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TITLE: Determinants of Stress Fracture and Bone Mass in Elite
Military Cadets

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13. Abstract (Maximum 200 Words) <i>(abstract should contain no proprietary or confidential information)</i> The aim of this 4-year prospective cohort study of 891 cadets at the United States Military Academy at West Point was to examine the determinants of stress fractures and the acquisition of peak bone mass in elite military cadets. Cadets BMD, on average, was above the population mean (1 SD) at the calcaneus, hip and lumbar spine. Determinants of bone mass we identified included: menstrual function in females and prior exercise and milk drinking in men. Bone density was also related to standardized run score, PT score and body mass index. The accrual of bone mass in women was related to current menstrual function, other factors related to peak bone mass in males and females are currently being investigated. There were 131 stress fractures during the 3.5 years of follow-up, with the majority occurring within the first 3 months. The incidence of stress fractures was higher in females versus males. In a nested case control design, PTH, BSAP, IGF-1 and NTX were unrelated to stress fracture. Collagen 1 A1 was not related to bone density or stress fracture. Fitness upon entry assessed by run score was significantly associated with stress fractures in both genders. In women with fractures, BMD at the heel, spine and hip were all lower than in women without fractures.
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SECTION I - INTRODUCTION:

The study "The Determinants of Peak Bone Mass and Stress Fractures in Elite Military Cadets" was designed to examine four specific aims. They had been modified slightly because full funding for multiple phlebotomies was not granted. A modification to this grant was received and accepted on June 25, 2001 when \$60,134 was sent based on a letter dated 2 March 2001. Other changes since the inception of the study was the addition of bio-electrical impedance to determine lean mass, because of the inadequacies of BMI as a measure of fat and lean mass in the cadet population. Bio-electrical impedance was selected for its reliability and ease of use. To facilitate the examination of relationship between disordered eating and the attainment of peak bone mass an addendum to the protocol was submitted to Keller Army Hospital IRB in September 2001. An additional assessment was made in conjunction with the interests of academy personnel. This change was to use the Eating Disorder Inventory -2 by Garner (Appendix A).

The specific aims of the study remain the same and they are:

- (1) To determine the epidemiology of stress fractures in West Point Cadets during their four years at the Academy. To identify the relative importance of bone mass, quality and turnover, calcium intake and physical training in determining the risk of stress fractures.
- (2) To examine the relationship of allelic variation in three separate genetic markers (Vitamin D Receptor, Type I Collagen and Estrogen receptor) to stress fractures and bone mass. Note: Funding was just obtained in June 2001 to accomplish this task.
- (3) To determine the incidence of abnormal gonadal function, including menstrual irregularity and sex steroid production, in male and female cadets during intensive physical training. Note: The procedure to research this technical objective was not funded. Women's menstrual function was still assessed by questionnaire but no longitudinal blood samples were collected. There will be no assessment of male gonadal dysfunction.
- (4) To determine prospectively the relative importance of gonadal function, calcium intake and physical activity as determinants of bone turnover, mass and quality at multiple sites in male and female cadets. NOTE: The procedure to longitudinally assess serum levels of sex steroids (in women: estradiol; in men: testosterone and estradiol) and the bone turnover markers (osteocalcin and crosslinked C-telopeptide) were not funded. Calcium intake was still assessed annually by food frequency questionnaire and physical activity was assessed by collecting class registration and corps squad information from the academy. Menstrual function in female cadets was determined by questionnaire. Because the investigative team believed that the turnover markers might be important as predictors of fracture risk, additional funding sources were requested and obtained in June 2001.

SECTION II - BODY:

The determinants of peak bone mass and stress fractures are of interest to members of the military community. A higher peak bone mass is believed to relate to a subsequent reduction in the risk of osteoporosis and osteoporotic fracture later in life.⁽¹⁻²⁾ There is also evidence that greater bone mass acquisition may reduce the incidence of both stress fractures and traumatic fracture.⁽³⁾ The major determinants of peak mass have been identified to be genetics, physical activity, nutrition and gonadal function.⁽⁴⁻⁷⁾ Predictors of stress fracture as well as the attainment of peak bone mass are the two main outcomes being assessed on the class of 2002 over a 4-year period at the United States Military Academy.

Prior to initiation of the study in June of 1998, each cadet of the incoming class of 2002 was mailed an overview and a consent form to review at home. The Class of 2002 was briefed by company and then subsequently enrolled in the study. Table 1 provides these initial participation rates.

TABLE 1- PARTICIPATION RATES IN 1998

Cadet Basic Training Company	% Participation
A	76%
B	78%
C	75%
D	46%
E	71%
F	63%
G	75%
H	78%
OVERALL	70.25%

The maximum cadet enrollment in the study was 891. Of that 891, 179 of the cadets withdrew from the academy for academic or other reasons. Thus, the number of participants available for final data collection was 712. Of these, 433 or 61% presented for their final visit.

The data collection efforts during this year focused on follow-up bone density measurements of the different skeletal sites, body composition data, dietary intakes (Appendix B) and menstrual function (Appendix C) and in addition the final year assessment included an eating disorder assessment (Appendix A). The eating disorder assessment examined historical characteristics of weight and weight loss as well as 11 variables examining current attitudes towards dieting, eating and body image. This information will be used to explore which cadets, if any, have an eating disorder and the relationship eating disorders might have on the acquisition of peak bone mass.

Stress fracture occurrence was updated until January 2002 with the remaining data pending. The study team had hoped to complete a mid-term visit during winter intercession, January 2002, to improve the follow up when cadets have less time constraints, however this data collection period was not approved (in part as a result of 9/11/01). Therefore, the final data collection period occurred during the period of May 6-30, 2002, a period which coincides with exams and graduation requirements. As in previous years, cadets were notified by e-mail both on a group and individual basis of the upcoming data collection period. The website <http://sql3.pica.army.mil/CadetStudy/htm>, and e-mail continued to be the prime method of communication between the cadet participants and the study researchers. The website also provides information to academy personnel who are interested in the study. The cadets signed up for appointments on the study website, which allowed them to choose a time that was most convenient for them.

The same 3 tools were used to assess various physiologic properties of the bone. The tools used for the bone densitometry included 2 Lunar Pixi peripheral DXA machines, 1 Norland peripheral XCT 2000 scanner and a mobile Lunar DPX-IQ. The Lunar Pixi machines were used to take a calcaneus bone density measurement. The Norland pXCT provided total, trabecular and cortical density for the tibia. The DPX-IQ was used to assess the bone mineral density of the hip, femoral neck, wards triangle, trochanter, and lumbar vertebrae (L2-L4) in a subset of cadets. The Tanita 305 total body fat analyzer was used to assess weight, impedance, percent body fat, fat mass, lean body mass and total body water.

Table 2 shows the number of participants each year for each outcome.

TABLE 2- SUMMARY OF DATA COLLECTION RESULTS 1998-2002

Data Collection	Baseline	1999	2000	2001	2002
Body Composition	-1	767	527	394	431
Calcaneus	841	786	527	394	432
Spine	292	261	211	199	179
Hip	292	261	211	199	234
Tibia	768	700	527	392	431
Food Frequency	786	786	527	393	433
Menstrual Fxn	118	92	73	88	103
EDI-2	N/A (2)	N/A	N/A	N/A	431
Blood Sample	891(3)	N/A	N/A	N/A	N/A
Baseline Questionnaire	851 (4)	N/A	N/A	N/A	N/A

- (1) Body Composition was not performed the first year.
- (2) The Eating Disorder Inventory-2 was only completed the final year.
- (3) Blood Samples were only taken the first year.
- (4) The baseline questionnaire was given to the cadets the first year to assess their level of prior physical activity and other historical lifestyle factors that could influence both stress fractures and peak bone mass.

Stress fractures, were continually assessed by the orthopedics department (Dr. Uhorochak) at USMA, on the basis of initial x-ray, confirmed stress fracture diagnoses, follow up x-ray or bone scan results. One hundred and thirty-one fractures have occurred among 91 cadets between initiation of cadet basic training, June 1998 and January 2002. **Table 3** provides details on the skeletal site stress fractures.

TABLE 3. Skeletal Sites of Stress Fracture in Consented Cadets thru JUNE 2002

SKELETAL SITE	TOTAL NUMBER
Metatarsal	71
Phalanges	3
Tibia	39
Femur	7
Calcaneus	2
Clavicle	1
Fibula	5
Metacarpal	3

In addition to the data described above we are working closely with the dietary department to get nutritional evaluation of the meal plan and with the Department of Physical Education to get detailed sports participation to include in the analysis of predicting of stress fractures and peak bone mass.

An additional related study was added this year for parents who wished to participate in the study, "The Relationship of Parental Bone Mineral Density and Genetic Markers to the Bone Mineral Density and Genetic Markers of their Young Adult Offspring" during their visit to the Academy during graduation. This study was approved by the Helen Hayes Hospital IRB on May 20,2002. (Appendix D). The information from this parent study may provide insight as to whether the bone mineral density of the cadets was genetically determined or if it is primarily a function of their active healthy lifestyle. Each parent was provided with information about the study through an e-mail communication with their cadets who were participating in our study. Each parent signed an informed consent. (Appendix E) The tools used for the bone densitometry in this study included 2 Lunar Pixi peripheral DXA machines for calcaneus BMD and a mobile Lunar DPX-IQ to assess the bone mineral density of the hip, femoral neck, wards triangle and the trochanter. The Tanita 305 total body fat analyzer was used to assess weight, impedance, percent body fat, fat mass, lean body mass and total body water. A Helen Hayes Clinical Research Center questionnaire assessed lifestyle factors (Appendix F) related to bone health and one 10 ml tube of blood was drawn for genetic assessment.

**TABLE 4-SUMMARY OF PARENTAL DATA COLLECTION RESULTS
SPRING 2002**

Data Collected	Number
Consenting Parents	111
Calcaneus	111
Hip	110
Blood	109
Body Composition	111
Life Style Questionnaire	111

SECTION 7-KEY RESEARCH ACCOMPLISHMENTS

PART 1-2002 ACCOMPLISHMENTS

- A related Genetics study, was designed and initiated “The Relationship of Parental Bone Mineral Density and Genetic Markers to the Bone Mineral Density and Genetic Markers of their Young Adult Offspring”. Accomplishments related to this study include:
 - a) Created Parent Appointment Page Website for Genetics Study
 - b) Performed and analyzed hip measurements using DXA on 110 cadet parents representing the parents of 62 participating cadets.
 - c) Collected heel measurements on 111 parents of cadets
 - d) Collected blood samples from 109 biological parents of participating cadets
 - e) Collected Body Mass Index, Body Composition, Lean Body Mass and Total body water measurements on 111 of the cadet parents
- Created Cadet webpage for appointments for 2002 and updated Webpage to keep participants informed
- Received Keller IRB Approval for the addition of the Eating Disorder Inventory –2 Survey
- Performed hip analysis on 234 cadets in 2002 using mobile Lunar DPX-IQ scanner (55 cadets hip were measured for the first time to relate to parental data)
- Performed spine analysis on 179 cadets in 2002 using the mobile Lunar DPX-IQ scanner
- Collected 431 measurements of trabecular and cortical density of the tibia using the Norland peripheral XCT 2000 scanner in the spring of 2002.

- Collected Body Composition, Lean Body Mass and Total body water measurements on 431 cadets.
- The Eating Disorder Inventory-2 was completed by 431 graduating cadets.
- 103 female cadets completed a menstrual function questionnaire.
- Collected 433 food frequency surveys on the participating members of the Class of 2002.
- Obtained detailed fitness reports for all participating cadets during each of their years at the academy.
- Briefed the West Point Dietician on the results of the average calcium consumption of participating cadets in the class of 2002 and requested sample menu dietary analysis.
- Scheduled a close out brief in October 2002 with key academy personnel on the findings of the study.

PART 2- SUMMARY OF KEY ACCOMPLISHMENTS DURING PERFORMANCE PERIOD

- Maintained and updated the study website to collect data and keep study participants informed throughout the study.
- A total of 2980 Calcaneus bone mineral density measurements were taken on the members of the class of 2002.
- Analyzed collagen I (COL1) A1 gene on 626 male and 104 female cadets and we are currently analyzing ER and vitamin D Receptor on same cadets.
- Performed and analyzed 1142 spine using mobile Lunar DPX-IQ scanner.
- Performed and analyzed 1197 hip using mobile Lunar DPX-IQ scanner.
- Collected 2818 measurements of trabecular and cortical density of the tibia using the Norland peripheral XCT 2000 scanner.
- Collected Body Mass Index, Body Composition, Lean Body Mass and Total body water measurements on 2119 cadets.
- Provided Academy personnel with updated reports annually and provided at least 3 briefings.
- Calculated the levels of BGP, BSAP, and NTX in 860 cadets.
- Collected menstrual function 474 questionnaires from the women in the Class of '02.
- Collected 2925 food frequency questionnaires during the study.
- Analyzed the relationship of stress fractures to variables of calcium homeostasis, bone turnover or IGF-1. (Manuscript in preparation).
- Analyzed the association of collagen Type I gene with bone mineral density and stress fracture occurrence. (Manuscript in preparation).
- Analyzed the effects of exercise and the dietary consumption on different skeletal sites in Caucasian male and female cadets (Manuscript in preparation).
- Assisted USARIEM with the data collection for their IGF study.
- Designed and conducted a genetics study on the parents of participating cadets.

SECTION VIII- REPORTABLE OUTCOMES

PRESENTATIONS-

- Nieves JW, Zion M, Ruffing J, Ralston S, Uhorchak J, Gordon S, Lindsay R, Cosman. F Collagen Type I Gene is not associated with BMD or Stress Fracture Occurrence in Elite Military Cadets 23rd Annual Meeting of the American Society for Bone and Mineral Research , Poster Presentation, Phoenix, AZ October 2001
- Cosman F, Nieves JW, Zion M, Ruffing J, Uhorchak J, Gordon S, Lindsay R. Stress Fracture Occurrence is not Related to Variables of Calcium Homeostasis, Bone turnover or IGF-1 in Elite Military Cadets 23rd Annual Meeting of the American Society for Bone and Mineral Research, Poster Presentation, Phoenix, AZ October 2001
- Nieves JW, Ruffing J, Zion M, Lindsay R, Cosman F. Menstrual Function Predicts Change in Bone Mass in Elite Female Cadets. 22nd Annual Meeting of the American Society for Bone and Mineral Research (ASBMR), Poster Presentation, Toronto, Canada, September 2000.
- Nieves JW, Zion M, Ruffing J, Lindsay L, Cosman F. Exercise and Milk Intake are Determinants of Bone Mass in Male Elite Military Cadets. Toronto Canada (Abstract 161) National Osteoporosis Foundation (NOF) Annual Meeting, Poster Presentation, Chicago Illinois June 2000
- Nieves JW. Exercise and Milk Intake are Determinants of Bone Mass in Male Elite Military Cadets, 4th International Symposium on Nutritional Aspects of Osteoporosis, Switzerland May 2000, Oral Presentation.
- Cosman F. Stress Fractures in Elite Military Cadets and Bone Body Mass Index and Bone Geometry Correlation Selected for American Society of Bone Mineral Research, Plenary Poster Presentation, St Louis Missouri Oct 1, 1999
- Formica CA, Nieves JW, Shen V, Ruffing J, Lindsay R, Cosman F. Differential Effects of Gender on Bone Mass and Biomechanical Competency of the Axial and Peripheral Skeleton In Adolescent Elite Military Cadets. Oral Presentation at the First International Congress of Children and Bone Health, Maastricht, May 1999, Oral Presentation.
- Ruffing J, Nieves JW, Formica C, Lindsay R, Cosman F. Correlation Between Body Mass Index and Bone Mineral Density with Standardized Fitness Test Scores in Elite Military Cadets. Poster Presentation at the Society for Epidemiologic Research, Baltimore Maryland, June 1999.

MANUSCRIPTS-

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- Nieves J, Formica C, Ruffing J, Zion M, Shen V, Lindsay R, Cosman F. Males Have Larger Skeletal Size Than Females, Despite Comparable Body Size (in preparation)
- Ruffing J, Nieves J, Zion M, Lindsay R, Cosman F. Lifestyle Determinants of Bone Mass In Elite Military Cadets (in preparation)
- Ruffing J, Nieves J, Tendy S, Zion M, Lindsay R, Cosman F. Sport and Fitness Differences in Bone Mass in 841 Entering College Students (in preparation)
- Ruffing J, Nieves J, Tendy S, Zion M, Lindsay R, Cosman F. The Relationship of Body Composition Changes and Changes in Bone Mineral Density in Elite Military Cadets over 4 years (in preparation)
- Cosman F, NievesJ, Ruffing J, Zion M, Lindsay R. Predictors of Stress Fracture Risk in Elite Military Cadets over 4 years. (in preparation)

SECTION IX- CONCLUSIONS

Peak Bone Mass and Bone Mineral Density

Cadet's bone density measurements at the spine, hip, tibia and calcaneus were one standard deviation above the population mean at the time of entry into USMA. The relationship between bone mineral density (BMD) at different skeletal sites, body mass index (BMI), fitness scores, past exercise and dietary habits and other lifestyle factors were assessed. Alcohol, tobacco, salt and caffeine consumption were not related to BMD at any skeletal site in either males or females. This could be a result of low prevalence of these negative influences or that the high level of fitness and load bearing prior to academy entrance mitigate the deleterious effect of these lifestyle factors. Males vs. Females seem to be influenced differentially by different lifestyle factors. In female cadets the number of menstrual cycles prior to entering the academy was predictive of bone density in the spine, hip and calcaneus with women who had 9 or less than cycles the year prior to entering the academy having significantly lower density ($p < 0.05$). In men, greater exercise and higher calcium intake (milk) prior to academy entrance was predictive of greater calcaneal and tibial density, tibial mineral content, and greater cortical thickness. Bone density was also related to standardized run scores, PT score and BMI. When partial correlations between the three fitness variables and BMD were run, controlling for age, there was still a significant relationship between run score in males ($r = -.20$; $p = .0001$) but this was no longer significant in females.

Now that all 4 years of bone density testing have been completed, rates of change will be determined for each cadet and the predictors of peak bone mass will be assessed. Factors to be evaluated will include detailed dietary assessment, eating disorders, fitness level, body composition, sports and physical activity and a further evaluation of menstrual function in female cadets. Preliminary data indicate that accrual of bone mass only occurred in female cadets with normal menstrual function. Additional analyses are currently underway.

Predictors of Stress Fractures:

In the cohort of military cadets participating during first three years there were 119 confirmed fractures in 79 cadets. Preliminary analyses suggest that run scores were lower in males and females that fractured. Bone density in females (heel, spine, hip) and males (tibia) who fractured was lower than in females/males without fracture. Although current menstrual function was not related to stress fractures in females, age at menarche occurred 6 months earlier in women with a stress fracture compared to those who did not fracture.

The collagen I A1 (COLIA1) gene has been associated with fracture and central bone density in some but not all cohorts of men and women. An analysis of COLIA1 gene in relationship to stress fracture showed that in this population COLIA1 genotype was not significantly associated with stress fracture occurrence. Stress fracture occurrence, based on a nested case control study, was not associated with NTX, BSAP or BGP, IGF-1, or calcium homeostasis variable, which were measured at entry to USMA. Based on preliminary analysis, stress fracture occurrence is not related to variables of calcium homeostasis, bone turnover IGF-1 or COLIA1.

TABLE 5 – Means of Bone Markers in Cadet Population

Data Collected	Male (n=723)	Female (n=127)
BGP	9±1.9	7±1.5
BSAP	26±11	17±5
NTX	19±7	13±5

SECTION X- REFERENCES

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David M. Garner, Ph.D.

DIRECTIONS

Enter your name, the date, your age, sex, marital status, and occupation. Complete the questions on the rest of this page. Then turn to the inside of the booklet and carefully follow the instructions.

Name _____ Date _____

*Age _____ Sex _____ Marital status _____ Occupation _____

- A. *Current weight: _____ pounds
- B. *Height: _____ feet _____ inches
- C. Highest past weight excluding pregnancy: _____ pounds
 How long ago did you first reach this weight? _____ months
 How long did you weigh this weight? _____ months
- D. *Lowest weight as an adult: _____ pounds
 How long ago did you first reach this weight? _____ months
 How long did you weigh this weight? _____ months
- E. What weight have you been at for the longest period of time? _____ pounds
 At what age did you first reach this weight? _____ years old
- F. If your weight has changed a lot over the years, is there a weight that you keep coming back to when you are not dieting? ____ Yes ____ No
 If yes, what is this weight? _____ pounds
 At what age did you first reach this weight? _____ years old
- G. What is the most weight you have ever lost? _____ pounds
 Did you lose this weight on purpose? ____ Yes ____ No
 What weight did you lose to? _____ pounds
 At what age did you reach this weight? _____ years old
- H. What do you think your weight would be if you did not consciously try to control your weight? _____ pounds
- I. How much would you like to weigh? _____ pounds
- J. Age at which weight problems began (if any): _____ years old
- K. Father's occupation: _____
- L. Mother's occupation: _____

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INSTRUCTIONS

First, write your name and the date on your EDI-2 Answer Sheet. Your ratings on the items below will be made on the EDI-2 Answer Sheet. The items ask about your attitudes, feelings, and behavior. Some of the items relate to food or eating. Other items ask about your feelings about yourself.

For each item, decide if the item is true about you ALWAYS (A), USUALLY (U), OFTEN (O), SOMETIMES (S), RARELY (R), or NEVER (N). Circle the letter that corresponds to your rating on the EDI-2 Answer Sheet. For example, if your rating for an item is OFTEN, you would circle the O for that item on the Answer Sheet.

Respond to all of the items, making sure that you circle the letter for the rating that is true about you. **DO NOT ERASE!** If you need to change an answer, make an "X" through the incorrect letter and then circle the correct one.

1. I eat sweets and carbohydrates without feeling nervous.
2. I think that my stomach is too big.
3. I wish that I could return to the security of childhood.
4. I eat when I am upset.
5. I stuff myself with food.
6. I wish that I could be younger.
7. I think about dieting.
8. I get frightened when my feelings are too strong.
9. I think that my thighs are too large.
10. I feel ineffective as a person.
11. I feel extremely guilty after overeating.
12. I think that my stomach is just the right size.
13. Only outstanding performance is good enough in my family.
14. The happiest time in life is when you are a child.
15. I am open about my feelings.
16. I am terrified of gaining weight.
17. I trust others.
18. I feel alone in the world.
19. I feel satisfied with the shape of my body.
20. I feel generally in control of things in my life.
21. I get confused about what emotion I am feeling.
22. I would rather be an adult than a child.
23. I can communicate with others easily.
24. I wish I were someone else.
25. I exaggerate or magnify the importance of weight.
26. I can clearly identify what emotion I am feeling.
27. I feel inadequate.
28. I have gone on eating binges where I felt that I could not stop.
29. As a child, I tried very hard to avoid disappointing my parents and teachers.
30. I have close relationships.
31. I like the shape of my buttocks.
32. I am preoccupied with the desire to be thinner.
33. I don't know what's going on inside me.
34. I have trouble expressing my emotions to others.
35. The demands of adulthood are too great.
36. I hate being less than best at things.
37. I feel secure about myself.

38. I think about bingeing (overeating).
39. I feel happy that I am not a child anymore.
40. I get confused as to whether or not I am hungry.
41. I have a low opinion of myself.
42. I feel that I can achieve my standards.
43. My parents have expected excellence of me.
44. I worry that my feelings will get out of control.
45. I think my hips are too big.
46. I eat moderately in front of others and stuff myself when they're gone.
47. I feel bloated after eating a normal meal.
48. I feel that people are happiest when they are children.
49. If I gain a pound, I worry that I will keep gaining.
50. I feel that I am a worthwhile person.
51. When I am upset, I don't know if I am sad, frightened, or angry.
52. I feel that I must do things perfectly or not do them at all.
53. I have the thought of trying to vomit in order to lose weight.
54. I need to keep people at a certain distance (feel uncomfortable if someone tries to get too close).
55. I think that my thighs are just the right size.
56. I feel empty inside (emotionally).
57. I can talk about personal thoughts or feelings.
58. The best years of your life are when you become an adult.
59. I think my buttocks are too large.
60. I have feelings I can't quite identify.
61. I eat or drink in secrecy.
62. I think that my hips are just the right size.
63. I have extremely high goals.
64. When I am upset, I worry that I will start eating.
65. People I really like end up disappointing me.
66. I am ashamed of my human weaknesses.
67. Other people would say that I am emotionally unstable.
68. I would like to be in total control of my bodily urges.
69. I feel relaxed in most group situations.
70. I say things impulsively that I regret having said.
71. I go out of my way to experience pleasure.
72. I have to be careful of my tendency to abuse drugs.
73. I am outgoing with most people.
74. I feel trapped in relationships.
75. Self-denial makes me feel stronger spiritually.
76. People understand my real problems.
77. I can't get strange thoughts out of my head.
78. Eating for pleasure is a sign of moral weakness.
79. I am prone to outbursts of anger or rage.
80. I feel that people give me the credit I deserve.
81. I have to be careful of my tendency to abuse alcohol.
82. I believe that relaxing is simply a waste of time.
83. Others would say that I get irritated easily.
84. I feel like I am losing out everywhere.

(Continued)

- 85. I experience marked mood shifts.
- 86. I am embarrassed by my bodily urges.
- 87. I would rather spend time by myself than with others.
- 88. Suffering makes you a better person.
- 89. I know that people love me.
- 90. I feel like I must hurt myself or others.
- 91. I feel that I really know who I am.

Additional copies available from:

PAR Psychological Assessment Resources, Inc.
P.O. Box 998/Odessa, Florida 33556/Toll-Free 1-800-331-TEST



ANSWER SHEET

David M. Garner, PhD

Name _____ Date _____

Fill in your name and the date above. Follow the Instructions in the EDI-2 Item Booklet and enter your ratings on this sheet.

A = ALWAYS U = USUALLY O = OFTEN S = SOMETIMES R = RARELY N = NEVER

1	AUOSRN	20	AUOSRN	39	AUOSRN	58	AUOSRN	76	AUOSRN
2	AUOSRN	21	AUOSRN	40	AUOSRN	59	AUOSRN	77	AUOSRN
3	AUOSRN	22	AUOSRN	41	AUOSRN	60	AUOSRN	78	AUOSRN
4	AUOSRN	23	AUOSRN	42	AUOSRN	61	AUOSRN	79	AUOSRN
5	AUOSRN	24	AUOSRN	43	AUOSRN	62	AUOSRN	80	AUOSRN
6	AUOSRN	25	AUOSRN	44	AUOSRN	63	AUOSRN	81	AUOSRN
7	AUOSRN	26	AUOSRN	45	AUOSRN	64	AUOSRN	82	AUOSRN
8	AUOSRN	27	AUOSRN	46	AUOSRN			83	AUOSRN
9	AUOSRN	28	AUOSRN	47	AUOSRN	65	AUOSRN	84	AUOSRN
10	AUOSRN	29	AUOSRN	48	AUOSRN	66	AUOSRN	85	AUOSRN
11	AUOSRN	30	AUOSRN	49	AUOSRN	67	AUOSRN	86	AUOSRN
12	AUOSRN	31	AUOSRN	50	AUOSRN	68	AUOSRN	87	AUOSRN
13	AUOSRN	32	AUOSRN	51	AUOSRN	69	AUOSRN	88	AUOSRN
14	AUOSRN	33	AUOSRN	52	AUOSRN	70	AUOSRN	89	AUOSRN
15	AUOSRN	34	AUOSRN	53	AUOSRN	71	AUOSRN	90	AUOSRN
16	AUOSRN	35	AUOSRN	54	AUOSRN	72	AUOSRN	91	AUOSRN
17	AUOSRN	36	AUOSRN	55	AUOSRN	73	AUOSRN		
18	AUOSRN	37	AUOSRN	56	AUOSRN	74	AUOSRN		
19	AUOSRN	38	AUOSRN	57	AUOSRN	75	AUOSRN		

PAR Psychological Assessment Resources, Inc./P.O. Box 998/Odessa, FL 33556/Toll-Free 1-800-331-TEST

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9876543

Reorder #RO-1762

Printed in the U.S.A.

FOOD FREQUENCY QUESTIONNAIRE: SUMMER 02

NAME: _____
 SSN: _____

Instructions: Please think about the foods you regularly ate over the past year, what size servings you ate, and how often you ate them. Then fill in the appropriate boxes. If you ate two medium bowls of cereal a day you would fill in the boxes like this:

EXAMPLE:

BREAKFAST	Medium Serving Size	Serving Size			No. of Servings	Frequency		
		S	M	L		Per day	Per week	Per month
Cereal with Milk	1 med bowl	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

START HERE.

DAIRY	Medium Serving Size	Serving Size			No. Of Servings	Frequency		
		S	M	L		Per Day	Per Week	Per Month
Cottage cheese	1/2 cup	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
cheese	2oz or 2 slices	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
yogurt	1 cup	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
tofu	2 oz	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BREAKFAST								
Cereal with Milk	1 med bowl	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LUNCH								
Cheese dishes, such as macaroni and cheese	1 cup	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Pizza/lasagna	2 slices	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SWEETS								
Ice Cream or frozen yogurt	1 scoop 1/2 cup	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
VEGETABLES								
Mustard or turnip greens or collards	1/2 cup	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Beans including pinto, kidney, baked or black eye beans	1/4 cup	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Broccoli or kale	1/2 cup	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BEVERAGES								
Glass of milk	8 oz	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Coffee/Tea (caffeinated)	1 cup	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cola Product (caffeinated diet or reg)	12 oz (1 can)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

To how many meals per day do you add salt? (circle the correct answer)

0 1 2 3 meals a day

Do you take any vitamin or nutritional supplements? Yes No

If yes, what is the name of your vitamin or nutritional supplement? _____

Do you take a calcium supplement or is calcium contained in your vitamin supplement? Yes No

MENSTRUAL FUNCTION AND BIRTH CONTROL USAGE: Summer 2002

NAME: _____

SSN: _____

BACKGROUND: Recent studies have shown that there is a correlation between different types of birth control, menstrual function and bone density therefore please take time in completing this survey.

INSTRUCTIONS: Please check the boxes that apply to you.

COW YEAR	DID YOU HAVE A PERIOD?		WHERE YOU ON BIRTH CONTROL?		WHAT TYPE OF BIRTH CONTROL?		
June 2001	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Oral <input type="checkbox"/>	Depoprovera <input type="checkbox"/>	Norplant <input type="checkbox"/>
July 2001	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Oral <input type="checkbox"/>	Depoprovera <input type="checkbox"/>	Norplant <input type="checkbox"/>
August 2001	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Oral <input type="checkbox"/>	Depoprovera <input type="checkbox"/>	Norplant <input type="checkbox"/>
September 2001	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Oral <input type="checkbox"/>	Depoprovera <input type="checkbox"/>	Norplant <input type="checkbox"/>
October 2001	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Oral <input type="checkbox"/>	Depoprovera <input type="checkbox"/>	Norplant <input type="checkbox"/>
November 2001	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Oral <input type="checkbox"/>	Depoprovera <input type="checkbox"/>	Norplant <input type="checkbox"/>
December 2001	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Oral <input type="checkbox"/>	Depoprovera <input type="checkbox"/>	Norplant <input type="checkbox"/>
January 2002	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Oral <input type="checkbox"/>	Depoprovera <input type="checkbox"/>	Norplant <input type="checkbox"/>
February 2002	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Oral <input type="checkbox"/>	Depoprovera <input type="checkbox"/>	Norplant <input type="checkbox"/>
March 2002	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Oral <input type="checkbox"/>	Depoprovera <input type="checkbox"/>	Norplant <input type="checkbox"/>
April 2002	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Oral <input type="checkbox"/>	Depoprovera <input type="checkbox"/>	Norplant <input type="checkbox"/>
May 2002	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Oral <input type="checkbox"/>	Depoprovera <input type="checkbox"/>	Norplant <input type="checkbox"/>

1. If you were on birth control prior to entering the academy which type was it?

Oral Depoprovera Norplant

INTER-OFFICE H MEMORANDUM

Helen Hayes Hospital Institutional Review Board

APPENDIX D

TO: Jeri Nieves, PhD, Principal Investigator

FROM: Laura Lennihan, M.D., Chairwoman IRB *LL*

DATE: May 20, 2002

SUBJECT: Protocol # 02-05: The Relationship of Parental Bone Mineral Density and Genetic Markers to the Bone Mineral Density and Genetic Markers of Their Young Adult Offspring

The IRB has approved solicitation of subjects for your research project. The revised protocol summary and informed consent on which the approval was based are attached. This approval is valid for one year and will expire unless an annual report is received and approved by the IRB. Listed below are your responsibilities to your study subjects regarding informed consent and confidentiality and to the IRB. Please sign, date, and return one copy of this memorandum to the IRB.

Research investigators are responsible for:

Insuring that informed consent is documented by the use of the written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative.

Insuring that each person signing the written consent form is given a copy of that form.

Placing the consent documents, signed by human research subjects, in a repository approved by the IRB.

Protecting study subject confidentiality and confidentiality of their records.

Submitting for IRB review, any advertisements to recruit research subjects. This includes, but is not limited to, newspaper, radio, and television advertisements and notices, public service announcements, posters and flyers.

Reporting the progress of the research to the IRB, as often as and in the manner prescribed by the IRB, but no less than once per year.

Reporting promptly in writing to the IRB, any injuries to human subjects or any unanticipated problems that involve risks to the human research subjects or others. Investigators are encouraged to call the IRB with these reports in addition to preparing a written report.

Reporting promptly, in writing to the IRB, any proposed changes in a research protocol that shall not be initiated by research investigators without IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subject.

Reporting promptly, in writing to the IRB, any serious or continuing noncompliance with the requirements of this approval or the determinations of the IRB.

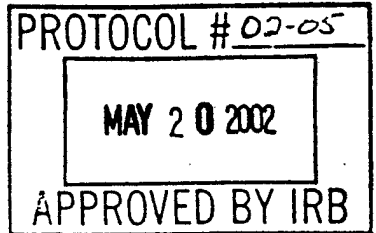
Notifying the IRB in writing of a planned leave of absence or termination of affiliation with the hospital and proposed replacement principal investigator. The IRB must approve any temporary or permanent replacement Principal Investigator.

Maintaining study subject records for six years after the close of the study.

All Key Personnel are to be certified by taking the NIH CBT Course on *Human Participants Protection Education for Research Teams*. A copy of their certification is to be sent to the IRB Secretary.

Jeri W. Nieves
Principal Investigator

5-22-02
Date



Clinical Research Center
Helen Hayes Hospital

THE RELATIONSHIP OF PARENTAL BONE MINERAL DENSITY AND GENETIC
MARKERS TO THE BONE MINERAL DENSITY AND GENETIC MARKERS OF THEIR
YOUNG ADULT OFFSPRING

PROTOCOL

a. Rationale:

Genetic factors are responsible for between 70-80% of peak bone mass. Environmental factors such as physical activity, oral contraceptive use, hormone replacement therapy and adequate calcium and vitamin D intake might help in maximizing an individual's peak bone mass. However, drinking excess alcohol, smoking, and decreased menstrual function might reduce a persons peak bone mass. The United States Military Academy cadets from the class of 2002 have been followed for 4 years in a Department of Army funded study (IRB approval for cadets was through Keller Army Hospital IRB). In this study the cadets have, on average, bone density one standard deviation above the mean young normal range. The assessment of the skeletal and genetic factors in the parents of cadets can provide some insight as to whether this was genetically determined or primarily a function of their active, healthy lifestyle. The power of the statistical analyses of genetic results found in the cadets will be substantially improved by the measurement of the same genetic markers in their parents.

b. Inclusion Criteria:

Subjects will be included if they are a biological parent of a cadet currently participating in the Department of Army funded study " The Determinants of Peak Bone Mass and Stress Fractures in Elite Military."

c. Exclusion Criteria:

Parents who are not biologically related to the cadet enrolled in the above-mentioned study.

Women who are currently pregnant.

d. Human Subjects:

Parents of participants of will be recruited through their children. We hope to recruit up to 200 parents (100 sets) for this genetic study. Parents who are found to have osteoporosis will be sent a letter to give to their physician or a specialist for treatment of their osteoporosis.

e. Procedures:

Written informed consent is obtained before the densitometry measurements are made, blood samples are taken or the questionnaire is administered.

Interview

The study subjects will self administer a detailed questionnaire, regarding diet, physical activity, lifestyle behaviors, health status, medications, disease, bone fractures, age of menarche and menopause (if applicable). A member of the Clinical Research Center at Helen Hayes Hospital will be available to answer any questions that the parents might have.

Bone Mass and Body Composition Measurements

There is good evidence that the effects of various factors on bone density differ according to the relative proportion of cortical and trabecular bone at particular skeletal sites. Therefore, bone mass at two sites is measured: the heel and proximal femur on the mobile Lunar DPX-IQ dual energy X-ray absorptiometers (DXA). If bone mass is found to be in the osteoporosis range subjects will be mailed a letter along with their results to give to their primary care physician. Body composition measurements will be taken by bioelectrical impedance on the Tanita 305 Body Fat analyzer. Study subjects are not charged for any of the measurements and the testing takes a total of 30-45 minutes.

Blood Samples

Two tubes (20 ml) of blood will be drawn on the morning of the BMD visit. Serum will be frozen at -70°C for future analysis of genetic markers. These indices will include polymorphisms that are related to bone and will be the same tests that are currently being measured in the cadet sample. These samples will be discarded two years after the collection date. There will be no testing done on the samples to determine biological parenting.

Evaluation

Parents will only be evaluated once during the week of graduation at West Point USMA. They will have the option of e-mailing to schedule their appointment or they will be provided a website and they can directly select the time of their visit to have bone density testing done on site at USMA. All testing will be done using the Helen Hayes Hospital Mobile densitometer and peripheral bone densitometers.

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f) Confidentiality of Records

Confidentiality and anonymity will be preserved. All information on study subjects is kept in locked file cabinets and is available only to the research staff. Names and other identifying information are kept separate from the questionnaires. Data are presented by group statistics, not individual names.

Any abnormalities found, on any of the tests in this study will be kept confidential and forwarded to subjects primary care physician with their approval.

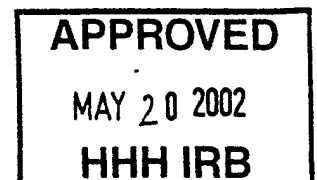
g. Potential Risks and Benefits.

There is exposure to very low levels of radiation from the bone densitometry measurements. The radiation dose for the heel assessment is 4 mrems. Finally, the exposure level for the hip is 4 mrems. The total radiation exposure is less than the exposure of one chest x-ray. The risks of drawing two tubes of blood are minimal in these healthy individuals and no complications are expected. The body composition has no known risk. The primary benefit of the study is that each subject will learn more about their bone health and body composition.

h. Compensation.

The parents of the cadets will not be compensated for participation in this study.

IRB #02-05 Revised 5/16/02



CONSENT FORM 02-05
JUN 20 2002
APPROVED BY IRB

Clinical Research Center
Helen Hayes Hospital

THE RELATIONSHIP OF PARENTAL BONE MINERAL DENSITY AND GENETIC
MARKERS TO THE BONE MINERAL DENSITY AND GENETIC MARKERS OF THEIR
YOUNG ADULT OFFSPRING

INFORMED CONSENT

I. Introduction:

Peak bone mass is the lifetime maximum bone mass (strength) of an individual and is usually reached at age 17-25. Genetic factors are responsible for between 70-80% of peak bone mass. Environmental factors such as physical activity, oral contraceptive use, hormone replacement therapy and adequate calcium and vitamin D intake might help in maximizing an individual's peak bone mass. However, excess alcohol drinking, smoking, and decreased menstrual function might reduce peak bone mass. Examining the relative role of genetics and environmental factors is important to understand determinants of peak bone mass and to learn how to prevent fractures and osteoporosis (a disease of reduced bone mass and high bone fracture risk).

In this study we plan to evaluate how your bone mass and genetic markers compare to other parents of cadets in the class of 2002 as well as the relationship of your bone mass to that of your child.

II. Procedures:

You will be eligible for this study if you are a parent of a cadet enrolled in the Class of 2002 at West Point who is participating in the study "Determinants of Peak Bone Mass and Stress Fractures in Elite Military Cadets."

Questionnaire

You will answer a detailed questionnaire, regarding diet, physical activity, lifestyle behaviors, health status, medications, disease, bone fractures, age of menarche and menopause (if applicable). A member of the Clinical Research Center at Helen Hayes Hospital will be available to answer any questions you might have.

Bone Mass Measurements

Bone mass will be measured at your heel and hip using technology called dual x-ray absorptiometry or DXA. These measurements will be done here at USMA and should take a total of 30 minutes. Your results will be forwarded to you, to discuss with your primary care physician.

Blood Samples

Two tubes (20 ml) of blood will be drawn during your visit. Blood samples will be analyzed for genetic variation that may be related to bone health. The same genetic markers for bone have been measured on your son or daughters blood sample we collected 4 years ago. Your samples will be kept two years after they are collected and then they will be discarded. The samples will not be evaluated

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to determine biological parents of the cadet.

Body Composition

Body Composition will be assessed by bioelectrical impedance, which involves stepping on a device similar to a scale that can determine your percent body fat.

III. Risks and Benefits:

There is exposure to very low levels of radiation from the bone density testing. Radiation exposure is less than a standard chest x-ray for all measurements of your bone. This radiation exposure is the same as the background radiation you would get flying from New York to California.

The risks of drawing two tubes of blood are minimal, possible risks include bruising, infection, bleeding, fainting and minor pain at the blood drawing site. Your blood sample will be discarded after two years in order to allow time for the specialized genetic tests related to bone health to be performed.

The primary benefit of the study is that each subject will learn more about his or her bones.

IV. Confidentiality of Records

Confidentiality will be maintained, all information from this study will be maintained in locked file cabinets and is available only to the research staff. Your name and other identifying information will be kept separate from your questionnaires. Data on your results will be presented by group statistics, not individual names or data. The testing of genetic markers related to bone health will be performed in a specialized lab in England. Since these results only have scientific meaning we will not send you results of the genetic tests. The only marking on your blood tube will be a study identification number. All data entered from your visit will be entered into a computer that will not have your name or other unique identities but instead a study identification number. The lab will send us back the levels of each genetic marker, which we will link with our database, which also only contain your study identification number. Your blood sample will be discarded after two years in order to allow time for the specialized genetic tests related to bone health to be performed.

V. Compensation:

You will not be compensated for participation in this study.

SIGNED CONSENT:

I have been satisfactorily informed of the procedure described above with its possible risks and benefits. I have been encouraged to ask any and all questions about this procedure. I understand that, if I think of more questions later, Dr. Cosman or her associates will be able to answer them (845-786-4494).

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I understand that:

a) If I experience illness or injury while participating in this research project, Drs. Cosman or Lindsay will arrange for appropriate medical care at Helen Hayes Hospital, or if medically necessary, I will be referred or transferred to another hospital. I understand that I will be responsible for the cost of care at a non Department of Health hospital, either personally or through my medical insurance. I understand that if I experience illness or injury as a result of this research project, the Commissioner of Health may waive or reduce the cost of care provided at Helen Hayes Hospital, but only with the prior approval of the State Comptroller and the Attorney General.

b) If I lose any wages because of participating in the study, Helen Hayes Hospital will not reimburse me.

c) By signing this consent form, I do not waive any legal rights.

d) My participation in this study is voluntary. I know I may withdraw from the study at any time without losing any rights or benefits I have as a patient of Helen Hayes Hospital now or in the future.

e) In participating in this study, I know that Helen Hayes Hospital has the right to stop the study at any time.

f) I will receive a copy of this form.

g) I will be told of any significant new medical progress during the course of this study that may change my willingness to continue my participation in this study.

Date

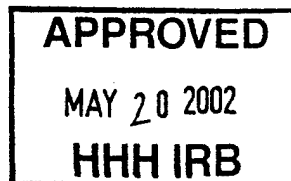
Participant's Signature

Date

Witness

Solicitation of subjects for this research protocol has been approved by the Institutional Review Board of Helen Hayes Hospital. If you have any questions concerning your rights as a research subject, you may call the Institutional Review Board (845-786-4856).

IRB # 02-05 Revised 5/16/02



CONSENT FORM # 02-05

JUN 20 2002

APPROVED BY IRB

Clinical Research Center
Helen Hayes Hospital

THE RELATIONSHIP OF PARENTAL BONE MINERAL DENSITY AND GENETIC
MARKERS TO THE BONE MINERAL DENSITY AND GENETIC MARKERS OF THEIR
YOUNG ADULT OFFSPRING

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In this study we plan to evaluate how your bone mass and genetic markers compare to other parents of cadets in the class of 2002 as well as the relationship of your bone mass to that of your child.

II. Procedures:

You will be eligible for this study if you are a parent of a cadet enrolled in the Class of 2002 at West Point who is participating in the study "Determinants of Peak Bone Mass and Stress Fractures in Elite Military Cadets."

Questionnaire

You will answer a detailed questionnaire, regarding diet, physical activity, lifestyle behaviors, health status, medications, disease, bone fractures, age of menarche and menopause (if applicable). A member of the Clinical Research Center at Helen Hayes Hospital will be available to answer any questions you might have.

Bone Mass Measurements

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Blood Samples

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to determine biological parents of the cadet.

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The primary benefit of the study is that each subject will learn more about his or her bones.

IV. Confidentiality of Records

Confidentiality will be maintained, all information from this study will be maintained in locked file cabinets and is available only to the research staff. Your name and other identifying information will be kept separate from your questionnaires. Data on your results will be presented by group statistics, not individual names or data. The testing of genetic markers related to bone health will be performed in a specialized lab in England. Since these results only have scientific meaning we will not send you results of the genetic tests. The only marking on your blood tube will be a study identification number. All data entered from your visit will be entered into a computer that will not have your name or other unique identities but instead a study identification number. The lab will send us back the levels of each genetic marker, which we will link with our database, which also only contain your study identification number. Your blood sample will be discarded after two years in order to allow time for the specialized genetic tests related to bone health to be performed.

V. Compensation:

You will not be compensated for participation in this study.

SIGNED CONSENT:

I have been satisfactorily informed of the procedure described above with its possible risks and benefits. I have been encouraged to ask any and all questions about this procedure. I understand that, if I think of more questions later, Dr. Cosman or her associates will be able to answer them (845-786-4494).

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MAY 20 2002
HHH IRB

I understand that:

a) If I experience illness or injury while participating in this research project, Drs. Cosman or Lindsay will arrange for appropriate medical care at Helen Hayes Hospital, or if medically necessary, I will be referred or transferred to another hospital. I understand that I will be responsible for the cost of care at a non Department of Health hospital, either personally or through my medical insurance. I understand that if I experience illness or injury as a result of this research project, the Commissioner of Health may waive or reduce the cost of care provided at Helen Hayes Hospital, but only with the prior approval of the State Comptroller and the Attorney General.

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e) In participating in this study, I know that Helen Hayes Hospital has the right to stop the study at any time.

f) I will receive a copy of this form.

g) I will be told of any significant new medical progress during the course of this study that may change my willingness to continue my participation in this study.

Date

Participant's Signature

Date

Witness

Solicitation of subjects for this research protocol has been approved by the Institutional Review Board of Helen Hayes Hospital. If you have any questions concerning your rights as a research subject, you may call the Institutional Review Board (845-786-4856).

IRB # 02-05 Revised 5/16/02

APPROVED

MAY 20 2002

HHH IRB

The Clinical
CRC
Research Center

BONE MINERAL LAB RETURN VISIT QUESTIONNAIRE

TODAYS DATE: ___/___/___

DEMOGRAPHICS:

Name: Last _____

First _____

Address _____

Phone #: () ___-____ (home)

() ___-____ (work)

Medical Record #: _____
(for office use only)

Birthdate (MM/DD/YY): ___/___/___

Sex: Male / Female

Age at Interview _____

Race: White / Black / Hispanic (Black) / Hispanic (White) / Asian / Other _____

PERSONAL HABITS:

If you were smoking at your last visit, are you still smoking? YES / NO

If yes # _____ smoked per day.

FRACTURES:

Since you were last here,

Circle One

- | | |
|---|----------|
| 1. Have you broken your hip? | YES / NO |
| 2. Have you broken your spine? | YES / NO |
| 3. Have you broken your wrist? | YES / NO |
| 4. Have you broken any other bone? | YES / NO |
| If yes, which bone? _____ | |
| 5. Have you lost 2 inches or more in height? | YES / NO |
| 6. Have you noticed a change in the shape of your back/trunk? | YES / NO |

OTHER MEDICAL HISTORY:

Since you were last here, have you been diagnosed with any of the following:

- | | |
|--|----------|
| 1. Rheumatoid Arthritis - - - - - | YES / NO |
| 2. Osteoarthritis - - - - - | YES / NO |
| 3. Inflammatory bowel disease - - - - - | YES / NO |
| 4. Irritable bowel syndrome or Spastic Colon - - - - - | YES / NO |
| 5. Graves disease or Hyperthyroidism - - - - - | YES / NO |
| 6. Paget's disease - - - - - | YES / NO |
| 7. Kidney stones - - - - - | YES / NO |
| 8. Cancer - - - - - | YES / NO |
| 9. Asthma or chronic lung disease - - - - - | YES / NO |
| 10. Hypertension - - - - - | YES / NO |
| 11. Diabetes - - - - - | YES / NO |
| 12. High Cholesterol - - - - - | YES / NO |
| 13. Scoliosis (curvature of the spine) - - - - - | YES / NO |

WOMEN ONLY:

Since you were last here, if you were still menstruating then -

1. Have you now reached menopause or stopped menstruating? YES / NO

If yes, at what age? _____

2. Have you ever had a hysterectomy, (an operation to remove your uterus)? YES / NO

If yes, at what age? _____

3. Have you had one or both ovaries removed? YES / NO

If yes, at what age? _____

3. If you have not stopped menstruating or are currently going through menopause, how many menstrual cycles have you had in the past 12 months? _____ (#cycles)

Personnel on Grant**Position**

Allen, Jennifer	Phlebotomist
Burnett, Sarah	Phlebotomist
Byrd, Gilbert	Phlebotomist
Belin, Hermina	Phlebotomist
Cahill, Elizabeth	Phlebotomist
Chauntay, Callwood	Phlebotomist
Franklin, Ann	Phlebotomist
Grom, Teresa	Phlebotomist
Joy, Stacey	Phlebotomist
Lukazewski, Dale	Phlebotomist
McHale, Joy	Phlebotomist
Melancon, Nanette	Phlebotomist
Mutia, Grenico	Phlebotomist
Ortega, Felicia	Phlebotomist
Quider, Sheila	Phlebotomist
Richardson, Rebecca	Phlebotomist
Rivera, Robin	Phlebotomist
Rivera, Martha	Phlebotomist
Selesky, Debbie	Phlebotomist
Smith, Belinda	Phlebotomist
Vasquez, Joan	Phlebotomist
Vasquez, Mayelin	Phlebotomist
Westfall, Erin	Phlebotomist
Williams, Gail	Phlebotomist
Wilson, Michele	Phlebotomist
Zanetich, Jody	Phlebotomist
Garrett, Patricia	Radiation Technologist
Finkelstein, Cynthia	Data Specialist
Silberman, Judith	Data Specialist
Ruffing, Jamie	Research Scientist
Doherty, Kelly	Data Specialist
Cruz, Joann	Research Nurse
Moreno, Annette	Laboratory Technologist
Zion, Marsha	Research Scientist
Milosevski, Ljupco	Radiation Technologist
Barbuto, Nancy	Research Nurse
Vardy, Michael	OB/Gyn
Mellender, Helen	Data Assistant