HEART RATE VARIABILITY OVER THREE DAYS RELATES TO
BODY MASS INDEX BUT NOT AEROBIC FITNESS
IN ADULT WOMEN

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ABSTRACT

BACKGROUND: Heart rate variability (HRV) is an efficient non-invasive method to represent the autonomic nervous system (ANS) activity. In clinical settings, HRV has been demonstrated to be a prognostic indicator related to cardiovascular diseases (CVD). A common approach for measuring HRV is to record within an isolated condition. However, HRV varies from day to day, hence an isolated measurement is often not suitable for reflecting a true change in ANS status. According to previous research utilizing isolated HRV recordings, both aerobic fitness and body mass index (BMI) are correlated with HRV. Yet, the extent to which aerobic fitness and BMI independently relate to HRV is less clear, especially when HRV is expressed as an average over time or as the coefficient of variation (CV) of multiple measures. Furthermore, our understanding of these relationships among young adult women subjects is limited as the majority of HRV research has involved men. PURPOSE: To determine if HRV collected over a period of days is associated with aerobic fitness and BMI in young adult women. METHODS: Healthy, untrained young adult women (n = 30; 20.6 ± 1.2 yr) who were overweight (26.9 ± 7.1 kg/m²) participated in this study. HRV was measured for three consecutive days at the same time in the early morning and averaged (3dayM). A maximal graded exercise test on the treadmill was performed to evaluate the peak oxygen consumption (VO₂peak) after 3-day HRV data collection. BMI was calculated using subjects’ height and weight. Independent associations between HRV (i.e., 3dayM and corresponding CV [3dayCV]) and aerobic fitness and BMI were evaluated using correlations. RESULTS: Aerobic fitness (VO₂peak) was not correlated with any of the HRV parameters for the 3dayM and 3dayCV values (all P > 0.05). BMI was not correlated with any of
the HRV parameters for the 3dayM values (all $P > 0.05$), however, BMI was correlated with all but one HRV parameter ($HF_{cv}$, $p > 0.05$) for 3daycv: $SDNN_{cv}$ ($r = 0.471$, $p = 0.009$), $RMSSD_{cv}$ ($r = 0.396$, $p = 0.030$), $LF_{cv}$ ($r = 0.499$, $p = 0.005$), $SD1_{cv}$ ($r = 0.394$, $p = 0.031$), and $SD2_{cv}$ ($r = 0.426$, $p = 0.019$). CONCLUSION: The results of this study showed that $HRV_{cv}$ values were significantly correlated to BMI among 30 healthy, untrained women subjects over 3-day measurement.
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<td>ANOVA</td>
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<td>ANS</td>
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m  Meter
min  Minute
ml  Milliliter
p  Probability associated with the occurrence under the null hypothesis of a value as extreme as or more extreme than the observed value
r  Correlation coefficient
RMSSD  Root square of the mean of the sum of differences between RR intervals
RMSSDM  Mean value of 3 days root square of the mean of the sum of differences between RR intervals
RMSSDCV  Coefficient of variation of 3 days root square of the mean of the sum of differences between RR intervals
SD  Standard deviation
SDNN  Standard deviation of RR intervals
SDNNM  Mean value of 3 days standard deviation of RR intervals
SDNNCV  Coefficient of variation of 3 days standard deviation of RR intervals
SD1  The graph that plots each RR interval against the next RR interval and provides a dispersion of points perpendicular to the line-of-identity
SD1M  Mean value of 3 days SD1 value
SD1CV  Coefficient of variation of 3 days SD1 value
SD2  The graph that plots each RR interval against the next RR interval and provides a dispersion of points perpendicular along the line-of-identity
SD2M  Mean value of 3 days SD2 value
SD2CV  Coefficient of variation of 3 days SD2 value
VO2peak  Peak oxygen consumption
VO2max  Maximum oxygen consumption
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INTRODUCTION

Autonomic nervous system (ANS) is the portion of peripheral nervous system that modulates the activity of the internal organs, such as the heart rate, blood pressure, body temperature and digestive system. The two branches of ANS: sympathetic and parasympathetic nervous system, act accordingly to initiate specific internal responses. Concerning the heart, the sympathetic nervous system has been suggested to be excitatory, while parasympathetic nervous is inhibitory. For instance, during exercise, sympathetic activity increases while parasympathetic activity decreases to increase heart rate and stroke volume [Perini, et al. 2003]. Following exercise, parasympathetic activity returns while sympathetic influence decreases to return the heart toward a resting state. Thus, cardiac activity is the result of the balance between the sympathetic and parasympathetic branches of the ANS.

Heart rate variability (HRV), which refers to the variation of consecutive normal-to-normal heart beats, has been suggested to be an efficient non-invasive marker of ANS activity [Sztajzel, et al. 2004; Buchheit, et al. 2014]. A high HRV suggests parasympathetic activity is dominate, while reduced HRV is indicative of sympathetic overdrive [Sztajzel, et al. 2004]. Resting HRV is often measured in applied and clinical settings for numerous applications. Lower resting HRV may represent a dysfunction of ANS activity and appears to be associated with mortality from cardiovascular disorders in patients and the general population [Thayer, et al. 2010; Rajendra Acharya, et al. 2006; Tsuji, et al. 1996]. For athletes training, HRV has been shown to be a predictor of adaptation and overtraining [Halson, et al. 2004; Plews. et al. 2013]. Furthermore, for untrained people, HRV is an efficient method to improve exercise performance.
For example, subjects in HRV-based training group showed more improvement on 5 km running performance than traditional training group in an 8-week training program [da Silva, et al. 2017]. The advanced technology of mobile HRV devices such as smartphone applications [Flatt, et al. 2013] and heart rate monitors [Esco, et al. 2017] further increases the popularity of HRV monitoring, allowing for convenient measures among any population.

HRV is assessed with time domain, frequency domain and non-linear parameters. The standard deviation of RR intervals (SDNN) and root square of the mean of the sum of differences between RR intervals (RMSSD) appear to be the most common time domain parameters for HRV analysis. The frequency domain involves a more complex calculation by using numerous mathematical algorithms that transform the electrocardiogram (ECG) data from time to frequency analysis to form the power spectrum [Rajendra Acharya, et al. 2006]. The low frequency (LF, 0.04 to 0.15 Hz), and high frequency (HF, 0.15 to 0.40 Hz) powers are regularly used frequency domain parameters. The Poincare method is a non-linear approach measures HRV by using a graph that plots each RR interval against the next RR interval. The graph provides a dispersion of points perpendicular to (SD1) or along (SD2) the line-of-identity. Among these metrics, RMSSD, HF, and SD1 are markers of parasympathetic nerve system activity, while SDNN is a marker of total variability of ANS, LF and SD2 are comprised of a mix of parasympathetic and sympathetic nerve system activity.

A common approach for measuring HRV is to record within an isolated condition, on a single day under tightly controlled laboratory conditions. This is the procedure undertaken by most research. However, HRV can be influenced by many of the internal and external factors that perturb homeostasis [Rajendra Acharya, et al. 2006]. Thus, HRV varies from day to day hence making an isolated measurement often not suitable for reflecting a true change in ANS
status [Plews, et al. 2014]. Alternatively, it has been recently suggested to measure HRV over a period of days at consistent times, preferably immediately upon wakening, and then calculating an average value [Plews, et al. 2014]. The average value is said to represent overall ANS control of the cardiovascular system [Buchheit, et al. 2014, Buchheit, et al. 2010]. Furthermore, acquiring the daily perturbation in ANS homeostasis can be performed by calculating the coefficient of variation (CV) over the recorded days [Nakamura, et al. 2017]. Apparently, the minimum number of days needed to calculate both the mean and CV for reflecting ANS changes in response to training is a 3-day period [Plews, et al. 2014].

According to previous research, both aerobic fitness and BMI may correlate to HRV. For instance, HRV has been shown to correlate to both maximal oxygen consumption (VO$_{2\text{max}}$) [Alderman, et al. 2014] and BMI [Koenig, et al. 2014, Molfino, et al. 2009] among healthy people. Alderman et al. (2014) reported that VO$_{2\text{max}}$ was significantly positively associated with parasympathetic markers of HRV. In addition, the CV of RMSSD has been shown to either positively [Esco, et al. 2016; Boullosa, et al. 2013] or negatively [Flatt, et al. 2017; Buchheit, et al. 2010] correlate with laboratory (r values ranged between 0.57 to 0.61) and field (r values ranged between 0.65 to 0.898) tests of aerobic fitness. Concerning BMI, higher values were related to lower HRV, suggesting a link to ANS dysfunction with elevated adiposity [Koenig, et al. 2014, Molfino, et al. 2009]. However, the correlation between BMI and VO$_{2\text{max}}$ is significant and negative [Radovanovic, et al. 2014]. Yet the extent to which aerobic fitness and BMI relate to HRV, independently from the other, is currently unknown especially when considering HRV expressed in averaged or CV values. This is an important area of research since aerobic fitness and BMI are both individual cardiovascular diseases (CVD) risk factors linked to ANS control.
In addition, the research is especially lacking in young adult women subjects. Most of the research regarding the relationship between HRV and either BMI or aerobic fitness have studied either men only [Boullosa, et al. 2013, Buchheit, et al. 2010] or have grouped men and women together without stratifying for sex [Koenig, et al. 2014, Molfino, et al. 2009]. Please refer to Table 1 for a summary of selected studies. Compared to men, women have been shown to have significantly higher level of estrogen before menopausal than men [Sookan, et al. 2012]. This hormone is cardiovascular protective and can increase vagal tone and suppress sympathetic modulation [Sookan, et al. 2012] perhaps independent of body mass level. Furthermore, young women tend to distribute adiposity in a gynoidal pattern. This fat distribution pattern does not negatively impact cardiovascular health as much as the android fat characteristic in men [Wiklund, et al. 2008]. Thus, further research is needed specifically in a female cohort to better understand how HRV can be used as an objective measure to gauge ANS changes linked with CVD. The purpose of this study was to determine if HRV collected over a period of days is associated with aerobic fitness and BMI in young adult women. The hypothesis was that both aerobic fitness and BMI will be related to all HRV parameters, expressed as the mean and CV across the 3-day period.
METHODS

1. Participants

According to a G*power (version 3.0.1) analysis, a sample of at least 26 was required when based on detecting a large correlation ($r = 0.50$) between two variables (i.e., $\text{VO}_{2\text{max}}$ or BMI independently) and one HRV parameter (RMSSD) at an alpha level of 0.05 and a power of 80%. Therefore, 30 women were recruited for this study. All the participants completed the health-history questionnaire before data collection and were apparently healthy, free from cardiopulmonary and metabolic disorders. All participants finished Online Screening Assessment questionnaire before involved in the study. Furthermore, The Participants were told to avoid vigorous exercise and refrain from consuming stimulants (e.g., caffeine) or depressants (e.g., alcohol) for 24 hours prior to fitness testing. On the testing day, participants were asked to avoid food or fluid after waking. Compliance to pre-testing instructions were confirmed upon arrival to the laboratory with a 24-hr recall. Whether participants experienced a stressful morning or event as well as the number of hours they slept (and whether this was more or less than usual) were also quantified in the 24-hr recall.

2. Heart rate variability

HRV was measured for 3 consecutive days at the same time of the day. Data collection for all participants occurred in the early morning of each day (form 5 am to 8 am) to make sure data collection was close to awaking from sleep. The data was collected in a quiet, dimly lit, climate-controlled laboratory (temperature was set at 22°C) to avoid the interference from sound, light and temperature. An ECG with three Ag/AgCl surface electrodes organized in a modified
Lead II arrangement was used to acquire heart rate data while the subjects assumed supine position. The electrodes were connected to a Biopac MP100 data acquisition system (BIOPAC Systems, inc. Goletta, CA, USA) that was interfaced with a Dell personal computer. According to the recommendation from software guide, the ECG data was collected at a sampling rate of 2000 Hz by Acqknowledge 4.4 (BIOPAC Systems, inc. Goletta, CA, USA). Then the data was transferred to Kubios HRV Standard (Kubios Oy. Kupio, Finland) for analysis. Kubios HRV is an advanced software system that supports several input data formats and calculates multiple HRV parameters. Task Force (1996) recommended standard HRV measurement is at least 5 minutes recording after a 5 minutes stabilization period. Thus, subjects were asked to lay on the examination bed for 10 minutes. The last 5 minutes was used for HRV analysis [Task Force, 1996].

All ECG data was collected by Acqknowledge 4.4 software, then transferred ECG image to digital format, which represents the time between consecutive normal-to-normal heart beats. The digital data was saved as txt file for analysis, after which Kubios HRV analysis software was used to convert the digital data in to RR images, and then used to calculate all HRV parameters. Before analyzing, when the extremely high RR value was found, the artifact correction (Threshold based) was performed using Kubios to correct each RR interval value according to average RR value [Tarvainen, et al. 2014]. If a RR interval different from the average value more than the specific threshold (in seconds), it was removed to correct the corrupted RR intervals and the next RR interval was used. Furthermore, disturbing low frequency baseline trend component was also removed by using smoothness priors method in Detrending options [Kubios HRV Users Guide]. These trend components affect the time and frequency domain, and after removing, better description for LF and HF was obtained. The smoothness of the removed component was
adjusted by changing the Lambda value. The Lambda value determines the cutoff frequency which removes frequency components below it. Since LF and HF were needed in this study (with frequency higher than 0.04 Hz), Lambda value was set to 500.

After cleaning the raw HRV data, the following HRV parameters were assessed: SDNN, RMSSD, LF, HF, SD1, and SD2. Both averaged (HRV<sub>M</sub>) and the CV (HRV<sub>CV</sub>) were calculated for each variable. The HRV<sub>CV</sub> calculation used the following equation: CV = (SD/M) * 100, where SD is the standard deviation of the HRV parameter and M is the mean of HRV parameter for the 3-day period.

3. Body Mass Index and Maximum Oxygen Consumption

Body Mass Index was calculated by the equation: BMI = kg/m<sup>2</sup>, where kg is participants’ weight in kilograms and m<sup>2</sup> is height in meter square. Participants’ height and weight were measured by seca height scale and TANITA electronic weight scale, respectively. The BMI levels of subjects were determined according to ACSM Guidelines for Exercise Testing and Prescription (Ninth Edition), with a BMI of < 18.5 kg/m<sup>2</sup> is Underweight, 18.5-24.9 is Normal, 25.0-29.9 is Overweight and ≥ 30 is Obese. In addition, all subjects’ physical activity status was determined according to step-define sedentary lifestyle index (sedentary lifestyle: < 5000 steps/day; low active lifestyle: 5000 - 7499 steps/day; somewhat active lifestyle: 7500 - 9999 steps/day; active lifestyle: 10000 - 12499 steps/day; highly active lifestyle: ≥ 12500 steps/day). The BMI and physical activity levels of all subjects were shown in Table 4&5.

After the 3-day HRV monitoring, each participant performed a maximal graded exercise test on the TRACKMASTER treadmill (FULLVISION, inc. Newton, KS, USA). The gas exchange was calculated by TrueOne 2000 Metabolic Measurement System (PARVO Medics, inc. Sandy, UT, USA). The Bruce protocol was used which started at a work rate of 1.7mph at
10% grade with increased in speed and grade every 3min until maximal oxygen consumption (VO2max) was reached. The criteria for VO2max which is predetermined as 2 of the following: a plateau in oxygen consumption despite an increased work (± 2ml/kg/min); respiratory exchange ratio of >1.10; a rating of perceived exertion of at least 9 on a modified Borg 0–10 scale, and a heart rate within 10 beats of age-predicted maximum (220-age). Since not all participants achieved the criteria, the VO2peak was used instead of VO2max. The aerobic fitness (VO2peak) levels for all subjects were determined by comparing to age-matched normative data [ACSM’s guidelines for exercise testing and prescription, ninth edition] and listed in Table 6.

4. Statistical Analyses

Statistical analyses were performed by using SPSS and Microsoft Excel 2010. The Shapiro-Wilks test was used to determine normality of all HRV parameters. Log transformed data was needed for HRV parameters that couldn’t meet the normality. Group means and standard deviations (SD) were calculated for each study variables. To determine if the 3day HRV values were significantly different, analysis of variance (ANOVA) was performed. Correlation coefficient (r) was determined if HRV parameters (Mean and CV values) were correlated to VO2peak and BMI. The r value qualified by the Hopkins method where a coefficient of 0–0.30 is considered small, 0.31–0.49 is moderate, 0.50–0.69 is large, 0.70–0.89 is very large, and 0.90–1.00 is near perfect. The descriptive data (mean ± standard deviation) for all subjects listed in Table 2.
RESULTS

The relationships between VO$_{2\text{peak}}$, BMI and all HRV parameters (Mean and CV values) are shown in Table 3. According to ANOVA, there were no significant differences among 3day HRV values. There were no significant correlations between VO$_{2\text{peak}}$ and any of the 3day$_M$ and 3day$_{CV}$ values of HRV parameters. In addition, there were no significant correlations between BMI and any of the 3day$_M$ HRV values for any parameter. However, the 3day$_{CV}$ of all HRV parameters, SDNN$_{CV}$, RMSSD$_{CV}$, LF$_{CV}$, SD1$_{CV}$, and SD2$_{CV}$, were significantly related to BMI. Furthermore, VO$_{2\text{peak}}$ significantly and negatively correlated to BMI ($r = -0.767$, $p < 0.001$).
DISCUSSION

The participants of this study were young-adult women who were considered on average to be “overweight” according to BMI standards and demonstrated a VO\textsubscript{2peak} level of “Poor” when compared to age-matched normative data [ACSM’s guidelines for exercise testing and prescription, ninth edition]. Therefore, the sample represents a group of women who would benefit from a lifestyle intervention designed to improve overall health and fitness. HRV has been considered an objective indicator reflecting changes in BMI and aerobic fitness [Karason, et al. 1999; Esco, et al. 2015; Hautala, et al. 2003]. However, limited research in this area exists specifically regarding the current population of women. Therefore, in the group of young-adult women, the purpose of this study was to determine whether HRV\textsubscript{M} and HRV\textsubscript{CV} values calculated from a 3-day period were correlated to VO\textsubscript{2peak} and BMI. The results of the study indicated that VO\textsubscript{2peak} did not relate to any of the HRV\textsubscript{M} (r ranged from 0.128 to 0.224) and HRV\textsubscript{CV} (r ranged from -0.306 to -0.135) values. Furthermore, no significant correlation was shown between BMI and any HRV\textsubscript{M} value (r ranged from -0.105 to 0.038). However, the 3-day CV of several HRV parameters showed moderate to large correlations to BMI. Among these, BMI showed significant correlations to the following (ordered from the largest-to-smallest significant correlation coefficient): LF\textsubscript{CV} (r = 0.499, p = 0.005); SDNN\textsubscript{CV} (r = 0.471, p = 0.009); SD2\textsubscript{CV} (r = 0.426, p = 0.019); RMSSD\textsubscript{CV} (r = 0.396, p = 0.03); and SD1\textsubscript{CV} (r = 0.394, p = 0.031). Only HF\textsubscript{CV} was not significantly correlated to BMI. Therefore, the results of this study suggest that the CV of HRV over a period of days was associated with BMI in women subjects.
The findings regarding no relationship between VO_{2\text{peak}} and HRV have been reported by others [Esco, et al. 2016; Flatt, et al. 2017; Boullosa, et al. 2013; Buchheit, et al. 2010], suggesting no predictive ability of HRV for reflecting aerobic fitness. Among these research, Esco and Flatt focused on young adult female athletes, and Boullosa and Buchheit involved male athletes in the research. Instead, HRV may be indicative of a change in aerobic fitness that occurs with training. For instance, Hautala et al. (2003) suggested that baseline HF significant correlated to the improvement of VO_{2\text{max}} among sedentary male subjects over 8 weeks training. Furthermore, the subjects were divided into four groups according to their training response (17 ± 1, 11 ± 1, 8 ± 1, and 5 ± 2% increase in VO_{2\text{max}}). Results indicated that higher baseline HF was found among groups with better training response than lower training response. In addition, Esco et al. (2015) reported the change of lnRMSSD_M from week 1 to week 3 significantly related to the change of VO_{2\text{max}} over the whole 11-week training program in female athletes. This finding indicates that the change of HRV at the beginning of training program also correlated to the change of aerobic fitness [Esco, et al. 2015]. Thus, the ANS activity at baseline or its immediate change that occurs with training may reflect the change of aerobic fitness, primarily because of the adaptation capacity of cardiovascular system correlates to the improvement of aerobic performance after physical training [Hautala, et al. 2003]. Thus, HRV measures may assist with exercise program development for specific individuals.

The relationship between aerobic fitness and HRV_{CV} values do not agree with previous studies. For example, previous studies reported that RMSSD_{CV} significantly correlated to Yo-Yo performance [Boullosa, et al. 2012; Flatt, et al. 2016], maximal aerobic speed [Buchheit, et al. 2010] and VO_{2\text{max}} [Flatt, et al. 2016] over weekly measurement. However, no relationship between aerobic fitness and any HRV CV value was found in this study. In previous research, all
participants were soccer players and HRV data was collected during the training program, but subjects in the current study were asked to not exercise during the 3-day data collection. Thus, aerobic fitness may relate to the CV of HRV collected with exercise stimulation. Therefore, fitness may correlate to the ability of maintaining homeostasis perturbation in response to decreases or increases in training load from week-to-week [Esco, et al. 2015; Buchheit, et al. 2010; Plews, et al. 2014]. Further study to evaluate this association is needed specifically in young-adult women who are involved in an exercise program, which divides them into different groups and provides different levels of exercise stimulation for each group to support this finding.

In addition, previous studies pointed out the inverse correlations between BMI and HRV parameters. For example, BMI has been shown to inversely relate to RMSSD [Koenig et al. 2014] and LF and HF [Molfino, et al. 2009] in groups of men and women that were not stratified by sex. However, when stratified by sex, Ramaekers et al. (1998) showed a similar inverse correlation between BMI and HRV in men, but no relationship in women. The lack of a link between HRV and BMI specifically in young women is difficult to explain. However, it may be related to the fact that young women tend to distribute adiposity in a gynoidal pattern. This fat distribution pattern does not negatively impact cardiovascular health as much as the android fat characteristic in men [Wiklund, et al. 2008]. This sex-specific characteristic is explained by the fact that before menopausal women have significantly higher levels of estrogen than men [Sookan, et al. 2012]. This hormone is cardiovascular protective and can increase vagal tone and suppress sympathetic modulation [Sookan, et al. 2012] perhaps independent of body mass level. Thus, there may be no influence of BMI on overall cardiac-parasympathetic modulation in young adult women, as indicated by 3-day mean values of the HRV parameters.
However, as mentioned previously, the CV of all but one HRV measure significantly correlated to BMI. This was the first study to report such findings. Indeed, all HRVcv values (include time domain, frequency domain and non-linear), except HFcv, were found to significantly correlate to BMI, and the higher BMI tend to display higher CV of HRV across three days. Among the HRV parameters, RMSSD, HF, and SD1 are markers of parasympathetic nerve system activity [Danieli, et al. 2014, Constantinescu, et al. 2018], while SDNN is a marker of total variability of heart rate [Antelmi, et al. 2008; Danieli, et al. 2014], LF and SD2 are comprised of a mix of parasympathetic and sympathetic nerve system activity [Sztajzel, et al. 2004; Kleiger, et al. 2005, Constantinescu, et al. 2018]. Thus, the finding that LFcv, SDNNcv and SD2cv presented higher correlations to BMI than RMSSDcv and SD1cv, with no such relationship to HFcv, may indicate that BMI is more related to the overall ANS activity rather than only parasympathetic nerve system activity. Body weight maintains by homeostatic system and dysfunction of this system lead to weight gain and obesity. ANS has been shown to play a major role in homeostatic system by communicating between central nervous system (CNS) and peripheral nervous system [Guarino, et al. 2017]. The sympathetic branch of ANS is the major factor that affects the energy expenditure by influencing on cardiorespiratory activity and thermogenesis. Furthermore, the parasympathetic branch transfers signals from gastrointestinal system to CNS [Guarino, et al. 2017]. Therefore, HRV parameters which reflect the overall activity of ANS show higher correlation to BMI than parasympathetic HRV parameters. This finding offers a better understanding of the relationship between HRV and BMI for the future studies. The results may indicate that women with lower BMI tend to have a better ability to maintain homeostatic perturbation. Though these explanations are speculative, the findings of the
study directly suggest that BMI significantly correlates to CV of HRV measuring over multiple
days in young-adult women.

There are several limitations in this study. First, this study did not include other co-
factors that may influence HRV, such as mental stress, sleep quality and daily dietary habits
did not fit into the specific purpose of the study, future studies should determine the impact of
co-factors on the relationship between HRV, BMI and aerobic fitness in women. Second,
comparing to BMI, adiposity distribution may provide a better understanding on relationship
between body composition and HRV. According to previous research, HF of HRV from an
isolated recording significantly correlated to waist circumference \(r = 0.50\) but not BMI \(r =
0.16\) [Chen, et al. 2008]. Furthermore, measures of body fat percentage have also been shown to
be more related to HRV compared to BMI [Yi, et al. 2013]. Thus, more specific measures of
body fat percentage and distribution may have shown stronger relationships to the HRV\(cv\), and
perhaps mean values, of HRV in the current study. Third, the correlational nature of the study
prevented determination of cause-effect. Thus, from the results, we cannot specifically indicate
whether HRV changes would have been found with changes in BMI or VO\(_{2}\)\(_{\text{peak}}\) following long-
term intervention such as physical training.
CONCLUSION

The results of this study showed that HRV_{cv} values (except HF_{cv}) significantly correlated to BMI in 30 healthy, untrained women subjects over 3-day measurement. However, HRV_{cv} values were not correlated with VO_{2peak} within the current sample. The findings indicated that women with lower BMI tend to maintain homeostatic perturbation better than higher BMI individuals over multiple consecutive days. Although the specific mechanism is unclear, these results provide a better understanding of the relationship between HRV and BMI in women and suggest the influence of weight status on HRV may be independent of fitness level.
REFERENCES


### TABLE 1. Summary of selected studies examining the association between heart rate variability, body mass index and aerobic fitness.

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Subjects</th>
<th>HRV Measurement</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Studies Examining the Relationship Between HRV and BMI</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fohr et al., 2016</td>
<td>6,863 men, 9,412 women</td>
<td>Isolated, 4.5 hr</td>
<td>Higher BMI correlated with lower HRV</td>
</tr>
<tr>
<td>Windham et al., 2012</td>
<td>88 men, 90 women</td>
<td>Isolated, 24 hr</td>
<td>BMI was not correlated with RMSSD or SDNN</td>
</tr>
<tr>
<td>Molfino et al., 2009</td>
<td>13 men, 12 women</td>
<td>Isolated, 24 hr</td>
<td>BMI inversely correlated to HF; marginally related to LF</td>
</tr>
<tr>
<td>Koenig et al., 2014</td>
<td>15 men, 44 women</td>
<td>Isolated, 5 min</td>
<td>BMI correlated with time domain but not frequency domain</td>
</tr>
<tr>
<td><strong>Studies Examining the Relationship Between HRV and VO(_{2\text{max}})</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Esco et al., 2015</td>
<td>9 female college soccer players</td>
<td>55 sec for two separate weeks</td>
<td>Change of RMSSD(M) correlated with change in VO(_{2\text{max}}) from pre- to post-training</td>
</tr>
<tr>
<td>Boullosa et al., 2012</td>
<td>8 professional soccer players</td>
<td>3 hr night-time for 4 days</td>
<td>RMSSD(_{CV}) correlated with Yo-Yo performance test</td>
</tr>
<tr>
<td>Buchheit et al., 2010</td>
<td>33 youth soccer players (18 under 15, 15 under 17)</td>
<td>3 min for 3 weeks</td>
<td>CV of HRV correlated with maximal aerobic speed</td>
</tr>
<tr>
<td>Flatt et al., 2016</td>
<td>10 female college soccer players</td>
<td>1 min for two weeks</td>
<td>RMSSD(<em>{CV}) correlated with VO(</em>{2\text{max}}) and Yo-Yo performance test</td>
</tr>
<tr>
<td>Grant et al., 2013</td>
<td>145 healthy volunteers</td>
<td>Isolated, 10 min</td>
<td>HRV correlated with VO(_{2\text{max}})</td>
</tr>
</tbody>
</table>

BMI = Body mass index; CV = Coefficient; HF = High frequency; HRV = Heart rate variability; LF = Low frequency; RMSSD = Root square of the mean of the sum of differences between RR intervals; RMSSD\(_{M}\) = Mean value of RMSSD; RMSSD\(_{CV}\) = CV of RMSSD; SDNN = Standard deviation of RR intervals; VO\(_{2\text{max}}\) = maximal oxygen consumption.
Table 2. Descriptive data of participants

<table>
<thead>
<tr>
<th>Subjects</th>
<th>Age (years)</th>
<th>Height (cm)</th>
<th>Weight (kg)</th>
<th>BMI (kg/m²)</th>
<th>VO_{2peak} (ml/kg/min)</th>
<th>PA (steps/day)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1001</td>
<td>23</td>
<td>171.45</td>
<td>147.60</td>
<td>50.72</td>
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<td>6962.80</td>
</tr>
<tr>
<td>1002</td>
<td>20</td>
<td>168.66</td>
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<td>16.14</td>
<td>6932.20</td>
</tr>
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<td>112.32</td>
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<td>21</td>
<td>170.18</td>
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<td>1005</td>
<td>20</td>
<td>164.00</td>
<td>77.00</td>
<td>28.63</td>
<td>31.90</td>
<td>—</td>
</tr>
<tr>
<td>1007</td>
<td>21</td>
<td>163.83</td>
<td>82.62</td>
<td>31.09</td>
<td>19.29</td>
<td>5093.50</td>
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<tr>
<td>1008</td>
<td>19</td>
<td>162.05</td>
<td>77.94</td>
<td>29.98</td>
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</tr>
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<td>72.36</td>
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<td>1010</td>
<td>22</td>
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<td>76.23</td>
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<td>2001</td>
<td>21</td>
<td>154.43</td>
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<td>35.52</td>
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<td>2002</td>
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<td>29.31</td>
<td>—</td>
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<td>2007</td>
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<td>167.49</td>
<td>109.30</td>
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<tr>
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<td>26.57</td>
<td>34.17</td>
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<tr>
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<td>173.70</td>
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<td>18.49</td>
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<tr>
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<td>22.05</td>
<td>37.50</td>
<td>8082.00</td>
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<tr>
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<td>78.30</td>
<td>26.31</td>
<td>34.80</td>
<td>4987.60</td>
</tr>
<tr>
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<td>22</td>
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<td>23.77</td>
<td>32.50</td>
<td>8480.00</td>
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<td>63.80</td>
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<td>8777.00</td>
</tr>
<tr>
<td>3007</td>
<td>20</td>
<td>169.00</td>
<td>57.30</td>
<td>20.06</td>
<td>36.40</td>
<td>—</td>
</tr>
<tr>
<td>3010</td>
<td>19</td>
<td>156.00</td>
<td>51.20</td>
<td>21.04</td>
<td>37.10</td>
<td>—</td>
</tr>
<tr>
<td>3011</td>
<td>20</td>
<td>173.00</td>
<td>79.10</td>
<td>26.43</td>
<td>33.50</td>
<td>10014.80</td>
</tr>
<tr>
<td>3014</td>
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<td>164.50</td>
<td>79.40</td>
<td>29.34</td>
<td>26.60</td>
<td>7140.60</td>
</tr>
<tr>
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<td>19</td>
<td>177.50</td>
<td>56.10</td>
<td>17.81</td>
<td>36.40</td>
<td>—</td>
</tr>
<tr>
<td>3016</td>
<td>22</td>
<td>163.50</td>
<td>64.30</td>
<td>24.05</td>
<td>39.70</td>
<td>—</td>
</tr>
<tr>
<td>3017</td>
<td>19</td>
<td>167.00</td>
<td>55.10</td>
<td>19.76</td>
<td>48.90</td>
<td>—</td>
</tr>
<tr>
<td>3018</td>
<td>20</td>
<td>155.00</td>
<td>48.00</td>
<td>19.98</td>
<td>34.80</td>
<td>—</td>
</tr>
<tr>
<td>3019</td>
<td>22</td>
<td>164.50</td>
<td>65.80</td>
<td>24.32</td>
<td>36.60</td>
<td>—</td>
</tr>
<tr>
<td>Mean</td>
<td>20.6</td>
<td>165.97</td>
<td>73.87</td>
<td>26.91</td>
<td>30.75</td>
<td>—</td>
</tr>
<tr>
<td>SD</td>
<td>1.2</td>
<td>6.10</td>
<td>20.76</td>
<td>7.08</td>
<td>8.25</td>
<td>—</td>
</tr>
<tr>
<td>Range</td>
<td>19 – 30</td>
<td>154.43 – 177.50</td>
<td>48.00 – 147.60</td>
<td>17.81 – 50.72</td>
<td>14.67 – 48.90</td>
<td>—</td>
</tr>
</tbody>
</table>

BMI = Body mass index; PA = Physical activity; VO_{2peak} = Peak oxygen consumption.
Table 3. Correlations between heart rate variability outcomes, aerobic fitness and body mass index.

<table>
<thead>
<tr>
<th></th>
<th>3-day Mean Values</th>
<th>3-day Coefficient of Variation Values</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>SDNN</td>
<td>RMSSD</td>
</tr>
<tr>
<td>Aerobic Fitness</td>
<td>0.210</td>
<td>0.166</td>
</tr>
<tr>
<td>(VO2peak)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Body Mass Index</td>
<td>-0.042</td>
<td>0.038</td>
</tr>
</tbody>
</table>

* P < 0.05. HF = High frequency; LF = Low frequency; RMSSD = Root square of the mean of the sum of differences between RR intervals; SDNN = Standard deviation of RR interval; SD1 = The graph that plots each RR interval against the next RR interval and provides a dispersion of points perpendicular to the line-of-identity; SD2 = The graph that plots each RR interval against the next RR interval and provides a dispersion of points perpendicular along the line-of-identity; VO2peak = Peak oxygen consumption.
Table 4. BMI levels of subjects

<table>
<thead>
<tr>
<th>BMI levels</th>
<th>Underweight</th>
<th>Normal weight</th>
<th>Overweight</th>
<th>Obese</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Subjects</td>
<td>1</td>
<td>12</td>
<td>10</td>
<td>7</td>
</tr>
</tbody>
</table>

Table 5. Physical activity levels of subjects

<table>
<thead>
<tr>
<th>Physical activity levels</th>
<th>Sedentary</th>
<th>Low active</th>
<th>Somewhat active</th>
<th>Active</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Subjects</td>
<td>5</td>
<td>7</td>
<td>6</td>
<td>6</td>
</tr>
</tbody>
</table>

Table 6. Aerobic fitness levels of subjects

<table>
<thead>
<tr>
<th>Aerobic fitness levels</th>
<th>Very poor</th>
<th>Poor</th>
<th>Fair</th>
<th>Good</th>
<th>Superior</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Subjects</td>
<td>15</td>
<td>6</td>
<td>5</td>
<td>3</td>
<td>1</td>
</tr>
</tbody>
</table>
Figure 1. Electrocardiogram lead II arrangement (Cardiovascular Physiology Concepts, Second Edition, published by Lippincott Williams & Wilkins, 2012).
Figure 2. Kubios heart rate variability standard software (Kubios Oy, Kupio, Finland) for artifact correction and removal of trend components.
APPENDIX

Online Screening Assessment

Default Question Block

Thank you for taking time to complete this online questionnaire which will help to determine if you are eligible to participate in the study.

Before you begin the online screening form, here is information about the research project. As you may have heard, overweight and obesity rates are increasing exponentially, especially in younger adults. Young adults (18-24 years of age) experience unique barriers to engaging in a healthy lifestyle, particularly on a college campus. The researchers hope to learn more about how to design effective exercise and weight loss interventions.

People who begin a new exercise program to lose weight often lose less weight than predicted. The purpose of this study is to determine if changes in your heart rhythm can be used to predict changes in physical activity during an exercise study. You will also be asked to answer some questions about your alcohol use, drug use, sleep, and motivation to try different activities. These questions are being included as part of our basic health history survey because these factors have been related to heart rate and physical activity markers being measured in this study.

This study will involve a total of 15 testing visits during the two week study period. The visits will be held in the Exercise Physiology Laboratory at The University of Alabama. If you choose to participate in this study, some information will be collected from you. This includes information about your health status (heart rate), as well as information about what your body is made of (fat, muscle, and bone), and physical activity (steps, minutes, and sitting time). During the exercise sessions, you will be asked to walk continuously on a treadmill in the Exercise Physiology Lab in Moore Hall. The treadmill will be set to a moderate walking speed, fast enough to increase your heart rate up to 75% of your maximum heart rate, but slow enough so that you can easily walk for 45-60 minutes. You will be asked to visit the lab 5 times during the one-week study for your supervised exercise sessions. This amount of
walking is similar to what is recommended for weight loss.

The screening will take approximately 10 minutes to complete. Once you have submitted the form, a member of the research team will contact you for follow-up information. The risks and discomforts associated with this online screening are minimal. You will be asked about your status as a UA student, age, and residence. You do not have to answer any questions that you do not wish to answer or are uncomfortable answering. Your participation in the screening is voluntary, and can refuse to answer any questions, or stop this online screening at any time without penalty or loss of benefits to which you are otherwise entitled. All individually-identifiable answers and information will be kept confidential. If you are not eligible for the study, your questions will be stored without your name or any way to identify the information back to you. If you are eligible for the study and decide to participate, your information will be coded with an identifying number. Please note that Internet communications are insecure and there is a limit to the confidentiality that can be guaranteed due to the technology itself. However, once the researchers receive your completed survey, you will receive a confidential identification number, which will be used solely on the data. Your identification code will be confidential and will only be available to specific members of the research team.

You are not expected to benefit directly from participating in this screening procedure. The research study, however, may benefit the greater community by helping to understand the health status and behaviors of students on a college campus. This information will be used in the future to design health behavior interventions and programs targeted to college-aged young adults.

If you are determined to be eligible for the study, a member of the research team will contact you via email or telephone to set the first appointment and provide instructions for the first appointment. The research team will also provide you with directions to the Exercise Physiology Lab inside Moore Hall on campus at the University of Alabama, where the majority of testing will occur.

If you are interested in continuing with this screening please click “Yes, I agree to continue with this screening.” If you are no longer interested in participating in this research study, please click “No, I do not wish to complete the online screening process.”

Yes, I agree to continue with this screening.
No, I do not wish to complete the online screening process.

Please enter your Screening ID number.

Please confirm your Screening ID number.

Are you a full-time student at UA?
Yes
No

Are you between the ages of 18 and 24 years old?
Yes
No

What is your gender?
Male
Female

Are you pregnant?
Yes
No
Are you planning on becoming pregnant in the next 6 months?
Yes
No

Have you given birth in the last 12 months?
Yes
No

Are you a varsity athlete? (play Division 1 sports?)
Yes
No

What is your age?

Do you take any drugs or medications for diabetes, blood pressure, or cholesterol?
Yes
No

Please list any medications you are currently taking.

In the past week, on how many days have you done a total of 30 minutes or more of physical activity, which was enough to raise your breathing rate? This may include sport, exercise, and
brisk walking or cycling for recreation, or to get to and from places, but should not include housework or physical activity that may be part of your job.

None
One
Two
Three or More

Do you have any orthopedic limitations that would prevent you from exercising at a moderate or vigorous intensity?

Yes
No

Do you have any cardiopulmonary or cardiovascular conditions that may be made worse by moderate or vigorous exercise?

Yes
No

Do you have any neuromuscular, musculoskeletal disorder that may be made worse by moderate or vigorous exercise?

Yes
No

Do you have a chronic physical or mental health condition for which moderate or vigorous intensity exercise may be unsafe?

Yes
No
Do you take medication that changes dietary intake, or that makes participation in moderate or vigorous physical activity unsafe?

Yes
No

Do you have a chronic physical or mental health condition that affects your diet, such as an eating disorder or bowel disease?

Yes
No

Do you have a diagnosed psychological condition that alters your personality, such as obsessive compulsive disorder?

Yes
No

Have you ever had weight loss surgery (bariatric or gastric bypass)?

Yes
No

Have you been clinically diagnosed with Type 1 or Type 2 Diabetes?

Yes
No

Are you a current smoker?

Yes
No
Are you able to speak and write English fluently?
Yes
No

Are you willing to meet the time commitments of this study?
Yes
No

Are you willing to undergo all testing procedures described as part of this study?
Yes
No

Are you willing to complete the DXA (body scan) test?
Yes
No

Are you willing to wear a physical activity measuring device?
Yes
No

Are you willing to answer potentially sensitive and personal questions, including those about alcohol and drug use?
Yes
No
Are you willing to attend the exercise training sessions?

Yes
No

Thank you for completing the Online Screening Questionnaire! A member of our research team will contact you via email within 48 hours regarding your eligibility to participate in the current study.

Powered by Qualtrics
August 10, 2017

Michael Fedewa, Ph.D.
Assistant Professor
Department of Kinesiology
College of Education
The University of Alabama
Box 870312

Re: IRB Protocol # 16-012-ME-R1
“Changes in HRV and Physical Activity during Exercise One Week of Exercise Training”

Dr. Fedewa:

The University of Alabama Medical IRB has received the revisions requested by the full board on 6/9/17. The board has reviewed the revisions and your protocol renewal application is now approved for a period of one year.

Your application will expire on June 7, 2018. You will receive a notice of the expiration date 90 days in advance. If your research will continue beyond this date, complete the renewal portions of the FORM: IRB Renewal Application. If you need to modify the study, please submit FORM: Modification of An Approved Protocol. Changes in this study cannot be initiated without IRB approval, except when necessary to eliminate apparent immediate hazards to participants. When the study closes, please complete the FORM: Request for Study Closure.

Please use reproductions of the IRB approved stamped consent form or information sheet to obtain consent from your participants. Should you need to submit any further correspondence regarding this application, please include the above application number.

Please provide the Office for Research Compliance with copies of the approvals from the UA Radiation Control Advisory Committee and from the State of Alabama Department of Public Health for the IRB file prior to conducting any dual-energy x-ray absorptiometry (DXA) work associated with the current protocol.

Good luck with your research.

Sincerely,

J. Grier Stewart, MD, FACP
Medical IRB Chair
Research Study

Female students age 18 to 24 years are invited to participate in a one-week exercise training study examining the effect of structured exercise on physical activity.

All testing will be performed at Moore Hall at the University of Alabama.

Participants will be asked to complete confidential body composition analysis, as well as surveys regarding health history and physical activity. Participants can earn up to $10 with successful completion of the study.

If you are interested in participating, please contact the Principal Investigator: Michael V. Fedewa, Ph.D. (mvfedewa@ua.edu)
UNIVERSITY OF ALABAMA
INFORMED CONSENT DOCUMENT

Study Title:
Changes in HRV and Physical Activity During Exercise One Week of Exercise Training

Principal Investigator:
Dr. Michael V. Fedewa (205-348-9779; mvfedewa@ua.edu)
Assistant Professor, The University of Alabama

Co-Investigator:
Dr. Michael R. Esco (205-348-2151; mresco@ua.edu)
Assistant Professor, The University of Alabama

Student Co-Investigators:
Togy Bazgdsuren M.A. (bzagdsuren@crimson.ua.edu)
Doctoral Student

Peter Inglett M.A. (pwinglett@crimson.ua.edu)
Doctoral Student

You are being invited to participate in a research study. The study is called “Changes in HRV and Physical Activity During Exercise One Week of Exercise Training.” The study is being done by Dr. Michael Fedewa and Dr. Michael Esco, who are assistant professors with the Department of Kinesiology at the University of Alabama. Our Doctoral Students, Togy Bazgdsuren and Peter Inglett will assist with the research study by obtaining informed consent and helping with data collection.

Is the study team being paid for this study?  No, the researchers are not receiving extra pay for this study.

Is this research developing a product that will be sold, and if so, will the study team profit from it? No, the researchers are not developing a product that will be sold and will not directly profit from this study.

Does the study team have any conflict of interest in this study? The researchers do not have any potential conflicts of interest.

What is this study about? What is the study team trying to learn?
The purpose of this study is to determine if changes in your heart rhythm can be used to predict changes in physical activity during an exercise study. You will also be asked to answer some questions about your alcohol use, drug use, sleep, and motivation to try different activities. These questions are being included as part of our basic health history survey because these
factors have been related to heart rate and physical activity markers being measured in this study.

**Why is this study important or useful?**
This information will be used to develop programs that will help people lose weight and become healthier with physical activity.

**Why have I been asked to be in this study?**
You have been asked to be in this study because you are eligible and have expressed interest in participating. You have also met the criteria to be included in this study. Based on the answers that you provided as part of the online screening process, you are a female student at the University of Alabama between 18 and 24 years of age. You have said that you do not currently have an exercise program, and our research team has determined that it is safe for you to exercise.

**How many people will be in this study?**
About 30 other people will be in this study.

**What will I be asked to do in this study?**
If you choose to participate in this study, some of the information will be collected from you. This includes information about your health status (heart rate), as well as information about what your body is made of (fat, muscle, and bone), and physical activity (steps, minutes, and sitting time). During the exercise sessions, you will be asked to walk continuously on a treadmill in the Exercise Physiology Lab in Moore Hall. The treadmill will be set to a moderate walking speed, fast enough to increase your heart rate up to 75% of your maximum heart rate, but slow enough so that you can easily walk for 45-60 minutes. You will be asked to visit the lab on 5 consecutive days at the same time each day during the one-week study for your supervised exercise sessions.

If you agree to participate, you will be asked to:
**Visit 1 (V1) [Before Week 1] (~90 minutes)**
**Exercise Physiology Laboratory, Department of Kinesiology**
When visiting the lab for V1, you will do the following:
1. Your on-line screening form will be checked for accuracy.
2. The study team will have you read an informed consent document (ICD), and then describe what you will be asked to do for this study. You will also read a consent document for the dual energy x-ray absorptiometry (DXA) body scan. After the study team feels that you understand what you will be asked to do for this study, both you and the study team member will sign the informed consent document and each will keep a copy.
3. Height, weight, and waist measurements will be performed, a lot like the measurements performed in a doctor’s office.
4. Your heart rate will be measured each morning by placing three electrodes on your skin just below your collar bone and above your hips. The electrodes will be connected to a desktop computer. You will be asked to lay quietly on an athletic training table for 10 minutes while...
the researchers record your heart rate. Next, you will be asked to sit quietly in a chair for 10 minutes, following by standing quietly for 10 minutes while the researchers record your heart rate.

5. You will then have a DXA whole body scan to see what you are made of (fat, muscle, and bone). During the scan, you will be asked to lay on the scanning bed for 7-24 minutes.

6. You will be asked to complete a fitness test to measure your fitness level. During the test, the study team will ask you to walk on a treadmill while breathing through a special mouthpiece to measure the air you breath in and out. The speed and incline of the treadmill will gradually increase until you fatigue and requests to stop. (~20 minutes duration).

7. You will complete a Demographic and Health History Questionnaire so the research team will be able to provide basic descriptive characteristics of the participants in the study. In addition, you will be asked to complete the “Self-Motivation Inventory” to assess your motivation to try new things, the “Pittsburgh Sleep Quality Index” to measure your sleep patterns, and the “GRIT” scale to measure your determination to complete day-to-day tasks. These questionnaires will be completed on a desktop computer in the exercise physiology laboratory (~20 minutes).

8. The activity monitor will be given to you. Everyone in this study will be asked to wear and track her activity during the study. These can measure how much you move around during the day, and also measure your sleep patterns.

Visit 2-5 (V2-V5) [Before Week 1] (~45 minutes)
Exercise Physiology Laboratory, Department of Kinesiology

When visiting the lab for V2-V5, participants will do the following:
1. Your heart rate will be measured each morning by placing three electrodes on your skin just below your collar bone and above your hips. The electrodes will be connected to a desktop computer.
2. You will be asked to lay quietly on an athletic training table for 10 minutes while the researchers record your heart rate. Next, you will be asked to sit quietly in a chair for 10 minutes, following by standing quietly for 10 minutes while the researchers record your heart rate.

Visit 6-10 (V6-V10) [During Week 1] (~90 minutes)
Exercise Physiology Laboratory, Department of Kinesiology

When visiting the lab for V6-V10, participants will do the following:
1. Prior to each exercise training session, 45 minutes will be spent measuring HRV similar to V2-V5, body weight, completing the Profile of Mood States survey, and preparing participants for exercise.
2. During each session, you will be asked to walk continuously on a treadmill at a moderate intensity, equal to 75% of maximum heart rate. A low-intensity warm-up and cool-down period will occur at the beginning and end of each session to ensure that your heart rate returns to normal levels.

Visit 11-15 (V11-V15) [After Week 1] (~45 minutes)
Exercise Physiology Laboratory, Department of Kinesiology
When visiting the lab for V11-V15, participants will do the following:
1. Your heart rate will be measured each morning by placing three electrodes on your skin just below your collar bone and above your hips. The electrodes will be connected to a desktop computer.
2. You will be asked to lay quietly on an athletic training table for 10 minutes while the researchers record your heart rate. Next, you will be asked to sit quietly in a chair for 10 minutes, following by standing quietly for 10 minutes while the researchers record your heart rate.

No contact between you and the study team personnel about missing information will take place after the study. If you choose to participate in the current study no further testing will be asked of you, outside of what is described in the consent document. You do not have to do anything else.

**How much time will I spend being this study?**
With 15 testing visits, around 16 hours (945 minutes) will be spent in the research lab for data collection.

**Will being in this study cost me anything?**
The only cost to you from this study is your time.

**Will I be paid for being in this study?**
You will be paid for being in this study. All participants will receive a total of $10 for completing all testing visits. If you are unable to complete the study or choose to withdraw from participation prior to completing the study, you will be compensated with a prorated amount of $5 for your participation. Because one of the important variables in this study is %Fat, a baseline DXA scan is required for participation in the study. As a result, if you are pregnant or become pregnant during the study you will be withdrawn from the study.

**Can the study team take me out of this study?**
Yes, the study team can remove you from the study if you do not follow directions or choose not to comply. You may also be removed if the study team determines it is unsafe for you to continue in the study.

**What are the risks (dangers or harms) to me if I am in this study?**
The results of the research study may be published, but your name or any information that could identify you will not be used. In fact, the published results will be given in summary form only. Your name, and all other personal information will be removed and replaced with a coded identification number. A potential risk of participating in this study is breach of confidentiality or loss of data-security. However, if you choose to participate in this research study, the research team will limit the potential risks by making sure that all research staff members working with participant data are trained in human subjects research and sensitivity. We also will take steps to keep your identifiable data confidential. During exercise, it is also possible that you may experience mild muscle soreness.
There may be some additional risks associated with this study. These may include:

1. Psychological stress from having your weight assessed, answering questions about body image and self-esteem, sexual history, alcohol use, and illicit drug use. However, you have the right to skip without penalty any questions you feel uncomfortable answering.
2. Breach of confidentiality or loss of data-security.
3. Small radiation dose associated with the DXA scan.
4. The occurrence of exercise-related events including the development of abnormal heart beats or death, as well as the less serious problems of injury to tendons, ligaments, joints and muscles.

We will reduce risks to you by doing the following:

1. We will provide you, after you have completed surveys with appropriate information about counseling and psychiatric services on the UA campus.
2. All members of the study team working with you are trained in human subjects research and sensitivity. We also will take steps to keep individually identifiable data private. We understand asking underage college students about alcohol consumption and illicit drug behaviors may cause some stress. But, it is important to collect this data because they are common among college behaviors. This data will help provide accurate descriptions of health statuses and behaviors of college students.
3. DXA scans used to determine body composition involve exposure to radiation from x-rays. The radiation exposure from this procedure is typically 1-5 mrem. A similar amount of radiation is received during a normal day because of natural background radiation exposure to adults in the United States each year. The risk from this amount of radiation exposure is too small to be measured directly and is considered to be low when compared with other everyday risks. Some experts believe there is a theoretical risk that low radiation doses from DXA scanning could harm a fetus but the available evidence shows no harms resulting from accidental scans of pregnant women. Because of the theoretical risk to the fetus, during the screening phase, no females will be enrolled in the study if they indicate they are currently pregnant, trying to become pregnant, or produce a positive pregnancy test during the consent process. A free pregnancy test will be offered to all females prior to the DXA testing. Confidentiality of the pregnancy test results will be followed. There is a risk of discomfort upon learning the results of a pregnancy test and the accuracy of the urine tests we will use are not 100%. Because the DXA scan is a required part of this study, individuals that choose not to take the pregnancy test will only be allowed to participate in the study if they indicate they are not currently pregnant, or not trying to become pregnant during the study. Again, current evidence suggest no harm resulting from accidental scans of pregnant women, however the participant will assume all responsibility from an accidental scan if pregnant.
4. The study team to reduce the possible risk will carefully supervise all testing. In the unlikely event of an emergency, laboratory personnel trained in CPR/AED will be present during all test conditions. In the event of a medical emergency, emergency medical services will be notified immediately. Emergency protocols for handling a cardiovascular problem will be posted in the laboratory during testing.
What are the benefits (good things) that may happen if I am in this study?
After the study, you will be provided with information about your body (fat, muscle, and bone). You will also receive information about your physical activity level. You will be provided supervised exercise training sessions aimed at weight loss under the supervision of exercise and fitness professionals. The exercise prescription will be tailored to you based on your fitness level.

What are the benefits to science or society?
The information gathered through this research study may help in future programs design more effective interventions to prevent overweight or obesity. The results of this study may increase the public health understanding of the health statuses and behaviors of college students and may be used in the future to design health behavior interventions and programs targeted to college students.

How will my privacy be protected?
No additional testing beyond what is described in this consent document will be asked of you after taking part in this study. Also, to protect your privacy, you do not have to answer any questions they do not want to as part of the study requirements.

How will my confidentiality be protected?
Your confidentiality as a student and as a participant in this research study will be protected by a number of methods. First, signed informed consent documents will be kept in a separate location, away from any personal information or research data. In addition, a coded study ID number will be assigned to your name and used with all research data to protect your personal information. Only the principal investigator and study team will have access to personal information before de-identification. The raw data and personal identifiers will be destroyed after the study has been completed. Finally, all hard copies of study information will be kept in a locked drawer and locked in a secure office when unattended. All electronic copies of research data will be kept in a password-protected file.

What are the alternatives to being in this study? Do I have other choices?
The alternative to being in this study is not to participate.

What are my rights as a participant in this study?
If you start the study, you can stop at any time. There will be no effect on your relations with the University of Alabama.

The University of Alabama Institutional Review Board ("the IRB") is the committee that protects the rights of people in research studies. The IRB may review study records from time to time to be sure that people in research studies are being treated fairly and that the study is being carried out as planned.
Is participating in this study voluntary?
Your involvement in this study is voluntary. You can choose not to participate, withdraw your consent, or stop at any time without penalty or loss of benefits to which you are otherwise entitled.

What happens if I am injured while participating in this study?
The study team will exercise all reasonable care to protect you from harm as a result of your participation. In the event that any research-related activities result in an injury, the sole responsibility of the study team will be to arrange for your transportation to an appropriate health care facility. If you think that you have suffered a research-related injury, you should seek immediate medical attention and then contact Dr. Michael Fedewa right away at 205-348-9779. In the event that you suffer a research-related injury, your medical expenses will be your responsibility or that of your third-party payer, although you are not precluded from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research.

Who do I call if I have questions or problems?
If you have questions about the study right now, please ask them. If you have questions about the study later on, please call the investigator, Dr. Michael Fedewa at 205-348-9779.

If you have questions, concerns, or complaints about your rights as a person in a research study, call Ms. Tanta Myles, the Research Compliance Officer of the University, at 205-348-8461 or toll-free at 1-877-820-3066.

You may also ask questions, make suggestions, or file complaints and concerns through the IRB Outreach website at http://osp.ua.edu/site/PRCO_Welcome.html or email the Research Compliance office at participantoutreach@bama.ua.edu.

After you participate, you are encouraged to complete the survey for research participants that is online at the outreach website or you may ask the study team for a copy of it and mail it to the University Office for Research Compliance, Box 870127, 358 Rose Administration Building, Tuscaloosa, AL 35487-0127.

I have read this consent form. I have had a chance to ask questions. I agree to take part in it.

I will receive a copy of this consent form to keep.

__________________________  ________________________
Signature of Research Participant  Date

__________________________  ________________________
Signature of Investigator  Date

UNIVERSITY OF ALABAMA IRB
CONSENT FORM APPROVED  8/7/17
EXPIRATION DATE:  6/7/18
February 8, 2018

Michael Fedewa, Ph.D.
Assistant Professor
Department of Kinesiology
College of Education
The University of Alabama
Box 870312

Re: IRB Protocol # 16-012-ME-R1-A
“Changes in HRV and Physical Activity during Exercise One Week of Exercise Training”

Dr. Fedewa:

The University of Alabama Medical Institutional Review Board has reviewed the revision to your previously approved full board protocol. The board has approved the minor change in your protocol.

Please remember that your protocol expires on June 7, 2018.

Should you need to submit any further correspondence regarding this proposal, please include the assigned IRB application number. Changes in this study cannot be initiated without IRB approval, except when necessary to eliminate apparent immediate hazards to participants.

Good luck with your research.

Sincerely,

[Signature]

Carpettato T. Myles, MSM, CQM, CIP
Director & Research Compliance Officer
Office of Research Compliance

358 Rose Administration Building | Box 870127 | Tuscaloosa, AL 35487-0127
205-348-8461 | Fax 205-348-7189 | Toll Free 1-877-820-3066
Research Study

Students age 18 to 24 years are invited to participate in a one-week exercise training study examining the effect of structured exercise on physical activity.

All testing will be performed at Moore Hall at the University of Alabama.

Participants will be asked to complete confidential body composition analysis, as well as surveys regarding health history and physical activity. Participants can earn up to $10 with successful completion of the study.

If you are interested in participating, please contact the Principal Investigator: Michael V. Fedewa, Ph.D. (mvfedewa@ua.edu)
UNIVERSITY OF ALABAMA
INFORMED CONSENT DOCUMENT

Study Title:
Changes in HRV and Physical Activity During Exercise One Week of Exercise Training

Principal Investigator:
Dr. Michael V. Fedewa (205-348-9779; mvedewa@ua.edu)
Assistant Professor, The University of Alabama

Co-Investigator:
Dr. Michael R. Esco (205-348-2151; mresco@ua.edu)
Assistant Professor, The University of Alabama

Student Co-Investigators:
Yuan Liu M.A. (yliu223@crimson.ua.edu)
Doctoral Student

Dano Tolusso M.A. (dtolusso@crimson.ua.edu)
Doctoral Student

You are being invited to participate in a research study. The study is called “Changes in HRV and Physical Activity During Exercise One Week of Exercise Training.” The study is being done by Dr. Michael Fedewa and Dr. Michael Esco, who are assistant professors with the Department of Kinesiology at the University of Alabama. Our Doctoral Students, Dano and Yuan will assist with the research study by obtaining informed consent and helping with data collection.

Is the study team being paid for this study? No, the researchers are not receiving extra pay for this study.

Is this research developing a product that will be sold, and if so, will the study team profit from it? No, the researchers are not developing a product that will be sold and will not directly profit from this study.

Does the study team have any conflict of interest in this study? The researchers do not have any potential conflicts of interest.

What is this study about? What is the study team trying to learn?
The purpose of this study is to determine if changes in your heart rhythm can be used to predict changes in physical activity during an exercise study. You will also be asked to answer some questions about your alcohol use, drug use, sleep, and motivation to try different activities. These questions are being included as part of our basic health history survey because these factors have been related to heart rate and physical activity markers being measured in this study.
Why is this study important or useful?
This information will be used to develop programs that will help people lose weight and become healthier with physical activity.

Why have I been asked to be in this study?
You have been asked to be in this study because you are eligible and have expressed interest in participating. You have also met the criteria to be included in this study. Based on the answers that you provided as part of the online screening process, you are a young adult between 18 and 24 years of age enrolled at the University of Alabama. You have said that you do not currently have an exercise program, and our research team has determined that it is safe for you to exercise.

How many people will be in this study?
About 30 other people will be in this study.

What will I be asked to do in this study?
If you choose to participate in this study, some of the information will be collected from you. This includes information about your health status (heart rate), as well as information about what your body is made of (fat, muscle, and bone), and physical activity (steps, minutes, and sitting time). During the exercise sessions, you will be asked to walk continuously on a treadmill in the Exercise Physiology Lab in Moore Hall. The treadmill will be set to a moderate walking speed, fast enough to increase your heart rate up to 75% of your maximum heart rate, but slow enough so that you can easily walk for 45-60 minutes. You will be asked to visit the lab on 5 consecutive days at the same time each day during the one-week study for your supervised exercise sessions.

If you agree to participate, you will be asked to:
Visit 1 (V1) [Before Week 1] (~90 minutes)
Exercise Physiology Laboratory, Department of Kinesiology
When visiting the lab for V1, you will do the following:
1. Your on-line screening form will be checked for accuracy.
2. The study team will have you read an informed consent document (ICD), and then describe what you will be asked to do for this study. You will also read a consent document for the dual energy x-ray absorptiometry (DXA) body scan. After the study team feels that you understand what you will be asked to do for this study, both you and the study team member will sign the informed consent document and each will keep a copy.
3. Height, weight, and waist measurements will be performed, a lot like the measurements performed in a doctor’s office.
4. Your heart rate will be measured each morning by placing three electrodes on your skin just below your collar bone and above your hips. The electrodes will be connected to a desktop computer. You will be asked to lay quietly on an athletic training table for 10 minutes while the researchers record your heart rate. Next, you will be asked to sit quietly in a chair for 10
minutes, following by standing quietly for 10 minutes while the researchers record your heart rate.

5. You will then have a DXA whole body scan to see what you are made of (fat, muscle, and bone). During the scan, you will be asked to lay on the scanning bed for 7-24 minutes.

6. You will be asked to complete a fitness test to measure your fitness level. During the test, the study team will ask you to walk on a treadmill while breathing through a special mouthpiece to measure the air you breath in and out. The speed and incline of the treadmill will gradually increase until you fatigue and requests to stop. (~20 minutes duration).

7. You will complete a Demographic and Health History Questionnaire so the research team will be able to provide basic descriptive characteristics of the participants in the study. In addition, you will be asked to complete the “Self-Motivation Inventory” to assess your motivation to try new things, the “Pittsburgh Sleep Quality Index” to measure your sleep patterns, and the “GRIT” scale to measure your determination to complete day-to-day tasks. These questionnaires will be completed on a desktop computer in the exercise physiology laboratory (~20 minutes).

8. The activity monitor will be given to you. Everyone in this study will be asked to wear and track her activity during the study. These can measure how much you move around during the day, and also measure your sleep patterns.

Visit 2-5 (V2-V5) [Before Week 1] (~45 minutes)
Exercise Physiology Laboratory, Department of Kinesiology
When visiting the lab for V2-V5, participants will do the following:

1. Your heart rate will be measured each morning by placing three electrodes on your skin just below your collar bone and above your hips. The electrodes will be connected to a desktop computer.

2. You will be asked to lay quietly on an athletic training table for 10 minutes while the researchers record your heart rate. Next, you will be asked to sit quietly in a chair for 10 minutes, following by standing quietly for 10 minutes while the researchers record your heart rate.

Visit 6-10 (V6-V10) [During Week 1] (~90 minutes)
Exercise Physiology Laboratory, Department of Kinesiology
When visiting the lab for V6-V10, participants will do the following:

1. Prior to each exercise training session, 45 minutes will be spent measuring HRV similar to V2-V5, body weight, completing the Profile of Mood States survey, and preparing participants for exercise.

2. During each session, you will be asked to walk continuously on a treadmill at a moderate intensity, equal to 75% of maximum heart rate. A low-intensity warm-up and cool-down period will occur at the beginning and end of each session to ensure that your heart rate returns to normal levels.

Visit 11-15 (V11-V15) [After Week 1] (~45 minutes)
Exercise Physiology Laboratory, Department of Kinesiology
When visiting the lab for V11-V15, participants will do the following:
1. Your heart rate will be measured each morning by placing three electrodes on your skin just below your collar bone and above your hips. The electrodes will be connected to a desktop computer.
2. You will be asked to lay quietly on an athletic training table for 10 minutes while the researchers record your heart rate. Next, you will be asked to sit quietly in a chair for 10 minutes, following by standing quietly for 10 minutes while the researchers record your heart rate.

No contact between you and the study team personnel about missing information will take place after the study. If you choose to participate in the current study no further testing will be asked of you, outside of what is described in the consent document. You do not have to do anything else.

**How much time will I spend being this study?**
With 15 testing visits, around 16 hours (945 minutes) will be spent in the research lab for data collection.

**Will being in this study cost me anything?**
The only cost to you from this study is your time.

**Will I be paid for being in this study?**
You will be paid for being in this study. All participants will receive a total of $10 for completing all testing visits. If you are unable to complete the study or choose to withdraw from participation prior to completing the study, you will be compensated with a prorated amount of $5 for your participation. Because one of the important variables in this study is %Fat, a baseline DXA scan is required for participation in the study. As a result, if you are pregnant or become pregnant during the study you will be withdrawn from the study.

**Can the study team take me out of this study?**
Yes, the study team can you remove you from the study if you do not follow directions or choose not to comply. You may also be removed if the study team determines it is unsafe for you to continue in the study.

**What are the risks (dangers or harms) to me if I am in this study?**
The results of the research study may be published, but your name or any information that could identify you will not be used. In fact, the published results will be given in summary form only. Your name, and all other personal information will be removed and replaced with a coded identification number. A potential risk of participating in this study is breach of confidentiality or loss of data-security. However, if you choose to participate in this research study, the research team will limit the potential risks by making sure that all research staff members working with participant data are trained in human subjects research and sensitivity. We also will take steps to keep your identifiable data confidential. During exercise, it is also possible that you may experience mild muscle soreness.
There may be some additional risks associated with this study. These may include:
1. Psychological stress from having your weight assessed, answering questions about body image and self-esteem, sexual history, alcohol use, and illicit drug use. However, you have the right to skip without penalty any questions you feel uncomfortable answering.
2. Breach of confidentiality or loss of data-security.
3. Small radiation dose associated with the DXA scan.
4. The occurrence of exercise-related events including the development of abnormal heart beats or death, as well as the less serious problems of injury to tendons, ligaments, joints and muscles.

We will reduce risks to you by doing the following:
1. We will provide you, after you have completed surveys with appropriate information about counseling and psychiatric services on the UA campus.
2. All members of the study team working with you are trained in human subjects research and sensitivity. We also will take steps to keep individually identifiable data private. We understand asking underage college students about alcohol consumption and illicit drug behaviors may cause some stress. But, it is important to collect this data because they are common among college behaviors. This data will help provide accurate descriptions of health statuses and behaviors of college students.
3. DXA scans used to determine body composition involve exposure to radiation from x-rays. The radiation exposure from this procedure is typically 1-5 mrem. A similar amount of radiation is received during a normal day because of natural background radiation exposure to adults in the United States each year. The risk from this amount of radiation exposure is too small to be measured directly and is considered to be low when compared with other everyday risks. Some experts believe there is a theoretical risk that low radiation doses from DXA scanning could harm a fetus but the available evidence shows no harms resulting from accidental scans of pregnant women. Because of the theoretical risk to the fetus, during the screening phase, no females will be enrolled in the study if they indicate they are currently pregnant, trying to become pregnant, or produce a positive pregnancy test during the consent process. A free pregnancy test will be offered to all females prior to the DXA testing. Confidentiality of the pregnancy test results will be followed. There is a risk of discomfort upon learning the results of a pregnancy test and the accuracy of the urine tests we will use are not 100%. Because the DXA scan is a required part of this study, individuals that choose not to take the pregnancy test will only be allowed to participate in the study if they indicate they are not currently pregnant, or not trying to become pregnant during the study. Again, current evidence suggest no harm resulting from accidental scans of pregnant women, however the participant will assume all responsibility from an accidental scan if pregnant.
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What are the benefits (good things) that may happen if I am in this study?
After the study, you will be provided with information about your body (fat, muscle, and bone). You will also receive information about your physical activity level. You will be provided supervised exercise training sessions aimed at weight loss under the supervision of exercise and fitness professionals. The exercise prescription will be tailored to you based on your fitness level.

What are the benefits to science or society?
The information gathered through this research study may help in future programs design more effective interventions to prevent overweight or obesity. The results of this study may increase the public health understanding of the health statuses and behaviors of college students and may be used in the future to design health behavior interventions and programs targeted to college students.

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What are the alternatives to being in this study? Do I have other choices?
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What are my rights as a participant in this study?
If you start the study, you can stop at any time. There will be no effect on your relations with the University of Alabama.

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Is participating in this study voluntary?
Your involvement in this study is voluntary. You can choose not to participate, withdraw your consent, or stop at any time without penalty or loss of benefits to which you are otherwise entitled.

What happens if I am injured while participating in this study?
The study team will exercise all reasonable care to protect you from harm as a result of your participation. In the event that any research-related activities result in an injury, the sole responsibility of the study team will be to arrange for your transportation to an appropriate health care facility. If you think that you have suffered a research-related injury, you should seek immediate medical attention and then contact Dr. Michael Fedewa right away at 205-348-9779. In the event that you suffer a research-related injury, your medical expenses will be your responsibility or that of your third-party payer, although you are not precluded from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research.

Who do I call if I have questions or problems?
If you have questions about the study right now, please ask them. If you have questions about the study later on, please call the investigator, Dr. Michael Fedewa at 205-348-9779.

If you have questions, concerns, or complaints about your rights as a person in a research study, call Ms. Tanta Myles, the Research Compliance Officer of the University, at 205-348-8461 or toll-free at 1-877-820-3066.

You may also ask questions, make suggestions, or file complaints and concerns through the IRB Outreach website at http://osp.ua.edu/site/PRCO_Welcome.html or email the Research Compliance office at participantoutreach@bama.ua.edu.

After you participate, you are encouraged to complete the survey for research participants that is online at the outreach website or you may ask the study team for a copy of it and mail it to the University Office for Research Compliance, Box 870127, 358 Rose Administration Building, Tuscaloosa, AL 35487-0127.

I have read this consent form. I have had a chance to ask questions. I agree to take part in it.

I will receive a copy of this consent form to keep.

_________________________________________  __________________________
Signature of Research Participant  Date

_________________________________________  __________________________
Signature of Investigator  Date