Acute Renal Injury During High Intensity Training (HIFRT-KH)– Study Protocol and Informed Consent Forms

Document Date – 05/02/2019

NCT Number - NCT03678285

Notes – There are two protocol numbers and informed consent documents associated with the project because data was collected in individual sessions (20180607EJ2013) and also as a part of a mass participation event (20190502EJ02396). Both approval documents and informed consents have been included here.

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May 13, 2019

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Nicole Sauls
Graduate Assistant
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Protocol #20180607EJ02013

Re: *"Risk Factors Related to Acute Renal Injury during High Intensity Training"*

Dear Evan, Boyi, Gretchen, Derek, Afzal, Evan, and Nicole:

Your annual review for the protocol referenced above has been approved. Your annual review and approval will be reported to the IRB at their next convened meeting June 20, 2019.

IRB approval for the project/research is for a one-year period. If this research project extends beyond ***June 6, 2020,*** a request to extend the approval accompanied by a report on the status of the project (Annual Review Form) must be submitted to the IRB at least one month prior to the expiration date. Any significant change(s) in the research/project protocol(s) from what was approved should be submitted to the IRB (Protocol Update Form) for review and approval prior to initiating any change. Per recent policy and compliance requirements, any investigator with an active research protocol may be contacted by the recently convened Data Safety Monitoring Board (DSMB) for periodic review. The DSMB's charge (sections 7.3 and 7.4 of the IRB Policy and Procedures Manual) is to review active human subject(s) projects to assure that the procedures, data management, and protection of human participants follow approved protocols. Further information and the forms referenced above may be accessed at the "Human Subjects" link on the Office of Research and Economic Development website: http://www.uwyo.edu/Research/Research/human-subjects/index.html.

You may proceed with the project and we wish you luck in the endeavor. Please feel free to call me if you have any questions.

Sincerely,

Nichole Person
Nichole Person

Staff Assistant, Research Office
On behalf of the Chairman,
Institutional Review Board

University of Wyoming IRB Proposal Form

Institutional Review Board
Room 308, Old Main
1000 East University Avenue, Dept. 3355
Laramie, WY 82071

Phone: 307-766-5322
Fax: 307-766-2608
email: irb@uwyo.edu
(Electronic submission via email is encouraged.)

1. Responsible Project Investigator, Co-Investigators, & Faculty Supervisor

Responsible Project Investigator:

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Phone number: 307-766-5282	**Fax number (if applicable):** 307-766-4098
Email address: evan.johnson@uwyo.edu	
Is the project funded? Y___ N__X__ **If Y, from where?**_____ **If N, have you applied for funding? Y __X__ N _____** **Where?** AMSSM-ACSM Clinical Research Grant	

Co-Investigators (add more boxes if necessary):

Name: Boyi Dai	**Title:** Associate Professor
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Name: Afzal Khan	**Title:** Medical Director
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Name: Evan Norby	**Title:** Interim Program Director
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Name: Nicole Sauls	**Title:** Graduate Assistant
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Is the project is funded? Y___ N____ **If Y, from where?**_____ **If N, have you applied for funding? Y ____ N _____ Where?**	

Faculty Supervisor (if PI is a student): n/a

Name:	**Title:**
Department:	
Office Address:	
Phone number:	**Fax number (if applicable):**
Email address:	
If the principal investigator is a graduate or undergraduate student, submit the Research Supervisor Approval form from the faculty advisor, thesis or dissertation committee chair indicating review and approval of the proposal for submission to the IRB. The IRB will not approve a proposal without the proper Approval form.	

2. Title of Study:

Pharmacological Risk Factors Related to Acute Renal Injury during High Intensity Training

3. Anticipated Project Duration:

May 1st, 2018 – September 31st, 2019

4. Purpose of Research Project:

In LAY LANGUAGE, summarize the objectives and significance of the research:

Physical activity is a well-established intervention used to improve a variety of health domains including cardiorespiratory, functional, and metabolic health. Despite the well-known health benefits, 31.1% of worldwide adults are considered physically inactive, and only 20.6% of adults in the United States meet both the current aerobic and muscle strengthening guidelines (ACSM's guidelines for exercise testing and prescription 2016). In response to the physical inactivity pandemic, barriers to exercise have been studied, and "lack of time" was a chief recurring response (Booth, Bauman, Owen, & Gore, 1997; Daskapan, Emine, & Levent, 2006; Sallis & Hovell, 1990).

As a result, recent investigations have made an attempt to find a more time-efficient exercise solution through the comparison of high intensity training (HIT) performed over shorter durations in comparison to traditional moderate intensity continuous exercise (MICE). The theory behind HIT is that through higher intensity exercise, increased muscle fiber recruitment occurs, resulting in maximal skeletal muscle adaptations within a short period of time. HIT has demonstrated equivalent and even superior training effects compared to MICE (Burgomaster et al., 2008; Gibala, 2007; Nybo et al., 2010); however, other studies have reported potential risk including post-exercise physical dysfunction (Drum, Bellovary, Jensen, Moore, & Donath, 2017; Nybo et al., 2010). Not all variations of HIT will elicit identical training effects, and there may be individuals who are at higher risk for adverse consequences based on their specific behavioral patterns.

High intensity ***interval*** training (HIIT) is the most recognized sub-class of HIT and is characterized by short bouts of high intensity cardiovascular exercise (i.e., running, cycling, rowing, stair-stepping) separated by brief periods of planned rest (Thompson, 2015). Traditional resistance and strength training methodologies have also been adapted to the HIT framework to create high intensity functional resistance training (HIFRT). This style of HIT incorporates various functional movements (e.g., pull-ups, Olympic lifts) performed at relatively high intensities that train the body in all planes of motion. Recent analyses have revealed this mode of training can improve metabolic conditioning, muscular strength, and the general physical preparedness of military members (Haddock, Roston, Heinrich, Jahnke, &

Jitnarin, 2016); however, as in any type of exercise, potential acute injury risks have also been identified.

Some forms of HIFRT have been linked with severe post-exercise physical dysfunction and incidences of acute exertional rhabdomyolysis (ER) developing from skeletal muscle damage (Dilip, Richmond, & Alfonso, 2009; Drum et al., 2017; Xavier, Esteban, & Josep, 2009). Due to demand on the kidney's filtering unit to clear excess from the blood stream, ER is the most common cause of exercise-related acute kidney injury (AKI) in trained populations (Dilip et al., 2009). Renal injury risk can be exacerbated by the ingestion of non-steroidal anti-inflammatory drugs (NSAIDS) which are taken in exercise populations to decrease inflammation and musculoskeletal pain. During normal exercise, sympathetic nervous activity constricts afferent arterioles to the kidney decreasing blood flow. However, this signal is partially mitigated by prostaglandin production, resulting in very few renal concerns with traditional MICE. The ingestion of NSAIDS prior to exercise can increase renal risk because the medication inhibits the cyclooxygenase-2 (COX-2) enzyme which in turn inhibits the vasodilation effects of prostaglandins in the renal arteries. The resulting ischemia can induce renal injury and decrease the kidney's ability to filter blood.

Those who participate in HIFRT may demonstrate increased prevalence of prophylactic NSAID use (i.e., medication taken before an exercise session) compared to the normal population. This style of exercise has demonstrated more reporting of severe physical dysfunction symptoms such as muscle pain and soreness following HIFRT exercise sessions compared to traditional MICE (Drum et al., 2017). Frequent NSAID ingestion may occur in an effort to decrease post-exercise discomfort or, when they are taken in anticipation of a strenuous workout, the purpose is to circumvent and decrease potential future discomfort from occurring in the first place.

There are many variations of HIFRT workouts, and some are more physically demanding than others. One of the most difficult and frequently performed workouts is "Murph" which consists of a 1 mile run, 100 pull-ups, 200 push-ups, 300 body-weight squats, and a second 1 mile run. The workout is performed by many members HIFRT community including 177 facilities in the United States that hosted "Murph" workouts in 2017 in honor of a Navy SEAL (LT. Michael P. Murphy) who died while serving overseas in Afghanistan (The murph challenge.2018). Symptoms of severe physical dysfunction have been reported following the completion of "Murph", so there may be a high ingestion rate of NSAIDs prior to the workout in anticipation of symptoms such as pain and muscle soreness (Drum et al., 2017).

Preliminary studies from out laboratory

A brief questionnaire (QNR) was implemented as a pilot study to evaluate the prevalence of NSAID ingestion among HIFRT athletes. One hundred and seven volunteers completed the QNR, and the number one reported reason for ingesting NSAIDs was to relieve musculoskeletal pain, inflammation, or soreness.

It was also found that 39 (36%) had taken NSAIDs within the last week (**Figure 1**), 21% had ingested NSAIDs prior to a workout, and 20% had consumed higher than the prescribed dose (e.g., > 400mg 3x a day of ibuprophen). The results suggest a population with a high proportion of NSAID use which supports an essential need to investigate the potential negative pharmacological renal effects of NSAIDs especially since 60% of respondents also reported that they have completed the strenuous workout "Murph" in the past.

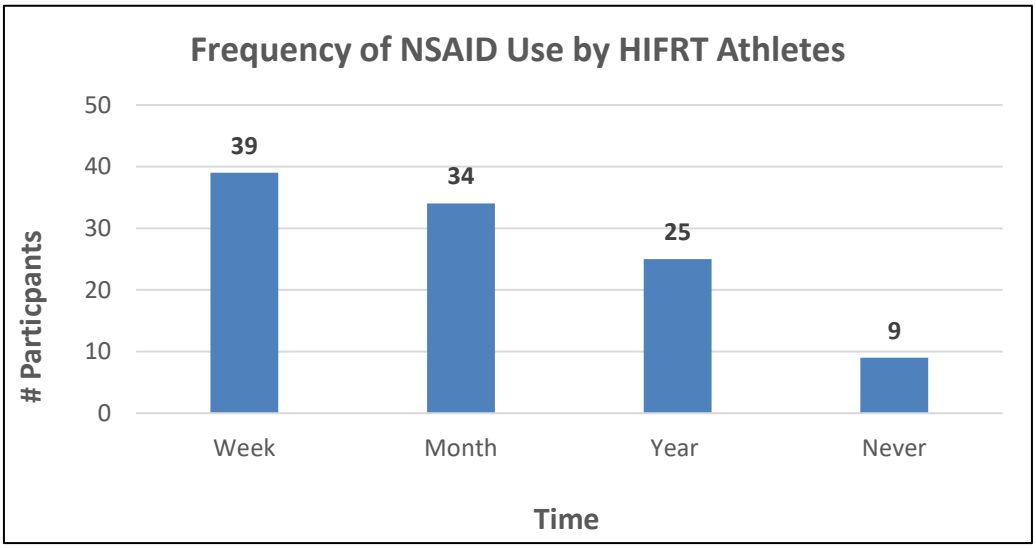

Figure 1. Frequency of NSAID use among HIFRT population.

A second ongoing pilot study within the Human Integrated Physiology Laboratory is seeking to quantify the exposure rate of the workout "Murph". This investigation is being performed via phone call or online QNR. There are about 6,000 HIFRT facilities in the United States, but the number of members of each of these gyms and the proportion of members who complete the workout "Murph" every year is unknown. Stratified methods of sampling have been performed to ensure gyms were randomly selected from all fifty states. Upon completion, an accurate estimate of the total exposure rate of "Murph" in the United States will be reported.

Purpose / Aims

HIT is a modality of exercise that can produce a high amount of health benefit in a minimal amount of time. However, it is clear that some forms of HIT, particularly within the resistance training style (i.e., HIFRT) can introduce risk of renal injury, especially when they are combined with NSAID self-administration. Therefore the aims of our current study are as follows:

Aim 1: To investigate the prevalence of AKI following the HIFRT workout, "Murph", and compare the results to previous research evaluating incidence rates in other forms of extreme exercise (i.e., marathon running). AKI will be determined through the sample analysis of

blood (serum creatinine, blood urea nitrogen, neutrophil gelatinase-associated lipocalin [NGAL], and kidney injury molecule 1 [KIM-1]) and urine (albumin, creatinine, NGAL, and KIM-1) biomarkers.

Aim 2: To evaluate if the ingestion of NSAIDs significantly increase the renal injury biomarker concentrations listed above.

Aim 3: To evaluate biomechanical risk of musculoskeletal injury during the duration of a HIFRT workout through the examination of movement patterns using 2D video analysis and measurement of potential bilateral asymmetries using force platforms.

The results from the study will be contribute to safe and efficacious prescription of HIFRT workouts similar to "Murph".

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Thompson, R. (2015). Worldwide survey of fitness trends for 2016: 10th anniversary edition. *ACSM's Health & Fitness Journal, 19*(6), 9-18.

5. Description of Potential Participants:

A. Age-range and gender: Men and women between the ages of 18-60

B. Describe how the participants will be recruited and/or selected:

Participants will be recruited from a Laramie, Wyoming HIFRT facility, CrossFit 7220. They will be asked to volunteer in a double blind, counterbalanced, and crossover investigation. Only individuals who: A) self-report having taken NSAIDs prior to workouts in the past, B) have at least one year of HIFRT training experience, and C) who have completed the prescribed version of the workout "Murph" at least one time will be recruited. These questions were specifically asked on our pilot QNR, along with the question if they would be interested in follow-up investigations. Individuals that answered "yes" to this question along with meeting the above criteria will be contacted first.

Additional participants will be recruited by word of mouth and enrolled in the study only after meeting the above criteria. Interested individuals will contact the principal investigator to hear full details on the study procedures, exclusionary criteria, risks and benefits prior to any involvement.

C. Describe the number of participants expected:

We plan to enroll 10 participants in this project. The clinical definition of acute kidney injury is a rise in serum creatinine (Scr) by ≥0.3 mg/dl. A 10% difference in Scr rise (i.e., 0.03mg/dl difference between trials) induced by NSAID administration would be considered clinically significant. Using the standard deviation of 0.02 mg/dl shown by Reid, Speedy, & Thomson, 2004, an effect size of 1.5 is estimated for a matched pair, two-tailed analysis. At a power level of 95%, a sample size of 8 is required. In order to account for any potential subject attrition we will enroll 10 participants in the current project.

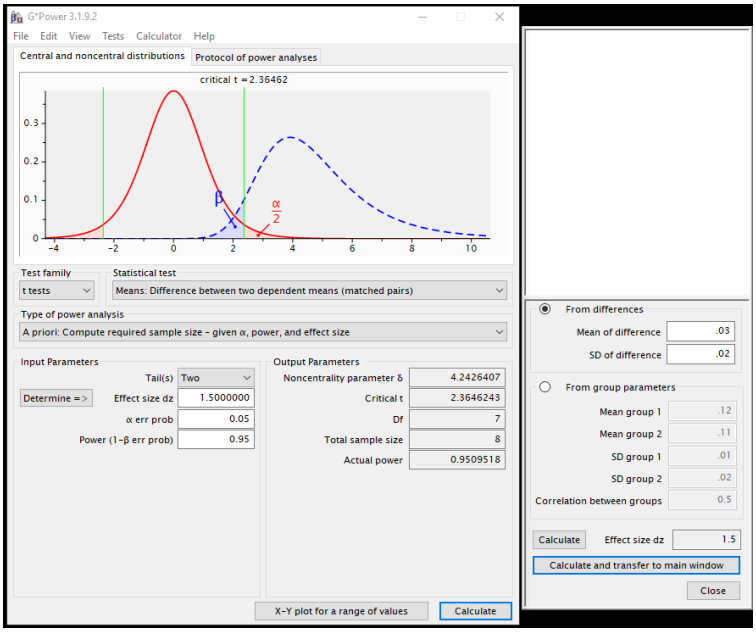


Figure 2. Power calculation as completed using G*Power 3.1.9.2

D. Will compensation or incentives be provided for participation ? Y__X__ N____
IF Y, please describe:

Participants will receive $100 for full participation in this study. This will be distributed at the participants' end of enrollment in the study. If they choose to be removed from the study prior to completion they will be compensated based on the below pro-rated basis.
$10 – Baseline measurements
$30 – Completion of initial workout
$30 – Completion of second workout
$30 – Completion bonus for finishing all study measurement periods

E. Description of special classes: n/a

F. Criteria for exclusion from participant pool:

1. Score of "0" on the Functional Movement Screening (FMS) test indicating pain during any of the seven functional movements
2. Kidney or other medical conditions contraindicating participation in HIFRT
3. Pregnancy, suspected pregnancy, or breastfeeding
4. Blood donations within the last eight weeks leading up to testing day
5. Any musculoskeletal injuries which have resulted in > 1 week of absence from HIFRT within the last six months
6. Not passing the physical activity readiness questionnaire (PAR-Q)
7. Evidence of clinically relevant metabolic, cardiovascular, hematologic, hepatic, gastrointestinal, renal, pulmonary, endocrine or psychiatric history of disease, based on the medical history questionnaire
8. Surgical operation on digestive tract or kidneys, except appendectomy
9. Inability to participate in the entire study
10. Recurrent urinary tract infections or kidney stones
11. History of protein or blood in urine
12. Moving from a location of low altitude to Laramie within the past 3 months
13. Inability to understand and write English*

*English is a required language because the questionnaires which will be used in this investigation are written in English language.

6. Procedure:

A. Description of participants' activities:

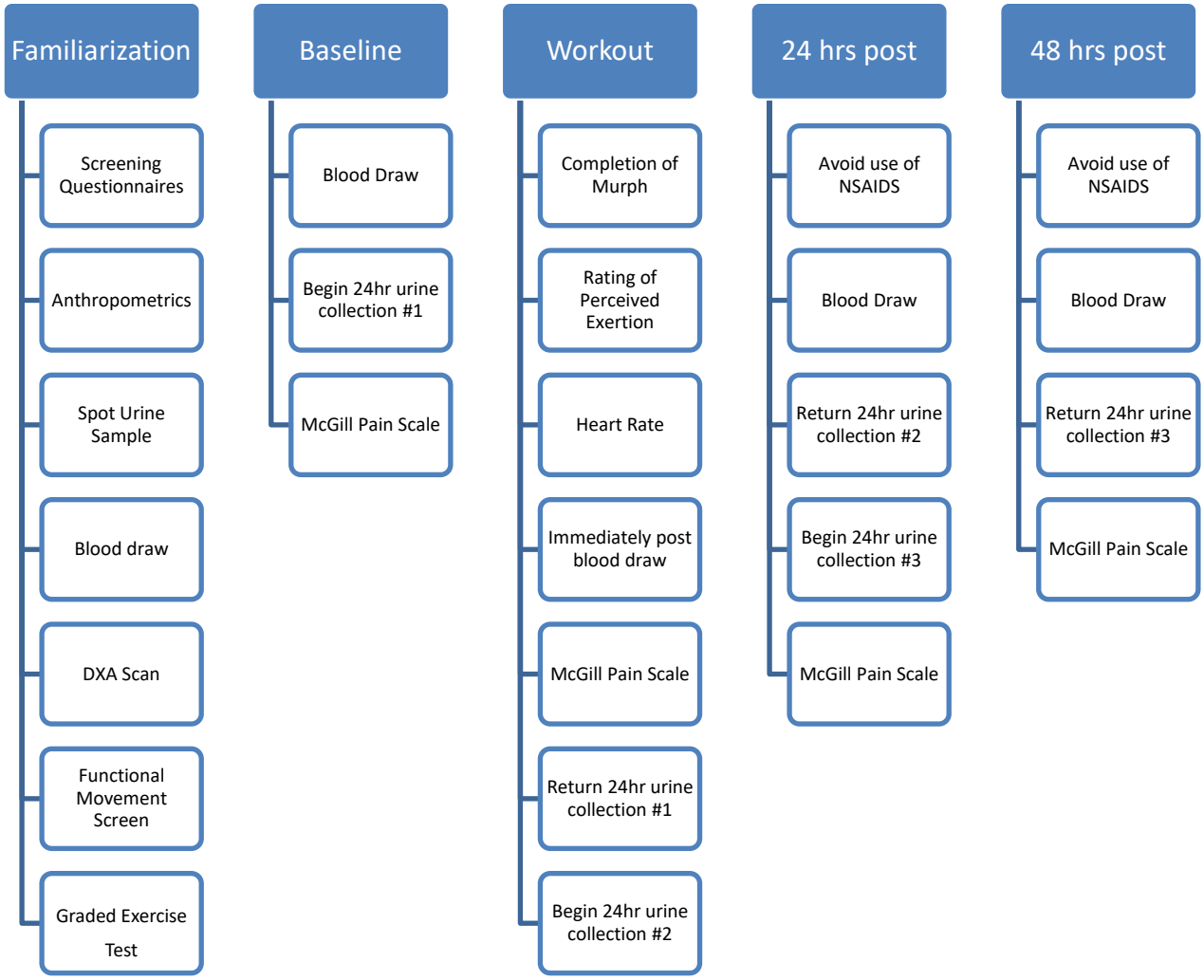


Figure 3. Overall outline of a single testing week for individual data collections. Each participant will complete two testing weeks one month apart.

Familiarization: Subjects will report to the Human Integrated Physiology (HIP) laboratory to provide informed consents (graded exercise testing, dual x-ray absorptiometry [DXA] scan, and form for overall study), complete initial screening procedures (physical activity readiness questionnaire (PAR-Q), medical history questionnaire, anthropometrics DXA scan, functional movement screening (FMS; **Figure 4**), and graded exercise test), spot urine sample, and blood draw. Female participants will review their menstrual cycle history with a female investigator (Attachment VIII), in order to schedule their first baseline visit to correspond with their early follicular phase (i.e. 4-5 days after the end of their period).

- Informed consent obtained for overall research study
- Informed consent for exercise stress testing (VO_{2max} test)
- Informed consent for DXA scan
- University of Wyoming medical history questionnaire
- PAR-Q
- Anthropometrics (age, height, weight)
- Spot urine sample (albumin, creatinine, NGAL, and KIM-1])

- Blood draw (serum creatinine, blood urea nitrogen, NGAL, and KIM-1)
- DXA scan
- FMS
- Graded exercise test to determine maximal heart rate and oxygen uptake

DXA scans will be administered by the principal investigator or a graduate student that has undergone the appropriate x-ray safety training at the University of Wyoming, Environmental Health and Safety Office. These graduate students include Nicole Sauls and Breton Van Syoc.

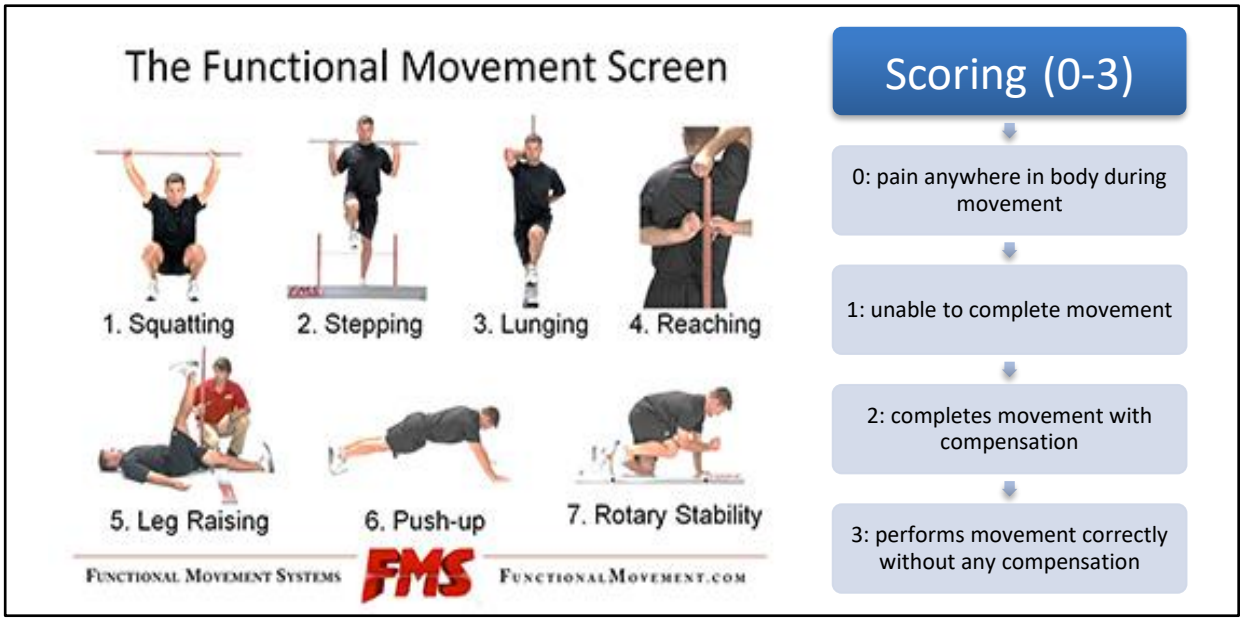


Figure 4. The seven movement patterns and scoring system for FMS.

Baseline (24 hours prior to workout session): Subjects will report the HIP Laboratory to provide baseline measures including a blood draw, McGill pain scale (Attachment 4), and begin the first 24 hour urine jug collection.

- The first 24 hour urine jug collection will be submitted to investigators the following day immediately prior to the workout session.

Workout Session: Participants will report to the CrossFit 7220 gymnasium. Once arrived they will turn in their first 24 hour urine sample jug, receive a new 24 hour urine sample jug, perform a full body dynamic warm-up, review movement standards for the exercises to be completed as part of the workout, and complete the workout "Murph" while performance measures are recorded (rating of perceived exertion (RPE), heart rate, 2D movement analysis, and force evaluations). Immediately following the workout, a blood draw will be taken by the primary investigator and the participant will be asked to mark their level of muscle soreness on the McGill pain scale.

- Turn in 24 hour urine sample jug
- Receive empty 24 hour urine sample jug
- Dynamic warm-up (500m row and two rounds of 10 wall push-ups, 10 ring rows, 5 body weight-squats, 10 each side forward leg swings, 10 arm circles in each direction, and a 30 second plank hold)
- Review of movement standards and practice opportunity
- Complete "Murph" (1 mile run, 100 pull-ups, 200 push-ups, 300 body weight squats, and a final 1 mile run)

- RPE and heart rate recorded after completion of every segment (e.g. 1 segment = 1 mile run, 100 pull-ups, 200 push-ups, 300 squats, or final 1 mile run)
- 2D movement analysis and bilateral force evaluations capturing repetitions at the beginning and end of each segment
- Post blood draw
- Post McGill pain scale to measure muscle soreness

24 hours post: Subjects will report to the HIP lab to turn in their second 24 hour urine collection jug and be provided with the third and final 24 hour collecting jug. They will also take part in a blood draw and fill out the McGill pain scale to continue monitoring muscle soreness.
Participants will be asked to abstain from the ingestion of NSAIDS during this time.
Participants will be asked to refrain from exercise during this time.

48 hours post: Subjects will turn in their third and final 24 hour collecting jug, provide one last blood draw, and complete the McGill pain scale. Once the 48 hour post tests have been finished, the subjects have officially completed one testing week of the study.

Pharmacological Intervention: All participants will complete the above cycle (baseline through 48 hours post measurements) on two occasions separated by one month. On one of their baseline visits they will be given a single dose of NSAIDs in the form of 400mg of ibuprofen (provided to investigators by Ivinson hospital) to consume 45 minutes prior to their arrival on the "workout session" day. On the other baseline visit participants will be given a single dose of a placebo pill (2 x 4g oral glucose pills, Walgreens) to consume 45 minutes prior to their arrival on the "workout session" day. The medications will be divided into individual doses by an investigator that does not have direct interaction with the participants during the data collection phases of this study into "A" medication and "B" medication. Which of the medications is ibuprofen will be unknown to the participants and the investigators who interact with the participants (e.g., guide them through the exercise sessions, assist with their completion of the pain scale). The order of dosing (i.e., which medication the participants are given during their first and second workout sessions) will be randomized and counterbalanced. The medication blinding investigator will reveal the content of each medication to the rest of the investigation team only following completion of all data collection.

A. What will non-participants do while participants participate? *Note: this only applies when research is conducted in the classroom and some students may participate and some may not.*

N/A

B. What will participants be told about the research project?

Participants will receive full disclosure of methods, risk and benefits. No deception will be used during the implementation of the above intervention. They will not be told if they are consuming the placebo or ibuprofen prior to their workout sessions. However, upon completion of the entire data collection, participants will be contacted with their results, including information about which medication was associated with each trial.

C. Estimated time required for participants:

Two testing weeks with a month in between will be completed by each participant. During the first testing week, they will visit the Human Integrated Physiology Laboratory (Corbett Building Rooms 208 and 206) on 4 occasions (Familiarization, baseline, 24 hours post, 48 hours post) and the CrossFit 7220 facility for the workout session. The second week will be identical to the first with the exemption of no familiarization day. This totals visiting the university laboratory on 7 occasions and CrossFit 7220 on 2 occasions. The following calculates the estimated total number of hours spent by each participant:

1st Testing Week

- Familiarization: 2 hours
- Baseline: 30 minutes
- Workout session: 2 hours
- 24 hours post: 30 minutes
- 48 hours post: 30 minutes

2nd Testing Week

- Baseline: 30 minutes
- Workout session: 2 hours
- 24 hours post: 30 minutes
- 48 hours post: 30 minutes

Total= 9 hours spent per participant performing study related activities

D. Where will research take place?

All familiarization, baseline, 24 hour post, and 48 hour post data collection days will take place in the Human Integrative Physiology (HIP) laboratory (Corbett Building Rooms 208 and 206). Both workout sessions will take place at the CrossFit 7220 facility.

E. Method of data collection: Qualitative ___ Quantitative__X_ (check one or both). In a paragraph or two, please describe how you will collect your data:

Data collection will occur via blood draws, urine sample collections, 2D video analyses, force evaluation, muscle soreness, heart rate monitoring, and RPE scale evaluations.

A qualified investigator will obtain a single blood sample via venipuncture to an antecubital vein using sterile technique and universal precaution standards. Samples will be drawn into vacutainers for later examination in the University of Wyoming's HIP lab. Samples will assess kidney injury biomarkers including serum creatinine and blood urea nitrogen. In concordance with the Acute Kidney Injury Network, occurrence of AKI will be defined as an increase in serum creatinine of 0.3 mg/dL or an increase of 1.5 times greater than baseline measures. Our lab group has successfully drawn and stored blood samples as part of a current project. Additionally, investigator Johnson has successfully performed similar sample collections within laboratory environments and on athletes in field based locations.

A total of three 24 hour urine collection jugs will be collected over a 72 hour period. Samples will assess albumin, creatinine, neutrophil gelatinase-associated lipocalin (NGAL), and kidney injury molecule 1 (KIM-1) kidney injury biomarkers. Total volume, urine color, and urine specific gravity will also be analyzed from every sample. Dipsticks will be used on fresh samples while three 2mL aliquots of each 24hr sample will be separated and stored at room temperature until they are returned to the University of Wyoming where they will be frozen at -80C for future analysis. Investigator Johnson has consistently used 24 hour urine collections as a part of his ongoing research regarding human hydration.

Two camcorders will be set up in front of and to the right of the participant to analyze body-weight squat, and push-up movement patterns. Reflective markers will be placed on anatomical landmarks (shoulder centers, greater trochanters, knee centers, ankle centers, elbow centers, and wrists) which will be manually digitized to measure elbow, shoulder, hip, and knee joint angles in the frontal and sagittal planes.

Two force platforms will be used to analyze bilateral force production at a sampling frequency of 1000 Hz (**Figures 5, 6**). The peak force for each limb during the concentric phases of the squat and push-up segments of the workout will be used to assess bilateral asymmetry which is calculated as: (right side-left side)/(larger value of the two sides).

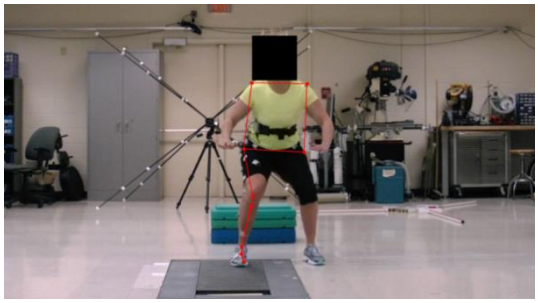


Figure 5. Frontal plane view

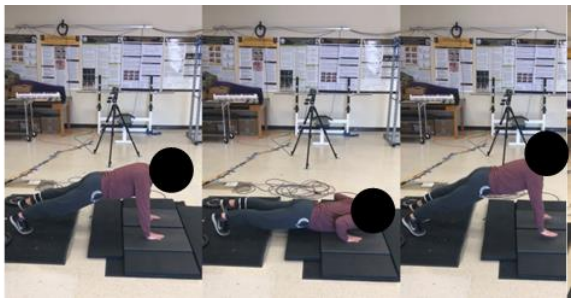


Figure 6. Sagittal plane view

Muscle soreness will be measured using a McGill short-form pain questionnaire to assess muscle pain and soreness (attachment IV).

A heart rate monitor will be worn by participants around their chest in order to record accurate heart rate continuously throughout the workout. The values will be compared with the maximal heart rate values from the maximal graded exercise test performed during the familiarization visit in order to quantify relative exercise intensity.

The Borg's RPE scale will be utilized to monitor how hard a subject is working after each segment of the workout as well (**Figure 7**).

Borg Rating of Perceived Exertion

6 No exertion at all
7
8 Extremely light
9 Very light
10
11 Light
12
13 Somewhat hard
14
15 Hard (heavy)
16
17 Very hard
18
19 Extremely hard
20 Maximal exertion

Figure 7. Borg's RPE Scale

F. Please describe how and when participants may terminate participation:

Participants are free to terminate their participation in the investigation at any time with no penalty.

G. Description of biological samples (examples may include blood or urine):

Blood samples will be collected on all days of data collection (familiarization, baseline, workout, 24 hours post, and 48 hours post) to analyze serum creatinine, blood urea nitrogen, NGAL, and KIM-1. A qualified investigator will obtain a single blood sample via venipuncture to an antecubital vein using sterile technique and universal precaution standards. Samples will be drawn into vacutainers for later examination at the University of Wyoming's HIP lab (serum creatinine and blood urea nitrogen). They will be analyzed via colormetric enzyme-linked immunosorbent assays (ELISA). ELISA antibodies will be supplied by Abcam (Cambridge, MA, USA) and microplates will be read according to the manufacturer's instructions on spectrophotometer (Epoch 2, Bitotek, Winooski, VT, USA).

A total of three, 24 hour urine collection samples will be collected over a 72 hour period. Samples will assess albumin, creatinine, neutrophil gelatinase-associated lipocalin [NGAL], and kidney injury molecule 1 [KIM-1] kidney injury biomarkers. A portion from each sample will be shipped to Yale University for analysis (NGAL and KIM-1). Total volume, urine color, and urine specific gravity will also be analyzed for every sample. Dipsticks will be used on fresh samples while three, 2mL aliquots of each 24hr sample will be separated and stored at room temperature until they are returned to the University of Wyoming where they will be frozen at -80C for future analysis. Fresh samples will be evaluated for urine color and specific gravity using a handheld refractometer to establish hydration state.

H. Description of equipment to be used on or by participants:

Participants will utilize spot and 24 hour urine collection containers (**Figure 8, 9**) which contain screw tops to avoid breakage or spilling. A "Go Girl" urinary funnel device will be provided to female participants to assist with urine collection (**Figure 10**).

Figure 8. 24 hour urine collection jug

Figure 9. Spot urine collection container

Figure 10. "Go Girl" urinary device

Blood draws will be collected using a winged infusion set with a tube holder. Samples will be drawn into vacutainers for later examination in the University of Wyoming's HIP lab (**Figure 11**).

Figure 11. Winged infusion set with a tube holder

Scans to assess fat mass, lean mass, and bone mineral density will be taken using a dual x-ray absorptiometry with a GE Lunar Prodigy (**Figure 12**).

Figure 12. General Electric Dual X-Ray Absorptiometry

A scale will be used to assess bodyweight on familiarization day (**Figure 13**).

Figure 13. Bodyweight scale

Participants will utilize the FMS testing kit (measuring device, hurdle, and measuring stick) during familiarization to assess movement patterns (**Figure 14**).

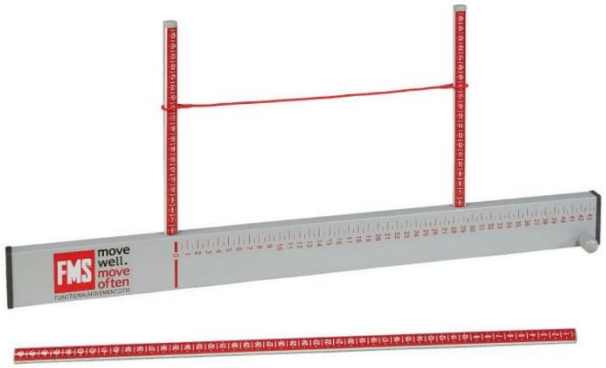


Figure 14. FMS testing kit

VO_{2max} testing equipment includes a treadmill (**Figure 14**), electrocardiogram (ECG) monitor (**Figure 15**), metabolic cart disposables (**Figures 16-22**), metabolic stress testing system (**Figure 23**) and heart rate monitors to record exercise intensity (**Figure 24**).

Figure 15. Trackmaster treadmill

Figure 16. Mortara Instrument X12+ ECG Monitor

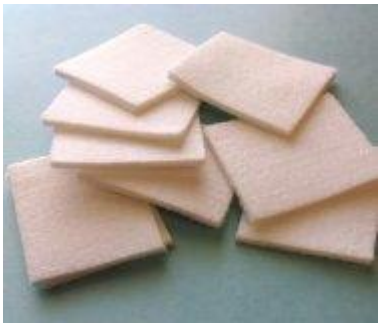


Figure 17. Prepster electrode skin prep pads

Figure 18. ECG Vermed Performance PlusDiagnositc Electrodes

Figure 19. Dynarex sterile alcohol prep pads

Figure 20. MGC Diagnostics Prevent mask

Figure 21. MGC Diagnostics Prevent Flow Sensors

Figure 22. MGC Diagnostics Adult mouthpiece

Figure 23. MGC Diagnostics pulmonary function filter

Figure 24. MGC Diagnostics metabolic stress testing system

Figure 25. Polar A300 activity heart rate Monitor

Biomechanics measures will collected using two JVC GC-PX100 camcorders with a resolution of 1920 to 1080 pixels and a sampling frequency of 60 Hz (**Figure 26**). Two portable force plates will be used to collect bilateral limb forces during the bodyweight squats and push-ups (**Figure 27**). Reflective markers will be placed on anatomical land marks to later analyze joint angles (**Figure 28**).

Figure 26. JVC GC-PX100 camcorder

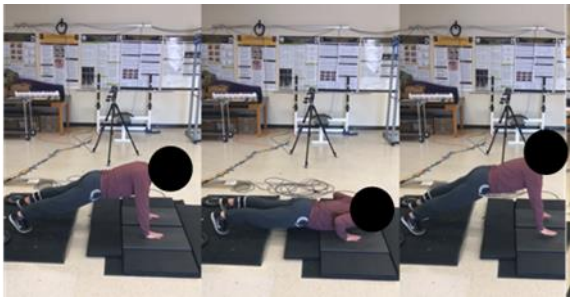


Figure 27. Portable bilateral force plates

Figure 28. Qualisys reflective markers

7. Confidentiality Procedures:

A. Explain whether or not participants will be identified by name, appearance, or nature of data:

Participants will not be identified by name, appearance, or nature of data.

B. Are you collecting personal health information? (See the IRB manual at: http://www.uwyo.edu/research/compliance/human-subjects/index.html).

Yes ____X_____ No _____

C. Will the data you collect be anonymous or confidential (check the one that applies)?
Note: research is only anonymous if the researcher does not know the identity of the participants and there are no identifiers linking the participant to the research.

Anonymous_____ Confidential __X____

D. Explain the procedure that will be used to protect privacy and confidentiality:

Each participant will receive an exclusive identification number to be used on all data collection sheets and samples. There will only be one master sheet where the subject's names will correspond to their identification number. This sheet will be held on a secure password protected computer by the graduate student investigator, Nicole Sauls. Participant names will not be used in presentations, reports, data bases, or publication based on the research investigation.

E. How and where will data be stored (may be indefinitely)?

Data sheets will be kept in a locked file cabinet. The data will be entered into an electronic spreadsheet on a password protected computer and will not include subject names. The original data sheets will be kept for at least six years following the completion of research. The electronic files will be held indefinitely in case questions about publications come up in the future.

F. How long will the data, research summary, and signed consent forms be stored (may be indefinitely)? *Note: The regulations require that The PI or project director maintain the signed informed consent forms, assent script/forms (if applicable), and the written research summary, relating to research for at least three years after completion of the research.*

All data, research summaries, and signed consent forms will be stored in a locked file cabinet in the principal investigator's office. These data files will be kept for at least six years following the completion of data collection.

G. Who will have access to the data?

The data will only be accessible to the primary investigator, co-investigators, and Responsible graduate and undergraduate students.

8. Benefits to Participants:

A. Describe the indirect research benefits for the participants:

Indirect research benefits include DXA scan measures, VO_{2max} performance, and functional movement screen results.

B. Describe the direct research benefits or state there are no direct benefits to the participants (do not include incentives in this section):

Participants will receive up to $100 for their participation.

9. Risks to Participants:

This section should include a detailed description of any reasonably foreseeable risks or discomforts to the participants as a result of each procedure, including discomfort or embarrassment with survey or interview questions, exposure to minor pain, discomfort, injury from invasive medical procedures, or harm from possible side effects of drugs. All projects are deemed to involve some level of risk to participants, however obvious or obscure. Consequently, **proposals must state** that minimal risk is involved when the proposed research is viewed as involving little or no risk to participants. Risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Even when risk is minimal, investigators must still state what the minimal is and why it is minimal (example would be potential for embarrassment or boredom).

Describe the risks to participants:

Urine collection inconvenience – The 24 hour urine collection jugs may present inconvenience and slight embarrassment for participants. To minimize these inconveniences, a reusable shopping tote will be provided to make carrying the samples more discrete. Also, a female urination device will be provided to appropriate participants to make urine collection easier.

Blood Draw and Venipuncture Risk- Blood draws performed on familiarization, baseline, 24 hours post, and 48 hours post will be performed by a trained investigator, Dr. Johnson, using sterile techniques and universal precautions. However, risk does include pain, bruising, fainting, hematoma, nausea, phlebitis, bleeding, blood clots, and sensitive responses to plastic or adhesive tape used during or as a reaction to the venipuncture. To minimize bleeding and the incidence of a hematoma, firm pressure with gauze will be placed on the site of needle removal.

X-Ray Radiation Risk (DXA Scan)- All tests will be performed by trained investigators with qualified supervision, and all precautions will be made to minimize the minimal risks associated with DXA Scans. The following are the four types of minimal risk:

1. Exposure to a small amount of radiation will occur during the scan (approximately $1/20^{th}$ of the amount of radiation that occurs with bone fracture x-rays). It is important to note this scan is performed routinely in hospitals and medical offices.
2. Females will be required to take a urine sample pregnancy test and it must be confirmed as negative prior to testing. There are no exceptions and the only risk that may occur is if the urine test is positive, the participant ***may*** be pregnant.
3. Radiation exposure can cause tissue damage or change in genes that could lead to other complications. The exact risks are unknown, but the chances of complications (cancer and/or tumors) increase the more an individual is exposure to radiation.
4. The DXA could identify an individual has low bone mineral density (BMD) meaning an individual either is at-risk for osteoporosis or currently has osteoporosis. If BMD is classified as low from the scan according to age, sex, and ethnicity, a copy of the DXA scan will be given to the participant and they will be referred to see their primary health care provider for a follow-up appointment to discuss the results. The University of Wyoming does not provide licensed health care provider interpretation of results; it is the responsibility of the individual's health care provider. The participant will be asked to sign a health care provider referral document acknowledging that they have been referred for a follow-up appointment with their personal health care provider.

Exercise Stress Test Risks- All tests will be performed by trained investigators with qualified supervision, and all precautions will be made to minimize the minimal risks associated with exercise stress testing. The risks associated with exercise stress testing include but are not limited to:

1. Minor jaw/mouth discomfort from wearing a mouthpiece
2. Feelings of claustrophobia from the mouthpiece and head gear
3. Redness or mild irritation from the skin electrodes, alcohol, or gel used to prepare the skin for electrodes
4. Dizziness, fatigue, shortness of breath, muscle or connective tissue strain, heart attack, irregular heartbeat, and death.
    a. The overall risk of exercise testing in a mixed population is approximately 6 cardiac (heart) events per 10,000 exercise tests and the risk of death during or immediately after an exercise test is less than or equal to 0.01%.
5. Muscle, ligament, tendon or joint discomfort, soreness, swelling, pain, strain, tear, or injury

Exercise intervention – As with any exercise participation there is some risk of musculoskeletal injury with the completion of "Murph" in this investigation. This risk will be minimized by the following:

1. Anyone with a pre-existing injury will be excluded
2. All exercise sessions will be overseen by an investigator with a certification as a CrossFit instructor. They will alert the participants if exercise form puts the individual at risk for injury
3. All participants will have at least 1 year of HIFRT experience and will have completed "Murph" on at least one occasion prior to their inclusion in the study.

Non-steroidal anti-inflammatory drug administration – As mentioned in the background to this investigation, NSAIDs have the potential to enhance risk of kidney injury when combined with exercise. Previous investigations have found significantly elevated Scr in individuals that use NSAIDs before or during endurance exercise. However, regardless of administration Scr levels returned to normal given proper rest. Additionally this risk will be minimized by the following:

1. Only individuals that have self-reported to taking NSAIDs prior to working out will be recruited
2. Individuals will be asked to refrain from any NSAID consumption in the day before or in the two days following the exercise session
3. Individuals will be asked to refrain from exercise in the day before and for the two days following the experimental exercise session

10. Description of procedure to obtain informed consent or other information to be provided to participant:

A. How and when will the participants be approached to obtain consent?

Participants will be recruited from the Laramie, Wyoming HIFRT facility, CrossFit 7220 to participate in a single blind, counterbalanced, and crossover investigation. Only individuals who: self-report having taken NSAIDs prior to workouts in the past, have at least one year of HIFRT training experience, and who have completed the prescribed version of the workout "Murph" at least one time will be recruited. These questions were specifically asked on our pilot QNR, along with the question if they would be interested in follow-up investigations. Individuals that answered "yes" to this question along with meeting the above criteria will be contacted first via e-mail or in person while at the gym.

Additional participants will be recruited by word of mouth and enrolled in the study only after meeting the above criteria. Interested individuals will contact principal investigator to hear full details on the study procedures, exclusionary criteria, and risk prior to any involvement.

B. Who will be responsible for obtaining consent (check the box that applies)?

Project Director ___X___ Evan Johnson, PhD

Member of Project team ___X____ Nicole Sauls (Co-investigator), or
Breton Van Syoc (Master's Student), or
Brandon Strannigan (Undergraduate Student), or
Hunter Anderson (Undergraduate Student), or
Brittany Wells (Undergraduate Student)

Other _____ (Please explain, and include name, affiliation, and title)

C. How will information be relayed to participant (read to, allowed to read, audio-recorded, video-recorded)?

Participants will have the consent form read to them by a responsible investigator. They will also have time to ask questions if any clarification is needed. A copy of the consent forms will also be given to take with them to the remaining sessions. The copies will include contact information for the primary investigator and the IRB office in case any questions or concerns arise during or after their time spent in the HIP Laboratory or CrossFit 7220 facilities.

D. Provide a description of feedback, debriefing, or counseling referral that will be provided if this is relevant to the research:

All participants will be sent individual reports following the completion of all data collection containing graded exercise testing, FMS, and heart rate results. Urine and blood analysis results will also be provided within a year from the completion date as these analyses take much more time to complete.

E. Explain the procedure that will be used to obtain assent of children, if relevant to the research (See: http://www.uwyo.edu/research/compliance/human-subjects/index.html): N/A
F. If children are involved, who will be responsible for obtaining assent (check the box that applies)? N/A **Project Director _____** **Member of Project team _____ (list name or position)** **Other _____ (Please explain, and include name, affiliation, and title)**

11A. Attach copies of survey instruments, interview questions, tests, and other pertinent documentation that will be used to conduct the research. Note: Please see the informed consent outline for suggested language for consent forms.

Attachment Name	Description
Attachment 1:	Informed consent for research participation
Attachment 2:	Medical History Questionnaire
Attachment 3:	Physical Activity Readiness Questionnaire (PAR-Q)
Attachment 4:	McGill Pain Questionnaire
Attachment 5:	Exercise stress testing informed consent
Attachment 6:	Exercise stress test data collection sheet
Attachment 7:	DXA scan informed consent
Attachment 8:	Letter of support from CrossFit 7220
Attachment 9:	Menstrual History (Female participants only)
Attachment 10:	List of additional student research assistants not listed as co-investigators

11B. If participants will be recruited through an institution such as a school or hospital, or if the research will be conducted at such an institution, provide a letter of agreement/approval to do so from an authorized representative of that institution. The IRB will not approve a proposal without the proper letter(s) of support. – See Attachment 8

11C. If collaborators and/or students will be helping with the research and those individuals are not listed as co-investigators on the proposal, please provide the names of those individuals in an attachment to the proposal so that human subjects training can be verified. – See Attachment 10

University of Wyoming Consent Form

I. General purpose of the study:

Ingestion of over-the-counter non-steroidal anti-inflammatory drugs (NSAIDS) prior to endurance exercise events has been associated with increased risk for acute kidney injury (AKI). High intensity functional resistance training (HIFRT) may also present risk for AKI due to high exercise intensities and NSAID ingestion. However, the direct effects of NSAID use prior to performing a long duration HIFRT workout on AKI is unknown.

The first aim of the study is to investigate the incidence of AKI following the commonly performed workout, "Murph" (1 mile run, 100 pull-ups, 200 push-ups, 300 body-weight squats, and a final 1 mile run) and compare these results seen in other forms of extreme exercise. Blood and urine samples are used in the diagnosis of kidney injury, so they will be used to determine AKI incidences.

The second aim is to evaluate if the ingestion of NSAIDS prior to performing "Murph" increases the rate of AKI incidence.

The third aim is to determine risk of musculoskeletal injury during "Murph" by analyzing movement patterns and force production during the push-up and body-weight squats portion of the workout.

By doing this we hope to assist in the continued programming of safe and efficacious HIFRT workouts. The goal is not to take away from the many benefits of HIFRT. Instead, we hope to educate the exercising population on the potential risks associated with HIFRT, so they can adjust behavioral or movement patterns that will minimize risk for injury.

II. Procedure:

All sessions will take place at CrossFit 7220 or University of Wyoming's Human Integrated Physiology Laboratory. Data will be collected by Evan Johnson PhD, graduate, and undergraduate students that have been appropriately trained to carry out the research protocol.

Participation will include two data collection weeks, one-month apart. Each week will consist of 4 consecutive data collection days. The only additional commitment is a familiarization day prior to the first week of testing where baseline measures will be assessed. We estimate the total time commitment for both weeks to be 9 hours. The schedule is outlined below:

1st Testing Week

- Familiarization: 2 hours
- Baseline: 30 minutes
- Workout session: 2 hours
- 24 hours post: 30 minutes
- 48 hours post: 30 minutes

2nd Testing Week

- Baseline: 30 minutes
- Workout session: 2 hours
- 24 hours post: 30 minutes
- 48 hours post: 30 minutes

On the familiarization day, consent and initial screening forms will be filled out if you choose to participate. Female participants will review their menstrual cycle history with a female investigator, in order to schedule your first baseline visit to correspond with your early follicular phase (i.e. 4-5 days after the end of your period). Next, you will have your blood drawn by a trained investigator and you will provide a spot urine sample. You will then receive a DXA scan to measure body fat percentage and bone mineral density followed by a functional movement screening (FMS) to analyze your ability to perform several movement patterns. Lastly, you will perform a graded exercise stress test to identify your maximal heart rate and maximal oxygen consumption (VO_{2max}). This session will take an estimated 2 hours.

Baseline collection days will take place and 24 hours prior to the workout session.
A second blood draw will be taken and the first 24 hour urine collection jug will be provided. This jug is to be returned 24 hours later at the beginning of your workout session. You will complete the McGill pain scale to evaluate your baseline measures of muscle pain or soreness. This session is estimated to take 30 minutes.

During the workout session, you will perform the standard version of "Murph" (1 mile run, 100 pull-ups, 200 push-ups, 300 body-weight squats, and a final 1 mile run). This day is also where you will be randomly assigned a placebo or 400mg of the over-the-counter NSAID, ibuprofen. This selection will be double-blind, so neither you nor the researcher will know which is given. However, if you receive ibuprofen the first data collection week, you will be administered the placebo the second data collection week. The same is applied if you are given the placebo first in which case you would receive ibuprofen the second week of data collection. You will not wear a weighted vest during this exercise session. Prior to exercising, you will return your first urine collection jug and receive a second to again return 24 hours later at the next session. Next, a certified trainer will lead you through a full body dynamic warm-up and review all movement and workout standards. If there are no other questions or concerns, you will perform all repetitions of "Murph" as prescribed. During the workout, your rating of perceived exertion and heart rate will be recorded. Your movements during the push-up and body-weight squat portions will be analyzed using 2D camcorders and your force production will be measured using portable force plates. Immediately after the completion of all repetitions, a post-exercise blood draw will be taken and you will be asked to fill out a McGill pain scale to quantity muscle soreness. This session is estimated to take 2 hours.

The day following the workout (approximately 24 hours post) will consist of turning in your second 24 hour urine collection jug and being provided with the third and final 24 hour jug. You will also provide another blood draw and fill out the McGill pain questionnaire to identify any muscle pain or soreness. This session is estimated to take 30 minutes.

The final day of the week will be approximately 48 hours post workout. You will turn in your third and final 24 hour urine collection jug and provide one last blood draw. After completing a final

McGill pain questionnaire, the single testing week is completed. This sessions is also expected to take about 30 minutes.

It is also important to note, you will be asked to abstain from ingesting NSAIDS and alcohol for 24 and 48 hours post workout. You will also be asked to avoid strenuous exercise for the 24 hours before and 48 hours post workout.

This exact procedure will be reproduced on two occasions, one-month apart. Thus, in the second occurrence the times to complete each segment will be replicated. For example if the initial run took you 10 minutes to complete during the first trial, you will not be allowed to move onto the pull-up segment during your second trial until at least 10 minutes has passed. It is OK if the second trial takes longer to complete.

III. Disclosure of risks

Urine collection inconvenience – The 24 hour urine collection jugs may present inconvenience and slight embarrassment. To minimize these inconveniences, a reusable shopping tote will be provided to you to make carrying the jugs more discrete. Also, a female urination device will be provided to if necessary to make urine collection easier.

Blood Draw and Venipuncture Risk- Blood draws performed during the familiarization, baseline, 24 hours post, and 48 hours post sessions will be performed by a trained investigator, Dr. Johnson, using sterile techniques and universal precautions. However, risks do include pain, bruising, fainting, hematoma, nausea, phlebitis, bleeding, blood clots, and sensitive responses to plastic or adhesive tape used during or as a reaction to the venipuncture. To minimize bleeding and the incidence of a hematoma, firm pressure with gauze will be placed on the site of needle removal.

X-Ray Radiation Risk (DXA Scan)- All tests will be performed by trained investigators with qualified supervision, and all precautions will be made to minimize the minimal risks associated with DXA Scans. The following are the four types of minimal risk:

1. Exposure to a small amount of radiation will occur during the scan (approximately $1/20^{th}$ of the amount of radiation that occurs with bone fracture x-rays). It is important to note this scan is performed routinely in hospitals and medical offices.
2. Females will be required to take a urine sample pregnancy test and it must be confirmed as negative prior to testing. There are no exceptions and the only risk that may occur is if the urine test is positive, the participant ***may*** be pregnant.
3. Radiation exposure can cause tissue damage or change in genes that could lead to other complications. The exact risks are unknown, but the chances of complications (cancer and/or tumors) increase the more an individual is exposure to radiation.
4. The DXA could identify an individual has low bone mineral density (BMD) meaning an individual either is at-risk for osteoporosis or currently has osteoporosis. If BMD is classified as low from the scan according to age, sex, and ethnicity, a copy of the DXA scan will be given to the participant and they will be referred to see their primary health care provider for a follow-up appointment to discuss the results. The University of Wyoming does not provide licensed health care provider interpretation of results; it is the responsible of the individual's health care provider. The participant will be asked to sign a health care provider referral document acknowledging that they have been referred for a follow-up appointment with their personal health care provider.

Graded Exercise Test Risks- All tests will be performed by trained investigators with qualified supervision, and all precautions will be made to minimize the minimal risks associated with exercise stress testing. The risks associated with exercise stress testing include but are not limited to:

1. Minor jaw/mouth discomfort from wearing a mouthpiece
2. Feelings of claustrophobia from the mouthpiece and head gear
3. Redness or mild irritation from the skin electrodes, alcohol, or gel used to prepare the skin for electrodes
4. Dizziness, fatigue, shortness of breath, muscle or connective tissue strain, heart attack, irregular heartbeat, and death.
    a. The overall risk of exercise testing in a mixed population is approximately 6 cardiac (heart) events per 10,000 exercise tests and the risk of death during or immediately after an exercise test is less than or equal to 0.01%.
5. Muscle, ligament, tendon or joint discomfort, soreness, swelling, pain, strain, tear, or injury

Exercise intervention – As with any exercise participation there is some risk of musculoskeletal injury with the completion of "Murph" in this investigation. This risk will be minimized by the following:

4. Anyone with a pre-existing injury will be excluded
5. All exercise sessions will be overseen by an investigator with a certification as a CrossFit instructor. They will alert the participants if exercise form puts the individual at risk for injury.
6. All participants will have at least 1 year of HIFRT experience and will have completed "Murph" on at least one occasion prior to their inclusion in the study.

Non-steroidal anti-inflammatory drug administration – NSAIDs have the potential to enhance risk of kidney injury when combined with exercise. Previous investigations have found significantly elevated Scr in individuals that use NSAIDs before or during endurance exercise. However, regardless of administration Scr levels returned to normal given proper rest. Additionally this risk will be minimized by the following:

4. Only individuals that have self-reported to taking NSAIDs prior to working out will be recruited
5. Individuals will be asked to refrain from any NSAID consumption in the day before or in the two days following the exercise session
6. Individuals will be asked to refrain from exercise in the day before and for the two days following the experimental exercise session

IV. Description of benefits:

You will receive up to $100 for your participation in this investigation. This will be distributed at the end of your enrollment in the study. If you choose stop participation in the study prior to completion you will be paid for your involvement based on the below pro-rated basis.

1. $10 – Baseline measurements
2. $30 – Completion of initial workout
3. $30 – Completion of second workout
4. $30 – Completion bonus for finishing all study measurement periods,

You will also receive indirect benefits including DXA scan measures, graded exercise test performance scores, and functional movement screen results. We will provide you with blood analysis results within a year of your participation as these measurements take longer to evaluate.

V. Confidentiality:

Each member of the research team has undergone certification for proper data management during human subject research. All information will be kept confidential and each participant will receive an exclusive identification number to use on all data collection sheets and samples. There will only be one master sheet where your name will correspond to an identification number. This sheet will be held on a secure and password protected computer by the graduate student investigator, Nicole Sauls. Your name will not be used in presentations, reports, data bases, or publication based on the research investigation.

Data sheets will be kept in a locked and secure file cabinet. The data will be entered into an electronic spreadsheet on a password protected computer and will not include identification information. The original data sheets will be kept for at least six years following the completion of research. The electronic files will be held indefinitely in case questions about publications come up in the future.

VI. Freedom of consent:

Participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled, and you may discontinue participation at any time. If you choose to discontinue your participation please contact Principal Investigatory Evan Johnson 202-431-4065, and return any equipment you may have been issued (i.e., 24 hour urine collection jugs and totes)

VII. Questions about the research:

Should you have any questions about this research following today please contact:

Evan Johnson
Corbett Building – Room 109 - 307-766-5282

If you have questions about your rights as a research subject, please contact the University of Wyoming IRB Administrator at 307-766-5320

UNIVERSITY OF WYOMING

Office for Research and Economic Development
1000 East University Avenue • Department 3355 • Laramie, WY 82071
Campus: Office of Research • Room 305/308 • Old Main
(307) 766-5353 • (307) 766-5320 • fax (307) 766-2608 • www.uwyo.edu/research

UNIVERSITY OF WYOMING
HEALTH HISTORY SCREENING QUESTIONNAIRE (UWHHSQ)

Please complete thoroughly and accurately.

Date _____/_____/_____

*Name:*_____ *Ethnicity:*_____
*Address:*_____*City:*_____*State:*_____*Zip:*_____
Date of Birth: _____/_____/_____ *Age:*_____ *Phone #:*_____
*Email:*_____*@*_____
*Emergency contact information: Name:*_____ *Phone #:*_____
Personal healthcare provider to contact in case of an emergency:
*Name*_____ *Phone #:*_____
*City:*_____

CARDIOVASCULAR HEALTH HISTORY

Have you ever been diagnosed with or had any of the following?

Heart Attack?	*Yes*	*No*
Heart Surgery ?	*Yes*	*No*
Cerebrovascular accident (e.g. Stroke)?	*Yes*	*No*
Transient Ischemic Attack (TIA)?	*Yes*	*No*
Carotid Artery Disease?	*Yes*	*No*
Cardiac Catheterization?	*Yes*	*No*
Coronary Angioplasty?	*Yes*	*No*
Pacemaker/Implantable Cardiac Device?	*Yes*	*No*
Irregular Heart Rate/Heart Rhythm Disturbance?	*Yes*	*No*
Atrial Fibrillation?	*Yes*	*No*
Heart Valve Disease?	*Yes*	*No*
Heart Failure?	*Yes*	*No*
Heart Murmur?	*Yes*	*No*
Heart Transplantation?	*Yes*	*No*
Congenital Heart Disease?	*Yes*	*No*

Have you ever experienced any of the following symptoms:

Chest discomfort with exertion?	*Yes*	*No*
Unreasonable breathlessness?	*Yes*	*No*

Dizziness, fainting, or blackouts? *Yes* *No*

Syncope (loss of consciousness)? *Yes* *No*
Hypoxia (low oxygen levels)? *Yes* *No*
Do you currently take heart medications? *Yes* *No*
*If yes, what?*_____
Have you been diagnosed with diabetes (Type 1 or Type 2) or problems with blood sugar levels? *Yes* *No*
*If yes, please note Type 1 or Type 2*_____
If you circled yes to any of the above statements in this section, consult your physician or other appropriate health care provider before engaging in exercise. You may need to use a facility with a ***medically qualified staff.***

CARDIOVASCULAR RISK FACTORS

Are you a male over 45 years old? *Yes* *No*

Are you a female over 55 years old? *Yes* *No*
Have you had a hysterectomy? *Yes* *No*
Have you had both of your ovaries surgically removed? *Yes* *No*
Are you postmenopausal? *Yes* *No*

Do you currently smoke or have you quit within the last six months? *Yes* *No*

Is your blood pressure greater than 140/90 mm Hg? *Yes* *No* *I Don't Know*
If known, what is your blood pressure? _____/_____ *mm Hg*
Do you currently take blood pressure medications? *Yes* *No*
Do you currently take any medications for your heart? *Yes* *No*
Is your total blood cholesterol level greater than 200 mg/dl? *Yes* *No* *I Don't Know*
Do you know your cholesterol level? *Yes* *No*
If yes, Total Cholesterol _____
LDL _____
HDL _____
Triglycerides _____

Do you have a close blood relative who has suffered a heart attack or had any kind of heart surgery before the age of 55 (for father or brother) or age 65 (for mother or sister)? *Yes* *No*

Are you more than 20 pounds overweight? *Yes* *No* *I Don't Know*

Are you physically <u>inactive</u> (i.e., do you get less than 30 minutes of physical activity less than three times a week)? *Yes* *No*

Have you had a recent surgery (in the past 2 years)? *Yes* *No*

Have you had an exercise stress test, heart catheterization,

or echocardiogram? *Yes* *No*

*If yes, please explain*_____

*To the best of your knowledge, is there any reason that might make it **unsafe** for you to participate in exercise?* *Yes* *No*

*If you circled yes to two or more of the statements in the above section you should consult your physician or other appropriate health care provider before engaging in exercise. You might benefit from using a facility with a **professionally/medically qualified exercise** program and staff.*

THYROID HEALTH HISTORY

Have you ever been diagnosed with or had any of the following?

Goiter (enlarged thyroid gland)?	Yes	No
Hyperthyroidism (overactive thyroid)?	Yes	No
Hypothyroidism (underactive thyroid))?	Yes	No
Thyroid nodule?	Yes	No
Thyroid Cancer?	Yes	No
Do you take any type of thyroid medication, i.e, synthroid?	Yes	No

If yes, please list _____

CARDIOVASCULAR HEALTH HISTORY

Have you ever been diagnosed with or had any of the following?

Heart Attack?	Yes	No
Heart Surgery ?	Yes	No
Cerebrovascular accident (e.g. Stroke)?	Yes	No
Transient Ischemic Attack (TIA)?	Yes	No
Carotid Artery Disease?	Yes	No
Cardiac Catheterization?	Yes	No

To the best of my knowledge, the information I have provided above is an accurate assessment of my health and medical history.

_____	_____	_____
Name of Participant	***Participant's Signature***	***Date***
_____	_____	_____
Name of Administering Staff	***Signature of Staff Member***	***Date***

Please stop here. The remainder of this Health History Screening Questionnaire will be administered to you by one of our staff.

STAFF: Administer the remaining portion of the UWHHSQ.

GENERAL MEDICAL AND DIETARY HISTORY

Height:_____ Weight:_____ BMI (calculated):_____

Circle One

Do you currently participate in > 7 hours of moderate to intense cardiovascular exercise per week? *Yes* *No*

Have you drastically changed your diet in the last month? *Yes* *No*

Has your weight fluctuated > 5lbs in the past month? *Yes* *No*

Do you have any history of acute or chronic Glomerulonephritis (such as post-streptococcal lupus rheumatoid arthritis, or other immune system diseases such as Amyloidosis or Sarcoidosis) *Yes* *No*

Do you have recurrent urinary tract infections (especially pyelonephritis) *Yes* *No*

Do you have a history of kidney stones? (especially those requiring surgical intervention or lithotripsy) *Yes* *No*

Do you have any history of diabetic-induced renal injury? *Yes* *No*

Do you have any history of hypertension-induced renal injury? *Yes* *No*

Have you had kidney surgery such as nephrectomy? *Yes* *No*

Have you ever had kidney dialysis? *Yes* *No*

Do you have any history of protein or blood in urine? *Yes* *No*

Do you drink alcohol? *Yes* *No*

*If yes, how many drinks per week?*_____

Are you taking any prescription or over-the-counter medication? *Yes* *No*

*If yes, what medication and what dosage?*_____

_____

Do you take any of the following vitamins, supplements, or herbal/homeopathic medications ***Calcium, Cat's claw, Chaparral, Chromium, Cranberry, Creatine, Ephedra, Germanium, Hydrazine, Licorice, l-Lysine, Pennyroyal, Thunder god vine, Vitamin C, Willow bark, Wormwood oil, Yellow oleander,Yohimbe****?*

Yes *No*

*If other, what type and what dosage?*_____

_____

Do you use table salt? *Yes* *No* *Sometimes*

If yes, is it iodized? *Yes* *No* *Not Sure*

*If yes, please list the brand*_____

Has your body weight been stable over the past 6 months? *Yes* *No*

*If no, please explain*_____

Have you been on a recent diet or a prescribed diet? *Yes* *No*

*If yes, please explain*_____

Are you currently restricting calories, i.e., "dieting" to lose weight? *Yes* *No*

Do you follow a vegetarian Diet? *Yes* *No*

Do you shop at the Farmers Market or Food Coop (Big Hallow)? *Yes* *No* *Sometimes*

Do you belong to a CSA (Community Supported Agriculture)? *Yes* *No*

Do you have a garden and grow your own food? *Yes* *No* *Sometimes*

Comments _____

_____

Have you been diagnosed with asthma, exercise-induced asthma, reactive airway disease, chronic obstructive pulmonary disease (COPD), or any other respiratory disease?

Yes *No*

*If yes, please describe:*_____

_____

_____

Have you ever been diagnosed with cancer? *Yes* *No*

*If yes, please describe when and what type:*_____

_____

Have you ever undergone a lymphectomy? *Yes* *No*

*If yes, please describe when and why?*_____

_____

Do you have musculoskeletal problems that limit your physical activity such as walking? *Yes* *No*

Have you recently (in last 3 months) had an X-ray or CT scan in which Contrasting dyes were used? *Yes* *No*

If yes, when _____

Have you recently (in last week) used an iodine-containing (brown-colored) antiseptic skin cleaner *Yes* *No*

If yes, when _____

Do you have concerns about your safety when you exercise *Yes* *No*

Do you have a history of chronic kidney stones? *Yes* *No*

*If yes, When was your last kidney stone?*_____

Do you have a history of frequent urinary tract infections? *Yes* *No*

If yes, When was your last urinary tract infection?_____

Have you ever experienced burning or cramping sensations in your l legs when walking short distances? *Yes* *No*

Do you have any other health problems, illnesses, diseases, infections, surgeries, allergies, or hospitalizations? *Yes* *No*

*If yes, please explain*_____

FAMILY HISTORY

Please check all that apply

Family Member	***High Blood Pressure***	***Diabetes Type I or II***	***Heart Diseases***	***Comments***
Mother				*If yes, was it before the age of 65?* ***Yes No***
Father				*If yes, was it before the age of 65?* ***Yes No***
Sibling				*Gender: Age:*
Sibling				*Gender: Age:*
Paternal Grandmother				*Age:*
Paternal Grandfather				*Age:*
Maternal Grandmother				*Age:*
Maternal Grandfather				*Age:*

FOR FEMALES ONLY:

Are you pre-____, peri-____ or post-____ menopausal?

*If premenopausal, are you using **any form** of contraception (birth control) or hormone therapy for any reason?* *Yes* *No*

*If yes, why and what type?*_____

Do you regularly use vaginal douches? *Yes* *No*

*If yes, please record the type used and date of your last douche*_____

If you are premenopausal:

Do you have regular menstral cycles? *Yes* *No* *I Don't Know*

*How frequent are your menstrual cycles?*_____

Are you pregnant? *Yes* *No* *I Don't Know*

Could you be pregnant? *Yes* *No* *I Don't Know*

Are you trying to become pregnant? *Yes* *No*

If you are peri- or postmenopausal:

*For how long?*_____

When was your last menstrual period? _____

Have you had a hysterectomy w/ or w/out ovary removal? *Yes* *No*

Have you had an oophorectomy without removal of your uterus? *Yes* *No*

Attachment II – Medical History Questionnaire

Are you currently taking any type of hormone replacement therapy or using any form of contraception (birth control)? *Yes* *No*

*If yes, what type?*_____ *How long?*_____ *Dosage*_

Name of Administering Staff	***Signature of Staff Member***	***Date***

Physical Activity Readiness Questionnaire

General Health Questions

Read the questions below and honestly check: YES or NO	**YES**	**NO**
1) Has your doctor ever said you have a heart condition ☐ or high blood pressure ☐?		
2) Do you feel pain in your chest at rest, during your daily activities, or when you perform physical activity?		
3) Do you lose balance because of dizziness OR have you lost consciousness in the last 12 months? *Please answer NO if your dizziness was associated with over-breathing during vigorous exercise.*		
4) Have you ever been diagnosed with another chronic medical condition other than heart disease or high blood pressure? Please list: _____		
5) Are you currently taking prescribed medications for a chronic medical condition? Please list condition(s) and medication(s): _____		
6) Do you currently have (or have had within the past 12 months) a bone, joint, or soft tissue (muscle, ligament, or tendon) problem that could be made worse by becoming more physically active? *Please answer NO if you had a problem in the past, but it does not limit your current ability to be physically active.*		
7) Has your doctor ever said that you should only do medically supervised physical activity?		

If you answered NO to all of the questions above, you are cleared for physical activity.

Name: _____ **Date:** _____

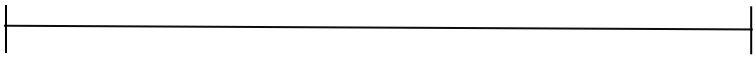
Signature: _____ **Witness:** _____

SHORT-FORM MCGILL PAIN QUESTIONNAIRE

Patient's Name: _____ **Date:** _____

	None	Mild	Moderate	Severe
Throbbing	**0)** _____	**1)** _____	**2)**_____	**3)**_____
Shooting	**0)** _____	**1)** _____	**2)**_____	**3)**_____
Stabbing	**0)** _____	**1)** _____	**2)**_____	**3)**_____
Sharp	**0)** _____	**1)** _____	**2)**_____	**3)**_____
Cramping	**0)** _____	**1)** _____	**2)**_____	**3)**_____
Gnawing	**0)** _____	**1)** _____	**2)**_____	**3)**_____
Hot-buring	**0)** _____	**1)** _____	**2)**_____	**3)**_____
Aching	**0)** _____	**1)** _____	**2)**_____	**3)**_____
Heavy	**0)** _____	**1)** _____	**2)**_____	**3)**_____
Tender	**0)** _____	**1)** _____	**2)**_____	**3)**_____
Splitting	**0)** _____	**1)** _____	**2)**_____	**3)**_____
Tiring-Exhausting	**0)** _____	**1)** _____	**2)**_____	**3)**_____
Sickening	**0)** _____	**1)** _____	**2)**_____	**3)**_____
Fearful	**0)** _____	**1)** _____	**2)**_____	**3)**_____
Punishing-Cruel	**0)** _____	**1)** _____	**2)**_____	**3)**_____

Visual Analog Scale (VAS)

No Pain  **Worst Possible Pain**

Present Pain Intensity

0) **No Pain** _____
1) **Mild** _____
2) **Discomforting** _____
3) **Distressing** _____
4) **Horrible** _____
5) **Excruciating** _____

University of Wyoming Consent Form

Informed Consent Form for

Exercise Stress Testing (maximal or submaximal)

Date: 2/10/2008

You are consenting to voluntarily participate in a graded exercise stress test (submaximal or maximal) with gas analysis (oxygen and carbon dioxide). This test is commonly referred to as a VO_2max test. This test is performed under the direction of Derek T. Smith, Ph.D. or Paul M. Thomas, Ph.D. in the Division of Kinesiology and Health, University of Wyoming, P.O. Box 3196, Laramie, WY 82070.

Purpose of Procedure The purpose of this test is to exercise you to a point of exhaustion or near exhaustion which is often call your "max". *The purpose of this form is to make you aware of the tests/measurements that will be performed, any risks to you that may arise, and the benefits to you if you agree to participate.*

Procedure

You will be asked to complete a maximal or submaximal graded exercise stress test. This procedure will include walking, jogging, running, or cycling on a treadmill or bike to either a pre-determined submaximal level or maximal level (volitional fatigue). You will exercise under your own power and will not be assisted. During the test your heart rate and rhythm will be monitored using 4-10 electrodes attached to your chest that are connected to a computer. Your oxygen consumed and carbon dioxide produced will be measured by a mouthpiece (similar to a snorkel) that will be placed in your mouth and supported by a head gear and your teeth. You will be breathing in only room air and aside from having the mouthpiece in position nothing will vary about the air you breath or how hard you breathe compared to when you exercise on your own. You may discontinue the test at any time. You will instructed on hand signals to use to communicate with the testing team since you will have a mouthpiece in and won't be able to talk.

Risks

All test procedures will be performed by trained personnel with appropriate supervision, and all attempts will be made to minimize the minimal risks associated with your participation in this test. Risks associated with participation in this test include but are not limited to:

1) Minor jaw/mouth discomfort from the mouthpiece.
2) Feelings of claustrophobia from the mouthpiece and head gear.
3) Redness or mild irritation from the skin electrodes, alcohol, or gel used to prepare the skin for the electrodes.
4) Dizziness, fatigue, shortness of breath, muscle or connective tissue strain, heart attack, irregular heart beat (dysrhythmia), and death.
    a. The overall risk of exercise testing in a mixed population is approximately 6 cardiac (heart) events per 10,000 exercise tests and the risk of death during or immediately after an exercise test is less than or equal to 0.01%.
5) Muscle, ligament, tendon or joint discomfort, soreness, swelling, pain, strain, tear or injury.

Attachment V – Exercise stress test informed consent

Benefits

The benefits to you with participation in this test include:

1) Information about your aerobic fitness;
2) Information about your heart rate, blood pressure, and maximal heart rate;
3) Information that you or others may use to improve your exercise training or sport performance.

Confidentiality

The confidentiality of your information will be insured during the test by not allowing anyone except the direct research team to have access to the information collected. The information collected will be stored on a secure computer and in a locked file cabinet. The data will not be used for any purposes other than for the research purposes stated above. No information about your participation or health will be released unless directed in writing by you to the research team.

Injury and Compensation: Under state law, the University of Wyoming, the faculty, graduate assistants, and other students are not liable for any injury you might sustain while participating in this test. The University of Wyoming, the faculty, graduate assistants, and other students are not able to offer financial compensation or absorb the costs of medical treatment should you become injured as a result of participating in this test.

If you have decided to participate in this test, please understand that your participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled, and you may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.

If you have questions about your rights, please contact:

Derek T. Smith, Ph.D. or Paul M. Thomas, Ph.D.
Division of Kinesiology and Health
smithdt@uwyo.edu or cymru@uwyo.edu
307-766-5285

Authorization

I have read the above and understand the benefits, discomforts, inconvenience, and risks associated with participation in this study. I understand that participation is voluntary and that my refusal to participate will not involve penalty or loss of benefits to which I am otherwise entitled and that I may discontinue participation at anytime without penalty or loss of benefits to which I am otherwise entitled.

Your name, First and Last (print) _____

Your signature _____

Witness (print and sign): _____

Date: _____

Attachment VI – Exercise stress test data collection sheet

Human Integrative Physiology Lab
Corbett Building Room 208
Dept. 3196 • 1000 E. University Ave. • Laramie, WY 82071
(307) 766-5285 • fax (307) 766-5790 • e-mail: hiplab@uwyo.edu

UNIVERSITY OF WYOMING

GXT/VO_{2max} Form

Subject Name:_____ Date:_____ ID #: _____

DOB: ____/____/____ Age:_____ Weight:_____ (kg) Height: _____ (cm) BMI: _____

Resting BP:_____Resting HR: _____ Resting O_2 Sat.: _____

Age-Predicted HR_{max}:_____ 85% APHRM: _____

History:_____

_____

Medications:_____

_____

Time (min)	Speed	Grade	HR	BP	RPE	S/S
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
Recovery						
IPE						
1						
3						
5						

Continued next page

Attachment VI – Exercise stress test data collection sheet

GXT/VO_{2max} Form

GXT/VO_2max Test Results

Predicted VO_2 max _____

Actual/Peak VO_2 (L/min) _____ Actual/Peak VO_2 (ml/kg/min) _____

Peak RPE: _____ Peak RER: _____

Reason for Termination

_____ SOB
_____ Orthopedic Limitation
_____ Physician Directed
_____ General Volitional Fatigue
_____ PVD
_____ Tech/team lead directed
_____ Leg Fatigue
_____ Faint/Dizzy
_____ Other (explain below)

Other: _____

_____

Graded Exercise Stress Test Interpretation

_____ Negative _____ Positive _____ Equivocal

Physician Interpretation

_____

_____

_____

_____

_____

_____

Physician name & signature: _____ _____

University of Wyoming Consent Form

Informed Consent Form for

Dual Energy X-ray Absorptiometry (DEXA) Scan

Approval Date: 9/14/2015

You are consenting to voluntarily participate in a Dual Energy X-ray Absorptiometry (DEXA) scan. This test is under the direction of Derek T. Smith, Ph.D., Emily Guseman, Ph.D. or Evan Johnson, Ph.D. in the Division of Kinesiology and Health, University of Wyoming, P.O. Box 3196, Laramie, WY 82070.

Purpose of Procedure The purpose of this test is to acquire your total body bone mineral density, percent body fat, and percent lean tissue mass and report it to you. *The purpose of this form is to make you aware of the tests/measurements that will be performed, any risks to you that may arise, and the benefits to you if you agree to participate.*

Test Procedures

Body composition: you will be asked to lie still on a padded table for 6-12 minutes. During this time an x-ray beam that emits a small amount of radiation will pass over your body to measure your body fat, the amount of muscle in your body, and the density of your bones.

Risks

All test procedures will be performed by trained personnel with appropriate supervision, and all attempts will be made to minimize the minimal risks associated with your participation in this test.

1) For the x-ray test, you will be exposed to a small amount of radiation. This level of radiation is approximately 1/20th of the amount of radiation that occurs with an x-ray of a broken bone. This test is performed regularly in hospitals and medical offices.
2) Females will be required to complete a pregnancy test by urine that must be confirmed as negative; the only risk you may encounter with this test is that you may not be able to complete the DEXA scan if your urine test is positive, that is you may be pregnant. There are no exceptions to this requirement regardless of age or reproductive status.
3) Exposure to radiation can cause changes to genes or damage body tissues that could lead to further complications. The exact risks are not known. The more radiation you receive or are exposed to the greater your likelihood of risk or complications which could include cancer and/or tumors.
4) The DEXA test could discover that you have low bone mineral density. Low bone mineral density has two general levels, at-risk for osteoporosis or osteoporosis. If your bone mineral density is low according to the population norms for your age, sex, and ethnicity, you will be given a copy of your DEXA scan and referred to your primary health care provider for follow-up. The University of Wyoming does not provide licensed health care provider interpretation of your results; it is your responsibility to seek care from your personal health care provider. You will be asked to sign the health care provider referral document acknowledging that you have been referred for follow-up consult from your health care provider. If warranted/prescribed by your health care provider, we will provide one additional DEXA assessments at no cost to you at a time desired by your health care provider. An order from your health care provider will be required prior to the follow-up assessment.

Benefits

The benefits to you with participation in this test include:

1) Information about your body composition (lean tissue mass, percent body fat, and bone mineral density);
2) Information that may be used to improve your health and/or sport performance; and
3) Information that may be used to modify your lifestyle (exercise, diet, etc.) to improve your health and reduce the chance of illness/disease.

Confidentiality

The confidentiality of your information will be protected during and after the test by not allowing anyone except the University of Wyoming team and/or your approved health care provider to have access to the information collected. The information collected will be stored on a secure computer. The data will not be used for any purposes other than for the purposes stated above, i.e. measuring your percent body fat, percent lean mass, bone mineral density and any changes that may occur or have occurred since a previous test. No information about your participation or health will be released unless directed in writing by you to the research team.

Injury and Compensation: The University of Wyoming, the faculty, graduate assistants, and other students are not liable for any injury you might sustain while participating in this test. The University of Wyoming, the faculty, graduate assistants, and other students are not able to offer financial compensation or absorb the costs of medical treatment should you become injured as a result of participating in this test.

If you have decided to participate in this test, please understand that your participation is VOLUNTARY, refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled, and you may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.

If you have questions about your rights, please contact:

Derek T. Smith, Ph.D.; Emily Guseman, Ph.D., or Evan Johnson, Ph.D.
Division of Kinesiology and Health
smithdt@uwyo.edu
eguseman@uwyo.edu
evan.johnson@uwyo.edu
307-766-5282

Authorization

I have read the above and understand the benefits, discomforts, inconvenience, and risks associated with participation in this study. I understand that participation is voluntary and that my refusal to participate will not involve penalty or loss of benefits to which I am otherwise entitled and that I may discontinue participation at any time without penalty or loss of benefits to which I am otherwise entitled.

Your name: First and Last (print) _____

Your signature: _____

UW Witness (print and sign): _____

Date: _____

Attachment VIII- Distant Data Collection Site Letter of Support

CrossFit 7220

411 South 20th Street

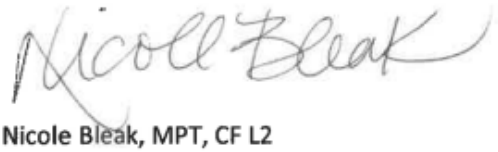
Laramie, WY 82072

October 23rd, 2017

Dear Dr. Johnson

This letter serves to exhibit that we (Nicole Bleak, and Mike Dorssom), have communicated in reference to the collection of research data outside of regular class sessions relevant to the research study, "Pharmalogical Risk Factors Related to Acute Renal Injury During High Intensity Training ", supervised by Dr. Johnson. I have agreed to allow Dr. Johnson and associated graduate and undergraduate students to collect data in our CrossFit 7220 facility. I have viewed the study design and I am comfortable with any and all procedures that will take place. I am aware that this data will not be provided to me as gym owner and that any and all information will be confidential and not identifiable in any way. I will not be awarding any type of reward or incentive for member participation in the data collection. Should the Institutional Review Board have any questions regarding my assistance with this research protocol they can contact me via the information provided below.

Thank you,



Nicole Bleak, MPT, CF L2

manager, CrossFit 7220

(307) 760-5898 (phone)

nicolebleak@gmail.com

Attachment IX- Menstrual cycle history

Participant # _____

Year: _____

Day	Jan.	Feb.	Mar.	Apr.	May	Jun.	Jul.	Aug.	Sep.	Oct.	Nov.	Dec.
1												
2												
3												
4												
5												
6												
7												
8												
9												
10												
11												
12												
13												
14												
15												
16												
17												
18												
19												
20												
21												
22												
23												
24												
25												
26												
27												
28												
29												
30												
31												

Last menstrual cycle dates: _____ (start) _____ (end)

Attachment X- Additional Student Researchers Not Included as Co-Investigators

Additional Student Researchers

1. Hillary Yoder
2. Miranda Zamora
3. Hunter Anderson
4. Brittany Wells
5. Brandon Stranigan
6. Breton Van Syoc
7. Emelda Malm

UNIVERSITY
OF WYOMING

Vice President for Research & Economic Development
1000 E. University Avenue, Department 3355 • Room 305/308, Old Main • Laramie, WY 82071
(307) 766-5353 • (307) 766-5320 • fax (307) 766-2608 • www.uwyo.edu/research

May 2, 2019

Evan Johnson
Assistant Professor
Kinesiology and Health
University of Wyoming

Derek Smith
Associate Professor
Kinesiology and Health
University of Wyoming

Nicole Sauls
Graduate Assistant
Kinesiology and Health
University of Wyoming

Christopher Bell
Associate Professor
Health and Exercise Science
Colorado State University

Protocol #20190502EJ02396

Re: *"Risk Factors Related to Acute Renal Injury during a Mass Participation High Intensity Functional Resistance Training Event"*

Dear Evan, Derek, Nicole, and Christopher:

The Institutional Review Board for projects involving human subjects reviewed the proposal referenced above at their meeting March 21, 2019. The proposal was approved as one that would not involve more than minimal risk to participants, subject to minor revisions. We have received the requested revisions and the revised protocol is approved.

IRB approval for the project/research is for a *one-year period*. If this research project extends beyond ***May 1, 2020***, a request to extend the approval accompanied by a report on the status of the project (Annual Review Form) must be submitted to the IRB *at least one month prior to the expiration* date. Any significant change(s) in the research/project protocol(s) from what was approved should be submitted to the IRB (Protocol Update Form) for review and approval prior to initiating any change. Per recent policy and compliance requirements, any investigator with an active research protocol may be contacted by the recently convened Data Safety Monitoring Board (DSMB) for periodic review. The DSMB's charge (sections 7.3 and 7.4 of the IRB Policy and Procedures Manual) is to review active human subject(s) projects to assure that the procedures, data management, and protection of human participants follow approved protocols. Further information and the forms referenced above may be accessed at the "Human Subjects" link on the Office of Research and Economic Development website: http://www.uwyo.edu/research/human-subjects/index.html.

You may proceed with the project and we wish you luck in the endeavor. Please feel free to call me if you have any questions.

Sincerely,

Nichole Person

Nichole Person
Staff Assistant, Research Office
On behalf of the Chairman,

University of Wyoming IRB Proposal Form

Institutional Review Board
Room 308, Old Main
1000 East University Avenue, Dept. 3355
Laramie, WY 82071

Phone: 307-766-5322
Fax: 307-766-2608
email: irb@uwyo.edu
(Electronic submission via email is encouraged.)

1. Responsible Project Investigator, Co-Investigators, & Faculty Supervisor

Responsible Project Investigator:

Name: Evan Johnson	**Title:** Assistant Professor
Department: Kinesiology and Health	
Office Address: Corbett Building 109	
Phone number: 307-766-5282	**Fax number (if applicable):** 307-766-4098
Email address: evan.johnson@uwyo.edu	
Is the project funded? Y_X__ N__ __ **If Y, from where? UW INBRE**	

Co-Investigators (add more boxes if necessary):

Name: Derek Smith	**Title:** Associate Professor
Department: Kinesiology and Health	
Office Address: Corbett Building 108	
Phone number: 307-766-5271	**Fax number (if applicable):**
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If the principal investigator is a graduate or undergraduate student, submit the Research Supervisor Approval form from the faculty advisor, thesis or dissertation committee chair indicating review and approval of the proposal for submission to the IRB. The IRB will not approve a proposal without the proper Approval form.	

2. Title of Study:

Risk Factors Related to Acute Renal Injury during a Mass Participation High Intensity Functional Resistance Training Event

3. Anticipated Project Duration:

May 1st, 2019 – April 30st, 2020

4. Purpose of Research Project:

In LAY LANGUAGE, summarize the objectives and significance of the research:

Physical activity is a well-established intervention used to improve a variety of health domains including cardiorespiratory, functional, and metabolic health. Despite the well-known health benefits, 31.1% of worldwide adults are considered physically inactive, and only 20.6% of adults in the United States meet both the current aerobic and muscle strengthening guidelines (ACSM's guidelines for exercise testing and prescription 2016). In response to the physical inactivity pandemic, barriers to exercise have been studied, and "lack of time" was a chief recurring response (Booth, Bauman, Owen, & Gore, 1997; Daskapan, Emine, & Levent, 2006; Sallis & Hovell, 1990).

As a result, recent investigations have made an attempt to find a more time-efficient exercise solution through the comparison of high intensity training (HIT) performed over shorter durations in comparison to traditional moderate intensity continuous exercise (MICE). The theory behind HIT is that through higher intensity exercise, increased muscle fiber recruitment occurs, resulting in maximal skeletal muscle adaptations within a short period of time. HIT has demonstrated equivalent and even superior training effects compared to MICE (Burgomaster et al., 2008; Gibala, 2007; Nybo et al., 2010); however, other studies have reported potential risk including post-exercise physical dysfunction (Drum, Bellovary, Jensen, Moore, & Donath, 2017; Nybo et al., 2010). Not all variations of HIT will elicit identical training effects, and there may be individuals who are at higher risk for adverse consequences based on their specific behavioral patterns.

High intensity interval training (HIIT) is the most recognized sub-class of HIT and is characterized by short bouts of high intensity cardiovascular exercise (i.e., running, cycling, rowing, stair-stepping) separated by brief periods of planned rest (Thompson, 2015). Traditional resistance and strength training methodologies have also been adapted to the HIT framework to create high intensity functional resistance training (HIFRT). This style of HIT incorporates various functional movements (e.g., pull-ups, Olympic lifts) performed at relatively high intensities that train the body in all planes of motion. Recent analyses have revealed this mode of training can improve metabolic conditioning, muscular strength, and the general physical preparedness of military members (Haddock, Roston, Heinrich, Jahnke, & Jitnarin, 2016); however, as in any type of exercise, potential acute injury risks have also been identified.

Some forms of HIFRT have been linked with severe post-exercise physical dysfunction and incidences of acute exertional rhabdomyolysis (ER) developing from skeletal muscle damage (Dilip, Richmond, & Alfonso, 2009; Drum et al., 2017; Xavier, Esteban, & Josep, 2009). Due to demand on the kidney's filtering unit to clear excess myoglobin from the blood stream, exercise-related acute kidney injury (AKI) can be a severe complication of ER in trained populations (Dilip et al., 2009).

There are many variations of HIFRT workouts, and some are more physically demanding than others. One of the most difficult and frequently performed workouts is "Murph" which consists of a 1-mile run, 100 pull-ups, 200 push-ups, 300 body-weight squats, and a second 1-mile run. The workout is performed by many members HIFRT community including 177 facilities in the United States that hosted "Murph" workouts in 2017 in honor of a Navy SEAL (LT. Michael P. Murphy) who died while serving overseas in Afghanistan (The murph challenge.2018). Symptoms of severe physical dysfunction have been reported following the completion of "Murph" (Drum et al., 2017).

Preliminary studies from our laboratory

An ongoing study within the Human Integrated Physiology Laboratory (Protocol #20180607EJ02013 "Pharmacological Risk Factors Related to Acute Renal Injury during High Intensity Training") is performing a similar data collection with participants reporting the laboratory on an individual basis. This allowed our research team to collect initial data for our overall kidney injury risk evaluation following the above workout and test an additional biomechanical question embedded within the protocol. Early findings from this study indicate that a majority of individuals exhibit proteinuria most prevalent in the 24h after the workout and a small proportion of individuals have presented with blood in the urine within the 24h after the workout. In almost all cases both protein and blood have resolved by the 48h point. One participant displayed trace blood in their 48h post, spot urine sample. This participant was followed up with at 72h and the urine reagent strip used at this time point was unremarkable. Six participants have displayed proteinuria in the 48h post, time point. All six of these were "trace" findings (i.e., 15 mg/dL) upon completion they were alerted to be aware of the signs and symptoms of more severe kidney injury including; decreased urine output, fluid retention, causing swelling in your legs, ankles or feet, shortness of breath, fatigue, confusion, nausea, weakness, irregular heartbeat, chest pain or pressure, or irregularly dark urine. If any participant noticed any of these symptoms following their completion of the study they were told to contact us or a doctor immediately. These findings suggest our hypothesis about the risk of AKI during this is founded and worth exploring in a greater number of individuals. The data from the individual trials will be combined with data collected from the proposed mass participation event so that we will be able to reach our required participant number specific to the evaluation of certain biomarkers and their ability to predict risk for AKI following HIFRT.

Purpose / Aims

HIT is a modality of exercise that can produce a high amount of health benefit in a minimal amount of time. However, it is clear that some forms of HIT, particularly within the resistance training style (i.e., HIFRT) can introduce risk of renal injury. Therefore the aims of our current study are as follows:

Aim 1: To investigate the prevalence of AKI following the HIFRT workout, "Murph", and compare the results to previous research evaluating incidence rates in other forms of extreme exercise (i.e., marathon running). AKI will be determined through the sample analysis of blood (serum creatinine, blood urea nitrogen, neutrophil gelatinase-associated lipocalin [NGAL], and kidney injury molecule 1 [KIM-1]) and urine (albumin, creatinine, NGAL, and KIM-1) biomarkers.

Aim 2: To evaluate if the baseline concentration of proenkephalin A is related to the risk or severity of renal injury biomarker concentrations listed above post-workout.

The proposed updates to the previous investigation (single subject research) will allow us to apply the data collection techniques we have practiced collecting data on a larger number of individuals in a shorter period. The results from the compiled studies will contribute to safe and efficacious prescription of HIFRT workouts like "Murph".

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5. Description of Potential Participants:

A. Age-range and gender: Men and women between the ages of 18-70

B. Describe how the participants will be recruited and/or selected:

Following registration for a charity event (The Murph Challenge, See Attachment 8) held at the University of Wyoming on Memorial Day (May 27, 2019) individuals will receive an e-mail asking if they would like to volunteer to take part in the observational study*. We plan to recruit charity registrants into the study from Laramie, Wyoming and the surrounding communities including the University of Wyoming Reserve Officers Training Corps (ROTC), Cheyenne, and Fort Collins. Only individuals who: A) have at least one year of HIFRT training experience, and B) have completed the workout "Murph" at least one time in any of the below repetition schemes described below (Table 1.) will be recruited.

Participants will be recruited by e-mail communication following their digital registration for The Murph Challenge at UW. Interested individuals will contact the principal investigator to hear full details on the study procedures, exclusionary criteria, risks and benefits prior to any involvement.

*Because the data collection will take place within a charity event that raises funds for the Lt. Michael Murphy Foundation, we have asked for explicit permission from Lt. Murphy's father (who is the executor of the Foundation). He has reviewed a summary of the research question and basic methodology and given us approval (See Attachment 11) to use the workout taking place at an Official Murph Challenge Site (See Attachment 8).

C. Describe the number of participants expected:

We plan to enroll 80 participants in this project, up to 20 of whom from the Fort Collins area. The number is based on our primary variable of interest, proenkaphalin A. The prospective nature of this investigation is based upon A) observation of acute kidney injury following extreme exercise (Monsour 2017) and, B) Proenkaphalin being identified as a predictor of AKI following cardiac surgery (Shah 2015). The statistical test driving this analysis will be similar to that used by Shah et. al. For our investigation the statistical test we have used to justify our sample size is an independent t-test of baseline proenkaphalin concentrations comparing those participants that develop AKI following the workout compared against those

that do not develop AKI. AKI is defined as an increase in serum creatinine of >1.5 fold over the observation period (Makris 2016).

Shah et. al. found that the baseline concentrations of proenkaphalin were 78.0±35.9 and 55.4±17.4 pmol/L within participants that developed AKI versus those that did not, respectively. Given a sample population of 84, $\alpha = 0.05$, power of .90, and a conservative estimate that 60% of participants will develop markers consistent with AKI an effect size of .80 can be calculated. Therefore, our goal is to enroll 100 participants between this investigation combined with the previous individual investigation with the knowledge that there will be some attrition and not all data will be usable. Up to 40 individuals will complete the individual version described in our previous iteration of this investigation. Thus, once the data from the two studies are combined, we will be able to meet our goal of 100 participants.

Plasma creatinine will be used to diagnose AKI. All other primary and secondary markers will be compared between groups similar to proenkaphalin. Because the aim of this investigation is to determine the feasibility of proenkaphalin as a predictor of AKI as a result of high intensity exercise, this variable and not the other primary and secondary variables has been used in the calculation of our eventual sample size.

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Shah KS, Taub P, Patel M, Rehfeldt M, Struck J, Clopton P, Mehta RL, Maisel AS. Proenkephalin predicts acute kidney injury in cardiac surgery patients. Clin.Nephrol., 2015, 83, 1, 29-35,.

D. Will compensation or incentives be provided for participation? Y__X__ N____
IF Y, please describe:

Participants will receive $100 for full participation in this study. This will be distributed at the participants' end of enrollment in the study. If they choose to be removed from the study prior to completion they will be compensated based on the below pro-rated basis.
$20 – Baseline measurements
$30 – Completion of workout
$10 – Completion of 24h post visit
$40 - Completion of 48h post visit plus bonus for finishing all study measurement periods

E. Description of special classes: n/a

F. Criteria for exclusion from participant pool:

1. Score of "0" on the Functional Movement Screening (FMS) test as evaluated by two investigators * indicating pain during any of the seven functional movements

2. Self- reported Kidney Disease (e.g., chronic kidney disease, polycystic kidney disease, glomerulonephritis, diabetic nephropathy, interstitial nephritis, Goodpasture syndrome) or other medical condition contraindicating participation in HIFRT (Hypertension, dyslipidemia, type II diabetes mellitus, BMI >30)
3. Pregnancy, suspected pregnancy, or breastfeeding
4. Blood donations within the last eight weeks leading up to testing day
5. Any musculoskeletal injuries which have resulted in > 1 week of absence from HIFRT within the last six months
6. Not passing the physical activity readiness questionnaire (PAR-Q)
7. Surgical operation on digestive tract or kidneys, except appendectomy
8. Inability to participate in the entire study
9. Recurrent urinary tract infections or kidney stones (> 3 within the past year)
10. History of protein or blood in urine
11. Moving from a location of low altitude (< 3,000') to Laramie within the past 3 months
12. Inability to understand and write English**

* If a participant scores a 0 on the FMS during the familiarization period, she/he will continue with the remainder of the familiarization protocol on that day. Participants who score a 0 will be re-screened by a second screener prior to the first workout. Although the FMS has demonstrated good interrater reliability, it has also been reported as varied (Bonazza 2016). If the participant scores a 0 a second time, she/he will be excluded from the study to avoid further risk of injury/exacerbation of current pain. It is possible for a participant to score a 0 on the familiarization day and a non-0 on the intervention day as participant pain rating may change based on prior day/week of activity. Regardless of this, there is value in performing the FMS on the familiarization day.

**English is a required language because the questionnaires which will be used in this investigation are written in English language.

The medical history questionnaire will be initially reviewed by the responsible graduate student (Nicole Sauls), if there are any questionable responses the principle investigator (Evan Johnson) will be contacted prior to any measurements being taken. Both may disqualify an individual if any responses meet the specified exclusionary criteria above.

6. Procedure:

- **Description of participants' activities:**

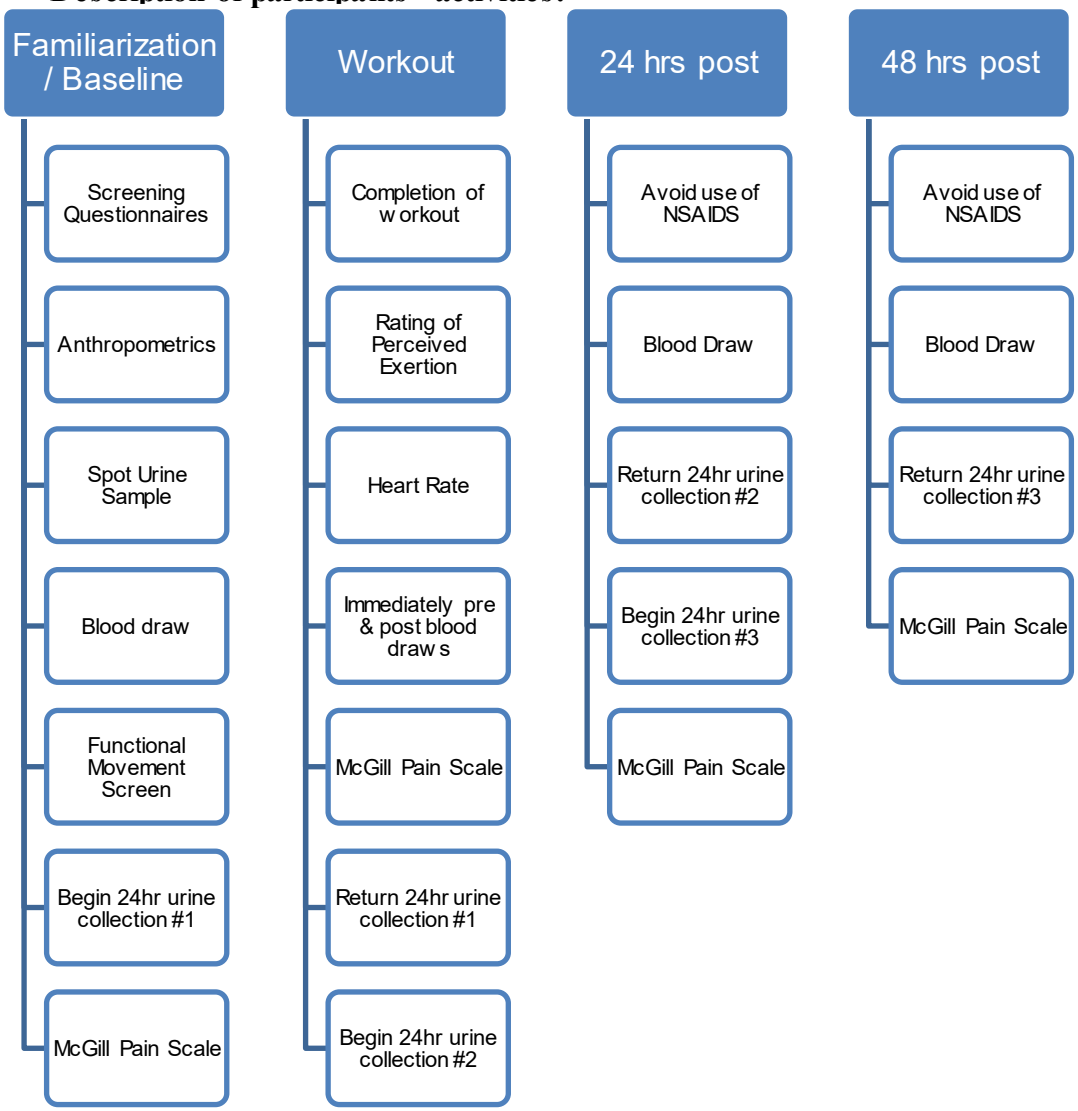

Figure 3. Overall outline of a single testing week for individual data collections. Each participant will complete two testing weeks one month apart.

Familiarization / Baseline: Subjects will report to the Human Integrated Physiology (HIP; University of Wyoming) or the Integrative Biology Laboratory (IBL; Colorado State University) within 3 days of the workout to provide informed consent complete initial screening procedures. The Colorado State location has been added because the investigators feel it may enhance the participant pool if individuals from Fort Collins can also be recruited. By allowing individuals from Fort Collins to complete baseline and post-workout measurements at Colorado State University this will limit the number of times they are required to drive to Laramie which could be a deterrent to participation (See Attachment 4 for CSU IRB statement showing their awareness of the protocol and willingness to cede to UW IRB upon approval).

Baseline measurements include, physical activity readiness questionnaire (PAR-Q; Attachment 3), medical history questionnaire, anthropometrics, functional movement screening (FMS; **Figure 4**),), spot urine sample, and blood draw. Informed consent will be obtained for overall research study. Participants will also complete the McGill pain scale (Attachment 5) and begin the first 24 hour urine jug collection. Participants will be asked to abstain from the ingestion of NSAIDS, caffeine, and alcohol, and refrain from exercise for 24h prior to this visit and between this visit and the end of their study participation.

- University of Wyoming medical history questionnaire
- PAR-Q
- Anthropometrics (age, height, weight)
- Spot urine sample (albumin, creatinine, NGAL, and KIM-1])
- Blood draw (serum creatinine, blood urea nitrogen, NGAL, and KIM-1)
- FMS
- The first 24-hour urine jug collection will be submitted to investigators immediately prior to the workout session.
- McGill pain scale
- Blood pressure measurement

All blood draws will be performed by a person trained in phlebotomy and supervised by Dr. Johnson, Dr. Smith or Dr. Bell. The named investigators have successfully completed >2,000 blood draws during exercise related research investigations. They have all completed required blood borne pathogen training.

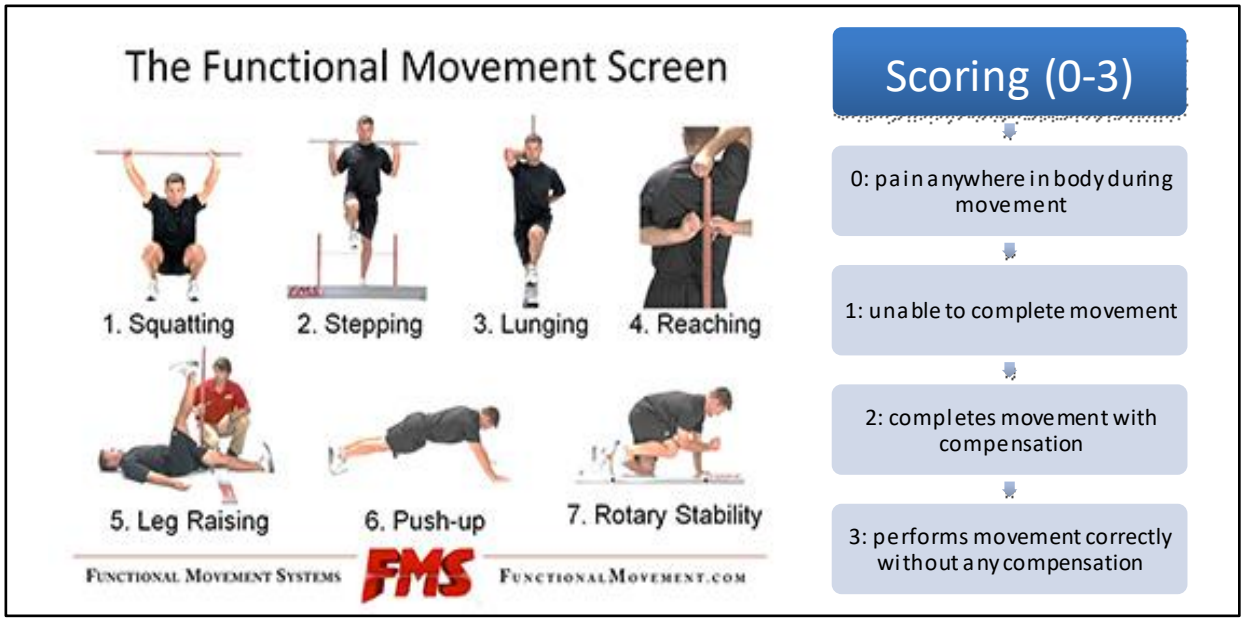

Figure 4. The seven movement patterns and scoring system for FMS.

Workout Session: Participants will report to the University of Wyoming, "Tailgate Field" in Laramie, WY for the workout. Once arrived they will be directed to the HIP lab within the Corbett building to turn in their first 24-hour urine sample jug and receive a new 24-hour urine sample jug. At this point they will have their pre-workout blood pressure measured and a blood draw performed.

All participants will have previously registered to complete the workout as part of a charity event being held at the University of Wyoming. Not all individuals completing the charity event will be participants in the research study. Participants and non-participants will work out side by side in a mass participation event similar to a 5k. Waves of charity participants will be instructed to start the event every 30 min so that it can be ensured there is adequate space for all people at the pull up stations. For this work out a modular pull up bar will be constructed on the UW Tailgate Field with the help of the UW engineering department. The charity event will have individuals stationed to allow flow of participants between stations (run, pull-ups, push-ups, squats, second run). An investigator will be paired with each research volunteer to individually guide the participant and ensure safety throughout the entire workout.

All research participants will be led through a full body dynamic warm-up, review movement standards for the exercises to be completed as part of the workout and complete the workout "Murph" while heart rate is recorded. Immediately following the workout, a blood draw will be taken by the primary investigator and the participant will be asked to mark their level of muscle soreness on the McGill pain scale.

Participants can complete the workout in any of the below iterations. They can only complete a version of the workout at or below a difficulty level that they have previously completed. For example if the hardest level of difficulty a participant had previously completed was "Prescription, Cindy" they would not be eligible to complete the workout as "Prescription" as a part of the research study. Participants are not expected to complete the most difficult version they have previously completed, and the difficulty decision will be left up to only the participant. This will be confirmed and recorded by their completion of the training history questionnaire (Attachment 7).

Table 1. Workout iteration descriptions

Difficulty	Iteration Title	Weight Vest (yes/no)	Repetition Scheme (consecutive or non-consecutive*)
Hardest	Prescription Plus	Yes	Consecutive
↕	Prescription Plus, Cindy	Yes	Non-Consecutive
↕	Prescription	No	Consecutive
↕	Prescription, Cindy	No	Non-Consecutive
↕	Scaled**	No	Consecutive
Easiest	Scaled, Cindy	No	Non-Consecutive

*non-consecutive – As opposed to completing all 100 pull-ups before moving on to the 200 push-ups individuals complete 20 rounds of 5 pull-ups, 10 push-ups, 15 squats. The same total number of repetitions for each exercise are completed.
**Scaled – Instead of pull-ups the individual can substitute "ring-rows" or other pulling motion of their choosing. Instead of traditional push-ups, the individual will complete the push-ups in a modified fashion with knees on the ground or by placing the hands on an elevated surface.

List of workout day measurements

- Turn in 24-hour urine sample jug
- Receive empty 24-hour urine sample jug
- Dynamic warm-up (500m jog and two rounds of 10 wall push-ups, 5 body weight-squats, 10 each side forward leg swings, 10 arm circles in each direction, and a 30 second plank hold)
- Review of movement standards and practice opportunity
- Complete "Murph" (1-mile run, 100 pull-ups, 200 push-ups, 300 body weight squats, and a final 1-mile run)
- heart rate recorded continuously via telemetric strap (i.e., heart rate monitor watch)
- Pre and Post workout spot urine samples
- Pre and Post workout blood draw
- Pre and Post workout McGill pain scale to measure muscle soreness

- Pre and Post workout blood pressure measurement

24 hours post: Subjects will report to the HIP or IPL to turn in their second 24-hour urine collection jug and be provided with the third and final 24 hour collecting jug. They will also take part in a blood draw and fill out the McGill pain scale to continue monitoring muscle soreness and have their blood pressure measured. Participants will be asked to abstain from the ingestion of NSAIDS, caffeine, and alcohol, and refrain from exercise during this time.

- Turn in 24-hour urine sample jug
- Receive empty 24-hour urine sample jug
- 24h Post workout spot urine samples
- 24h Post workout blood draw
- 24h Post workout McGill pain scale to measure muscle soreness
- 24h Post workout blood pressure measurement

48 hours post: Subjects will report to the HIP or IPL and turn in their third and final 24-hour collecting jug, provide one last blood draw, and complete the McGill pain scale. Once the 48-hour post tests have been finished, the subjects have officially completed the study and will be paid.

- Turn in 24-hour urine sample jug
- 48h Post workout spot urine samples
- 48h Post workout blood draw
- 48h Post workout McGill pain scale to measure muscle soreness
- 48h Post workout blood pressure measurement

A. What will non-participants do while participants participate?

Non-participants will be completing the workout of their choosing alongside the research participants. Research investigators will have minimal interaction with non-participants and only provide information about logistics of their own completion of the workout.

B. What will participants be told about the research project?

Participants will receive full disclosure of methods, risk and benefits. No deception will be used during the implementation of the above intervention. Upon completion of the entire data collection, participants will be contacted with their results.

C. Estimated time required for participants:

During the testing week, they will visit the Human Integrated Physiology Laboratory (Corbett Building Rooms 208 and 206) or a combination of HIP and IPL at CSU for a total of 4 occasions (Baseline, workout, 24 hours post, 48 hours post). The following calculates the estimated total number of hours spent by each participant:

- Familiarization/Baseline: 2 hours
- Workout session: 2 hours
- 24 hours post: 30 minutes
- 48 hours post: 30 minutes

Total= 5 hours spent per participant performing study related activities

D. Where will research take place?

All familiarization/baseline, 24-hour post, and 48-hour post data collection days will take place in the Human Integrative Physiology (HIP) laboratory (Corbett Building Rooms 208 and 206) or at the Integrative Biology Laboratory (IBL) located at Colorado State University. The workout session will take place outdoors on the Tailgate Field located at the University of Wyoming. All blood draws on the day of the workout will take place for all subjects within the HIP laboratory.

E. Method of data collection: Qualitative ___ Quantitative _X (check one or both). In a paragraph or two, please describe how you will collect your data:

Data collection will occur via blood draws, urine sample collections, muscle soreness, heart rate monitoring, and RPE scale evaluations.

A qualified investigator will obtain a single blood sample via venipuncture to an antecubital vein using sterile technique. At all times when blood samples are being handled, either for processing or analysis, the investigators will follow universal precaution standards. Samples will be drawn into vacutainers for later examination in the University of Wyoming's HIP lab. Samples will assess kidney injury biomarkers including serum creatinine and blood urea nitrogen. In concordance with the Acute Kidney Injury Network, occurrence of AKI will be defined as an increase in serum creatinine of 0.3 mg/dL or an increase of 1.5 times greater than baseline measures. Our lab group has successfully drawn and stored blood samples as part of a current project. Additionally, investigator Johnson has successfully performed similar sample collections within laboratory environments and on athletes in field-based locations as well as in collaboration with multi-site data collection.

A total of three x 24-hour urine collection jugs will be collected over a 72 hour period. Samples will assess albumin, creatinine, neutrophil gelatinase-associated lipocalin (NGAL), and kidney injury molecule 1 (KIM-1) kidney injury biomarkers. At all times when urine samples are being handled, either for processing or analysis, the investigators will follow universal precaution standards and assume that small amounts of blood may be contained in the urine samples. Total volume, urine color, and urine specific gravity will also be analyzed from every sample. Dipsticks will be used on fresh samples while five 2mL aliquots of each 24hr sample will be separated and stored at room temperature until they are returned to the University of Wyoming where they will be frozen at -80C for future analysis. Investigator Johnson has consistently used 24-hour urine collections as a part of his ongoing research regarding human hydration.

Muscle soreness will be measured using a McGill short-form pain questionnaire to assess muscle pain and soreness (Attachment 5).

A heart rate monitor will be worn by participants around their chest in order to record accurate heart rate continuously throughout the workout. The values will be compared with age predicted maximal heart rate values in order to quantify relative exercise intensity.

The Borg's RPE scale will be utilized to monitor how hard a subject is working after each segment of the workout as well (**Figure 5**).

Borg Rating of Perceived Exertion

6 No exertion at all
7
Extremely light
8
9 Very light
10
11 Light
12
13 Somewhat hard
14
15 Hard (heavy)
16
17 Very hard
18
19 Extremely hard
20 Maximal exertion

Figure 5. Borg's RPE Scale

F. Please describe how and when participants may terminate participation:

Participants are free to terminate their participation in the investigation at any time with no penalty.

G. Description of biological samples (examples may include blood or urine):

Blood samples will be collected on all days of data collection (familiarization/baseline, workout, 24 hours post, and 48 hours post) to analyze serum creatinine, blood urea nitrogen, NGAL, and KIM-1. A qualified investigator will obtain a single blood sample via venipuncture to an antecubital vein using sterile technique. At all times when blood samples are being handled, either for processing or analysis, the investigators will follow universal precaution standards. Samples will be drawn into vacutainers for later examination at the University of Wyoming's HIP lab or at John's Hopkins University (serum creatinine and blood urea nitrogen). They will be analyzed via colorimetric enzyme-linked immunosorbent assays (ELISA). ELISA antibodies will be supplied by Abcam (Cambridge, MA, USA) and microplates will be read according to the manufacturer's instructions on spectrophotometer (Epoch 2, Bitotek, Winooski, VT, USA). Samples for proenkaphalin quantification will be sent to Lund University for quantification of Proenkaphalin-A.

A total of three, 24-hour urine collection samples will be collected over a 72-hour period. Samples will assess albumin, creatinine, neutrophil gelatinase-associated lipocalin [NGAL], and kidney injury molecule 1 [KIM-1] kidney injury biomarkers. At all times when urine samples are being handled, either for processing or analysis, the investigators will follow universal precaution standards and assume that small amounts of blood may be contained in the urine samples. A portion from each sample will be shipped to John's Hopkins University for analysis (NGAL and KIM-1). Total volume, urine color, and urine specific gravity will also be analyzed for every sample. Dipsticks will be used on fresh samples while five, 2mL aliquots of each 24hr sample will be separated and stored at room temperature until they are returned to the University of Wyoming where they will be frozen at -80C for future analysis. Fresh samples will be evaluated for urine color and specific gravity using a handheld refractometer to establish hydration state.

H. Description of equipment to be used on or by participants:

Participants will utilize spot and 24-hour urine collection containers (**Figure 6, 7**) which contain screw tops to avoid breakage or spilling. A "Go Girl" urinary funnel device will be provided to female participants to assist with urine collection (**Figure 8**).

Figure 6. 24 hour urine collection jug

Figure 7. Spot urine collection container

Figure 8. "Go Girl" urinary device

Blood draws will be collected using a winged infusion set with a tube holder. Samples will be drawn into vacutainers for later examination in the University of Wyoming's HIP lab or John's Hopkins University (**Figure 9**).

Figure 9. Winged infusion set with a tube holder

A scale will be used to assess bodyweight on familiarization day (**Figure 10**).

Figure 10. Bodyweight scale

Participants will utilize the FMS testing kit (measuring device, hurdle, and measuring stick) during familiarization to assess movement patterns (**Figure 11**).

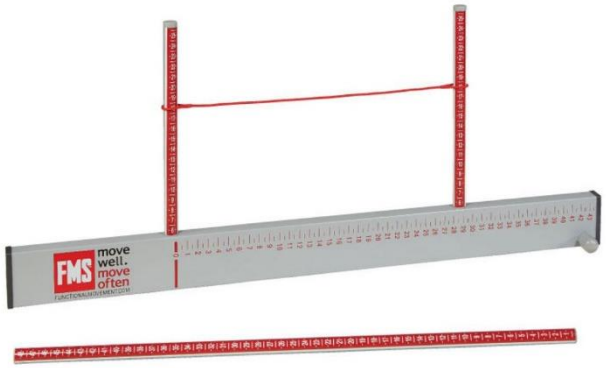

Figure 11. FMS testing kit

Heart rate will be recorded telemetrically during the workout by heart rate monitor watch and chest strap (Figure 12).

Figure 12. Polar A300 activity heart rate Monitor

7. Confidentiality Procedures:

A. Explain whether or not participants will be identified by name, appearance, or nature of data:

Participants will not be identified by name, appearance, or nature of data.

B. Are you collecting personal health information? (See the IRB manual at: http://www.uwyo.edu/research/compliance/human-subjects/index.html).

Yes ____X_____ No _____

C. Will the data you collect be anonymous or confidential (check the one that applies)? *Note: research is only anonymous if the researcher does not know the identity of the participants and there are no identifiers linking the participant to the research.*

Anonymous_____ Confidential __X____

D. Explain the procedure that will be used to protect privacy and confidentiality:

Each participant will receive an exclusive identification number to be used on all data collection sheets and samples. There will only be one master sheet where the subject's names will correspond to their identification number. This sheet will be held on a secure password protected computer by the graduate student investigator, Nicole Sauls. Participant names will not be used in presentations, reports, data bases, or publication based on the research investigation.

Because the data collection for this protocol will take place in a group setting it is very possible that participants will be visually identifiable by other participants and by those non-participants who are simultaneously completing the charity workout. However, any data or written information respective to the participant's engagement in the study will be kept confidential.

Participants can grant the researchers associated with this project the permission to use pictures taken of them during data collection as part of scientific presentations and publications (Attachment 6). The participant names will never be used in any presentations or publications. This permission is not required to be part of the study. If a participant chooses not to grant this permission they can still participate in all aspects of the research, but no pictures of their participation will be taken at any time.

E. How and where will data be stored (may be indefinitely)?

Data sheets will be kept in a locked file cabinet. The data will be entered into an electronic spreadsheet on a password protected computer and will not include subject names. The original data sheets will be kept for at least six years following the completion of research. The electronic files will be held indefinitely in case questions about publications come up in the future.

F. How long will the data, research summary, and signed consent forms be stored (may be indefinitely)? *Note: The regulations require that The PI or project director maintain the signed informed consent forms, assent script/forms (if applicable), and the*

written research summary, relating to research for at least three years after completion of the research.

All data, research summaries, and signed consent forms will be stored in a locked file cabinet in the principal investigator's office for at least six years following the completion of data collection.

G. Who will have access to the data?

The data will only be accessible to the primary investigator, co-investigators, and Responsible graduate and undergraduate students. These are students listed in attachment 10.

8. Benefits to Participants:

A. Describe the indirect research benefits for the participants:

Indirect research benefits include, and functional movement screen results.

B. Describe the direct research benefits or state there are no direct benefits to the participants (do not include incentives in this section):

Participants will receive up to $100 for their participation.

9. Risks to Participants:

This section should include a detailed description of any reasonably foreseeable risks or discomforts to the participants as a result of each procedure, including discomfort or embarrassment with survey or interview questions, exposure to minor pain, discomfort, injury from invasive medical procedures, or harm from possible side effects of drugs. All projects are deemed to involve some level of risk to participants, however obvious or obscure. Consequently, **proposals must state** that minimal risk is involved when the proposed research is viewed as involving little or no risk to participants. Risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Even when risk is minimal, investigators must still state what the minimal is and why it is minimal (example would be potential for embarrassment or boredom).

Describe the risks to participants:

Urine collection inconvenience – The 24-hour urine collection jugs may present inconvenience and slight embarrassment for participants. To minimize these inconveniences, a reusable shopping tote will be provided to make carrying the samples more discrete. Also, a female urination device will be provided to appropriate participants to make urine collection easier.

Blood Draw and Venipuncture Risk- Blood draws performed on familiarization, baseline, 24 hours post, and 48 hours post will be performed by a trained investigator, Dr. Johnson, using sterile techniques and universal precautions. However, risk does include pain, bruising, fainting,

hematoma, nausea, phlebitis, infection, bleeding, blood clots, and sensitive responses to plastic or adhesive tape used during or as a reaction to the venipuncture. To minimize bleeding and the incidence of a hematoma, firm pressure with gauze will be placed on the site of needle removal.

Exercise intervention – Participation in any physical activity or exercise has risk. These risks include but are not limit to, pain, fainting, dizziness, fatigue, nausea, shortness of breath, chest pain or angina, swelling, bruising, muscle/bone/joint soreness, joint damage, bone fracture, ligament/tendon/connective tissue damage, head and cervical spine injuries, hospitalization, and death. As with any exercise participation there is some cardiovascular risk (arrhythmia, sudden cardiac death, acute myocardial infarction). The incidence of sudden cardiac death in young adults has been estimated at 0.9 and 2.3 per 100,000 for non-athletes and athletes, respectively. These risks will be minimized by the following:

1. Anyone with a pre-existing injury will be excluded
2. All exercise sessions will be overseen by an investigator and an individual with a high intensity exercise training instructor certificate. Both supervisors will alert the participants if exercise form puts the individual at risk for injury
3. All participants will have at least 1 year of HIFRT experience and will have completed "Murph" on at least one occasion prior to their inclusion in the study

Injury Liability

The University of Wyoming, the project investigator, and the research team are not liable for any injury participants might sustain while participating in this study and are not able to offer financial compensation or absorb the costs of medical treatment should the participant sustain such an injury.

Emergency Action Plan

In the event of an emergency, the responsible investigators will immediately report the situation to 911 and provide pertinent information describing severity of event, including any health and safety risks, to emergency responders. In the event of a cardiac emergency (cardiac arrest), a CPR-certified investigator will initiate the chain of survival until the arrival of emergency responders. An ambulance with an Emergency Medical Technician will be present at The Murph Challenge

10. Description of procedure to obtain informed consent or other information to be provided to participant:

A. How and when will the participants be approached to obtain consent?

Participants will be recruited from individuals who register online for The Murph Challenge charity event in Laramie, Wyoming. Following contact with the principal investigator, a responsible graduate student (listed below in Section B) will schedule the individual's initial appointment (Familiarization Day) or in the case of individuals from the Fort Collins area speak by phone. At this meeting, prior to any measurements being recorded, the responsible graduate student will review the consent document with the potential volunteer to clarify any questions they may have. The individual will complete the medical history questionnaire (Attachment 2) which will be reviewed by the responsible graduate student prior to the participant taking part in any exercise, hematological, or urinary testing. If an individual

chooses to volunteer, the signed consent form will be returned to the responsible graduate student. All consent documents, medical history questionnaires, and the research summary will be returned to the principle investigator who will store the document in a locked and secure file cabinet for 6 years.

B. Who will be responsible for obtaining consent (check the box that applies)?

Project Director ___X___ Evan Johnson, PhD
Member of Project team ___X____ Nicole Sauls (Co-investigator), or
Brittany Wells (Undergraduate Student)
Lauren Elliot (Undergraduate Student)
Other _____ (Please explain, and include name, affiliation, and title)

C. How will information be relayed to participant (read to, allowed to read, audio-recorded, video-recorded)?

Participants will have the consent form read to them by a responsible investigator. They will also have time to ask questions if any clarification is needed. A copy of the consent forms will also be given to take with them to the remaining sessions. The copies will include contact information for the primary investigator and the IRB office in case any questions or concerns arise during or after their time spent in the HIP Laboratory the IPL or outside during the workout.

D. Provide a description of feedback, debriefing, or counseling referral that will be provided if this is relevant to the research:

All participants will be sent individual reports following the completion of all data collection containing FMS, and heart rate results. Urine and blood analysis results will also be provided within a year from the completion date as these analyses take much more time to complete.

E. Explain the procedure that will be used to obtain assent of children, if relevant to the research (See: http://www.uwyo.edu/research/compliance/human-subjects/index.html): N/A

F. If children are involved, who will be responsible for obtaining assent (check the box that applies)?

N/A
Project Director _____
Member of Project team _____ (list name or position)
Other _____ (Please explain, and include name, affiliation, and title)

11A. Attach copies of survey instruments, interview questions, tests, and other pertinent documentation that will be used to conduct the research. Note: Please see the informed consent outline for suggested language for consent forms.

Attachment Name	Description
Attachment 1:	Informed consent for research participation
Attachment 2:	Medical History Questionnaire
Attachment 3:	Physical Activity Readiness Questionnaire (PAR-Q)
Attachment 4:	Colorado State University – IRB – e-mail chain
Attachment 5:	McGill Pain Questionnaire
Attachment 6:	Photo release waiver
Attachment 7:	Training History Questionnaire
Attachment 8:	The Murph Challenge – Website Description
Attachment 9:	Christopher Bell – Colorado State Collaborator – Letter of Support
Attachment 10:	Additional Student Researchers List
Attachment 11:	Daniel Murphy – Research within charity event approval e-mails

11B. If participants will be recruited through an institution such as a school or hospital, or if the research will be conducted at such an institution, provide a letter of agreement/approval to do so from an authorized representative of that institution. The IRB will not approve a proposal without the proper letter(s) of support.

11C. If collaborators and/or students will be helping with the research and those individuals are not listed as co-investigators on the proposal, please provide the names of those individuals in an attachment to the proposal so that human subjects training can be verified. – See Attachment 10

University of Wyoming Consent Form

I. General purpose of the study:

High intensity functional resistance training (HIFRT) may present risk for acute kidney injury (AKI) due to high exercise intensities and skeletal muscle damage. However, the direct effects of a specific long duration HIFRT workout on AKI risk is unknown.

The first aim of the study is to investigate the incidence of AKI following the commonly performed workout, "Murph" (1-mile run, 100 pull-ups, 200 push-ups, 300 body-weight squats, and a final 1-mile run) and compare these results seen in other forms of extreme exercise. Blood and urine samples are used in the diagnosis of kidney injury, so they will be used to determine AKI incidences.

The second aim is to evaluate if the baseline concentration of the blood biomarker "proenkephalin A" is related to the occurrence or severity of AKI following HIFRT.

By doing this we hope to assist in the continued programming of safe and efficacious HIFRT workouts. The goal is not to take away from the many benefits of HIFRT. Instead, we hope to educate the exercising population on the potential risks associated with HIFRT, so they can adjust behavioral or movement patterns that will minimize risk for injury.

II. Procedure:

All sessions will take place at University of Wyoming's Human Integrated Physiology Laboratory or Colorado State University's Integrated Physiology Laboratory. Data will be collected by Evan Johnson PhD, Christopher Bell PhD, graduate, and undergraduate students that have been appropriately trained to carry out the research protocol.

You are / will be ineligible for the study if any of the following are true

1. Score of "0" on the Functional Movement Screening (FMS) test as evaluated by two investigators, indicating pain during any of the seven functional movements
2. Self- reported Kidney Disease (e.g., chronic kidney disease, polycystic kidney disease, glomerulonephritis, diabetic nephropathy, interstitial nephritis, Goodpasture syndrome) or other medical condition contraindicating participation in HIFRT (Hypertension, dyslipidemia, type II diabetes mellitus, BMI >30)
3. Pregnancy, suspected pregnancy, or breastfeeding
4. Blood donations within the last eight weeks leading up to testing day
5. Any musculoskeletal injuries which have resulted in > 1 week of absence from HIFRT within the last six months
6. Not passing the physical activity readiness questionnaire (PAR-Q)

7. Surgical operation on digestive tract or kidneys, except appendectomy
8. Inability to participate in the entire study
9. Recurrent urinary tract infections or kidney stones (> 3 within the past year)
10. History of protein or blood in urine
11. Moving from a location of low altitude (< 3,000') to Laramie within the past 3 months
12. Inability to understand and write English**

Participation will include one data collection week. The week will consist of 4 data collection days. The only additional commitment may be a familiarization phone call, e-mail, or visit prior to the first week of testing where exclusionary criteria will be assessed. We estimate the total time commitment to be 5 hours. The schedule is outlined below:

Testing Week

- Familiarization / Baseline: 2 hours minutes
- Workout session: 2 hours
- 24 hours post: 30 minutes
- 48 hours post: 30 minutes

On the familiarization day, consent and initial screening forms will be filled out if you choose to participate, if you are located in the Fort Collins area this will take place over the phone. For individuals in the Laramie area the familiarization and baseline visits will take place simultaneously. On the baseline day at either the University of Wyoming's Human Integrated Physiology Laboratory or Colorado State University's Integrated Physiology Laboratory we will measure your height, weight, and waist girth. You will then take part in a functional movement screen (FMS) to analyze your ability to perform several movement patterns. If you score a 0 on the FMS during the familiarization period, you will continue with the remainder of the familiarization protocol, however you will be re-screened by a second screener prior to the first workout. Although the FMS has demonstrated good interrater reliability, it has also been reported as varied. Therefore, we want to make sure we are certain that this measure disqualifies you from participation. You will have your blood drawn by a trained investigator, provide a spot urine sample, and have your blood pressure measured. The first 24-hour urine collection jug will be provided. This jug is to be returned 24 hours later at the beginning of your workout session. You will complete the McGill pain scale to evaluate your baseline measures of muscle pain or soreness. This session is estimated to take 2 hours total which could be divided over multiple days.

During the workout session, you will the workout "Murph" (1-mile run, 100 pull-ups, 200 push-ups, 300 body-weight squats, and a final 1-mile run) at a difficulty level similar to what you have done previously. You can choose to do a less difficult version (e.g., with scaled push-ups) but cannot choose to do a more difficult version (e.g., with a weight vest) than you have previously completed. Prior to exercising, you will tell the investigator what you have eaten prior to exercise and then return your first urine collection jug and receive a second to again return 24 hours later at

the next session. Next, a trainer with a coaching certificate will lead you through a full body dynamic warm-up and review all movement and workout standards. If there are no other questions or concerns, you will perform all repetitions of "Murph" as chosen. You must complete this workout at a level equal or of lesser difficulty than your previous attempts. For example, if you have only completed the workout with scaled push-ups and ring-rows substituted for pull ups previously, you are not eligible to perform the workout in this study with un-modified push-ups or traditional pull ups. If you have completed the workout "un-scaled" previously and attempt that version, you can change your mind during the workout if the effort level progresses out of your comfort zone. During the workout, your heart rate will be recorded through a heart rate monitor watch and chest strap. Immediately after the completion of all repetitions, a post-exercise blood pressure will be measured, a draw will be taken, you will submit a second spot urine sample and you will be asked to fill out a McGill pain scale to quantity muscle soreness. This session is estimated to take 2 hours. All workouts will be completed in Laramie Wyoming on the University of Wyoming campus.

The day following the workout (approximately 24 hours post) at either the University of Wyoming's Human Integrated Physiology Laboratory or Colorado State University's Integrated Physiology Laboratory you will turn in your second 24-hour urine collection jug and being provided with the third and final 24-hour jug. You will also provide another spot urine sample, have your blood pressure measured, have your blood drawn and fill out the McGill pain questionnaire to identify any muscle pain or soreness. This session is estimated to take 30 minutes.

The final day of the participation approximately 48 hours post workout you will report to either the University of Wyoming's Human Integrated Physiology Laboratory or Colorado State University's Integrated Physiology Laboratory. You will turn in your third and final 24-hour urine collection jug provide a final spot urine sample, have your blood pressure measured, and provide one last blood draw. After completing a final McGill pain questionnaire, the testing is completed. This session is also expected to take about 30 minutes. If blood is apparent in your 48hour post exercise urine sample, we will ask you to report at 72 hours to ensure that urine measurements have returned to normal. After participation you should be alert for signs and symptoms of kidney injury such as; decreased urine output, fluid retention, causing swelling in your legs, ankles or feet, shortness of breath, fatigue, confusion, nausea, weakness, irregular heartbeat, chest pain or pressure, or irregularly dark urine. If any of these symptoms are apparent following your completion of the study, you should contact us or a doctor immediately.

It is also important to note; you will be asked to abstain from ingesting NSAIDS and alcohol for 48 hours before and 48 hours post workout. You will also be asked to avoid strenuous exercise for the 48 hours before and 48 hours post workout.

III. Disclosure of risks

Urine collection inconvenience – The 24-hour urine collection jugs may present inconvenience and slight embarrassment. To minimize these inconveniences, a reusable shopping tote will be provided to you to make carrying the jugs more discrete. Also, a female urination device will be provided to if necessary, to make urine collection easier. A female investigator will give instructions on how best to utilize the female urination device should it be requested.

Blood Draw and Venipuncture Risk- Blood draws performed during the familiarization, baseline, 24 hours post, and 48 hours post sessions will be performed by a trained investigator, Dr. Johnson, Dr. Smith, Dr. Bell, or an individual with phlebotomy training using sterile techniques and universal precautions. The named investigators have performed >2,000 of blood draws during scientific research studies. However, risks do include pain, bruising, fainting, hematoma, nausea, phlebitis, infection, bleeding, blood clots, and sensitive responses to plastic or adhesive tape used during or as a reaction to the venipuncture. To minimize bleeding and the incidence of a hematoma, firm pressure with gauze will be placed on the site of needle removal.

Exercise intervention – Participation in any physical activity or exercise has risk. These risks include but are not limit to, pain, fainting, dizziness, fatigue, nausea, shortness of breath, chest pain or angina, swelling, bruising, muscle/bone/joint soreness, joint damage, bone fracture, ligament/tendon/connective tissue damage, head and cervical spine injuries, hospitalization, and death. As with any exercise participation there is some cardiovascular risks (arrhythmia, sudden cardiac death, acute myocardial infarction). The incidence of sudden cardiac death in young adults has been estimated at 0.9 and 2.3 per 100,000 for non-athletes and athletes, respectively. These risks will be minimized by the following:
Anyone with a pre-existing injury will be excluded

1. All exercise sessions will be overseen by an investigator with a high intensity exercise training instructor certificate. They will alert the participants if exercise form puts the individual at risk for injury. A member of the research team will serve as a second observer to ensure that all
   exercise is completed safely. Either of the individuals named above can stop an exercise session at any time if they feel there is apparent risk for musculoskeletal or other injury.
2. All participants will have at least 1 year of HIFRT experience and will have completed "Murph" on at least one occasion prior to their inclusion in the study.

Injury Liability

The University of Wyoming, the project investigator, and the research team are not liable for any injury participants might sustain while participating in this study and are not able to offer financial compensation or absorb the costs of medical treatment should the participant sustain such an injury.

IV. Description of benefits:

You will receive up to $100 for your participation in this investigation. This will be distributed at the end of your enrollment in the study. If you choose stop participation in the study prior to completion you will be paid for your involvement based on the below pro-rated basis.

$20 – Baseline measurements
$30 – Completion of workout
$10 – Completion of 24h post visit
$40 - Completion of 48h post visit plus bonus for finishing all study measurement periods

You will also receive indirect benefits including functional movement screen results. We will provide you with blood analysis results within a year of your participation as these measurements take longer to evaluate.

V. Confidentiality:

Each member of the research team has undergone certification for proper data management during human subject research. All information will be kept confidential, to the extent allowed by law, and each participant will receive an exclusive identification number to use on all data collection sheets and samples. There will only be one master sheet where your name will correspond to an identification number. This sheet will be held on a secure and password protected computer by the graduate student investigator, Nicole Sauls. Your name will not be used in presentations, reports, data bases, or publication based on the research investigation.

Because the data collection for this protocol will take place in a group setting it is very possible that you will be visually identifiable by other participants and by non-participants who are simultaneously completing the charity workout. However, any data or written information respective to the participant's engagement in the study will be kept confidential.

Data sheets will be kept in a locked and secure file cabinet. The data will be entered into an electronic spreadsheet on a password protected computer and will not include identification information. The original data sheets will be kept for at least six years following the completion of research. The electronic files will be held indefinitely in case questions about publications come up in the future. All documents related to your participation in this research will only be accessible by the principle investigator and graduate students involved in data collection. Each member of the research team has undergone certification for proper data management during human subjects' research. Other students using the data will only have access to de-identified data.

If you choose, you can grant the researchers associated with this project the permission to use pictures taken of you during data collection as part of scientific presentations and publications. Your name will never be used in any of these presentations or publications. This permission is not

required to be part of the study. If you choose not to grant this permission you can still participate in all aspects of the research, but no pictures of your participation will be taken at any time.

VI. Freedom of consent:

Participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled, and you may discontinue participation at any time. If you choose to discontinue your participation please contact Principal Investigatory Evan Johnson 202-431-4065, and return any equipment you may have been issued (i.e., 24-hour urine collection jugs and totes)

VII. Questions about the research:

Should you have any questions about this research following today please contact:
Evan Johnson
Corbett Building – Room 109 - 307-766-5282

If you have questions about your rights as a research subject, please contact the University of Wyoming IRB Administrator at 307-766-5320

I _____ have read the information on this study and understand the commitments, risks, and benefits associated with the protocol.

Any questions I had, have been answered, and I agree to participate. I understand that I can change my mind and stop at any time. I understand the purpose of the study as well as the potential benefits and risks that are involved. I understand that participation is voluntary. I understand that significant new findings developed during this research will be shared with the participant. I understand that no rights have been waived by signing the consent form. I have been given a copy of the consent form.

	Participant		**Investigator**
Printed name	_____	Printed name	_____
Signature	_____	Signature	_____
Date	_____	Date	_____

UNIVERSITY OF WYOMING

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UNIVERSITY OF WYOMING
HEALTH HISTORY SCREENING QUESTIONNAIRE (UWHHSQ)

Please complete thoroughly and accurately.

Date _____/_____/_____

*Name:*_____ *Ethnicity:*_____
*Address:*_____*City:*_____*State:*_____*Zip:*_____
Date of Birth: _____/_____/_____ *Age:*_____ *Phone #:*_____
*Email:*_____@_____
*Emergency contact information: Name:*_____ *Phone #:*_____
_____
Personal healthcare provider to contact in case of an emergency:
*Name*_____ *Phone #:*_____
*City:*_____

CARDIOVASCULAR HEALTH HISTORY

Have you ever been diagnosed with or had any of the following?

Heart Attack?	*Yes*	*No*
Heart Surgery ?	*Yes*	*No*
Cerebrovascular accident (e.g. Stroke)?	*Yes*	*No*
Transient Ischemic Attack (TIA)?	*Yes*	*No*
Carotid Artery Disease?	*Yes*	*No*
Cardiac Catheterization?	*Yes*	*No*
Coronary Angioplasty?	*Yes*	*No*
Pacemaker/Implantable Cardiac Device?	*Yes*	*No*
Irregular Heart Rate/Heart Rhythm Disturbance?	*Yes*	*No*
Atrial Fibrillation?	*Yes*	*No*
Heart Valve Disease?	*Yes*	*No*
Heart Failure?	*Yes*	*No*
Heart Murmur?	*Yes*	*No*
Heart Transplantation?	*Yes*	*No*
Congenital Heart Disease?	*Yes*	*No*

Have you ever experienced any of the following symptoms?

Chest discomfort with exertion?	*Yes*	*No*
Unreasonable breathlessness?	*Yes*	*No*

Dizziness, fainting, or blackouts? *Yes* *No*

Syncope (loss of consciousness)? *Yes* *No*
Hypoxia (low oxygen levels)? *Yes* *No*
Do you currently take heart medications? *Yes* *No*
*If yes, what?*_____
Have you been diagnosed with diabetes (Type 1 or Type 2) or problems with blood sugar levels? *Yes* *No*
*If yes, please note Type 1 or Type 2*_____

If you circled yes to any of the above statements in this section, consult your physician or other appropriate health care provider before engaging in exercise. You may need to use a facility with a ***medically qualified staff.***

CARDIOVASCULAR RISK FACTORS

Are you a male over 45 years old? *Yes* *No*

Are you a female over 55 years old? *Yes* *No*
Have you had a hysterectomy? *Yes* *No*
Have you had both of your ovaries surgically removed? *Yes* *No*
Are you postmenopausal? *Yes* *No*

Do you currently smoke or have you quit within the last six months? *Yes* *No*

Is your blood pressure greater than 140/90 mm Hg? *Yes* *No* *I Don't Know*
If known, what is your blood pressure? _____/_____ *mm Hg*
Do you currently take blood pressure medications? *Yes* *No*
Do you currently take any medications for your heart? *Yes* *No*
Is your total blood cholesterol level greater than 200 mg/dl? *Yes* *No* *I Don't Know*
Do you know your cholesterol level? *Yes* *No*
If yes, *Total Cholesterol* _____
LDL _____
HDL _____
Triglycerides _____

Do you have a close blood relative who has suffered a heart attack or had any kind of heart surgery before the age of 55 (for father or brother) or age 65 (for mother or sister)? *Yes* *No*

Are you more than 20 pounds overweight? *Yes* *No* *I Don't Know*

Are you physically <u>inactive</u> (i.e., do you get less than 30 minutes of physical activity less than three times a week)? *Yes* *No*

Have you had a recent surgery (in the past 2 years)? *Yes* *No*

Have you had an exercise stress test, heart catheterization, or echocardiogram? *Yes* *No*

*If yes, please explain*_____

*To the best of your knowledge, is there any reason that might make it **unsafe** for you to participate in exercise?* *Yes* *No*

*If you circled yes to two or more of the statements in the above section, you should consult your physician or other appropriate health care provider before engaging in exercise. You might benefit from using a facility with a **professionally/medically qualified exercise** program and staff.*

THYROID HEALTH HISTORY

Have you ever been diagnosed with or had any of the following?

Goiter (enlarged thyroid gland)?	Yes	No
Hyperthyroidism (overactive thyroid)?	Yes	No
Hypothyroidism (underactive thyroid))?	Yes	No
Thyroid nodule?	Yes	No
Thyroid Cancer?	Yes	No
Do you take any type of thyroid medication, i.e., Synthroid?	Yes	No

If yes, please list _____

CARDIOVASCULAR HEALTH HISTORY

Have you ever been diagnosed with or had any of the following?

Heart Attack?	Yes	No
Heart Surgery ?	Yes	No
Cerebrovascular accident (e.g. Stroke)?	Yes	No
Transient Ischemic Attack (TIA)?	Yes	No
Carotid Artery Disease?	Yes	No
Cardiac Catheterization?	Yes	No

To the best of my knowledge, the information I have provided above is an accurate assessment of my health and medical history.

_____	_____	_____
Name of Participant	***Participant's Signature***	***Date***
_____	_____	_____
Name of Administering Staff	***Signature of Staff Member***	***Date***

Please stop here. The remainder of this Health History Screening Questionnaire will be administered to you by one of our staff.

STAFF: Administer the remaining portion of the UWHHSQ.

GENERAL MEDICAL AND DIETARY HISTORY

Height:_____ Weight:_____ BMI (calculated):_____

Circle One

Do you currently participate in > 7 hours of moderate to intense cardiovascular exercise per week? *Yes* *No*

Have you drastically changed your diet in the last month? *Yes* *No*

Has your weight fluctuated > 5lbs in the past month? *Yes* *No*

Do you have any history of acute or chronic Glomerulonephritis (such as post-streptococcal lupus rheumatoid arthritis, or other immune system diseases such as Amyloidosis or Sarcoidosis) *Yes* *No*

Do you have recurrent urinary tract infections (especially pyelonephritis) *Yes* *No*

Do you have a history of kidney stones? (especially those requiring surgical intervention or lithotripsy) *Yes* *No*

Do you have any history of diabetic-induced renal injury? *Yes* *No*

Do you have any history of hypertension-induced renal injury? *Yes* *No*

Have you had kidney surgery such as nephrectomy? *Yes* *No*

Have you ever had kidney dialysis? *Yes* *No*

Do you have any history of protein or blood in urine? *Yes* *No*

Do you drink alcohol? *Yes* *No*

*If yes, how many drinks per week?*_____

Are you taking any prescription or over-the-counter medication? *Yes* *No*

*If yes, what medication and what dosage?*_____

_____

Do you take any of the following vitamins, supplements, or herbal/homeopathic medications?
Calcium, Cat's claw, Chaparral, Chromium, Cranberry, Creatine, Ephedra, Germanium, Hydrazine, Licorice, l-Lysine, Pennyroyal, Thunder god vine, Vitamin C, Willow bark, Wormwood oil, Yellow oleander, Yohimbe *?*

Yes *No*

*If other, what type and what dosage?*_____

_____

Do you use table salt? *Yes* *No* *Sometimes*
If yes, is it iodized? *Yes* *No* *Not Sure*
*If yes, please list the brand*_____

Has your body weight been stable over the past 6 months? *Yes* *No*
*If no, please explain*_____

Have you been on a recent diet or a prescribed diet? *Yes* *No*
*If yes, please explain*_____

Are you currently restricting calories, i.e., "dieting" to lose weight? *Yes* *No*
Do you follow a vegetarian Diet? *Yes* *No*
Do you shop at the Farmers Market or Food Coop (Big Hallow)? *Yes* *No* *Sometimes*
Do you belong to a CSA (Community Supported Agriculture)? *Yes* *No*
Do you have a garden and grow your own food? *Yes* *No* *Sometimes*
*Comments*_____
_____

Have you been diagnosed with asthma, exercise-induced asthma, reactive airway disease, chronic obstructive pulmonary disease (COPD), or any other respiratory disease?
Yes *No*
*If yes, please describe:*_____
_____
_____

Have you ever been diagnosed with cancer? *Yes* *No*

*If yes, please describe when and what type:*_____
_____

Have you ever undergone a lymphectomy? *Yes* *No*
*If yes, please describe when and why?*_____
_____

Do you have musculoskeletal problems that limit your physical activity such as walking? *Yes* *No*

Have you recently (in last 3 months) had an X-ray or CT scan in which Contrasting dyes were used? *Yes* *No*
*If yes, when*_____

Have you recently (in last week) used an iodine-containing (brown-colored) antiseptic skin cleaner *Yes* *No*
*If yes, when*_____

Do you have concerns about your safety when you exercise *Yes* *No*

Do you have a history of chronic kidney stones? *Yes* *No*
*If yes, when was your last kidney stone?*_____

Do you have a history of frequent urinary tract infections? *Yes* *No*

*If yes, When was your last urinary tract infection?*_____

Have you ever experienced burning or cramping sensations in your l legs when walking short distances? *Yes* *No*

Do you have any other health problems, illnesses, diseases, infections, surgeries, allergies, or hospitalizations? *Yes* *No*

*If yes, please explain*_____

Do you have any allergies to ibuprofen or other NSAIDs (naproxen, meloxicam, indomethacin)
Yes ***No***

FAMILY HISTORY

Please check all that apply

Family Member	***High Blood Pressure***	***Diabetes Type I or II***	***Heart Diseases***	***Comments***
Mother				*If yes, was it before the age of 65?* ***Yes No***
Father				*If yes, was it before the age of 65?* ***Yes No***
Sibling				*Gender: Age:*
Sibling				*Gender: Age:*
Paternal Grandmother				*Age:*
Paternal Grandfather				*Age:*
Maternal Grandmother				*Age:*
Maternal Grandfather				*Age:*

FOR FEMALES ONLY:

Are you pre-___, peri-___ or post-___ menopausal?

If premenopausal, are you using ***any form*** *of contraception (birth control) or hormone therapy for any reason?* *Yes* *No*

*If yes, why and what type?*_____

Do you regularly use vaginal douches? *Yes* *No*

*If yes, please record the type used and date of your last douche*_____

If you are premenopausal:

Do you have regular menstrual cycles? *Yes* *No* *I Don't Know*

*How frequent are your menstrual cycles?*_____

Are you pregnant? *Yes* *No* *I Don't Know*

Could you be pregnant? *Yes* *No* *I Don't Know*

Are you trying to become pregnant? *Yes* *No*

If you are peri- or postmenopausal:

*For how long?*_____

*When was your last menstrual period?*_____

Attachment 2 – Medical History Questionnaire

Have you had a hysterectomy w/ or w/out ovary removal? *Yes* *No*

Have you had an oophorectomy without removal of your uterus? *Yes* *No*

Are you currently taking any type of hormone replacement therapy or using any form of contraception (birth control)? *Yes* *No*

*If yes, what type?*_____ *How long?*_____ *Dosage*

Name of Administering Staff	***Signature of Staff Member***	***Date***

Physical Activity Readiness Questionnaire

General Health Questions

Read the questions below and honestly check: YES or NO	**YES**	**NO**
1) Has your doctor ever said you have a heart condition ☐ or high blood pressure ☐?		
2) Do you feel pain in your chest at rest, during your daily activities, or when you perform physical activity?		
3) Do you lose balance because of dizziness OR have you lost consciousness in the last 12 months? *Please answer NO if your dizziness was associated with over-breathing during vigorous exercise.*		
4) Have you ever been diagnosed with another chronic medical condition other than heart disease or high blood pressure? Please list: _____		
5) Are you currently taking prescribed medications for a chronic medical condition? Please list condition(s) and medication(s): _____		
6) Do you currently have (or have had within the past 12 months) a bone, joint, or soft tissue (muscle, ligament, or tendon) problem that could be made worse by becoming more physically active? *Please answer NO if you had a problem in the past, but it does not limit your current ability to be physically active.*		
7) Has your doctor ever said that you should only do medically supervised physical activity?		

If you answered NO to all of the questions above, you are cleared for physical activity.

Name: _____ **Date:** _____

Signature: _____ **Witness:** _____

Attachment 4 – Colorado State University Acknowledgement of Research Collaboration with UW

From: Bell,Christopher <Christopher.Bell@ColoState.EDU>
Sent: Thursday, February 21, 2019 2:39 PM
To: Felton-Noyle,Tammy <Tammy.Felton-Noyle@colostate.edu>
Cc: Evan C. Johnson <evan.johnson@uwyo.edu>
Subject: Question about request for CSU IRB to cede to UW IRB

Hi Tammy

I've been invited to collaborate with a researcher from University of Wyoming, Dr. Evan Johnson (cc'd). University of Wyoming will be the primary data collection site, and Dr. Johnson will be the project PI, but we hope that some data can be collected here at CSU (e.g. some screening, blood and urine samples). Can you remind me of what materials we will need to submit to you as part of a request for CSU to cede to the University of Wyoming IRB?

Thanks,
Chris

Christopher Bell, Ph.D.
Department of Health and Exercise Science
1582 Campus Delivery
205E Moby B Complex
Colorado State University
Fort Collins
Colorado
80523-1582
USA

Telephone: 970-491-7522
Fax: 970-491-0445

From: "Felton-Noyle,Tammy" <Tammy.Felton-Noyle@colostate.edu>
Date: Thursday, February 21, 2019 at 2:57 PM
To: Christopher Bell <Christopher.Bell@ColoState.EDU>
Cc: "Evan C. Johnson" <evan.johnson@uwyo.edu>, Carolyn Broccardo <Carolyn.Broccardo@uwyo.edu>
Subject: RE: Question about request for CSU IRB to cede to UW IRB

That is great!! I am cc'ing a fantastic friend and colleague up that way.
If you can share with us the following:

- Protocol #
- Protocol Title
- Copy of currently approved protocol.
- Is this federally funded?
- Provide whether there is a pending amendment to include CSU as a research site.
- Will you be doing the same work just a CSU or will you be delegated to different work?

Carolyn, I just want to pull in you in the loop and we can discuss when more information is gathered!
At your service,

Tammy L. Felton-Noyle, CIP, CCRP
Research Integrity and Compliance Review Office
Colorado State University
Phone: (970) 491-1655
Fax: (970) 491-2293

Attachment 4 – Colorado State University Acknowledgement of Research Collaboration with UW

On Thu, Feb 21, 2019 at 3:01 PM Bell,Christopher <Christopher.Bell@colostate.edu> wrote:

Thanks Tammy.
Hello Carolyn!
We'll be back in touch with you both again soon.
Thanks,
Chris

From: Evan C. Johnson <evan.johnson@uwyo.edu>
Sent: Thursday, February 21, 2019 3:09 PM
To: Bell,Christopher <Christopher.Bell@ColoState.EDU>
Cc: Felton-Noyle,Tammy <Tammy.Felton-Noyle@colostate.edu>; Carolyn Broccardo <Carolyn.Broccardo@uwyo.edu>
Subject: Re: Question about request for CSU IRB to cede to UW IRB

Thank you Tammy and Carolyn -

This is Evan Johnson from UW here. We are in the process of our initial submission and I just wanted to make sure we were getting out ahead of the curve for our application. We don't have much of the information you requested above, but we do have a title,

"Risk Factors Related to Acute Renal Injury during a Mass Participation High Intensity Functional Resistance Training Event"
I know it's not the most poetic, but it gets the point across.

I will keep everyone updated as we progress through our initial approval. Thank you!

-Evan

Felton-Noyle,Tammy via uwy.onmicrosoft.com 3:37 PM (4 hours ago)

to Carolyn, Evan, Christopher

This is great, then! We are getting in on the development side!! Far easier! As you write your submission, please be sure to include CSU as a research site and include what activities will be done here. As you are the primary, we would be willing to cede IRB review to UW's IRB and can work with Carolyn to do this in parallel to the IRB review process.

Looking forward to working with all of you.

Tammy
At your service,

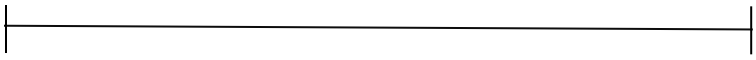
Tammy L. Felton-Noyle, CIP, CCRP
Research Integrity and Compliance Review Office
Colorado State University
Phone: (970) 491-1655
Fax: (970) 491-2293
Web site: https://vprnet.research.colostate.edu/RICRO/

SHORT-FORM MCGILL PAIN QUESTIONNAIRE

Patient's Name: _____ **Date:** _____

	None	Mild	Moderate	Severe
Throbbing	0) _____	1) _____	2)_____	3)_____
Shooting	0) _____	1) _____	2)_____	3)_____
Stabbing	0) _____	1) _____	2)_____	3)_____
Sharp	0) _____	1) _____	2)_____	3)_____
Cramping	0) _____	1) _____	2)_____	3)_____
Gnawing	0) _____	1) _____	2)_____	3)_____
Hot-buring	0) _____	1) _____	2)_____	3)_____
Aching	0) _____	1) _____	2)_____	3)_____
Heavy	0) _____	1) _____	2)_____	3)_____
Tender	0) _____	1) _____	2)_____	3)_____
Splitting	0) _____	1) _____	2)_____	3)_____
Tiring-Exhausting	0) _____	1) _____	2)_____	3)_____
Sickening	0) _____	1) _____	2)_____	3)_____
Fearful	0) _____	1) _____	2)_____	3)_____
Punishing-Cruel	0) _____	1) _____	2)_____	3)_____

Visual Analog Scale (VAS)

No Pain  **Worst Possible Pain**

Attachment 5 – McGill Pain Scale

Present Pain Intensity

0) **No Pain** _____
1) **Mild** _____
2) **Discomforting** _____
3) **Distressing** _____
4) **Horrible** _____
5) **Excruciating** _____

Attachment 6 – Photo Release Form

UNIVERSITY
OF WYOMING

University Public Relations
Dept. 3226 • 1000 E. University Avenue • Laramie, WY 82071
(307) 766-2379 • fax (307) 766-6729 • e-mail: dur@uwyo.edu • www.uwyo.edu

MODEL RELEASE

I, _____ (_____), do hereby
Print full name *Age* *

authorize the University of Wyoming, its agents, successors, and assigns, to use and reproduce photograph(s) in which I appear in official UW publications, and I waive any right that I may have to inspect and approve said photograph (or any copy that may be used in connection therewith) or to receive compensation for the use of said photograph.

_____ _____
Sign full name *Parent or Guardian*

_____
Street or box number

_____
City, state, zip code

_____
Phone

_____
Date

* If under the age of 18, signature of a parent or legal guardian is required to participate.

Sovereign Immunity. The University of Wyoming does not waive its sovereign immunity or its governmental immunity and fully retains all immunities and defenses provided by law.

Status: freshman ____; sophomore ____; junior ____; senior ____; graduate ____; law ____;
doctoral ____; faculty ____; staff ____; administration ____; student family ____;
other _____.

Area(s) of Study: _____.

Home Town: _____.

E-mail address: _____

Attachment 7- Training History Questionnaire

As a part of this study, you will be completing the workout "Murph" (1-mile run, 100 pull-ups, 200 push-ups, 300 body-weight squats, and a final 1-mile run) within an estimated 1 – 2 hours.

This is a high intensity, large volume exercise session that should not be completed by an individual that is not properly trained. The following questionnaire ensures that you have completed Murph previously and confirms the difficulty level of that previous experience so that this workout will not introduce excessive risk of musculoskeletal and/or kidney injury.

1. **On how many occasions have you completed "Murph" in the past?**
    - Once
    - Twice
    - Three times
    - Other (how many times?) _____

2. **Please check the last version of "Murph", you completed below.**

    Prescribed Repetitions: 1-mile run, 100 Pull-Ups, 200 Push-Ups, 300 Air-Squats, 1-mile run
    Cindy Repetitions: 1-mile run, 20 rounds of: 5 Pull-Ups, 10 Push-Ups, 15 Air Squats, 1-mile run

    - I have never performed Murph
    - Prescribed repetitions with a 20lb weighted vest
    - Cindy style repetitions with a weighted vest
    - Prescribed repetitions without a weighted vest
    - Cindy Style repetitions without a weighted vest
    - Other (e.g., modified push-ups, pull-ups, air-squats, run, or other scales)
        - Describe modified version here_____

3. **On average how many times per week over the past 1 year have you participated in high intensity resistance training exercise** (e.g., CrossFit classes, Gym based high intensity interval training)**?**

    □ <1X per week □ 1X per week □ 2X per week □ 3 or more X per week

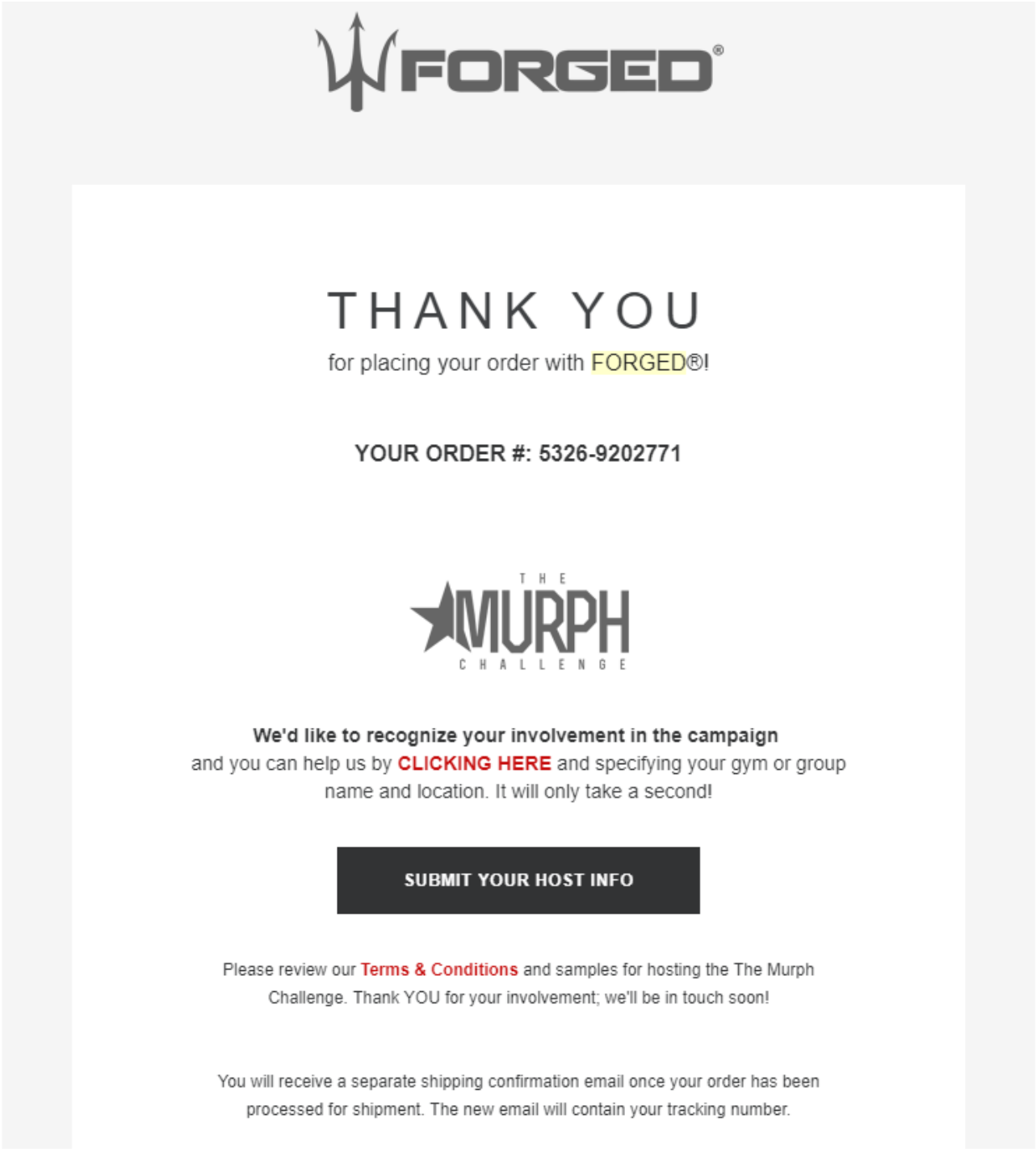
4. **How many times years have you participated in high intensity resistance training exercise** (e.g., CrossFit classes, Gym based high intensity interval training)**?**

    □ 1 year □ 2 years □ 3 years □ Other (describe)_____

5. **What other training do you take part in on at least a weekly basis?**

    _____
    _____
    _____
    _____

Attachment 8- Confirmation for the University of Wyoming's registration as official host of "The Murph Challenge"



Attachment 9 – Colorado State University – Collaboration Acknowledgement

Colorado State University

Christopher Bell, Ph.D.
Department of Health and Exercise Science
205E Moby B Complex
Fort Collins, Colorado 80523-1582
(970) 491-7522
FAX: (970) 491-0445
http://www.hes.chhs.colostate.edu/
christopher.bell@colostate.edu

Evan C. Johnson, PhD
Division of Kinesiology & Health
Corbett Building 109, Dept. 3196
1000 E. University Ave.
Laramie, WY 82071

February 21, 2019

Dear Evan

Thank you for the opportunity to collaborate with you on your proposed studies of hydration and kidney function following high intensity exercise. Please consider this letter as formal acceptance of your invitation.

As you know, the facilities within the Human Performance Clinical Research Laboratory in the Department of Health and Exercise Science at Colorado State University meet all of the requirements necessary to operate as a satellite research site for the proposed work. In addition, the members of my research team have the necessary qualifications and experience to fulfill the protocol.

As per university policy, I will be submitting a letter to our Research Integrity and Compliance Review Office requesting that the Colorado State University Institutional Review Board cede to the oversight of The University of Wyoming.

I look forward to completing this important work with you.

Christopher Bell, Ph.D.
Associate Professor

Attachement 10 – Additional Student Researchers

Carson Keeter

Miranda Zamora

Carly Hibbs

Joshua Loseke

Brittney Wells

Lauren Elliot

Summer Taube

Emelda Malm-Anann

Riley Veis

Attachement 11 – Daniel Murphy – Research within charity event approval e-mails

Gmail

Evan Johnson <evancjohnson@gmail.com>

University Official Site for Murph Challenge 2019

----- Forwarded Message -----
From: Evan C. Johnson <evan.johnson@uwyo.edu>
To: LTMichaelMurphyFoundation@yahoo.com <LTMichaelMurphyFoundation@yahoo.com>
Cc: Derek (Kines. & Health) Smith <SmithDT@uwyo.edu>; Laura Lynn Betzold <lpeter18@uwyo.edu>
Sent: Tuesday, March 5, 2019, 3:49:38 PM EST
Subject: University Official Site for Murph Challenge 2019

Mr. William Andes

We are in the process of planning our event for Memorial Day 2019. I previously was in communication with Katie G. from the Forged website, because I had ordered the official host site package early. She recommended that I contact youe to help us answer a few questions to ensure we are doing everything we can for, and in line with the Lt. Michael P. Murphy Memorial Scholarship Foundation.

I am an employee of the University of Wyoming and planning to host this charity event in conjunction with our University's and the community's support. The event is planned to take place on University property and I plan to reach out to local restaurants to see if they will offer food and drink specials to individuals who come in after the event with their bib number. I also plan to have no-cost online registration so that we can properly manage the flow of participants. Within this registration we will allow participants to be able to donate directly to the foundation. I also wanted to check if the organization provides any type of receipts. For example, if a participant chose to donate $100 would we be able to provide them with a receipt for tax purposes?

Second, with the plan for this to be a larger event we were hoping you could direct us towards a person that might be willing to provide opening remarks prior to the national anthem. In past years where I have participated we have had a local veteran say a few words before the workout and this has been very powerful. I'd like to replicate this at our event.

Lastly, we were thinking of using the exercise stimulus of this workout as part of an ongoing research investigation (only for individuals who volunteer). I wanted to check with you to ensure that we would not be infringing on any policies that the Murph Foundation may have regarding official host sites. I'd be happy to discuss the project in more detail if needed.

Thank you! We're looking forward to a fun day!

--
Evan C. Johnson, PhD

Division of Kinesiology & Health
Corbett Building 109, Dept. 3196
1000 E. University Ave.
Laramie, WY 82071

Mobile:(202) 431-4065
Email: Evan.Johnson@uwyo.edu

Daniel J. Murphy <modan5776@aol.com> Tue, Mar 5, 2019 at 4:41 PM
To: evan.johnson@uwyo.edu
Cc: smithDT@uwyo.edu, lpeter18@uwyo.edu

Mr. Johnson,

Thank you for your interest in running the "Murph Challenge" at your school. This is Dan Murphy, father of Navy SEAL LT Michael P. Murphy and to answer some of your questions, I acknowledge with a letter on Foundation stationary and a Michael Murphy stamp (that I order special) all donations and provide the foundation tax exempt number for tax purposes. Also any donation either by check to Foundation headquarters or on our web site through Pay Pal in an amount of $100 or more receives a Michael Murphy Challenge coin.

As for your second question, I can't think of anyone in Wyoming or in the area who could speak to your group. As a Combat wounded veteran myself and a member of the Military Order of the Purple Heart, you might want to reach out to The Wyoming chapter of The Purple Heart organization and see if one of them are willing to speak.. or if you prefer I'll reach out to the SEAL community and see if there is a retired SEAL in your area who would speak to your group.

As to your third question, the answer is No .... you would not be running afoul of any foundation issues should you engage in a research project about the "Murph" workout. I wish you much luck with your research investigation and thank you for your interest in Michael's Scholarship Foundation.

W/R

Dan

Sent from my iPad

On Mar 5, 2019, at 5:16 PM, Michael Murphy Foundation <ltmichaelmurphyfoundation@yahoo.com> wrote:

Attachement 11 – Daniel Murphy – Research within charity event approval e-mails

Evan Johnson <evan.johnson@uwyo.edu> Thu, Apr 4, 2019 at 1:35 PM
To: "Daniel J. Murphy" <modan5776@aol.com>
Cc: "Derek (Kines. & Health) Smith" <smithDT@uwyo.edu>

Dan -

I wanted to reach back out to you briefly regarding the University of Wyoming's hosting of the 2019 Murph Challenge event. In our planning, UW's legal department requested that I give you a more specific description of our planned research project (see attached document). If you have any questions, concerns or otherwise regarding our resarch project please feel free to get in touch. I appreciate all of your time. Thank you.

-Evan

UNIVERSITY OF WYOMING

College of Health Sciences
Division of Kinesiology and Health
Dept. 3196 • 1000 E. University Avenue • Corbett Building • Laramie, WY 82071
(307) 766-5284 • fax (307) 766-4098 • e-mail: kinesiology@uwyo.edu • www.uwyo.edu/kandh

Mr. Murphy –

I hope this letter finds you well and I appreciate your response back in March regarding the acknowledgement for donations, guest speakers, and our plan to have some "Murph Challenge" participants also volunteer to be part of a research project.

As part of our Institutional Review Board protocol, all research proposals are put through a stringent review to ensure that minimal risk is imparted to any volunteers. Our proposed data collection is different because it will take place during an event at an "official site". Because of this our review board wanted to ensure you had a full explanation of the research question.

The goal of our protocol is to evaluate the blood "biomarker" pro-enkaphalin. With any long duration exercise (for example marathon running) temporary skeletal muscle and organ impairment occur. In the literature, injuries specific to the kidney have been observed during exercise. However, the biomarker pro-enkaphalin has shown to be predictive of decline in kidney function in a hospital setting. Our goal with this project is to determine if this biomarker is able to predict the amount of change in kidney function that occurs in the 48 hours following completion of the "Murph Challenge". We will do this by collecting urine and blood samples in the 24 hours before and 48 hours following the workout.

I want to be very clear that we are only allowing individuals into this study who are healthy and free of any injury that could influence their kidney function. Second, only volunteers who have completed the "Murph Challenge" on at least one prior occasion will be able to enroll in our study. Further, all volunteers will be required to complete the workout at a difficulty level no harder than what they have done in the past. Our goal is to demonstrate the relative safety of the "Murph Challenge" workout and we are doing everything we can to ensure that our data is reflective of the workout and not external factors.

If you have any further questions about our protocol, research question, or anything else please do not hesitate to contact me or my department head. I can think of no better cause than the Lt. Michael Murphy Foundation and I am hopeful that our event and research will only increase the number of people honoring Lt. Murphy each year. Thank you for your time.

Respectfully,

Evan Johnson Assistant Professor University of Wyoming 307-766-5282

Attachement 11 – Daniel Murphy – Research within charity event approval e-mails

Daniel J. Murphy via uwy.onmicrosoft.com
to Derek, Evan

Apr 4, 2019, 3:02 PM (6 days ago)

Evan,

Read the letter and the biometrics etc... I don't see a problem. Just so we all understand, it appears from the letter that those subjects will be doing the " Murph Challenge" at an official host (CrossFit) Facility... I just wanted to make sure that you understand the "Murph Challenge" is used by Forged for their annual Memorial Day fundraiser so if you use the name "Murph Challenge" the participants must be registered through the Forged web site

You can use the Murph Workout in your plans but the " Murph Challenge" is owned by Forged...

W/R

Dan

Evan Johnson <evan.johnson@uwyo.edu>
to Daniel, Derek

Apr 9, 2019, 11:12 AM (1 day ago)

Dan -

Thank you again for reviewing. I want to clarify one point. The University of Wyoming will be purchasing the official site license through Forged and will host the workout on University property. The workout will not take place at a CrossFit Facility. We plan to only use the marketing materials provided by and approved by Forged.

•••

-Evan

modan5776@aol.com via uwy.onmicrosoft.com
to evan.johnson, SmithDT

Tue, Apr 9, 1:34 PM (1 day ago)

Evan,

As long as you are an official host of the "Murph Challenge" with Forged, you can have it anywhere.... Maybe next year, if you get a good showing, I can fly out and attend and give the participants a pep talk and show them a cool 7 I/2 minute video of Michael's life that was professional produced for a huge (1400) gala in Washington DC back in 2009

Dan