D data is to develop 3-D human face forms. The traditional measurements will be first analyzed using principal component analysis approach and typical and extreme cases will be defined. Actual individual scans that are similar to these cases will then be located from the 3-D database.

Generally, a panel of fifty face forms may be adequate to characterize the face size and shape. However, those fifty forms must be selected to be representative of the cases identified above. If the traditional measurements from all 4000 subjects were available for analysis prior to the scanning study, then we would be able to select only the appropriate 50 individuals to scan. But since those 50 individuals will likely be spread across the country, that is not a practical or cost-effective solution. Instead we will scan a larger number at the same time the traditional data collection is taking place. When the analysis of the traditional data is complete, we will then have enough scans to make sure that all the extreme forms can be represented in the 3-D database.

As a practical matter, the pace of subjects through the data collection process is set by the manual measurer. The manual measurement takes about 15 minutes and the scanning operation takes about 5 minutes. If we are scanning only selected subjects, the scanner operator is simply standing idle while the manual measurer continues to work. So there is no labor savings in reducing the number of people scanned. Thus, scanning operation will be setup at two of the five sites and about 500 subjects will be measured at these two locations. At present, there are no statistical approaches that allow us to estimate a required sample for 3-D shape analysis. But our experience in facial variability suggests that this number should be enough to contain the shape variability in the population. About 1,000 subjects will be measured at each of the other three locations.

3.2.6 Enrollment

Potential participants in the study will be recruited at their workplace, via posters and the internal communication system (e.g., bulletin boards) of the various host locations. The text of the announcement is in Appendix A.

The specific enrollment method will depend on the type of workplace. At the sites where the consulting companies can help recruit subjects, the consulting companies will pass the recruitment announcement to potential subjects. The consulting companies usually conduct fit-tests throughout the day and we hope most of these workers will be willing to participate in this study and be measured right after their fit-tests. At some establishments, we will post the announcement with a phone number which people can call to enroll in this study in advance of our arrival, and potential subjects will be scheduled for a specific time on a specific day. At other locations, we will operate on a first-come/first-served basis. In any case, if a potential participant does not

satisfy the needs of our sample, he/she will not be scheduled for the study. If a participant chooses to withdraw from the study, the data collected on that person will not be used, and it will be documented in the final report for the protocol.

3.3 Selection of Survey Dimensions

The traditional measurement methods and anthropometric parameters critical to the good fit and performance of respirators were selected based on the published literature and in-house laboratory investigations. The measurements themselves are listed and described in Appendix D.

3.4 Apparatus

3.4.1 Study Instruments, Including Questionnaires, Laboratory Instruments, and Analytical Tests

Data Collection Forms
The data collection will consist of 2 forms, which are found in Appendices C and D.

Anthropometric Instruments
The traditional anthropometric instruments consist of the anthropometer and beam caliper, as well as a steel tape measure. The anthropometer and beam caliper are manufactured by GPM in Switzerland. The tape measure is manufactured by Lufkin in the United States.

3-D Head Scanner
The 3-D head scanner, Model 3030/RGB, is manufactured by Cyberware, Inc., of Monterey CA.

INTEGRATE is a Unix-based 3-D data visualization, analysis, and manipulation tool developed by the Air Force specifically for 3-D anthropometry (Burnsides et al, 1996).

CYSCAN/ARN version is an automated anthropometric data extraction tool developed by the Apparel Research Network (ARN) for the purpose of quickly determining sizes for Marine recruits based on 3-D surface data.

VPSculpt is a PC-based commercial software package developed by researchers at the University of Colorado for editing and measuring high resolution surface data.

3.4.2 Training for All Study Personnel

We will practice the traditional measurements as well as the scanning procedures. Traditional measurements will be practiced with paid models until pre-established observer error limits are reached. This will help assure the quality of the final data set.

3.5 Data Collection Procedures

3.5.1 Data Analysis Plan, Including Statistical Methodology and Planned Tables and Figures

Traditional Anthropometry Data Collection
- Dependent variables will be stored in a spreadsheet format.
- Dependent variables will be graphed using Excel.
- Statistical analysis will be done using SPSS.

Scan Data Collection
- Visual data will be stored as .ply files.
- Extracted data will be stored in a spreadsheet format.
- Data will be graphed using Excel.
- Statistical analysis will be done using SPSS.

The following tables will be generated using the data collected.-
- Traditional anthropometry summary statistics, using demographically weighted data
-
- Traditional anthropometry summary statistics, by age group, racial group and by sex
S Traditional anthropometry summary statistics, by geographic area, and by occupation to confirm that geographic area is not a main factor affecting face size.

3.5.2 Data Collection

The data will be collected using the data collection forms found in Appendices C and D, as described above.

3.5.3 Information Management and Analysis Software

The software packages that will be used in managing and analyzing data for this project are shown below.

INTEGRATE B used to visualize, analyze, and manipulate 3-D scans (Burnsides et al, 1996).
CYSCAN/ARN version B used to extract anthropometric data.
VPSculpt B used for editing and measuring high-resolution surface data.
Proprietary software B used for editing traditional anthropometric data.
Microsoft Excel - used to graph and analyze data.
SPSS - used to perform the statistical analysis on data.

3.5.4 Data Entry, Editing and Management, Including Handling of Data Collection Forms, Different Versions of Data, and Data Storage and Disposition

Data will be entered on a laptop computer at the time of data collection. For the anthropometric data, we use Anthrotech-developed data entry and editing software, which identifies potential measurement or recording errors. These potential errors are signaled to the measurer, and the measurement is redone. If the measurement is confirmed by a second measure, then the software allows the recording of data.

Data will also be edited after data collection is complete using a combination of regression and outlier identification techniques.

Demographic data are edited after entry by examining frequency distributions and identifying unusual values. These values will be changed to missing if they cannot be verified.

3D data are not manually entered, but will be extracted directly from the image file.

After data collection is complete and the data are edited, they will be stored on the hard drive of two Anthrotech computers, and one NIOSH computer. All computers are backed up daily.

3.5.5 Quality Control/Assurance

In order to insure the quality of the data, the steps of the testing procedure have been laid out very carefully. We will have a two-day practice and training session before data collection actually begins.

3.5.6 Handling Results in the Absence of a Reference Test

This is a baseline study which will give us the reference we need for future work.

3.5.7 Bias in Data Collection, Measurement and Analysis

We are not aware of any potential for bias in the anthropometric data collection or in the analysis of any of the data.

3.6 Study Time Line

The study time line is in Appendix E.

It is estimated that four months will be needed to develop the study protocol and complete human subject review board review, six months to complete OMB approval, three months to conduct data collection, and six months (including review periods) to perform data analyses and to complete a technical report for the study. Note that some of these phases overlap; see Appendix E.

3.7 Safety Precautions/Emergency Procedures

The study will be carried out in environments where the subjects perform their routine day-to-day work. The subjects are respirator users and should have gone through a medical screening before being allowed to wear a respirator in accordance with Occupational Safety and Health Administration (OSHA) standards on respiratory protection (29 CFR 1910.134). They will be required only to stand or sit quietly in a chair. Thus, the subjects do not have to undergo medical screening before being allowed to participate in this study.

All members of the research team will be instructed to follow the safety rules at the facility. Instructions will be provided by the on site industrial hygienists or safety professionals. The on site industrial hygienists will also guide the research team on a tour of the facility to help them get familiar with the facility layout. When the research team members enter workshops, they will be required to wear appropriate personal protection equipment such as respirators, goggles, hard hats, steel-toe shoes, etc. as required for the workers at the facility.

Injury due to study is unlikely, however in the event of a medical emergency the participant will follow the safety procedures already in place in the facility. We will insure that research staff have the local emergency number and immediate access to a phone to call the local emergency number. Research staff will also know how to notify plant personnel of any injury and direct medical personnel to the proper location. At least one member of each data collection team will have CPR training in order to provide immediate subject treatment and care until help arrives if necessary.

4. Informed Consent Procedures

Written informed consent will be obtained from volunteers prior to inclusion in this research project (Appendix B). The subjects will be given adequate time to read the document and ask questions before signing it. Subjects will be given a copy of the signed consent document. Subjects will be informed that they may voluntarily withdraw from the study at any point without prejudice to themselves.

5. Records Management

Confidentiality of human subject data will be assured in the final data set. During data collection, the participant=s name is recorded on the data sheet, as well as in the scan file name. A subject number is also used on the data sheet, and in the scan file name. Since numeric entry errors of subject number could mis-match one person=s measured data with another person=s 3-D scan, the participant=s name is the best cross-check to assure this central element of data validity. After data collection is complete, and the names have been used to verify all subject numbers against the file name of each image file, then names will be removed. The data field containing participant names will be eliminated from the Excel files, and the names will be eliminated from the 3-D scan file names. At that point, it will no longer be possible to identify any individual in the data set. The original subject data sheets will then be transferred from the contractor to NIOSH and kept in a locked file cabinet at NIOSH. Confidentiality is also enhanced through controlled access to the NIOSH facility and to the office/laboratory where the files will be stored. These same steps will also be taken at Anthrotech to protect confidentiality.

6. Confidentiality Provisions

The identity of the subjects and their specific information derived from their participation in this study will be kept confidential and will not be disclosed to others without written consent except as required by law. This information will be used for statistical and research purposes in such a

manner that no one can be personally identified.

7. Notification of Results

The individual results will be available to the subjects if they request them. The individual results are available to them right after measurements are taken. The results will be confidential, as provided under the privacy act. The study findings will be provided to each participant in summary form if they desire. We will provide a phone number to the subjects and ask them to call if they want the summary report. The method of disseminating the results of this study to the public will be to submit the results to peer-reviewed journals, as well as presenting oral reports at scientific meetings.

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APPENDIX A. Information Sheet for Potential Subjects

Two Versions:
1st Version for Sites where 3-D scanning will take place
2nd Version for Sites where 3-D scanning will not take place

WANTED
VOLUNTEERS FOR RESPIRATOR PROJECT

HEAD AND FACE SIZE SURVEY OF RESPIRATOR USERS

The National Institute of Occupational Safety and Health (NIOSH) is asking for volunteers to be in a study. The workplace study will gather information to improve the fit and comfort of respirators (Aprotective masks@). Respirators have been in use for many years, but it is important to adjust their design to fit the faces of the different people who use them.

Subjects will be measured for 18 head and face measurements, plus height and weight. The researchers will use a tape measure and calipers. Subjects will also be scanned with a digital head scanner. This uses a beam of light that is like a supermarket checkout scanner. The light does not go inside the body. *It is not like an X-ray or MRI*. The scan produces a picture of the head on a computer screen.

Subjects will be needed for about 20 minutes. Subjects will be compensated $20 for their time.

Anyone who wears a respirator as part of their work might be able to participate in the study. But, there are certain goals for the study, based on sex, age and race. So, you should check with the study scheduler to see if you fall into a category that is needed. Before you participate in this study, NIOSH scientists will explain the study to you and ask if you want to participate in the study.

For more information, call your industrial hygienist or safety officer, FILL IN NAME AND PHONE OF LOCAL CONTACT HERE.

WANTED
VOLUNTEERS FOR RESPIRATOR PROJECT

HEAD AND FACE SIZE SURVEY OF RESPIRATOR USERS

The National Institute of Occupational Safety and Health (NIOSH) is asking for volunteers to be in a study. The workplace study will gather information to improve the fit and comfort of respirators (Aprotective masks@). Respirators have been in use for many years, but it is important to adjust their design to fit the faces of the different people who use them.

Subjects will be measured for 18 head and face measurements, plus height and weight. The researchers will use a tape measure and calipers.

Subjects will be needed for about 15 minutes. Subjects will be compensated $15 for their time.

Anyone who wears a respirator as part of their work might be able to participate in the study. But, there are certain goals for the study, based on sex, age and race. So, you should check with the study scheduler to see if you fall into a category that is needed. Before you participate in this study, NIOSH scientists will explain the study to you and ask if you want to participate in the study.

For more information, call your industrial hygienist or safety officer, FILL IN NAME AND PHONE OF LOCAL CONTACT HERE.

APPENDIX B. Human Subject Consent Form

Two Versions:
1st Version for Sites where 3-D Scanning will take place
2nd Version for Sites where 3-D scanning will not take place

October 12, 2001

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH (NIOSH)
CENTERS FOR DISEASE CONTROL AND PREVENTION
U.S. PUBLIC HEALTH SERVICE
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

You have been asked to participate in a NIOSH research study. We explain here the nature of your participation, describe your rights, and specify how NIOSH will treat your records.

I. DESCRIPTION

- Title: Anthropometric Survey of Respirator Users

- Project Officer: Ziqing Zhuang, Ph.D.

- Purpose and Benefits: The purpose of the present study is to develop information on head and face size and shape to develop fit-test panels for testing respirators, and to make better respirators. These fit-test panels are similar to the nation=s workers, just smaller in number. If the respirators fit the people on the panel, then they should fit almost all people who wear respirators.

  The testing will be done at your normal work location.

  You will not benefit directly from being in the study, but over time the information we discover will help:

  - You, because you will know that you helped make better respirators.

  - You and other workers who are exposed to dangerous materials by making respirators work better and fit better.

  - The companies that make respirators by providing them with information on how to improve the fit and design of respirators.

II. CONDITIONS OF THE STUDY

1. This study has three parts:

(1). You will be asked to fill out a short questionnaire (five questions). It asks your age, race and sex, as well as some about the kind of work you do. This is important because we need to make sure that we get information from all sorts of Americans, so respirators will be able to fit most people. This part takes about 1 minute.

(2). The researcher will feel your head and face for some bony points. These points will be marked with eye-liner pencil, which is easily removed when you are done. After marking, we will measure 18 dimensions using a tape measure and calipers. We will also measure your weight and height. The measurer is specially trained to do this. This part takes about 14 minutes.

(3). The researcher will cover the marked points with small sticky dots. These allow the scanner to find the bony points. These dots are easily removed after scanning. For the 3-dimensional scanning, you will be asked to sit on a chair while the scanner moves around your head. You will need to hold your head still for about 20 seconds for the scan. You will be able to see a picture of yourself on the computer screen when the scan is finished. The scanner uses a low-level laser light, like a supermarket checkout scanner. When the scanning is finished, the dots and the eye-liner marks will be removed, and you will be compensated for your time, with our thanks. This part takes about 5 minutes.

2. The risk of injury is very low since you only need to sit or stand and be measured. Other possible risks include discomfort of having the tape measure and calipers on your face. It is possible that you will have an allergic reaction to the sticky dots. There is a slight risk that the caliper may slip into the eye, but the instrument is not sharp. Also, we measure in a certain way, so the risk of slipping into the eye is very small. If it does slip into the eye, you may feel some discomfort.

If you have any reaction to the tests/procedures, you should contact Ziqing Zhuang, Ph.D., General Engineer, National Personal Protective Technology Laboratory, (304) 285-6167.

3. There are no alternative test procedures.

4. Injury from this project is unlikely. But if you are injured, we do not have medical care available, other than emergency treatment. If you are injured through negligence of a NIOSH employee, you may be able to obtain compensation under Federal Law. If you want to file a claim against the Federal government your

contact point is: Public Health Service Claims Office (301) 443-1904. If you are injured through the negligence of a NIOSH contractor, your claim would be against the contractor, not the federal government. If an injury should occur to you as the result of your participation, you should also contact: Ziqing Zhuang, Ph.D., General Engineer, National Personal Protective Technology Laboratory, (304) 285-6167, or Dr. Michael J. Colligan, Chairperson, NIOSH Human Subjects Review Board, (513) 533-8222.

5. If you have questions about this research contact, Ziqing Zhuang, Ph.D., General Engineer, National Personal Protective Technology Laboratory, (304) 285-6167. If you have any questions about your rights as a member of this study, contact Dr. Michael Colligan, Chair of the NIOSH Human Subjects Review Board at (513) 533-8222.

6. Your participation is voluntary and you may withdraw your consent and your participation in this study at any time without penalty or loss of benefits to which you are otherwise entitled.

   You will receive compensation of $20 for the testing which will take about 20 minutes of your own time.

7. The overall results of the study will be documented in a journal article or a National Personal Protective Technology Laboratory research report. Copies will be provided to you upon publication at your request. Please call Dr. Zhuang, the project officer, at the end of 2002 if you want the summary report.

III. USE OF INFORMATION

The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), an agency of the Department of Health and Human Services, is authorized to collect this information, including your social security number (if applicable), under provisions of the Public Service Act, Section 301 (42 U.S.C. 241); Occupational Safety and Health Act, Section 20 (29 U.S.C. 669); and the Federal Mine Safety and Health Act of 1977, Section 501 (30 U.S.C. 95). The information you supply is voluntary and there is no penalty for not providing it. The data will be used to improve the representativeness of respirator test panels, and to provide face size and shape information for developing new respirators. Data will become part of CDC Privacy Act system 09-20-0159 "Records of Subjects in Certification, Testing, Studies of Personal Protective Devices, and Accident Investigations" and may be disclosed; to appropriate state or local health departments to report certain communicable diseases; to the State Cancer Registry to report cases of cancer where the state has a legal reporting program providing for the information's confidentiality; to private contractors assisting NIOSH; to collaborating researchers under certain limited circumstances to conduct further investigations; to one or more potential sources of vital statistics to make a determination of death; to the Department of Justice in the event of litigation,

and to a congressional office assisting individuals in obtaining their records. An accounting of the disclosures that have been made by NIOSH will be made available to you upon request. Except for these and other permissible disclosures expressly authorized by the Privacy Act, or in limited circumstances when required by the Freedom of Information Act, no other disclosure may be made without your written consent.

IV. SIGNATURES

I have read this consent form and I agree to participate in this study.

PARTICIPANT _____ AGE _____
(signature)
_____ DATE _____
(and Guardian, if required)

I, the NIOSH representative, have accurately described this study to the participant.

REPRESENTATIVE _____ DATE _____
(signature)

1 copy to participant
1 copy to project officer

October 12, 2001

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH (NIOSH)
CENTERS FOR DISEASE CONTROL AND PREVENTION
U.S. PUBLIC HEALTH SERVICE
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

You have been asked to participate in a NIOSH research study. We explain here the nature of your participation, describe your rights, and specify how NIOSH will treat your records.

I. DESCRIPTION

1. Title: Anthropometric Survey of Respirator Users

2. Project Officer: Ziqing Zhuang, Ph.D.

3. Purpose and Benefits: The purpose of the present study is to develop information on head and face size and shape to develop fit-test panels for testing respirators, and to make better respirators. These fit-test panels are similar to the nation=s workers, just smaller in number. If the respirators fit the people on the panel, then they should fit almost all people who wear respirators.

   The testing will be done at your normal work location.

   You will not benefit directly from being in the study, but over time the information we discover will help:

   1. You, because you will know that you helped make better respirators.

   2. You and other workers who are exposed to dangerous materials by making respirators work better and fit better.

   3. The companies that make respirators by providing them with information on how to improve the fit and design of respirators.

II. CONDITIONS OF THE STUDY

1. This study has two parts:

   (1). You will be asked to fill out a short questionnaire (five questions). It asks your age, race and sex, as well as some about the kind of work you do. This is important because we need to make sure that we get information from all sorts of Americans, so respirators will be able to fit most people. This part takes about 1 minute.

   (2). The researcher will feel your head and face for some bony points. These points will be marked with eye-liner pencil, which is easily removed when you are done. After marking, we will measure 18 dimensions using a tape measure and calipers. We will also measure your weight and height. The measurer is specially trained to do this. When the measurement is finished, the eye-liner marks will be removed, and you will be compensated for your time, with our thanks. This part takes about 14 minutes.

2. The risk of injury is very low since you only need to sit or stand and be measured. Other possible risks include discomfort of having the tape measure and calipers on your face. It is possible that you will have an allergic reaction to the sticky dots. There is a slight risk that the caliper may slip into the eye, but the instrument is not sharp. Also, we measure in a certain way, so the risk of slipping into the eye is very small. If it does slip into the eye, you may feel some discomfort.

   If you have any reaction to the tests/procedures, you should contact Ziqing Zhuang, Ph.D., General Engineer, National Personal Protective Technology Laboratory, (304) 285-6167.

3. There are no alternative test procedures.

4. Injury from this project is unlikely. But if you are injured, we do not have medical care available, other than emergency treatment. If you are injured through negligence of a NIOSH employee, you may be able to obtain compensation under Federal Law. If you want to file a claim against the Federal government your contact point is: Public Health Service Claims Office (301) 443-1904. If you are injured through the negligence of a NIOSH contractor, your claim would be against the contractor, not the federal government. If an injury should occur to you as the result of your participation, you should also contact: Ziqing Zhuang, Ph.D., General Engineer, National Personal Protective Technology Laboratory, (304) 285-6167, or Dr. Michael J. Colligan, Chairperson, NIOSH Human Subjects Review Board, (513) 533-8222.

5. If you have questions about this research contact, Ziqing Zhuang, Ph.D., General

Engineer, National Personal Protective Technology Laboratory, (304) 285-6167. If you have any questions about your rights as a member of this study, contact Dr. Michael Colligan, Chair of the NIOSH Human Subjects Review Board at (513) 533-8222.

6. Your participation is voluntary and you may withdraw your consent and your participation in this study at any time without penalty or loss of benefits to which you are otherwise entitled.

   You will receive compensation of $15 for the testing which will take about 15 minutes of your own time.

7. The overall results of the study will be documented in a journal article or a National Personal Protective Technology Laboratory research report. Copies will be provided to you upon publication at your request. Please call Dr. Zhuang, the project officer, at the end of 2002 if you want the summary report.

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IV. SIGNATURES

I have read this consent form and I agree to participate in this study.

PARTICIPANT _____ AGE _____
(signature)
_____ DATE _____
(and Guardian, if required)

I, the NIOSH representative, have accurately described this study to the participant.

REPRESENTATIVE _____ DATE _____
(signature)

1 copy to participant
1 copy to project officer

APPENDIX C. Demographic Data Form

Anthropometric Survey of Respirator Users Data Collection

Date

Subject No. _____

Name

Sex

Age

Race:

1. White (non-Hispanic)
2. Hispanic
3. Black (non-Hispanic)
4. Others

Occupations:

1. Construction
2. Manufacturing
3. Mining
4. Fire Fighting
5. Health Care
6. Law Enforcement
7. Others

Respirator User:

1. Yes
2. No

APPENDIX D. Anthropometric Data Form, Landmark List, and Dimension List

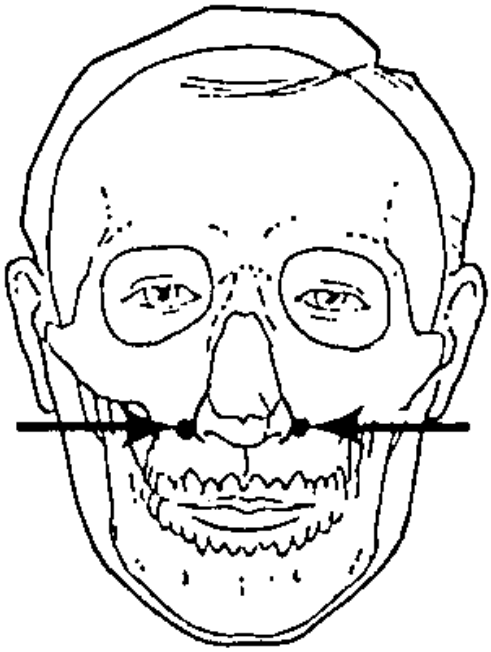
Name _____ Subject No.

Dimension	**Traditional Measurement (mm)**
Bigonial Breadth	
Bitragion Chin Arc	
Bitragion Frontal Arc	
Bitragion Subnasale Arc	
Bizygomatic Breadth (face width)	
Interpupillary Breadth	
Lip Length	
Menton-Sellion Length (face length)	
Nasal Root Breadth	
Nose Breadth	
Nose Protrusion	
Sellion-Subnasale Length (nose length)	
Bitragion Coronal Arc	
Maximum Frontal Breadth	
Minimum Frontal Breadth	
Head Breadth	
Head Circumference	
Head Length	
Stature	
Weight	

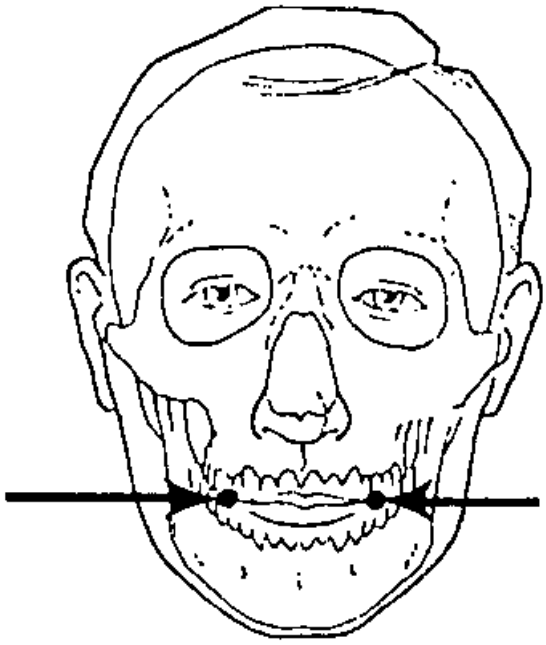
Measurer _____ Recorder

LANDMARK LIST

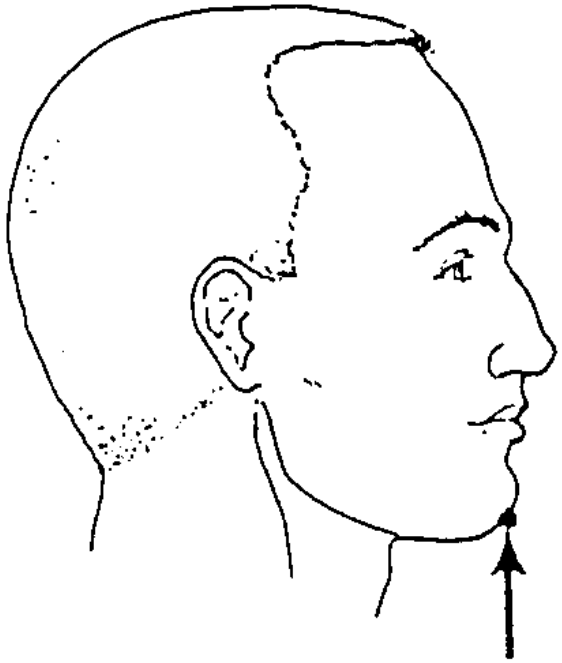
Alare, right and left: The lateral point on the flare or wing of the nose.



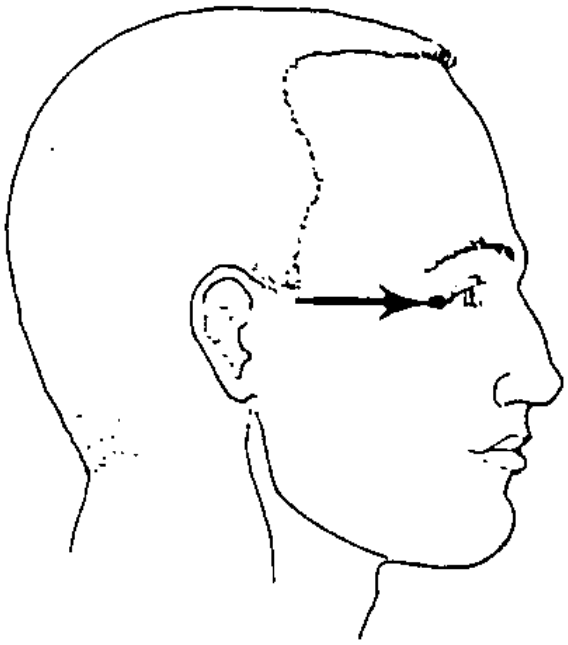
Cheilion, right and left: The lateral point of the juncture of the fleshy tissue of the lips with the facial skin at the corner of the mouth.



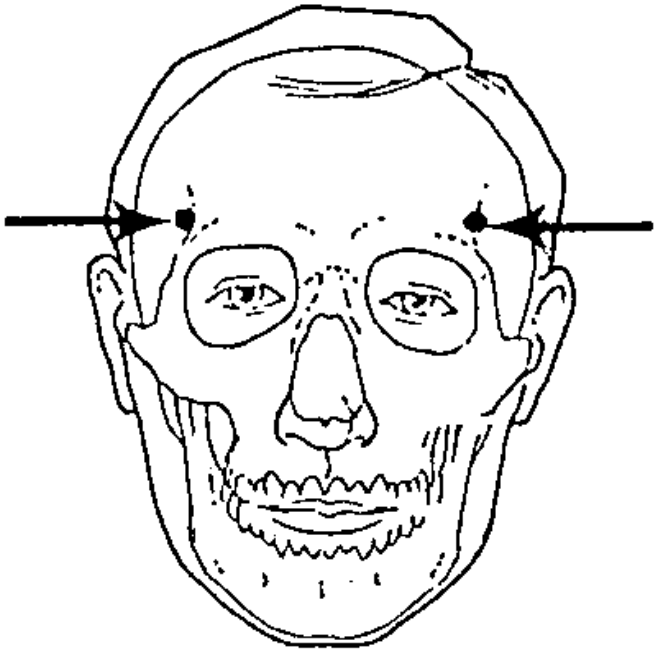
Chin: The most protruding point on the bottom edge of the chin, along the jawline.



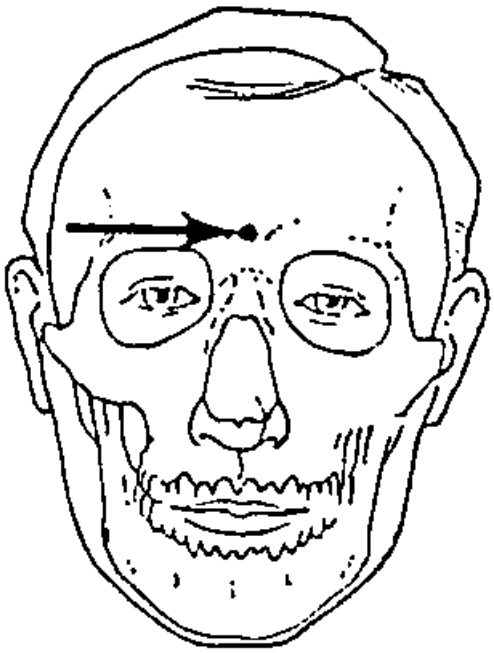
Ectocanthus: The outside corner of the right eye formed by the meeting of the upper and lower eyelids.



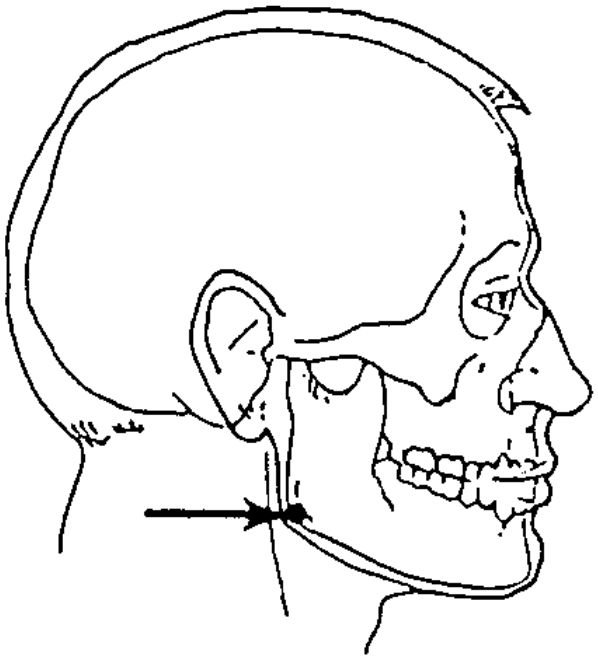
Frontotemporale, right and left: The point of deepest indentation of the temporal crest of the frontal bone above the browridges.



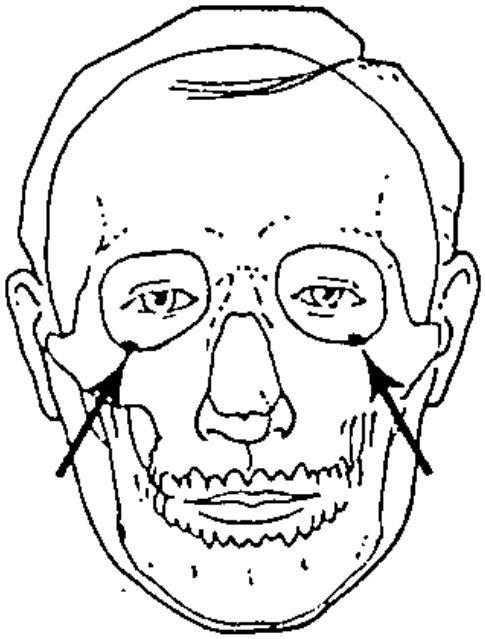
Glabella: The anterior point on the frontal bone midway between the bony browridges.



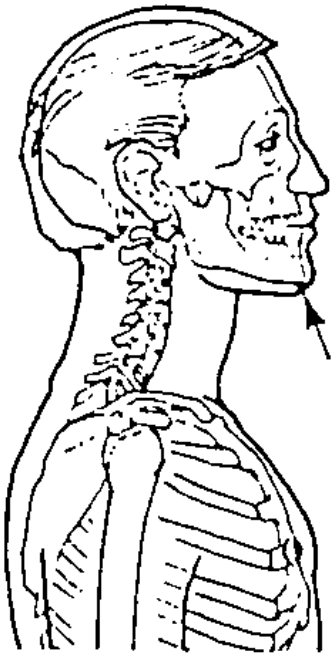
Gonion, right and left: The lateral point on the posterior angle of the mandible (jawbone).



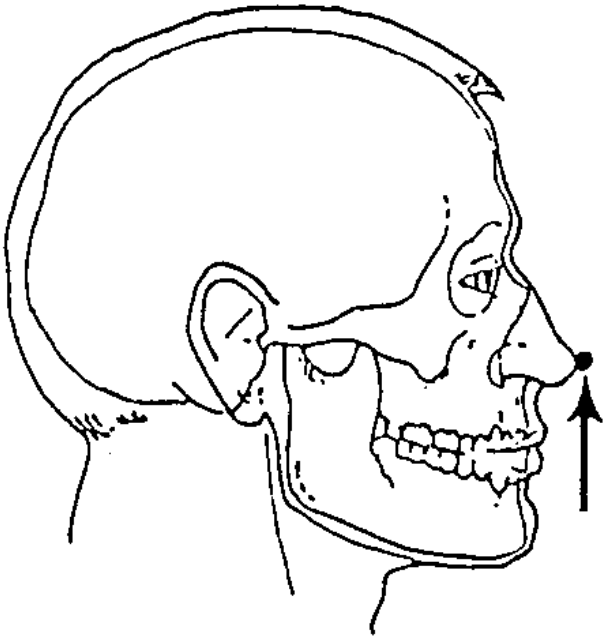
Infraorbitale, right and left: The lowest point on the anterior border of the bony eye socket.



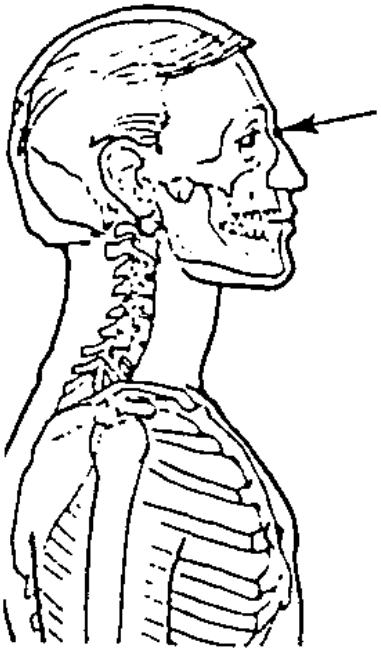
Menton: The inferior point of the mandible in the midsagittal plane (bottom of the chin).



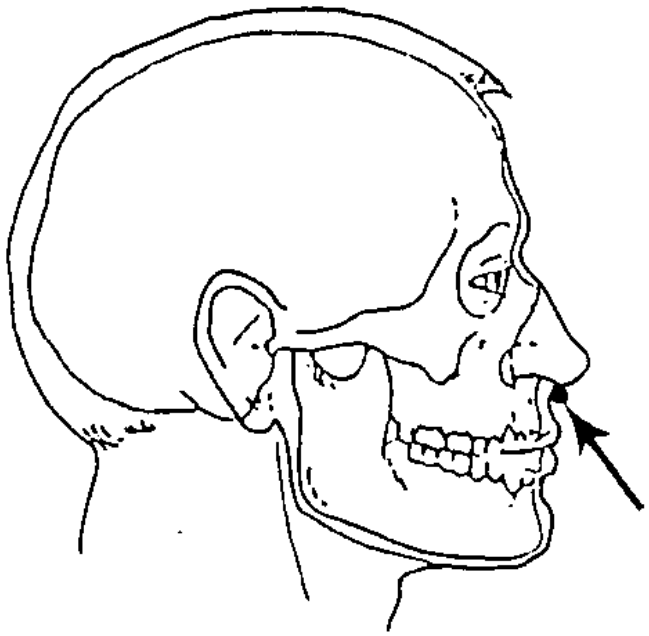
Pronasale: The point of the anterior projection of the tip of the nose.



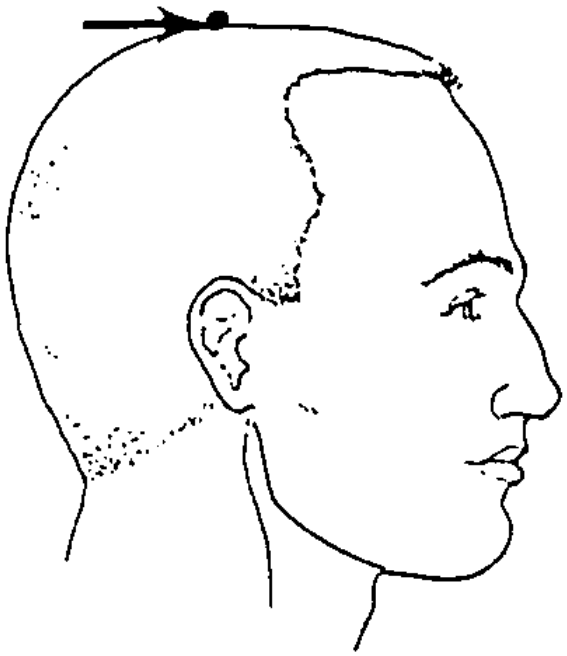
Sellion: The point of the deepest depression of the nasal bones at the top of the nose.



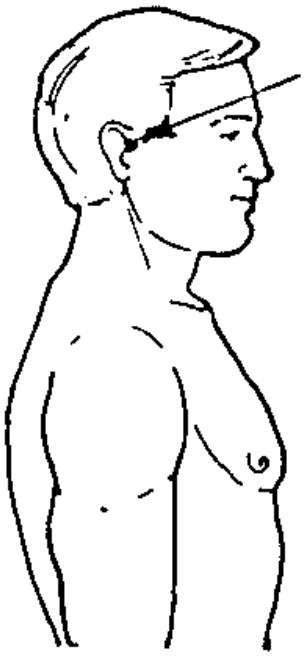
Subnasale: The point of intersection of the philtrum (groove of the upper lip) with the inferior surface of the nose, in the midsagittal plane.



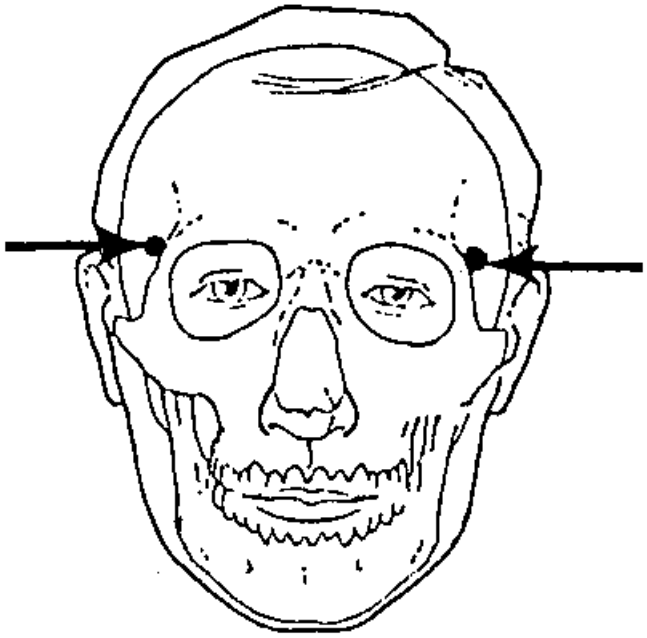
Top of head: The highest point on the head when the head is in the Frankfort plane.



Tragion, right and left: The superior point on the juncture of the cartilaginous flap (tragus) of the ear with the head.



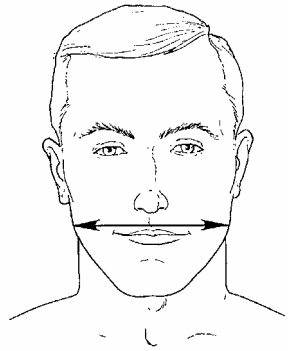
Zygofrontale, right and left: The lateral point of the frontal bone on its zygomatic process.



DIMENSION DESCRIPTIONS

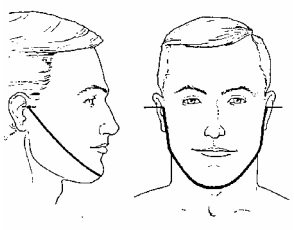
BIGONIAL BREADTH

The straight-line distance between the right and left Gonion landmarks on the corners of the jaw is measured with a spreading caliper. The subject sits looking straight ahead and with the teeth together (lightly occluded). Only enough pressure is exerted to ensure that the caliper tips are on the landmarks.



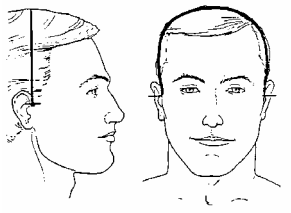
BITRAGION CHIN ARC

The surface distance between the right and left Tragion landmarks across the anterior point of the chin is measured with a tape. The subject sits looking straight ahead and with the teeth together (lightly occluded). Enough tension is exerted to maintain light contact between the tape and the skin. The chin will be slightly compressed.



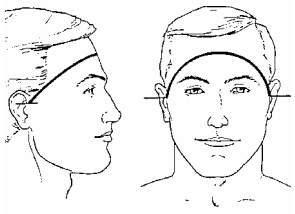
BITRAGION CORONAL ARC

The surface distance between the right and left Tragion landmarks across the top of the head in the coronal plane is measured with a tape. The subject sits with the head in the Frankfort plane. Enough tension is exerted to compress the hair.



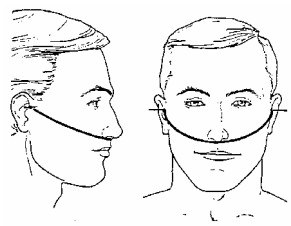
BITRAGION FRONTAL ARC

The surface distance between the right and left Tragion landmarks across the forehead just above the ridges of the eyebrows (supraorbital ridges) is measured with a tape. The subject sits looking straight ahead. Enough tension is exerted to maintain light contact between the tape and the skin.



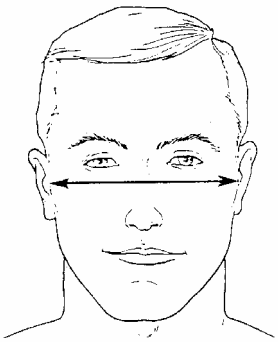
BITRAGION SUBNASALE ARC

The surface distance between the right and left Tragion landmarks across the Subnasale landmark at the bottom of the nose is measured with a tape. The subject sits looking straight ahead. Enough tension is exerted to maintain light contact between the tape and the skin, but not enough to compress the soft tissue under the nose.



BIZYGOMATIC BREADTH

The maximum horizontal breadth of the face between the zygomatic arches is measured with a spreading caliper. The subject sits looking straight ahead and with the teeth together (lightly occluded). Only enough pressure to ensure that the caliper tips are on the zygomatic arches is exerted.



HEAD BREADTH

The maximum horizontal breadth of the head above the level of the ears is measured with a spreading caliper. The subject sits looking straight ahead. Enough pressure is exerted to obtain contact between the caliper and the skin.

HEAD CIRCUMFERENCE

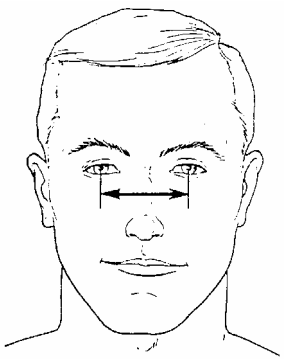
The maximum circumference of the head just above the ridges of the eyebrows (supraorbital ridges) and the attachment of the ears is measured with a tape. The subject sits looking straight ahead. The plane of the tape will be higher in the front than in the back and the sides should be parallel. Enough tension is exerted to compress the hair.

HEAD LENGTH

The maximum length of the head in the midsagittal plane is measured with a spreading caliper. The subject sits looking straight ahead. One tip of the caliper is placed on the Glabella landmark between the brow ridges and the other tip is moved up and down the back of the head until a maximum measurement is obtained. Light pressure is exerted on Glabella and enough pressure is exerted at the back of the head to compress the hair.

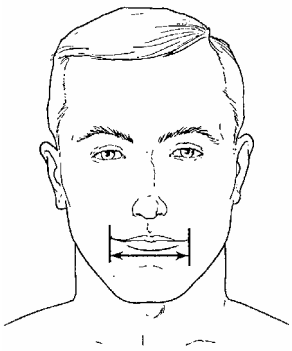
INTERPUPILLARY BREADTH

The horizontal distance between the center of the right and the center of the left pupil is measured with a pupillometer. The subject sits looking at the light inside the pupillometer.



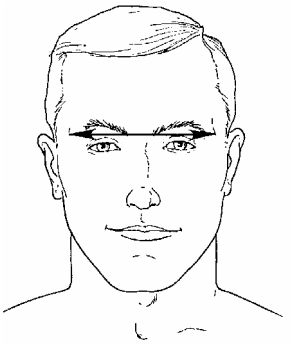
LIP LENGTH

The straight-line distance between the right and left Chelion landmarks at the corners of the closed mouth is measured with a sliding caliper. The subject sits looking straight ahead with the teeth together (lightly occluded). The facial muscles are relaxed, and the mouth is closed.



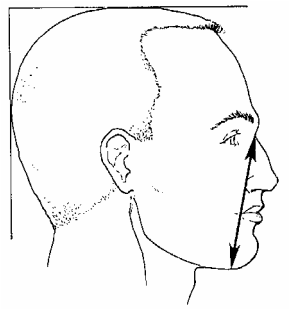
MAXIMUM FRONTAL BREADTH

The straight-line distance between the right and left Zygofrontale landmarks at the upper margin of each bony eye socket is measured with a spreading caliper. The subject sits looking straight ahead. Only enough pressure to ensure that the caliper tips are on the landmarks is exerted.



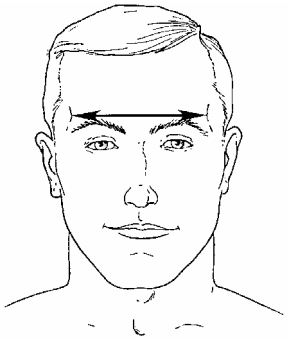
MENTON-SELLION LENGTH

The distance in the midsagittal plane between the Menton landmark at the bottom of the chin and the Sellion landmark at the deepest point of the nasal root depression is measured with a sliding caliper. The subject sits looking straight ahead and with the teeth together (lightly occluded). The fixed blade of the caliper is placed on Sellion. Only enough pressure to attain contact between the caliper and the skin is exerted.



MINIMUM FRONTAL BREADTH

The straight-line distance between the right and left Frontotemporale landmarks on the temporal crest on each side of the forehead is measured with a spreading caliper. The subject sits looking straight ahead. Only enough pressure to ensure that the caliper tips are on the landmarks is exerted.

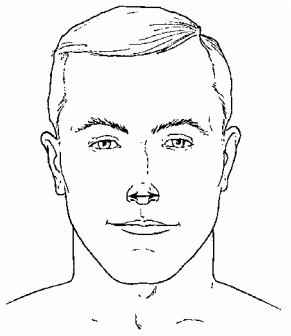


NASAL ROOT BREADTH

The horizontal breadth of the nose at the level of the deepest depression in the root (Sellion landmark) and at a depth equal to one-half the distance from the bridge of the nose to the eyes is measured with a sliding caliper. The subject sits looking straight ahead. The blunted points of the sliding caliper are used. Only enough pressure to attain contact between the caliper and the skin is exerted.

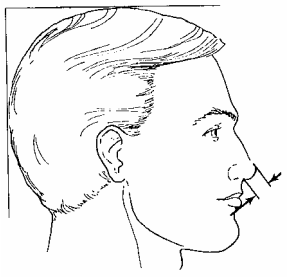
NOSE BREADTH

The straight-line distance between the right and left Alare landmarks on the sides of the nostrils is measured with a sliding caliper. The subject sits looking straight ahead. Only enough pressure to attain contact between the caliper and the skin is exerted.



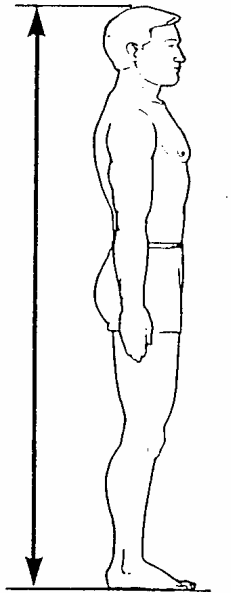
NOSE PROTRUSION

The straight-line distance between the Pronasale landmark at the tip of the nose and the Subnasale landmark under the nose is measured with a sliding caliper. The subject sits looking straight ahead.



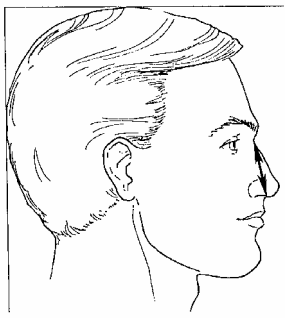
STATURE

The vertical distance between the standing surface and the top of the head is measured with an anthropometer. The subject stands erect with heels together and with the head in the Frankfort plane. The shoulders and arms are relaxed. Enough pressure is exerted to compress the hair. The measurement is taken at the maximum point of quiet respiration.



SUBNASALE-SELLION LENGTH

The straight-line distance between the Subnasale landmark under the nose and the Sellion landmark at the deepest point of the nasal root is measured with a sliding caliper. The subject sits looking straight ahead. Only enough pressure to attain contact between the caliper and the skin is exerted.



WEIGHT

The weight of the subject is taken to the nearest half kilogram. The subject stands on the center of the platform looking straight ahead. The heels are together and the weight evenly distributed on both feet.

APPENDIX E. Project Time Line

	2001					2002												2003	
	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb
Kickoff Meeting	X																		
Protocol Devel.																			
Sampling Strategy																			
Data Collection Plan																			
Data Analysis Plan																			
Develop 3D Methods																			
HURC Review																			
OMB Review																			
Data Collection																			
Contact Work Sites																			
Collect Data																			
Summary Stats (Trad.)																			
3D Shape Stats																			
Final Report, Slides																			
Government Review																			
Respond to Review																			
Final Brief																			