APPENDIX B: RAW DATA TABLES

Table 4. Individual Body Weight Data – Pre-treatment

Subject	Group	Weight (kg)
1	H	81.5
2	H	125.3
3	H	93.2
4	H	89.1
5	H	105.2
6	M	130.5
7	H	122.3
8	M	95.7
9	M	143.2
11	M	145.5
12	H	138.7
13	M	92.3
14	M	96.2
Mean ± SEM		**112.2 ± 6.3**
H Group Mean ± SEM		**107.9 ± 8.1**
M Group Mean ± SEM		**117.2 ± 10.3**

Table 5. Individual Body Weight Data – Post-treatment

Subject	Group	Weight (kg)
1	H	78.5
2	H	125
3	H	91.8
4	H	85.0
5	H	98.0
6	M	129.5
7	H	115.5
8	M	95.5
9	M	135.9
11	M	143.7
12	H	142.0
13	M	87.5
14	M	92.0
Mean ± SEM		**109.2 ± 6.5**
H Group Mean ± SEM		**105.1 ± 8.7**
M Group Mean ± SEM		**114.0 ± 10.2**

Table 6. Pre-treatment BMI values for each subject.

Subject	Group	BMI (kg/m2)
1	H	26.9
2	H	34.1
3	H	28.7
4	H	28.1
5	H	32.8
6	M	43.8
7	H	35.6
8	M	33.0
9	M	38.9
11	M	35.2
12	H	40.9
13	M	30.9
14	M	28.4
Mean ± SEM		**33.6 ± 1.4**
H Group Mean ± SEM		**32.4 ± 1.9**
M Group Mean ± SEM		**36.9 ± 1.6**

Table 7. Post-treatment BMI values for each subject.

Subject	Group	BMI (kg/m2)
1	H	25.9
2	H	33.9
3	H	28.2
4	H	26.9
5	H	30.6
6	M	43.4
7	H	34.1
8	M	32.9
9	M	36.9
11	M	34.8
12	H	41.9
13	M	29.3
14	M	27.1
Mean ± SEM		**32.7 ± 1.5**
H Group Mean ± SEM		**31.7 ± 2.1**
M Group Mean ± SEM		**34.1 ± 2.4**

Table 8. Individual body composition data – Pre-treatment.

Subject	Group	%BF	FFM (kg)	FM (kg)
1	H	25.8	60.5	21.0
2	H	38.7	76.8	48.5
3	H	28.6	66.5	26.7
4	H	25.4	66.5	22.6
5	H	37.0	66.3	38.9
6	M	39.9	78.4	52.1
7	H	40.7	72.5	49.8
8	M	33.0	64.1	31.6
9	M	33.0	95.9	47.3
12	H	40.1	83.1	55.6
13	M	36.3	58.8	33.5
14	M	30.7	66.7	29.5
Mean ± SEM		**34.1 ± 1.6**	**71.3 ± 3.1**	**38.1 ± 3.5**
H Group Mean ± SEM		**33.8 ± 2.6**	**70.3 ± 2.9**	**37.6 ± 5.4**
M Group Mean ± SEM		**34.6 ± 1.6**	**72.8 ± 6.6**	**38.8 ± 4.5**

Table 9. Individual body composition data – Post-treatment.

Subject	Group	%BF	LBM (kg)	FM (kg)
1	H	26.3	57.9	20.7
2	H	38.6	76.8	48.3
3	H	26.1	67.8	23.9
4	H	21.9	66.4	18.6
5	H	33.0	65.7	32.3
6	M	39.8	77.9	51.5
7	H	40.8	68.4	47.1
8	M	29.8	67.0	28.5
9	M	25.9	100.7	35.2
12	H	39.7	85.6	56.4
13	M	29.4	61.8	25.7
14	M	28.7	65.6	26.4
Mean ± SEM		**31.7 ± 1.9**	**71.8 ± 3.4**	**34.6 ± 3.7**
H Group Mean ± SEM		**32.3 ± 2.9**	**69.8 ± 3.4**	**35.3 ± 5.7**
M Group Mean ± SEM		**30.7 ± 2.4**	**74.6 ± 7.1**	**33.5 ± 4.8**

Table 10. Subject body fat distribution values – Pre-treatment.

Subject	Group	WHR	WTR	Waist Cir. (cm)
1	H	0.89	1.48	90.42
2	H	1.00	1.73	119.63
3	H	0.98	1.66	105.41
4	H	0.89	1.52	95.50
5	H	0.91	1.48	103.63
6	M	0.91	1.63	118.11
7	H	0.91	1.54	114.80
8	M	0.86	1.28	93.98
9	M	0.95	1.54	121.92
11	M	0.90	1.7	122.68
12	H	0.87	1.6	118.87
13	M	0.87	1.55	101.09
14	M	0.88	1.63	97.54
Mean ± SEM		**0.91 ± 0.01**	**1.56 ± 0.03**	**107.97 ± 3.26**
H Group Mean ± SEM		**0.92 ± 0.02**	**1.57 ± 0.04**	**106.90 ± 4.32**
M Group Mean ± SEM		**0.90 ± 0.01**	**1.56 ± 0.06**	**109.22 ± 5.34**

Table 11. Subject body fat distribution values – Post-treatment.

Subject	Group	WHR	WTR	Waist Cir. (cm)
1	H	0.88	1.50	85.85
2	H	1.01	1.73	119.63
3	H	0.93	1.67	97.28
4	H	0.91	1.47	90.42
5	H	0.89	1.45	97.03
6	M	0.94	1.75	119.38
7	H	0.87	1.60	107.44
8	M	0.86	1.32	93.98
9	M	0.95	1.58	117.35
11	M	0.89	1.71	119.63
12	H	0.89	1.56	119.63
13	M	0.90	1.60	97.54
14	M	0.89	1.58	95.25
Mean ± SEM		**0.91 ± 0.01**	**1.57 ± 0.03**	**104.65 ± 3.56**
H Group Mean ± SEM		**0.91 ± 0.02**	**1.57 ± 0.04**	**102.47 ± 5.10**
M Group Mean ± SEM		**0.90 ± 0.01**	**1.59 ± 0.06**	**107.19 ± 5.22**

Table 12. Individual activities of HADH – Pre-treatment.

Subject	Group	Activity 1	Activity 2	Activity 3	Average
2	H	9.508	13.035	10.428	10.990
3	H	19.016	18.402	16.409	17.942
4	H	16.102	12.420	15.949	14.824
6	M	17.635	26.683	24.844	23.054
9	M	16.102	18.095	19.169	17.789
13	M	13.342	15.949	11.962	13.751
14	M	15.489	17.636	16.869	16.665
Mean ± SEM					**16.431 ± 1.443**
H Group Mean ± SEM					**14.585 ± 2.010**
M Group Mean ± SEM					**17.814 ± 1.943**

Table 13. Individual activities of HADH – Post-treatment.

Subject	Group	Activity 1	Activity 2	Activity 3	Average
2	H	26.530	19.323	20.703	22.185
3	H	35.425	28.677	36.805	33.636
4	H	32.051	26.990	32.664	30.568
6	M	23.157	34.045	36.805	35.425
9	M	18.556	18.403	19.169	18.709
13	M	18.709	15.182	24.996	19.629
14	M	26.837	18.863	25.734	23.811
Mean ± SEM					**26.281 ± 2.584**
H Group Mean ± SEM					**28.796 ± 3.422**
M Group Mean ± SEM					**24.394 ± 3.841**

Table 14. Individual nutrient intake for week 1.

Subject	Group	Total Energy (kJ)	Total Energy (kcal)	% Fat	%CHO	% Pro
1	H	8368	1999	30	38	32
2	H	5764	1377	47	28	25
3	H	12650	3022	24	64	12
4	H	7300	1744	30	46	16
5	H	12047	2878	27	53	20
6	M	15358	3669	22	65	13
7	H	8753	2091	25	64	11
8	M	12273	2932	34	53	13
9	M	13265	3169	35	48	16
11	M	19565	4674	37	45	18
12	H	21583	5156	16	53	12
13	M	13738	3282	21	62	17
14	M	10515	2512	24	58	12
Mean ± SEM		**12398 ± 1266**	**2961 ± 302**	**28 ± 2**	**52 ± 3**	**16 ± 1**
H Group Mean ± SEM		**10923 ± 2005**	**2609 ± 479**	**28 ± 4**	**49 ± 5**	**18 ± 3**
M Group Mean ± SEM		**14119 ± 1271**	**3373 ± 303**	**29 ± 3**	**55 ± 3**	**15 ± 1**

Table 15. Individual nutrient intake for week 4.

Subject	Group	Total Energy (kJ)	Total Energy (kcal)	% Fat	%CHO	% Pro
1	H	7979	1906	33	44	23
2	H	3654	873	38	37	25
3	H	10092	2411	24	62	14
4	H	10603	2533	11	54	29
5	H	7811	1866	15	58	27
6	M	17351	4145	33	49	18
7	H	8171	1952	26	37	37
8	M	10034	2397	35	50	15
9	M	9536	2278	29	49	22
11	M	12403	2963	28	46	26
12	H	28628	6839	33	46	15
13	M	8225	1965	30	46	24
14	M	6371	1522	23	65	9
Mean ± SEM		**10835 ± 1730**	**2588 ± 413**	**28 ± 2**	**49 ± 2**	**21 ± 2**
H Group Mean ± SEM		**10991 ± 3059**	**2626 ± 731**	**26 ± 4**	**48 ± 4**	**24 ± 3**
M Group Mean ± SEM		**10653 ± 1568**	**2545 ± 374**	**30 ± 2**	**51 ± 3**	**19 ± 3**

Table 16. Individual nutrient intake for week 7.

Subject	Group	Total Energy (kJ)	Total Energy (kcal)	% Fat	%CHO	% Pro
1	H	5555	1327	25	47	28
2	H	3562	851	27	35	38
3	H	11717	2799	31	54	15
4	H	5572	1331	29	48	17
5	H	8837	2111	16	65	19
6	M	11482	2743	27	55	18
7	H	10628	2539	17	69	13
8	M	10467	2500	24	55	19
9	M	20859	4983	22	58	19
11	M	11013	2631	23	54	23
12	H	19369	4627	15	73	12
13	M	9134	2182	20	59	22
14	M	7878	1882	39	46	14
Mean ± SEM		**10467 ± 1379**	**2500 ± 329**	**24 ± 1**	**55 ± 2**	**19 ± 1**
H Group Mean ± SEM		**9320 ± 2012**	**2226 ± 481**	**23 ± 3**	**56 ± 5**	**20 ± 4**
M Group Mean ± SEM		**11806 ± 1889**	**2820 ± 451**	**26 ± 3**	**54 ± 2**	**19 ± 1**

Table 17. Individual nutrient intake for week 9.

Subject	Group	Total Energy (kJ)	Total Energy (kcal)	% Fat	%CHO	% Pro
1	H	7041	1682	22	50	28
2	H	9863	2356	22	58	19
3	H	7706	1841	24	61	16
4	H	3851	920	33	42	17
5	H	8431	2014	15	64	20
6	M	12190	2912	33	44	17
7	H	11465	2739	19	66	15
8	M	9863	2356	22	58	19
9	M	7238	1729	15	62	23
11	M	12759	3048	14	66	20
12	H	18577	4438	21	64	13
13	M	4370	1044	18	55	26
14	M	14869	3552	27	60	13
Mean ± SEM		**9863 ± 1147**	**2356 ± 274**	**21 ± 1**	**57 ± 2**	**19 ± 1**
H Group Mean ± SEM		**9562 ± 1750**	**2284 ± 418**	**22 ± 2**	**58 ± 3**	**18 ± 2**
M Group Mean ± SEM		**10214 ± 1583**	**2440 ± 378**	**21 ± 3**	**57 ± 3**	**20 ± 2**

Table 18. Individual changes in energy intake from baseline.

Subject	Group	Week 1 to Week 4 (kJ)	Week 1 to Week 7 (kJ)	Week 1 to Week 9 (kJ)
1	H	-389	-2813	-1327
2	H	-2110	-2202	4099
3	H	-2558	-933	-4944
4	H	3303	-1728	-3449
5	H	-4236	-3210	-3616
6	M	1993	-3876	-3168
7	H	-582	1875	2712
8	M	-2239	-1806	-2410
9	M	-3729	7594	-6027
11	M	-7162	-8552	-6806
12	H	7045	-2214	-3006
13	M	-5513	-4604	-9368
14	M	-4144	-2637	4354
Mean ± SEM		**-1563 ± 1074**	**-1931 ± 1025**	**-2535 ± 1149**
H Group Mean ± SEM		**+67 ± 1463**	**-1603 ± 642**	**-1361 ± 1303**
M Group Mean ± SEM		**-3466 ± 1287**	**-2313 ± 2199**	**-3904 ± 1947**

APPENDIX C: ANOVA TABLES

Table 19. Two-Way Repeated Measures ANOVA table for weight changes over time.

Source of Variation	DF	SS	MS	F	P
Group	1	537.182	537.182	0.485	0.501
Subject (Group)	11	12185.332	1107.757		
Time	1	58.200	58.200	10.789	0.007
Group X Time	1	0.300	0.300	0.0556	0.818
Residual	11	59.338	5.394		
Total	25	12840.054	513.602		

Table 20. Two-Way Repeated Measures ANOVA table for BMI changes over time.

Source of Variation	DF	SS	MS	F	P
Group	1	41.235	41.235	0.697	0.422
Subject (Group)	11	651.198	59.200		
Time	1	4.832	4.832	11.102	0.007
Group X Time	1	0.0433	0.0433	0.0996	0.758
Residual	11	4.788	0.435		
Total	25	702.055	28.082		

Table 21. Two-Way Repeated Measures ANOVA table for %BF changes over time.

Source of Variation	DF	SS	MS	F	P
Group	1	19.639	19.639	0.256	0.624
Subject (Group)	10	767.220	76.722		
Time	1	40.568	40.568	13.822	0.004
Group X Time	1	8.723	8.723	2.972	0.115
Residual	10	29.350	2.935		
Total	23	841.753	36.598		

Table 22. Two-Way Repeated Measures ANOVA table for FM changes over time.

Source of Variation	DF	SS	MS	F	P
Group	1	126.289	126.289	0.370	0.556
Subject (Group)	10	3410.255	341.026		
Time	1	83.835	83.835	13.658	0.004
Group X Time	1	13.673	13.673	2.228	0.166
Residual	10	61.382	6.138		
Total	23	3560.970	154.825		

Table 23. Two-Way Repeated Measures ANOVA table for FFM changes over time.

Source of Variation	DF	SS	MS	F	P
Group	1	26.793	26.793	0.100	0.758
Subject (Group)	10	2671.899	267.190		
Time	1	2.464	2.464	0.888	0.368
Group X Time	1	8.042	8.042	2.900	0.119
Residual	10	27.731	2.773		
Total	23	2786.886	121.169		

Table 24. Two-Way Repeated Measures ANOVA table for waist circumference changes over time.

Source of Variation	DF	SS	MS	F	P
Group	1	80.048	80.048	0.252	0.626
Subject (Group)	11	3497.781	317.980		
Time	1	67.389	67.389	14.983	0.003
Group X Time	1	9.265	9.265	2.060	0.179
Residual	11	49.475	4.498		
Total	25	3708.280	148.331		

Table 25. Two-Way Repeated Measures ANOVA table for WHR changes over time.

Source of Variation	DF	SS	MS	F	P
Group	1	0.00173	0.00173	0.547	0.475
Subject (Group)	11	0.0348	0.00317		
Time	1	0.0000162	0.0000162	0.0545	0.820
Group X Time	1	0.000506	0.000506	1.708	0.218
Residual	11	0.00326	0.000296		
Total	25	0.0404	0.00161		

Table 26. Two-Way Repeated Measures ANOVA table for WTR changes over time.

Source of Variation	DF	SS	MS	F	P
Group	1	0.0000206	0.0000206	0.000688	0.980
Subject (Group)	11	0.329	0.0299		
Time	1	0.00152	0.00152	1.378	0.265
Group X Time	1	0.00249	0.00249	2.255	0.161
Residual	11	0.0122	0.00111		
Total	25	0.345	0.0138		

Table 27. Two-Way Repeated Measures ANOVA table for HADH activity changes over time.

Source of Variation	DF	SS	MS	F	P
Group	1	1.181	1.181	0.0213	0.890
Subject (Group)	5	276.833	55.367		
Time	1	370.481	370.481	46.297	0.001
Group X Time	1	49.925	49.925	6.239	0.055
Residual	5	40.012	8.002		
Total	13	707.523	54.425		

Table 28. Two-Way Repeated Measures ANOVA table for changes in energy intake (kJ) over time.

Source of Variation	DF	SS	MS	F	P
Group	1	25898859.386	25898859.386	0.350	0.566
Subject (Group)	11	814751681.690	74068334.669		
Time	3	49432769.247	16477589.749	1.569	0.216
Group X Time	3	29880688.324	9960229.441	0.948	0.429
Residual	33	346647763.214	10504477.673		
Total	51	1263277418.827	24770145.467		

Table 29. Two-Way Repeated Measures ANOVA table for changes in energy intake (kcal) over time.

Source of Variation	DF	SS	MS	F	P
Group	1	1657044.3971	1657044.397	0.388	0.546
Subject (Group)	11	46960951.833	4269177.439		
Time	3	2775520.112	925173.371	1.563	0.217
Group X Time	3	1464401.342	488133.781	0.825	0.490
Residual	33	19527986.119	591757.155		
Total	51	72216107.231	1416002.103		

Table 30. Two-Way Repeated Measures ANOVA table for changes in percent of fat consumed over time.

Source of Variation	DF	SS	MS	F	P
Group	1	35.044	35.044	0.526	0.483
Subject (Group)	11	732.524	66.593		
Time	3	373.870	124.623	2.410	0.085
Group X Time	3	47.385	15.795	0.305	0.821
Residual	33	1706.514	51.713		
Total	51	2889.417	56.655		

Table 31. Two-Way Repeated Measures ANOVA table for changes in percent of carbohydrates consumed over time.

Source of Variation	DF	SS	MS	F	P
Group	1	35.221	35.221	0.206	0.659
Subject (Group)	11	1880.803	170.982		
Time	3	474.208	158.069	2.252	0.101
Group X Time	3	98.148	32.716	0.466	0.708
Residual	33	2316.779	70.205		
Total	51	4830.361	94.713		

Table 32. Two-Way Repeated Measures ANOVA table for changes in percent of protein consumed over time.

Source of Variation	DF	SS	MS	F	P
Group	1	56.250	56.250	0.582	0.462
Subject (Group)	11	1064.026	96.7305		
Time	3	172.424	57.475	2.499	0.077
Group X Time	3	81.800	27.267	1.186	0.330
Residual	33	758.963	22.999		
Total	51	2139.361	41.948		

Table 33. Two-Way Repeated Measures ANOVA table for differences in energy intake from baseline.

Source of Variation	DF	SS	MS	F	P
Group	1	49588608.061	49588608.061	2.821	0.121
Subject (Group)	11	193381173.683	17580106.698		
Time	2	6005276.206	3002638.103	0.225	0.800
Group X Time	2	13258126.053	6629063.026	0.496	0.615
Residual	22	293853803.127	13356991.051		
Total	38	556342273.744	14640586.151		

APPENDIX D: INTERNAL REVIEW BOARD PROPOSAL

Virginia Tech
Department of Human Nutrition, Foods, and Exercise
Request for Approval of Research Proposal

Investigators: Roxann L. Polo, MS candidate and Janet Walberg-Rankin, PhD, advisor

TITLE:

The Effect of Interval Training on Obesity

PURPOSE:

The purpose of this study is to examine the effects of high intensity interval training on body composition, aerobic capacity, insulin and glucose metabolism, and skeletal muscle fat oxidation in obese subjects.

JUSTIFICATION OF PROJECT:

The recent **National Health and Nutritional Examination Survey III** study estimates that the percentage of Americans considered obese has increased from 25% to 33% of the population over the last 10 years (American Dietetic Association, 1997). Obese individuals have three times the risk of diabetes and hypertension and two times the risk of hypercholesterolemia (NIH, 1985). The development of safe and effective weight reduction strategies can have major public health benefits.

The combination of diet ad exercise is considered most appropriate for weight loss. However, the optimal exercise prescription is open to debate. Historically, exercise prescriptions for weight loss have been of moderate and constant intensity to maximize total energy and fat utilization (Atkinson and Walberg-Rankin, 1994). Several reports suggest that higher intensity exercise may be superior for both body fat loss and improved aerobic fitness.

Tremblay et al. (1990) surveyed over 2,500 people and found that those who reported engaging in vigorous activity on a regular basis had lower body fat than those who exercised at lower intensities.

Subsequently testing their hypothesis in a longitudinal study, Tremblay et al. (1994) compared the effects of a 20 week endurance training (ET) program and a 15 week high intensity intermittent training (HIIT) program on 27 male and female young adults. The ET group trained on an ergocycle program consisting of uninterrupted, constant intensity cycling 4 times a week for 30 minutes increasing to 5 times a week for 45 minutes. Exercise intensity was initially set at 60% and increased to 85% of maximal heart rate reserve over the 20 weeks. The HIIT group began with uninterrupted constant intensity training for 30 minutes at 70% of maximal heart rate. In addition, the HIIT group included short intervals consisting of 10 and later 15 X 30 second sessions and long intervals, 4-5 X 60 seconds increasing to 90 second sessions.

The sum of six skinfolds (estimate of body fat) tended to decrease more over the training period for HIIT even though the calculated energy expenditure of the exercise was less. When expressed per energy cost of exercise there was a significant decrease in body fat in the interval-

trained group when compared tot he endurance trained group. This study suggests that there is a greater decrease in fat with HIIT than with ET.

Data suggests that acute exercise improves insulin sensitivity and glucose tolerance, but the importance of exercise intensity is unclear. Ben-Ezar et al. (1995) concluded that exercise intensity rather than total energy expenditure plays a significant role in improving glucose tolerance. Twenty-four untrained non-obese women with normal insulin response exercise for either 50 minutes at 70% VO_2max, 85 minutes at 40% VO_2max, or not at all. The higher intensity group showed significantly lower insulin responses to an oral glucose tolerance test. No change was noted for the lower intensity exercise bout. This study favors the importance of exercise intensity over total energy expenditure in decreasing post-exercise insulin response.

Braun et al. (1995) studied the effects of exercise intensity on insulin sensitivity in women with non-insulin dependent diabetes mellitus (NIDDM). Eight women with NIDDM were each studied under three conditions, low intensity exercise (treadmill walking at 50% VO_2max), high intensity exercise (treadmill walking at 75% VO_2max), and no exercise. Energy expenditure was equalized in all conditions by variations in total duration. Insulin sensitivity, as measured one day after each condition showed identical improvements for both exercise groups as compared to the no exercise condition. This study showed improved insulin sensitivity due to exercise but no significant difference in the effect between high and low intensity exercise. This suggests total energy expenditure rather than specific exercise intensity is more important for improving glucose metabolism.

The potential value of chronic HIIT for improving glucose tolerance is yet to be established. The increased glycogen use and eventual depletion in high intensity exercise may improve glucose tolerance more effectively than moderate constant intensity exercise. Research in this area need to examine insulin sensitivity and glucose tolerance in the obese population focusing on chronic HIIT and its effects on insulin sensitivity and glucose tolerance.

The effect of various training intensities on muscle fuel utilization has not been well studied. Tremblay et al. (1994) looked at the biochemical adaptation of skeletal muscle to different exercise intensities. They demonstrated a significantly greater skeletal muscle enzyme 3-hydroxacyl dehydrogenase (HADH), a marker of ß-oxidation (fat breakdown) by the HIIT group relative to the ET group. This may suggest a potential explanation for enhanced body fat loss and improved ability of muscle to oxidize fat by the HIIT group when compared to the ET group.

In conclusion, research to date has not determined the ideal exercise prescription (i.e., moderate of high intensity, constant or interval). Some studies suggested that interval training could be of greater benefit then moderate, constant intensity exercise in the treatment of obesity. Clinical practicality of prescribing HIIT in the obese population needs additional investigation. Therefore, this study will examine the effects of HIIT on body composition, aerobic capacity, insulin and glucose metabolism, and skeletal muscle fat oxidation in obese subjects.

METHODS:

Subjects and Design

Twenty-four untrained moderately obese males between 20 and 40 years of age with a BMI $\geq$ 25 and $\leq$ 33 kg/m^2 will be recruited for a **12 week study.** The potential subjects will be medically screened to disqualify individuals with major risk factors such as **cardiovascular disease, diabetes, pulmonary disease, seizures, mental illness (Beck inventory),**

hypoglycemia, and orthopedic limitations (appendix A). High risk individuals will be identified using ACSM's guidelines for exercise and testing prescription. Subjects will be divided into two groups of 12 with both groups receiving the same diet counseling. Groups will participate in a twelve-week exercise program consisting of either a moderate constant intensity or high intensity interval cycling protocol. Pre and post testing to measure body composition, aerobic capacity (fitness), glucose tolerance, and a skeletal muscle fat oxidative enzyme will be conducted on both groups.

Diet

Diet treatment will consist of a weekly 45-minute group nutrition education class to limit your fat intake to 20-25% of caloric intake and modest energy restriction (-500 kcal/day). Diet records will be performed four times (0, 3, 6, 9, 12 wk) to assess your dietary intake during the study. You will be instructed and also given descriptive packets in which to write down everything you eat over a three-day duration for each dietary measurement period. Diet records will be analyzed using the Nutritionist III program.

Moderate Constant Intensity Exercise Protocol

All exercise sessions will be conducted in the Laboratory for Health and Exercise in War Memorial Hall and supervised by undergraduate and graduate students from the department of Human Nutrition, Foods, and Exercise (HNFE). Heart rate will be monitored to validate exercise intensity **and resistance on the bike will be altered to maintain appropriate heart rate**. The moderate constant intensity protocol will begin cycling at 40% VO_2max for 15 minutes increasing to 45% VO_2max for 20 minutes by week four. Beginning at week five you will increase 5% VO_2max every two weeks reaching 60% VO_2max by week 9. Energy expenditure will be equally matched between the moderate intensity and high intensity groups for all sessions. **Exercise will be stopped if any subject complains of symptoms suggesting cardiovascular problems (i.e. dizziness, nausea, and chest pain). In this case, subjects will lie down on a cot. The rescue squad will be called if symptoms do not cease.**

High Intensity Interval Exercise Protocol

The high intensity interval group protocol will begin cycling at 40% VO_2max for 15 minutes, increasing to 45% VO_2max for 20 minutes by week four. Heart rate will be monitored to evaluate exercise intensity. In addition, subjects will perform three high intensity interval sessions per week beginning at week five. Each week will include three exercise sessions: short interval, medium interval, and long interval. Each exercise session will include a total of eight to twelve minutes of high intensity exercise and a five minute warm-up and warm-down at 50% VO_2max. The short session will consist of 16 X 30 second intervals beginning at 80% of VO_2max and increasing 5% each week to 100% VO_2max by week 8. This workload will be maintained weeks 9-12. Each 30 second interval will be followed by a 60 second interval at 40% VO_2max. The medium session will consist of 6 X 90 second intervals beginning at 70% VO_2max and increasing 5% each week to 90% VO_2max by week 8. This workload will be maintained weeks 9-12. Each 90 second interval will be followed by a 2 minute interval at 40% VO_2max. The long session will consist of 4 X 3 minute intervals beginning at 65% VO_2max and increasing 5% each week to 85% VO_2max by week 8. This workload will be maintained weeks 9-12. Each three minute interval will be followed by a three minute interval at 40% VO_2max. All exercise sessions will be supervised and heart rate will be monitored to validate exercise

intensity. (Note that this protocol will be pilot tested and alterations made as needed to make it tolerable to obese, untrained individuals)

Body Weight

Body weight will be measured to the nearest 0.1 kg on a medical scale each week.

Body Composition

Pre and post body composition will be measured through **underwater** weighing using the three highest measurements from eight submersions. The subject will **wear a bathing suit and sit in a chair** in a tank of warm (95°F) filtered water. The subjects will then be asked to make a forced maximal exhalation as you lower your head underwater. The subjects will be asked to remain submersed for 2-4 seconds while body weight is measured. Weighing procedure is repeated 8 times because the subjects "learn" to expel more air from your lungs with each additional trial. The average of the last 2-3 trials represents your true underwater weight. Residual lung volume is the volume of air that remains in the lungs after one exhales maximally. Residual lung volume will be measured by the oxygen dilution technique. Residual lung volume will be measured by having the subjects breathe 5 times into a bag filled with oxygen. Residual volume is determined following assessment of the oxygen and carbon dioxide content of the bag.

Aerobic Capacity

Aerobic capacity will be measured using a cycle ergometer test protocol. Oxygen consumption will be measured by indirect calorimetry using a Medgraphics metabolic cart. The subject will be seated on a stationary bicycle and the seat will be adjusted for comfort. The subject will then be fitted with a mouthpiece, nose clip, and breathing tube. One end of the breathing tube will open to room air allowing the subject to breathe freely. The opposite end of the breathing tube will be connected to the Medgraphics metabolic cart to analyze expired air during exercise. The subject will then begin cycling with a three-minute warm-up before beginning at a work rate of 0.5 kp (easy) with work rate increased by 0.5 kp every three minutes until voluntary maximal effort. Rate per minute (RPM) will be maintained at 60 throughout the test. Maximal oxygen consumption and maximal heart rate will be determined from the point of highest oxygen consumption. This information will be used to assess fitness and also to prescribe the exercise for each individual training program.

Glucose Tolerance

The subjects will be asked to consume a prescribed dinner the evening prior to the glucose tolerance test. **You will be given several sample menus for the prescribed dinner that you will prepare on your own. The dinner will contain approximately 600 kcal (60% carbohydrate, 20% protein, and 20% fat).** Subjects will be tested between 7:30 and 9:30 am after a 12-14 hour fast. A 75 g glucose (sugar) solution and 5 ml blood samples will be drawn immediately before and at 30, 60, 90, 120, and 150 minutes after ingestion via venipuncture. Samples will be collected in sterile tubes containing EDTA and immediately centrifuged. Plasma will then be stored at –80°C. Plasma will be analyzed for glucose spectrophotometrically and for insulin by radioimmunoassay.

Skeletal Muscle Enzyme and Fuel Utilization

The skeletal muscle enzymes HADH, hexokinase, and citrate synthase will be measured from vastus lateralis muscle biopsies. Muscle biopsies will be performed pre and post exercise training. The subject will be placed in a reclined position. All hair will be shaved from the site and the area will be cleaned with iodine antiseptic. A sterile drape will be placed over the skin site. The site will then be numbed with ethyl chloride spray. A local anesthetic (xylocaine, 1.5cc) will be injected with a 25 gauge needle over the proposed incision site in 3-4 punctures (3 cm area in diameter). A scalpel blade will be used to make a 1.5-cm incision through skin and fascia. Immediate pressure will be applied with a sterile 4 x 4-gauze pad until bleeding ceases. A sterile biopsy needle is then inserted into the incision and the tip is pressed lightly against the fascia. The needle will be inserted 2 cm into the muscle. This will be perceived as pressure to the subject and may result in muscle cramping. Once in position the needle is opened and suction is applied by the assistant. The needle is then closed to cut the muscle and suction is released. The needle is withdrawn from the muscle. Total muscle sample is 25-75 mg, approximately the size of half a pencil eraser. Total time to insert the needle, cut the sample and withdraw the needle is 5-10 seconds. Pressure will be applied with sterile gauze for 20 minutes along with a cold pack to minimize bleeding and soreness. The incision will be closed with steristrip and Band-Aid. Pressure bandage will be applied and left on for eight hours. The steristrip and Band-Aid will be left on the leg for three days. Subjects will be encouraged to continue their normal routines to prevent stiffness. Subjects will also be educated on signs of infection and asked to contact researchers in the event of any indications of such. Subjects will be asked to remain in laboratory for 20 minutes after completion of the biopsy and **return to the laboratory to show the experimenter the incision for two days following each biopsy.** Each sample will be weighed and frozen in liquid nitrogen and stored at –80°C for later analysis.

Recruitment and Time Line

Subjects will be recruited by announcements in both **faculty and student publications and possible contacts with self help groups and private physicians** during February/March 1998. Screening will consist of a detailed group explanation and instruction session. Potential subjects will be allowed to consider participation over a 72 hour time frame and be asked to **read and sign an informed consent form**. **Each individual will be required to complete our medical screening form and receive written permission from their physician (they will be asked to have the physician read the informed consent, which outlines contraindications and procedures).** Final selection and notification will be completed by March 20, 1998. **We will test each subject's blood pressure and go over the medical screening form orally prior to their participation. Pre-testing will be conducted March 21-April 5, 1998. Exercise programs will begin April 6, 1998 and conclude June 22, 1998. Post-testing will be conducted June 23-July 5, 1998.**

POSSIBLE RISKS OF PARTICIPATION:

1. Exercise testing and training – Fatigue, muscle soreness, muscle strains/pulls, tendinitis and bursitis **may result for exercise testing and prescribed exercise protocols**. Additional exercise testing and training risk factors include irregular heart rhythm and unexpected sudden death. **Note that risk of irregular heart rhythm and/or unexpected deaths are extremely low. The incidence of cardiac arrest for**

male joggers is 1 per 18,000 men (ACSM guidelines). There are no scientifically based studies of exercise –related cardiac events among women.

2. Muscle biopsies – Scarring, minor swelling and/or bruising, fainting **due to blood removal or needle muscle biopsy**, allergic reaction to anesthetic and **possible risk of infection at biopsy site**.

3. Glucose tolerance – minor swelling and/or bruising, fainting, and infection at **site of venipuncture**.

4. **Energy restricted diet – hunger, irritability, constipation, and fatigue may result from a low calorie diet. However, symptoms if present will be alleviated after a return to unrestricted caloric intake.**

All exercise testing, prescribed exercise protocols and physiological procedures will be carefully performed and monitored in a controlled environment and risk of injury and/or sudden death will be minimal. Precaustions (see "efforts to minimize risk" below) will be taken at all times to ensure your safety and comfort. In addition you will have written approval to participate from your primary care physician.

EFFORTS TO MINIMIZE RISK:

1. American College of Sports Medicine guidelines (appendix B) will be used to eliminate high risk subjects who require further medical evaluation and an exercise stress test by a physician.

2. All supervision of exercise sessions will be done by undergraduate or graduate students in the HNFE department. **All student exercise assistants will be trained concerning exercise training and emergency procedures by the principal investigator and faculty advisor.** Only students certified in CPR and first aid will be eligible to help in the exercise sessions.

3. All phlebotomy procedures will be done by a certified medical technician from the HNFE department. **Blood will be screened for HIV if there is exposure of blood or muscle to any experimenter. This will be done immediately upon exposure to provide a baseline value and identify possible infection. Thus, if they already have HIV prior to exposure to your blood, any subsequent infection will not be attributable to this exposure.**

4. All muscle biopsies will be done by a certified medical technician from HNFE department and in the presence of a physician thus, minimizing the chance of described complications. The medical technician has previously completed more than 90 biopsies without any complications. **You will be instructed on proper care of your biopsy site further reducing risk of infection. In the case of injury or infection medical expenses will not be covered unless Virginia Tech is found negligent.**

5. Researchers who will handle blood or muscle tissue will comply with OSHA regulations for the handling of human samples.

6. In the event of a medical emergency, lab procedures will be followed (appendix C) and a telephone will be accessible and used to call the **Virginia Tech rescue squad**.

7. We will ask you about know allergies to lidocaine (novocaine) and sensitivity to iodine on written screening forms and then again verbally just prior to the biopsy.

BENEFITS OF PARTICIPATION:

1. Diet analysis and education – **Proper nutrition is central to the maintenance of optimal health. Many chronic diseases are a result of dietary deficiencies or excesses and may be eliminated with proper nutrition. Diet analysis will provide you with valuable information concerning current nutritional status while educational meetings will provide guidelines for nutritional improvement and prevention of disease.**

2. Body composition analysis – **Many chronic disease such as coronary heart disease and diabetes have been linked to excess body fat. Body composition analysis will determine your body density and from this measurement the ratio of lean body mass to body fat can be calculated. Underwater weighing is considered the "gold standard" in body composition analysis and will provide you with valuable information concerning current lean body mass and hence determine individual optimal values obtainable through proper diet and exercise.**

3. Fitness assessment and prescribed fitness program – **A combination of diet and exercise offers the best solution to achieving and maintaining desired weight loss and optimal cardiovascular fitness. Your current fitness level will be assessed and an exercise program designed to improve overall cardiovascular fitness and weight loss will be implemented. This program will provide you with a foundation for the continuation of a life fitness program.**

4. Glucose tolerance – **Glucose tolerance measured the body's ability to use the pancreatic hormone insulin to transport glucose from the blood stream into the cell for use in body metabolism. This information is critical in the prevention of obesity and chronic diseases such as diabetes.**

5. If supplementary funding is obtained researchers will offer up to $100 per subject for study participation.

CONFIDENTIALITY AND ANONYMITY:

All individual data of this study will be kept strictly confidential. Without prior written consent, at no time will the researcher release or discuss the results of a test with anyone other then other researchers working on the study. The information provided and all results and data will be identified by number only, all name references will be removed. The results will be reported as group averages in future publications and presentations.

CONSENT:

In order to participate an informed signed consent explaining detailed testing procedure, require time, conditions, and subjects responsibility will be obtained. Subjects will be informed they may withdraw for the study at any time. Subjects will also be informed that their dismissal at any point from the study is at the discretion of the researchers.

BIOGRAPHICAL SKETHCH:

Janet Walberg-Rankin, PhD, Faculty Advisor: She received a bachelor's degree in zoology from Duke University and doctorate in nutrition with a minor in exercise physiology from the University of California at Davis. She has been on the faculty at Virginia Tech since 1982 and is currently an Associate Professor in the Department of Human Nutrition, Foods, and Exercise. She teaches undergraduate classed in "Exercise Physiology" and "Nutrition and Physical Performance" as well as a graduate class in "Metabolic Aspects of Exercise". Her primary research areas are nutrition manipulations in athletes and weight control. Her research has been published in journals such as: International *Journal of Sports Nutrition, Medicine and Science in Sports and Exercise, and International Journal of Sports Medicine.*

Roxann L. Polo, MS candidate: Graduate student in the Nutrition for Sport and Chronic Disease Option in the Department of Human Nutrition, Foods, and Exercise. She received her bachelor's degree in biology with a minor in psychology from Virginia Tech. She is currently certified in CPR and First Aid. She has worked in human research at the University of Texan Southwestern Medical School, Baylor Hospital, Dallas Texas and has assisted with other research projects at Virginia Tech. She is currently an assistant coach for the Women's Virginia Tech Track and Field team. She will be doing a medical preceptorship through the Virginia Tech honors department in the fall of 1997.

APPENDIX E: INFORMED CONSENT

Virginia Tech
Department of Human Nutrition, Foods, and Exercise

Informed Consent for Participants of Investigative Projects

PRINICPAL INVESTIGATORS:

Roxann L. Polo, MS candidate and Dr. Janet Walberg Rankin, PhD, advisor

TITLE:

The Effects of Differing Exercise Intensities on Weight Loss

PURPOSE:

The recent National Health and Nutritional Examination Survey III study estimates that the percentage of Americans considered obese has increased from 25% to 33% of the population over the last 10 years (American Dietetic Association, 1997). Obese individuals have three times the risk of diabetes and hypertension and two times the risk of hypercholesterolemia (NIH, 1985). The development of safe and effective weight reduction strategies can have major public health benefits.

The combination of diet ad exercise is considered most appropriate for weight loss. However, the optimal exercise prescription is open to debate. Historically, exercise prescriptions for weight loss have been of moderate and constant intensity to maximize total energy and fat utilization (Atkinson and Walberg-Rankin, 1994). Several reports suggest that higher intensity exercise may be superior for both body fat loss and improved aerobic fitness.

The purpose of this study is to compare the effects of constant, moderate intensity to high intensity interval training (sprints with low intensity exercise between) on body composition, fitness, insulin and glucose metabolism, and skeletal muscle fat oxidation in weight loss treatment.

The importance of exercise intensity for decreasing body fat, improving both aerobic and anaerobic systems, improving insulin sensitivity and glucose tolerance and improving muscle fat oxidation capacity is controversial. This study will compare the effects of two exercise prescriptions on body composition, aerobic capacity, insulin and glucose metabolism, and skeletal muscle fat oxidation in overweight subjects.

PROCEDURES:

Subjects will be randomly divided into two groups of 12 with both groups receiving the same diet counseling. Groups will participate in a twelve week exercise program consisting of either a moderate constant intensity or high intensity interval cycling protocol. Pre and post testing to measure body composition, aerobic capacity (fitness), glucose tolerance, and a skeletal muscle fat oxidative enzyme will be conducted on both groups.

Body Weight

Body weight will be measured to the nearest 0.1 kg on a medical scale each week.

Body Composition

Pre and post body composition will be measured through underwater weighing using the three highest measurements from eight submersions. You will wear your bathing suit and sit in a chair in a tank of warm (95°F) filtered water. You will then be asked to make a forced maximal exhalation as you lower your head underwater. You will be asked to remain submersed for 2-4 seconds while body weight is measured. Weighing procedure is repeated 8 times because you will "learn" to expel more air from your lungs with each additional trial. The average of the last 2-3 trials represents your true underwater weight. Residual lung volume is the volume of air that remains in the lungs after one exhales maximally. Residual lung volume will be measured by having you breathe 5 times into a bag containing oxygen.

Aerobic Capacity

Pre and post aerobic capacity (cardiovascular fitness) will be measured using a stationary bicycle. You will be seated on a stationary bicycle and the seat will be adjusted for comfort. You will then be fitted with a mouthpiece, nose clip, and breathing tube. One end of the breathing tube will open to room air allowing you to breathe freely. The opposite end of the breathing tube will be connected to a machine to analyze expired air during exercise. You will then begin cycling with a 5-10 minute warm-up before beginning at a set work rate, which will be increased slightly every three minutes until your maximal effort is obtained. Maximal oxygen consumption and maximal heart rate will be determined from the point of maximal effort.

Glucose Tolerance

The ability of your body to handle glucose will be measured before and after training program with an oral glucose tolerance test. You will be asked to consume a prescribed dinner the evening prior to the glucose tolerance test. You will be given several sample menus for the prescribed dinner that you will prepare on your own. The dinner will contain approximately 600 kcal (60% carbohydrate, 20% protein, and 20% fat). You will be tested between 7:30 and 9:30 am after a 12-14 hour fast. You will be asked to ingest a 75 g glucose (sugar) solution and blood samples will be drawn immediately before and at 30, 60, 90, 120, and 150 minutes after ingestion via venipuncture. Blood will be drawn in a seated position by a certified medical technician from the department of Human Nutrition, Foods, and Exercise. This test requires approximately three hours to complete.

Skeletal Muscle Enzyme and Fuel Utilization

Pre and post exercise training, muscle biopsies of your thigh muscle will be performed by a certified medical technician from the department of Human Nutrition, Foods, and Exercise and in the presence of a physician using the following procedure. You will be asked to lie flat on a cot. The hair on a small area of your leg will be shaved and cleaned with iodine, an antiseptic that will temporarily turn the skin yellow. A sterile drape will be placed over the skin site and a substance designed to cool and numb the area (ethyl chloride) will be sprayed on the skin site. A local anesthetic (xylocaine) will be injected with a needle over the site in several punctures. This will sting slightly. After the area is numb, an incision (about 1.5 cm) will be made in the skin with a scalpel blade. Pressure will be applied to the area with sterile gauze for several minutes to reduce bleeding. A sterile biopsy needle about the diameter of a pencil will then be inserted

about 2.0 cm into your thigh. A piece of muscle about half the size of a pencil eraser (25-75 mg) will be removed. The time required to insert the needle and remove the sample is about 3-5 seconds. Pressure will be applied to the area for 20 minutes in addition to a cold pack for 5 minutes to reduce bleeding and any swelling. The incision will then be closed with a sterile strip and Band-Aid. The incision does not need to be closed with stitches. You will have a small scar as a result of the incision. You will remain in the laboratory for at least 20 minutes after the biopsy so that pressure can be applied to the site and we can be certain you are okay. You will be asked to keep a pressure wrap on the leg for 8 hours after the biopsy and the sterile strip and Band-Aid for 3 days. You will be encouraged to stay on your daily routine and to use the leg as you normally do. This will reduce stiffness. You will be instructed to keep the site clean to avoid infection. You will be asked to return to the lab in 2 days so we may examine the area for appropriate healing.

Diet

Diet treatment will consist of a weekly 45 minute group nutrition education class to limit your fat intake to 20-25% of caloric intake and modest energy restriction (-500 kcal/day). Diet records will be performed four times (0, 3, 6, 9, 12 wk) to assess your dietary intake during the study. You will be instructed and also given descriptive packets in which to write down everything you eat over a three day duration for each dietary measurement period. Diet records will be analyzed using the Nutritionist III program.

Moderate Constant Intensity Exercise Protocol

If you are assigned to the moderate constant intensity group you will begin cycling at 40% VO_2max for 15 minutes increasing to 45% VO_2max for 20 minutes by week four. Beginning at week five you will increase 5% VO_2max every two weeks reaching 60% VO_2max by week 9. Energy expenditure will be equally matched between the moderate intensity and high intensity groups for all sessions. All exercise sessions will be supervised and heart rate will be monitored to validate exercise intensity. All exercise sessions will be conducted in the Laboratory for Health and Exercise in War Memorial Hall (room 230) and supervised by undergraduate or graduate students from the department of Human Nutrition, Foods, and Exercise.

High Intensity Interval Exercise Protocol

If you are assigned to the high intensity interval group you will begin cycling at 40% VO_2max for 15 minutes, increasing to 45% VO_2max for 20 minutes by week four. Heart rate will be monitored to evaluate exercise intensity. In addition, you will perform three high intensity interval sessions per week beginning at week five. Each week will include three exercise sessions: short interval, medium interval, and long interval. Each exercise session will include a total of eight to twelve minutes of high intensity exercise and a five minute warm-up and warm-down at 50% VO_2max. The short session will consist of 16 X 30 second intervals beginning at 80% of VO_2max and increasing 5% each week to 100% VO_2max by week 8. This workload will be maintained weeks 9-12. Each 30 second interval will be followed by a 60 second interval at 40% VO_2max. The medium session will consist of 6 X 90 second intervals beginning at 70% VO_2max and increasing 5% each week to 90% VO_2max by week 8. This workload will be maintained weeks 9-12. Each 90 second interval will be followed by a 2 minute interval at 40% VO_2max. The long session will consist of 4 X 3 minute intervals beginning at 65% VO_2max and increasing 5% each week to 85% VO_2max by week 8. This

workload will be maintained weeks 9-12. Each three minute interval will be followed by a 3 minute interval at 40% VO_2max. All exercise sessions will be supervised and heart rate will be monitored to validate exercise intensity. All exercise sessions will be conducted in the Laboratory for Health and Exercise in War Memorial Hall (room 230) and supervised by undergraduate or graduate students from the department of Human Nutrition, Foods, and Exercise.

REQUIRED TIME AND CONDITIONS:

1. Initial meeting and required health screening, 1-1.5 hours.
2. Pre and post body composition and residual volume assessment, 1-1.5 hours.
3. Pre and post aerobic capacity assessment, cycle ergometer protocol, 1-1.5 hours.
4. Pre and post muscle biopsy, 45 minutes.
5. Diet education and records, 1 hour per week.
6. Cycle exercise program, 15-40 minutes 3-4 times a week for 12 weeks.
7. Glucose tolerance test, 3 hours.

POSSIBLE RISKS OF PARTICIPATION:

1. Exercise testing and training – Fatigue, muscle soreness, muscle strains/pulls, tendinitis and bursitis may result for exercise testing and prescribed exercise protocols. Additional exercise testing and training risk factors include irregular heart rhythm and unexpected sudden death. Note that risk of irregular heart rhythm and/or unexpected deaths are extremely low. The incidence of cardiac arrest for male joggers is 1 per 18,000 men (ACSM guidelines). There are no scientifically based studies of exercise –related cardiac events among women.

2. Muscle biopsies – Scarring, minor swelling and/or bruising, fainting due to blood removal or needle muscle biopsy, allergic reaction to anesthetic and possible risk of infection at biopsy site.

3. Glucose tolerance – minor swelling and/or bruising, fainting, and infection at site of venipuncture.

4. Energy restricted diet – hunger, irritability, constipation, and fatigue may result from a low calorie diet. However, symptoms if present will be alleviated after a return to unrestricted caloric intake.

All exercise testing, prescribed exercise protocols and physiological procedures will be carefully performed and monitored in a controlled environment and risk of injury and/or sudden death will be minimal. Precaustions (see “efforts to minimize risk” below) will be taken at all times to ensure your safety and comfort. In addition you will have written approval to participate from your primary care physician.

EFFORTS TO MINIMIZE RISK:

1. American College of Sports Medicine guidelines (appendix B) will be used to eliminate high risk subjects who require further medical evaluation and an exercise stress test by a physician.

2. All supervision of exercise sessions will be done by undergraduate or graduate students in the HNFE department. All student exercise assistants will be trained concerning exercise training and emergency procedures by the principal investigator and faculty advisor. Only students certified in CPR and first aid will be eligible to help in the exercise sessions.

3. All phlebotomy procedures will be done by a certified medical technician from the HNFE department. Blood will be screened for HIV if there is exposure of blood or muscle to any experimenter. This will be done immediately upon exposure to provide a baseline value and identify possible infection. Thus, if they already have HIV prior to exposure to your blood, any subsequent infection will not be attributable to this exposure.

4. All muscle biopsies will be done by a certified medical technician from HNFE department and in the presence of a physician thus, minimizing the chance of described complications. The medical technician has previously completed more than 90 biopsies without any complications. You will be instructed on proper care of your biopsy site further reducing risk of infection. In the case of injury or infection medical expenses will not be covered unless Virginia Tech is found negligent.

5. Researchers who will handle blood or muscle tissue will comply with OSHA regulations for the handling of human samples.

6. In the event of a medical emergency, lab procedures will be followed (appendix C) and a telephone will be accessible and used to call the Virginia Tech rescue squad.

7. We will ask you about know allergies to lidocaine (novocaine) and sensitivity to iodine on written screening forms and then again verbally just prior to the biopsy.

BENEFITS OF PARTICIPATION:

1. Diet analysis and education – Proper nutrition is central to the maintenance of optimal health. Many chronic diseases are a result of dietary deficiencies or excesses and may be eliminated with proper nutrition. Diet analysis will provide you with valuable information concerning current nutritional status while educational meetings will provide guidelines for nutritional improvement and prevention of disease.

2. Body composition analysis – Many chronic disease such as coronary heart disease and diabetes have been linked to excess body fat. Body composition analysis will determine your body density and from this measurement the ratio of lean body mass to body fat can be calculated. Underwater weighing is considered the “gold standard” in body composition analysis and will provide you with valuable information concerning current lean body mass and hence determine individual optimal values obtainable through proper diet and exercise.

3. Fitness assessment and prescribed fitness program – A combination of diet and exercise offers the best solution to achieving and maintaining desired weight loss and optimal cardiovascular fitness. Your current fitness level will be assessed and an exercise program designed to improve overall cardiovascular fitness and weight loss will be implemented. This program will provide you with a foundation for the continuation of a life fitness program.

4. Glucose tolerance – Glucose tolerance measured the body's ability to use the pancreatic hormone insulin to transport glucose from the blood stream into the cell for use in body metabolism. This information is critical in the prevention of obesity and chronic diseases such as diabetes.

5. If supplementary funding is obtained researchers will offer up to $100 per subject for study participation.

APPROVAL OF RESEARCH:

This project has been approved by the Institutional Review Board for projects involving subjects at Virginia Tech. You will receive a copy of this form.

SUBJECTS RESPONSIBILITIES:

I know of no reason why I cannot participate in this study. I have the following responsibilities:

1. To advise the researchers of any pre-existing medical problems that may affects my participation such as, but not limited to diabetes, heart conditions, muscle, bone, or joint problems, major organ diseases, allergies to lidocaine/novocaine or sensitivity to iodine.
2. To advise of any medical problems that might arise in the course of this study such as signs of strain, sprains, pulls, tendinitis, or bursitis; any signs and/or symptoms of illness or infection of the muscle biopsy site.
3. Perform only prescribed exercise.
4. Adhere to prescribed diet.
5. Give maximal efforts on all required maximal testing.

Should you have any questions regarding any of the above please ask an investigator.

CONFIDENTIALITY AND ANONYMITY:

All individual data of this study will be kept strictly confidential. Without prior written consent, at no time will the researcher release or discuss the results of a test with anyone other then other researchers working on the study. The information provided and all results and data will be identified by number only, all name references will be removed. The results will be reported as group averages in future publications and presentations.

WITHDRAWAL:

You are free to withdraw from this study at any time without penalty. If circumstances arise such as:

1. Failure to comply with prescribed exercise or diet.
2. Illness.
3. Other unforeseen circumstances.

The investigator may determine at any time during this study that you may no longer continue and you will be removed from the study.

SUBJECT'S PERMISSION:

I, (please print full name) _____ have read and understand the informed consent and conditions of this study. I have had all my questions answered. I thereby acknowledge the above and give my voluntary consent for participation in this study. I understand that I am free to withdraw at anytime. I agree to abide by the rules of this study.

Signature of Participant:

_____ Date: _____

Signature of Investigator:

_____ Date: _____

Should I have any questions about procedure or conduct, I may contact:

Janet Walberg-Rankin, PhD
Associate Professor
Department of Human Nutrition, Foods, and Exercise
231-6355

Roxann L. Polo
Master's Candidate
Department of Human Nutrition, Foods, and Exercise
953-5580

Tom Hurd, PhD
Chairman of the IRB at Virginia Tech
231-5281

APPENDIX F: SUBJECT INSTRUCTIONS

GENERAL INFORMATION AND INSTRUCTIONS

Underwater weighing:

Things to bring: towel, shorts to wear in the tank

How it works: you will be in a tank (like an oversized bathtub) sitting on a chair that is suspended from a bar across the top of the tank. You will make sure that no part of your body is touching any part of the tank (arms and legs should be resting on the chair). Next, you will blow out all of your air and lean forward completely submerging your body under the water. If you have any excess air in your body you will blow it out as soon as possible. Once all of the air is out you will remain under the water for about 3 seconds so that the computer can take a reading of your underwater weight. This procedure will be repeated 8 times.

There will be some practice times before an actual reading is taken to allow you to become familiar with the procedure. Also, it is important that all of your air be expelled, this allows for the most accurate reading. Will be done before and after the training program.

Residual volume:

Things to bring: nothing, will be done same day as underwater weighing, so remember towel and shorts.

How it works: While sitting comfortably in a chair you will be asked to breathe from a bag with oxygen. First, you will have your nose clipped and will have a mouthpiece inserted in your mouth (the mouthpiece is connected to the apparatus that has the bag with the oxygen). You will then be asked to blow out all of your air and then hold up a hand when complete. At that time you will take 5 deep breaths from the bag with the oxygen and on the 5th breath you will again blow all of your air out. This procedure will be done 2-3 times.

What is this for: This is a measurement of the amount of air that remains in the lungs after a maximal exhalation. It is used in the equation with the results from the underwater weighing to calculate the percent of body fat. Done before and after the training program.

Muscle biopsy:

Things to bring: a pair of shorts

How it works: The lab technicians with a physician's supervision will perform the procedure. A portion of the outer side of the thigh will be prepped and numbed with a local anesthetic. A 1 cm incision will be made into the leg, after which a suction apparatus will be used to extract a small portion of the muscle. This procedure does leave a small scar. This procedure will not hinder any regular activity. Performed before and after the training program.

Diet:

According to your body weight at the beginning of the program you will be placed on 1 of 3 diets depending on you caloric needs. The diet is using the Food Guide Pyramid and the Exchange System to determine the number of servings and the size of the servings from each of the food groups (this will all be taught in nutrition education). Other than the caloric restriction and number of servings from each group you will be able to choose the foods you want to eat. Four times during the program you will be asked to keep a 3 day food record. Once the records are analyzed you will then receive individual nutrition counseling. This is required for the 1st

and 2nd food record, the 3rd is optional and the 4th will be used as an exit interview. Total time will be no more that 30 minutes for the counseling session.

Nutrition education:

Done weekly to teach about nutrition and lifestyle modification. The sessions will be no longer than 1 hour in length. You will be asked to do small assignments such as collect food labels, set weekly goals, etc. that will help prepare you for the next lesson. The topics include:

Week 1: Introduction
Week 2: Food Guide Pyramid, exchange lists, and reading food labels
Week 3: Fat Facts
Week 4: Fast food, eating on the go, travelling, and vacationing
Week 5: Recipe modification, bring a spouse/friend
Week 6: What happens to the foods I eat??
Week 7: Exercise and weight loss
Week 8: Weight Maintenance
Week 9: Open (choice of participants), may include popular/fad diets, wrap up and evaluation

APPENDIX G. DIET PRESCRIPTION

DIETARY RECOMMENDATIONS USING THE FOOD GUIDE PYRAMID AND EXCHANGE SYSTEM

55-60% CHO, 15-20% protein, 25% fat

1800 kcal diet
990-1080 kcal from CHO
270-360 kcal from protein
450 kcal from fat

2000 kcal diet
1100-1200 kcal from CHO
300-400 kcal from protein
500 kcal from fat

2200 kcal diet
1210-1320 kcal from CHO
330-440 kcal from protein
550 kcal from fat

2500 kcal diet
1375-1500 kcal from CHO
375-500 kcal from protein
625 kcal from fat

2800 kcal diet
1540-1680 kcal from CHO
420-560 kcal from protein
700 kcal from fat

Number of servings from each food group for the five different diets

	STARCH/ GRAIN	FRUIT	VEGETABLE	MEAT	MILK	FAT
1800	10	3	4	6	2	4
2000	11	3	4	7	2	4
2200	11	4	4	8	3	4
2500	12	4	4	8	4	4
2800	14	4	4	8	5	5

ONE DAY SAMPLE MENU FOR 2200 KCAL DIET

BREAKFAST	
1 cup shredded wheat cereal	2 starch
1 cup 1% milk	1 milk
1 banana	2 fruit
4 oz. Orange juice	1 fruit
SNACK	
1 cup raw carrots	1 vegetable
6 graham crackers	2 starch
LUNCH	
1 turkey sandwich	
- 2 slices rye bread	2 starch
- 3 oz turkey breast	3 meat
- 1 T mustard	freebie
- 1 slice Swiss cheese	1 milk, 1 fat
1 orange	1 fruit
1 diet cola	freebie
1 ½ oz. Pretzels	2 starch
DINNER	
5 oz. Grilled chicken breast	5 meat
1 large baked potato	2 starch
1 T fat free sour cream	
1 T butter	1 fat
2 oz cheddar cheese	2 milk, 1 fat
½ cup broccoli	1 vegetable
Tossed salad	2 vegetable
-1 cup green leaf lettuce	
-2 tomato wedges	
-3 slices cucumber	
SNACK	
½ cup fat free frozen yogurt	1 starch

TOTALS: 11 starch, 4 fruit, 4 vegetable, 4 milk, 8 meat, 3 fat

APPENDIX H: DIET EVALUATION FORM

DIET EVALUATION

Name _____
Food record # _____
Diet Recommendation _____kcal/d

1. Total calories consumed _____kcal
   Recommendations:

2. Total amount of fat in the diet _____g, _____%
   Recommendations:

3. Amounts of different fats in the diet:
   SFA:

   MUFA:

   PUFA:

4. Total amount of protein in the diet _____g, _____g/kg, _____%
   Recommendations:

5. Total amount of carbohydrate in the diet _____g, _____%
   Recommendations:

6. Total amount of cholesterol in the diet _____mg

Recommendations:

7. Fat soluble vitamins less than 67% of the RDA and recommendations:

8. Water soluble vitamins less than 67% of the RDA and recommendations:

9. Minerals less than 67% of the RDA and recommendations:

10. Total sodium in the diet _____g
    Recommendations:

11. Total fiber in the diet _____g
    Recommendations:

12. Changes to the prescribed diet:

13. Additional comments and notes based on the subjects response to the diet and eating habits, and my observations:

APPENDIX I: OUTLINES OF WEEKLY NUTRITION EDUCATION SESSIONS

WEEK 1: INTRODUCTION

15 minutes

- Introduce self, go around the room and have subjects introduce and tell a little about themselves. Let subjects tell if there is something in particular they wish to learn/gain during the next 10 weeks, or if the subjects prefer they can write something down and give to me later (this will let me know if any changes need to be made to the nutrition education programs).
- True/false IQ quiz
- Background information sheet

15 minutes

ESTIMATING SERVING SIZES

- Use food models as visuals
- Hand outs to aid in estimation
- Using your hand as a tool
- Bring measuring cups and bowls and plates to help with the visualization process

15 minutes

TAKING A FOOD RECORD

- Go over what a food record is and why we have them
- Handouts
- Go over how to break mixed foods down into component parts
- Remember condiments
- Include 2 weekdays and 1 weekend day in each of the 3 day food records taken
- Note if a meal or a day of meals is special in any way (i.e., at a party, away from home, etc.)
- Good vs. poor food records, examples

10 minutes

Next Week: Food Guide Pyramid and Food Labels

Assignment:

- Complete nutrition questionnaire
- Bring 1-2 labels from food products
- Complete a 3 day food record
- Write down a personal goal to achieve within the next week

WEEK 2: FOOD GUIDE PYRAMID AND FOOD LABELS

15 minutes

- Collect 3 day food records, and information sheet
- Divide into three groups:
  discuss previous week
  go over reward system for achieving goals
  discuss any problems encountered with recording foods eaten
- In entire group, have a spokesperson from each group tell of anything that should be shared with everyone

15 minutes

FOOD GUIDE PYRAMID

- 6 categories and # servings from each
- from exchange list, learn what constitutes a serving size in each group
- as a group plan a days menu based on the pyramid to give the recommended # of servings

15 minutes

FOOD LABELS

- Components of the label and meanings of each
- Why certain things are included on the label
- Hand technique when reading labels in the grocery store
- Look at labels brought in and read them carefully

10 minutes

DIETARY ASSIGNMENT

- Give assignment to each person to follow for the remainder of the study (previously determined based on the BEE equation)
- Answer any questions from subjects

NEXT WEEK:

- Fat Facts
- Assignment: follow diet for 1 week, keep track of difficulties and problems
- Set a new goal

WEEK 3: FAT FACTS

10 minutes

- Break into groups and discuss techniques used to achieve personal goals
- Discuss any problems with the diet plans
- As a whole group discuss any important findings

5 minutes

Demonstration of fat in foods using the white grape juice.

20 minutes

1. check list of foods most likely to eat and true/false quiz
2. importance of fats (6 categories)
3. kinds of fats
4. amount of fat in the diet
5. main sources of dietary fats
6. body composition and fat placement and how it associates with increased risk of disease

15 minutes

1. compare regular and low fat products in the grocery store
2. change a diet/menu from a higher fat to a lower fat version

10 minutes

Assignment:

- While following diet, record major sources of fat in your diet
- Reduce the amount of fat consumed in one high fat food found in your diet by replacing it with a lower fat food choice
- Set a new goal

Next Week: Fast Food and Eating Out

WEEK 4: FAST FOOD, EATING ON THE GO, EATING WHILE TRAVELLINGA AND VACATIONING, AND PACKING A HEALTHY MEAL

10 minutes

- Discuss major sources of fat found in the participants diets
- Discuss acceptability of lower fat food choices

10 minutes

- Fill out “Eating on the Run” quiz
- Discuss answers

20 minutes

- Pick a nutrient booklet from a fast food restaurant that you frequent
- Look at what you typically eat at the restaurant and note the number of calories, amount of fat and sodium
- Come up with ways to cut down on calories, fat and sodium
- Each participant to tell of choices and changes aloud

10 minutes

- Information packet of better choices when eating away from home
- Next Week: Recipe Modification, Bring a Friend/Spouse
- Set a new goal
- Second food record is due next week

WEEK 5: RECIPE MODIFICATION (BRING A FRIEND/SPOUSE*)*

10 minutes

- Break into groups and discuss the previous week
- Collect food records (2nd food record)

10 minutes

- Sample foods brought in and rate the foods (low fat and regular fat cake made from a mix)
- Look at the recipes used and the differences in the amounts of the macronutrients in each recipe

15 minutes

- Go over easy ways to decrease fat and calorie content in foods "Trimming the Fat Handout"

10 minutes

- Break into groups: each group will have a different high fat recipe to modify into a low fat version

10 minutes

- Give recipe booklet and cooking tips
- Assignment: find a favorite recipe and alter it to a low fat version and prepare the food and rate the meal and be prepared to tell about it next week, set a new goal for the upcoming week
- Next Week: What happens to the foods I eat??
- Set a new goal

WEEK 6: WHAT HAPPENS TO THE FOOD I EAT?

10 minutes

- Go over recipes modified at home
- Discuss anything concerning the subjects

40 minutes

- Jeopardy to learn about digestion and metabolism of foods – Categories to include: Carbohydrates, Fat, Protein, Vitamins and Minerals, and Anatomy of the Digestive System.
- Discussion of any part of lesson that was unclear.
- Handout of the anatomy of the digestive system.

5 minutes

- Assignment: try to eat a high fiber breakfast each day and note any changes you experience.
- Next Week: Exercise and Weight Loss
- Set a new goal

WEEK 7: EXERCISE AND WEIGHT LOSS

10 minutes

- Discuss fiber assignment of last week.
- Finish distributing food record analyses

5 minutes

Quick quiz about exercise

30 minutes

- 13 things exercising can do (handout)
- exercise that fits (handout
- go over benefits of incorporating exercise into your life (includes a little more detail about some of the 13 things exercising can do)
- basics of metabolism and the components of the body's metabolism
- practical ways to increase activity level and energy expenditure once the weight loss program is complete

5 minutes

Next week: Weight Maintenance

Assignment:

- The third 3-day food record is due next week
- Write a list of favorite activities/hobbies, determine if they are restricted by season, weather. Think of some new activities that you would like to try.
- Set a new goal

WEEK 8: WEIGHT MAINTENANCE

10 minutes

- Collect food records
- Discuss hobbies/interests written down. Find out another person in the group who may be interested in doing the activity with you.

30 minutes

- Use the hat to put questions into. Each participant will pick a question out of the hat dealing with weight loss, diet and exercise and answer it to the group.
- Discuss any questions that are brought up as a group if appropriate, if not, an individual response is appropriate.
- Go over handouts briefly:
    1. 10 Helpful Hints to Maintain an Exercise Program
    2. Hints for Lasting Solutions and a Healthier You
    3. Planning

5 minutes

- Next Week: Popular Diets, Wrap-up, and Evaluation
- Assignment: Have a good week and try a new activity

WEEK 9: POPULAR DIETS, WRAP – UP AND EVALUATION

1. Discuss upcoming post testing and answer any questions.
2. Assign the final 3-day food record to be turned in the week of the muscle biopsies.
3. Collect the names and hobbies sheet so that the list can be compiled and given out at the biopsies.
4. Discuss the sample diets and the pros and cons about each one. The participants should now be able to pick out things that are wrong with the programs based on the education they have received over the past two months.
5. Go over sheet of how to rate a weight loss program.
6. Give handout of the description of the fad diets, let them look over and ask any questions. This will serve mainly as a resource for the participants, most of the topics included in the handout will have been previously discussed.
7. Go over anything else the participants may have a question about.
8. Give out the previous food record evaluation.
9. Have participants fill out the program evaluation sheet.