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Directions for Using This Guidance Document

This document suggests language for how to describe common research procedures and associated risks during your informed consent process, much have which has been approved by the Appalachian State University IRB as part of past applications. Please use the wording provided as a base and tailor the details to fit your particular study. The language in this document is appropriate for use in the consent processes of exempt, expedited, and full board studies.

Audio/Video Recording (Transcription/Coding Purposes)

Procedure language:

As part of this study, we would like to take a(n) [audio/video] recording of [the part of the study that will be recorded]. We will use this recording for the purposes of [e.g. transcribing your answers during the interview, coding your responses, etc.].

Risk/Discomfort language:

Since voice recordings [and facial images] are identifiable, there is always a risk that someone who does not have permission may see the recording and find out what you said during the study. In order to protect your privacy and keep your responses confidential, we will store the [audio/video] file on a [password protected, encrypted, etc.] [university-owned laptop, M drive, etc.]. Once we have [transcribed your responses, coded your facial expressions, completed the study, etc.], we will delete your file from [the location of the file, e.g. the cloud, lab computer, etc.].

Blood Draw (Venipuncture)

Procedure language:

We will draw about [state as X teaspoons or tablespoons] at [each study visit]. This will be done by putting a needle into a vein in your arm. We may require more than one attempt to obtain a blood sample.

In the rare case of exposure of your blood or tissue to research staff, your blood will be tested for HIV and hepatitis. The results of these tests will not be reported back to you.

Risk/Discomfort language:

Although the blood draw will be conducted by trained personnel, there are still risks and discomforts associated with this procedure. These include: discomfort at the injection site (feeling of a pinch when the needle enters your skin), minor bruising or bleeding, feeling lightheaded or fainting, infection, or development of a blood clot.

Bod Pod

Procedure language:

The Bod Pod test measures your body composition (how much body fat and muscle you have). For this test, you will put on a skin-tight suit and sit in a chamber while air pressure changes. These procedures will take approximately 10 minutes total.

Risk/Discomfort language:

There is a possibility that you may feel uncomfortable during the Bod Pod test. Some people feel uncomfortable or embarrassed wearing skin-tight clothing. To reduce this risk, you may request for the Bod Pod test to be conducted by a researcher of your gender. Another risk is that the chamber may cause you to feel claustrophobic. There is a window in the chamber to reduce the risk of claustrophobia, and you can stop the test at any time if you feel uncomfortable.

Breach of Confidentiality

Procedure language:

[Describe how data will be attained, e.g. through interview, survey, physical procedures, review of medical records, etc. If data will be attained through interaction, explain that subjects can skip any question]

Risk/Discomfort language:

[This risk exists for all studies.] There are risks with any study involving collection of data, there is the possibility of breach of confidentiality. A breach of confidentiality occurs when private information you share with the research team is seen by or made accessible to people who do not have permission to see the data. In order to reduce the risk of a breach of confidentiality, the study team will [describe confidentiality protections, e.g. not collecting identifiers, storing data on an encrypted and password-protected computer, etc.].

CO₂ for Anxiety Induction

Procedure language:

For this task, you will take a single vital capacity breath of a mixture containing 35% carbon dioxide and 65% oxygen. Before this procedure, we will ask you to place this nose clip on your nose and subsequently hold your breath for five seconds. The goal is

to take in as much air as possible. Therefore, you will need to exhale completely, and then take a full and complete inhalation using the mouthpiece that is attached to the bag. A researcher will then count to five for you before asking you to exhale.

Risk/Discomfort language:

Completion of the carbon dioxide inhalation task and hyperventilation task may cause some participants to experience arousal symptoms, such as elevated heart rate, which may be uncomfortable for some individuals. Participants who have asthma or lung disease are not permitted to participate in this procedure.

Cold Pressor

Procedure language:

You will be asked to place your hand in a bucket of ice-cold water. At some point, you will begin to feel pain. [If applicable: We ask that you notify us when that occurs.] Once the pain is too uncomfortable for you, you will remove your hand from the water.

Risk/Discomfort language:

It is likely that you'll feel some pain from the cold. In order to minimize the length of this pain, you will place your hand in a recovery bath immediately after removing your hand from the cold water. This will quickly return your hand to its previous comfort level. You can remove your hand at any time.

You should not participate in this study if you have ever experienced fingers or toes turning blue or white after exposure to the cold.

Deception (Prospective consent to be deceived)

Some research requires that the full purpose of the study not be explained before you participate. If you are not okay with this possibility let us know. [Chose one] We will give you a full explanation at the end of the study. [OR] We will give you a full explanation as soon as you complete the study.

DEXA

Procedure language:

You will have a DEXA (Dual Energy X-Ray Absorptiometry) scan to measure your [purpose of DEXA Scan]. This procedure will take place at [X] and will take about [20 minutes] to complete. To complete the scan, we will ask you to lie still on a padded table

while the instrument scans your body. We will do [3] different scans: [1 of your whole body, 1 of your lower back, and 1 of your forearm].

Risk/Discomfort language:

The primary risk associated with a DEXA scan is radiation exposure. The DEXA scan technique exposes you to the equivalent of about 4 extra days' worth of natural radiation. If you are pregnant or trying to become pregnant, you should not get a DEXA scan.

Electrocardiogram (ECG)

Procedure language:

We will measure your heart activity using an electrocardiogram (ECG). This involves placing electrodes on the chest and arms/legs to measure your heart while you lie still. This will take approximately [5] minutes.

Risk/Discomfort language:

We will need to expose select areas on your chest during electrode placement. We will maintain your privacy during this process. You may experience some minor skin irritation from the electrodes and the preparation of the sites where the electrodes will be placed. The preparation involves clipping or shaving body hair, cleaning the skin with an alcohol pad, and lightly scraping the skin at each site an electrode will be applied. There is a small chance of redness or swelling where the electrodes are placed on the skin.

Eye Tracking

Procedure language:

As part of this study, we will track your eye movements so that we can record where you look and for how long. To do this we will use [equipment name] to shine infrared light (which is not visible to humans) into your eyes while [equipment name] video records your eye movements. Infrared light is not visible to humans, and the amount we will use to track your eye movement is not known to cause any adverse effects.

Risk/Discomfort language:

There is a risk of physical discomfort in the places where [equipment name] touches your head.

Focus Group

Procedure language:

You are being asked to take part in a focus group. The group will have about [#] members and will last for about [time frame]. During that time, you and the other group members will be asked questions about your opinions and experiences with [X, Y and Z].

Please do not share what is said during the group discussion with people who were not in the group. We also ask that you please do not share private identifiable information about anyone [include whichever is applicable to your study: other than yourself/including yourself] during the focus group

Risk/Discomfort language:

The main risk of participating in a focus group is loss of confidentiality. Although all participants are instructed to respect the privacy and confidentiality of others in the focus group, we cannot guarantee that the information you share will be kept confidential by other participants. Please keep this in mind when choosing what to share with the group.

Interviews

Procedure language:

We would like to interview you about [your experiences with XYZ]. This interview will take place at [place and time, if known] and last approximately [estimated time range for interview].

Risk/Discomfort language:

Some of the questions the interviewer will ask may be upsetting or make you feel uncomfortable. You do not have to answer any questions you do not want to answer and you can stop at any time. [Also see Breach of Confidentiality above]

Investigator is Instructor of Record (Research on Students)

The survey/activity is being done for research. Because I am both a researcher and your instructor for the class, I want to clarify:

1. Being in the research is separate from the assignments you have for this class, which means you still need to complete your coursework whether or not you join the study.
2. You do not have to participate in the research. If you choose to participate, your participation will not affect your grade or class standing in this course. If you choose not to participate it will also have no effect on your class standing or grade.

3. You can opt out of being in the research at any time, just let me know by [describe]. If you have any questions you can ask [name].
4. [If applicable: I will not know who has agreed to be in the research until after final grades are administered, so there is no way for me to be influenced by your participation.]

MSNA

Procedure language:

During this part of the study, we will ask for you to lay on your back for up to an hour while we attempt to measure your nerve activity. This involves inserting a small needle (the size of an acupuncture needle) into the side of your knee to record nerve activity. The needle insertion may feel like a blood draw needle stick. [If applicable: We can use a topical numbing cream if you would prefer.] You may experience small zings (twitching or tingling sensations) down your leg or muscle cramps as we work to get the signal. Nerves are small and sometimes hard to find. [If applicable: If we cannot find the nerve near your [left/right knee/arm, etc.], we will ask for your permission to try for a nerve in your [(other) knee, arm, etc.] or ask to reschedule for another day when we can try to find one of these nerves again [If applicable]: Once we get the signal, we will see how your nerves respond to several tests.

Risk/Discomfort language:

There is a slight risk of temporary “pins and needles” sensation or increased sensitivity to touch in the leg following the test. Some people have said they feel some tiredness, soreness, or tingling in their leg muscles up to one week after the study. These feelings may be related to the muscle twitches which are part of the test for finding the nerve. About 7% of people may feel some aching or tingling in the area of the recording site. [If applicable, as typical safety monitoring procedures for MSNA]: To reduce chances of any problems, subjects will be asked not to rub the site, stretch, or perform strenuous leg activity for 24-48 hours after the testing. You are encouraged to let us know if you feel sick, and we may end your participation in the entire study if we feel you may be sick from any of the tests. While lingering sensations are generally uncommon, we will ask you to send/email/return a questionnaire asking about any unusual feelings in your leg 1 week after the testing.

MTurk Recruitment

Please be aware that any work performed on Amazon MTurk can potentially be linked to information about you on your Amazon public profile page, depending on the settings

you have for your Amazon profile. We will not access any personally identifiable information about you that you may have put on your Amazon public profile page. We will store your MTurk worker ID separately from the other information you provide to us.

Muscle Biopsy

Procedure language:

In this part of the study, we will collect a skeletal muscle biopsy. This means that we will remove a small bit of muscle tissue from your [upper/lower] [left/right] [arm/leg]. Before we do this, we will numb the area with a local anesthetic. We will then insert a special needle to collect a sample of your muscle tissue. We will close the muscle biopsy incision site by [a steri-strip/stitches] and send you home with a symptom checklist. If you experience any symptoms on the checklist, please report these to the research staff as soon as possible.

Risk/Discomfort language:

There are some risks associated with the skeletal muscle biopsy technique. You may feel some discomfort (burning or stinging) when we inject the anesthetic. This discomfort should quickly pass as the area becomes numb, although there is a small risk that you may have an allergic reaction. During the procedure, you might feel an unpleasant pressure or “tugging” sensation. Most discomfort will subside 1-2 days after the technique. Other risks include: bleeding, bruising, lightheadedness or fainting, and infection.

All muscle biopsy procedures will be performed under sterile conditions in a hygienic setting with biohazard protections under the supervision of a licensed medical professional to minimize risks. In the rare case of exposure of blood or tissue to research personnel, testing will be conducted for HIV and hepatitis. [If you will not report results of HIV and hepatitis tests back to subjects]: The results of these tests will not be reported back to you.

pQCT Scan

Procedure language:

We will use a pQCT scan to measure your bone density. For this procedure, we will ask you to place your [arm/leg] through a ring and rest it on the provided support. Please try to hold your [arm/leg] still during the measurement. This process will take about [20 minutes].

Risk/Discomfort language:

The pQCT scan will expose you to a small dose of radiation, equivalent to less than one day's worth of natural radiation exposure at sea level. Even though the radiation dose will be small, you should not participate in this study if you may be pregnant.

SONA (ELCs)

Please note that [if applicable: while we have no intention of trying to match your data back to you,] for a brief period of time you will be listed in SONA as signed up for this study. This list is visible to the research team and necessary for us to issue ELCs.

If you participate, you'll receive [x] ELCs. There are other research options and non-research options for obtaining extra credit or ELC's. One non-research option to receive 1 ELC is to read an article and write a 1-2 page paper summarizing the article and your reaction to the article. More information about this option can be found at: psych.appstate.edu/research. You may also wish to consult your professor to see if other non-research options are available.

SONA (Embedded ID)

For a brief period of time, you will be listed as a participant in this study on SONA. In order to provide credit for participation, we are using a feature in our survey called "EmbeddedData" to generate a code that automatically credits your SONA account with 1 ELC when you have completely finished the study. Although your name will not be directly linked with your survey results, the research team will be able to see in SONA whether you completed the study. Your participation in this study will be kept confidential.

Transcranial Direct Current Stimulation (tDCS)

Procedure language:

To conduct Transcranial Direct Current Stimulation (tDCS), we will put 2 sponges on your head and then run an electric current through them. This current will feel like an itching or tingling sensation. These electrodes will be connected to a stimulator that you will wear in a backpack.

Risk/Discomfort language:

You will be asked to fill out a tDCS screening sheet before this procedure is conducted. It is important that you be completely honest during the screening process so that the research team can minimize the risks associated with tDCS. Risks of tDCS include skin

irritation with light itching/tingling/ burning, mild headache, or nausea. Rarely, mild burns can occur at the procedure site.

Transcranial Magnetic Stimulation (TMS)

Procedure language:

Transcranial magnetic stimulation (TMS) will be used to administer magnetic pulses over your head. By measuring your muscles' responses to the pulses, we can determine the strength of the connections between your brain and your ankle. You will be asked to wear a tight fitting cap so that measurements may be made on your head and earplugs to decrease the sound of the machine. You will then be familiarized with the magnetic stimulator which sends very short (less than half a second long) pulses through a large coil. The coil will touch the top of your head during the stimulation. Once familiarized, we will deliver one pulse every 5 seconds at different locations in an approximately 3-cm radius on your head. Up to 100 pulses may be delivered at varying intensities.

While TMS pulses are being delivered, you will be asked to remain seated with either your muscles relaxed or contracted slightly with your heel out. You will hear a click every time the TMS pulse is delivered. The TMS pulse will feel like a tap on your head and will cause twitching of your leg muscles. At higher intensities, the TMS pulse may cause your forehead or face to twitch.

Risk/Discomfort language:

During electrical stimulation, the pulses applied will cause a muscle twitch and a tingling sensation shooting down the leg that may be uncomfortable; however, each pulse will last less than one second and every effort will be made to minimize the number of pulses that must be applied. Metal objects close to the coil may be damaged during magnetic stimulation, so you should not participate in this study if you have metal implants in your head. There is a possibility of headaches, scalp discomfort, or lightheadedness associated with TMS testing. These side effects are usually mild and short-lasting. There may be some minor irritation of the skin around the site of the electrodes following the experiment. In rare cases, fainting may occur.

Rare cases of seizures during or immediately after TMS have been reported. This is a risk of participation, even if you have no history of seizures. Some medications may contribute to an increased risk of seizure, so make sure to provide an accurate list of all medications you are taken when asked by the researcher.

VO₂max

Procedure language:

For this test, we will ask you to [add specific exercise procedure]. After a brief warm-up period, we will ask you [add specific mode of exercise and duration]. [Specific mode of exercise] will become more and more difficult as this test progresses. You will continue performing [exercise procedure] until exhaustion or signs/symptoms prohibit further exercise testing. You may need to communicate with the lab personnel during the test by hand signals. Following completion of the test, you will perform a short, light intensity cool-down on the [specific exercise equipment].

Before the test begins, [describe how equipment will be fitted onto subjects] we will fit you with [a nose clip to prevent you from breathing through your nose and a rubber mouthpiece, similar to a scuba diving mouthpiece that allows your exhaled air to be analyzed] or [a face mask a facemask that allows your exhaled air to be analyzed] and a chest strap for heart rate monitoring. [see Electrocardiogram procedure language above, if ECG is being used to measure heart rate]. Your blood pressure may also be measured through the use of the automated blood pressure cuff on your upper arm. You will be asked to wear this equipment for the duration of the exercise test.

Risk/Discomfort language:

The risks associated with the VO₂max may include abnormal heart beats, abnormal blood pressure responses, muscle cramps, muscle strain and/or joint injury, delayed muscle soreness (1 to 2 days afterwards), feelings of breathlessness, lightheadedness, fatigue, and, in rare instances, heart attack.