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For Office Use Only

Date Received \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Proposal # \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Review Type: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Reviewer #1 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Reviewer #2 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date Approved: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Application to the Institutional Review Board   
for Protection of Human Subjects**

Directions and Tips for Filling Out the IRB Form (Spring 2018)

You need to use the current MS Word version provided on the WSC IRB web page to complete the form. The form must be typed.

**Title of Project**:

**Name of Principal Investigator (PI):**

**PI is WSC:**  **Faculty**  **Staff**  **Undergraduate Student**  **Graduate Student**

**If PI is student, name of research advisor:**

**If class project, name of professor:**

**PI’s mailing address:**

**PI’s telephone number:**

**PI’s email address:**

**Are there human subjects involved in this project?** \_\_\_ Yes \_\_\_ No

Human subjects are involved in a project if it uses data from human responses, observations of human beings or human materials, whether such data are obtained directly from human sources or from secondary sources. **If the answer to the above is “no,” do not complete or submit this form.**

**Certification Statement**

By making this application, I certify that I have read and understand Wayne State College’s policy governing research with human subjects and the Ethical Principles for the Conduct of Research with Human Subjects as formulated by the HSIRB. I shall comply with the letter and the spirit of those documents. Furthermore, I am aware that certain departments may have their own standards for conducting human research and that it is up to me to familiarize myself with them. I also acknowledge my obligation to obtain written approval for any significant deviations from the originally approved protocol before making those deviations and to report immediately all adverse effects of the study on the participants to the Chairperson of the HSIRB and to the Academic Vice President. I also certify that the rights and welfare of the subjects are adequately protected and that informed consent of subjects will be obtained by methods that are adequate and appropriate.

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Principal Investigator Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Advisor Date  
*(The advisor’s signature is required for graduate and undergraduate student applications.)*

Additional Tips:

* Do not delete anything from the form.
* Proof read your proposal and all supporting documents before submitting it for review.
* Use consistent wording throughout your proposal and supporting documents to ensure they all say the same thing.
* Don’t think that you have to use “research design lingo” when completing this form. Just clearly and completely tell us exactly what you plan to do and how you plan to do it.
* Have your research methods ironed out before you begin completing this form.
* Ask your research advisor to review your proposal and supporting documents to ensure they accurately explain what you plan to do for your research project.
* Explain everything so a non-major could understand and envision exactly what you plan to ask of your research subjects. This includes defining all non-standard terminology.
* If you have questions about how to fill out any section of this form, feel free to contact an IRB committee member. We can assist you with the process.

**Section A. Research Proposal**

1. Research Project Start Date:  
(we recommend “upon IRB approval” rather than a specific calendar date)

These dates need to include the time you need to advertise for, recruit, and screen potential subjects as well as collect and statistically analyze your data. Rather than giving a specific starting date, we suggest using “upon IRB approval”. If you do put a specific start date, make sure it is going to be after you have completed the IRB process (with revisions if necessary) and received full approval.

Research Project End Date:

(If the end date is more than one calendar year after the start date, you will need to apply for an extension as IRB approval can only be given for up to one year.)

2. **Research Problem**  
Please provide a brief statement (3-5 sentences) of the research problem.

Make it clear why this research study needs to be conducted. Tell us why we need to know this information you hope to obtain through this study. This should come from your literature review. This is not where you tell us about your research procedures.

3. **Participants**

a. Who are they? Be specific here and include all inclusion/exclusion criteria. Examples: Males/Females; WSC College Students; Briar Cliff Soccer Team Members; Recreationally Trained (defined as those who exercise at least 30 minutes 3 times per week for the past 6 weeks or however you want to define it, just define it); Individuals whose parents are divorced; Free from illness or injury that would prevent them from participating in a maximal squat exercise; Community College students who also work at least 20 hours each week. This information needs to match the information you include in the Informed Consent when you identify your subject criteria.

b. How many? A range is fine here

c. Age(s)?

d. How will potential subjects be identified for purposes of recruitment?

*(class, phone book, membership lists, etc.)*

Explain how will you identify people that you could ask to participate in your research study? This is not where you identify your sampling method. You have not made contact with your potential subjects yet. You are just identifying who you will want to make contact with. Examples: Basketball Players 🡪 Team Roster posted on the school website; Psychology Students 🡪 identify the Psychology courses being offered on campus that these students would take; WSC College students 🡪 people on the WSC campus who appear to be students

e. How will potential subjects be recruited and screened once they are identified?

*(Provide documentation of agreement from individuals or organizations that are cooperating with you to recruit subjects. If your research has outside organizations involved, a letter agreeing to the participation must be attached.)*

Recruited – This is where you address how you will make contact with the people you identified in the previous section in order to ask them to participate in your study. Explain whether you are asking people to volunteer through fliers, class presentations about your study, requesting faculty to share information about your study with their students, contacting people directly through publically available means of communication, asking a coach to speak to his/her team before a practice, etc.

Screened - If you are completing any sort of health history questionnaire, physical activity questionnaire, or gathering any information from potential subjects to verify that they qualify to participate in your study, you need to explain that process here and include a copy of the survey/tool with your IRB proposal. Include this step in your procedures in A.3 as well. This is how you ensure that your subjects do in fact meet all the criteria you identified in A.2.a.

If you are using class time to administer a survey or collect data, you will need written documentation providing approval from the class instructor. If you are specifically recruiting athletes, you will need written documentation providing approval from the team coach. If you are using a few minutes of class time to tell students about your study and sending a sign-up sheet around (and all data will be collected outside of class), you do not need the instructor’s approval for IRB purposes. If you are recruiting college students and student-athletes can participate along with non-athletes, you do not need a letter of support from the coach. If you are requesting access to a group of high school students, you will need a letter of approval from the school administrator. If you are recruiting subjects from the local medical clinic population, you will need a letter of approval from the medical clinic director.

All agreement letters must be typed and include the name of the project, the primary research’s name, the research advisor’s name, what the subjects will be asked to do as part of the study, and the start/end dates for the study. It also needs to include exactly what the cooperating person (i.e. teacher, coach, administrator) is doing to contribute to the success of your research project. This ensures that the person assisting with recruitment (i.e. teacher allowing you do collect data during class) is fully aware of what s/he is agreeing to assist you with. The name of the agreeing person should be clearly typed or printed so identification can be matched with the signature.

f. If participants are under 18 years of age, will parental permission be obtained?

\_\_\_ Yes \_\_\_ No \_\_\_N/A (participants will be 18 or older)

If no, please explain.

*Note: Persons under 18 years of age should be informed of their right to choose to*

*participate and to withdraw from participation, even if parental permission has been*

*obtained.*

g. Are subjects to be told that participation is voluntary and that they are free to withdraw at any time?

\_\_\_ Yes \_\_\_ No

If no, why?

3. **Procedures**

Step-by-step description from the point of view of the participants, what they will experience:

1. Participants will receive 2 copies of Informed Consent document to sign.

2. Participants keep one copy of signed Inform Consent document and return the other signed copy to the researcher.

3.

4.

5.

6.

7.

8.

Walk us through, step by step, what the participants will do, not what the researcher will do. Even though the first 2 steps are provided, you may modify these as long as you obtain informed consent from each participant before doing anything else AND you make it clear that you provided each participant with a copy of the informed consent document. You do not need to use all 8 steps and you can certainly have more than 8 steps. Take as must space as you need to clearly walk us through your entire data collection process from the perspective of the subjects.

Make sure to describe/explain any equipment or procedures that the general person (a person not from your field) would not understand. You can also attach a detailed description of any protocols and reference that attachment here. You can also attach a detailed description with a photo of any specialized equipment and reference that attachment here to make this flow better.

Write out all acronyms the first time you use them.

4. **Debriefing Statement/Process**

Debriefing should be a part of the procedure. Debriefing generally includes a statement of

appreciation to participants, an explanation of the overall purpose of the research, a way to learn about the results, and sometimes information resources to access assistance if subjects would benefit from a service related to the research problem. If the research involves deception, a written debriefing statement is required.

This document is ONLY required if you are using deception in your study. It is OPTIONAL for all other types of studies.

If the study involves medical risks, physical discomforts, or mental discomforts, please include the contact information (telephone number) for Students Health or the Counseling Center here as well as in the Informed Consent (if you are using WSC students as your subjects). If you are using non-WSC students as your subjects, you will need to provide referrals to outside medical facilities (i.e. Providence Medical Center, Suicide Hotline, etc.) If you are specifically using student-athletes, include the contact information for the Athletic Training Room here and in the Informed Consent, in addition to the Student Health contact information.

**Section B. Risk Evaluation**

A research subject is considered to be at risk if s/he may be exposed through the procedures of the proposed research to the possibility of physical or mental harm, coercion, deceit, or invasion of privacy. Examples of placing subjects at risk of harm include administration of drugs, requiring unusual physical exertion, deception, and public embarrassment and humiliation.

Coercion is a potential risk when subjects are not able to exercise their right to decline to participate. This is a special concern where the principal investigator or his/her advisor is in a relationship of greater power over the participants (e.g. professor-student relationship).

Additionally, risks arise when subjects could potentially experience discomfort, anxiety, invasion of privacy or loss of dignity. Risks also arise from the use of stored data or information that was initially obtained for other purposes.

If the study involves any risk that is managed through a referral to some sort of medical or mental health center, you must indicate this in the specific risk management section(s) below. In addition, you must provide the name and contact information (including telephone number) for the specific facility. If you are working with WSC students, please include WSC Student Health and the WSC Counseling Center since these services are free to all students. If you are working specifically with WSC student-athletes, please include the WSC Athletic Training Room in addition to the other WSC campus resources. If you are working with non-WSC students, please provide referrals to outside sources. This information must be provided up front in the consent form for all participants.

1. **Risk Assessment**
   * Indicate whether or not the following risks are present in the research.
   * Provide a rationale for why you are using a special group, equipment, and/or procedure.
   * Describe and assess any potential risks. Consider this from the perspective of the participant. Could s/he feel frightened, intimidated, embarrassed, become ill, etc.? If another research method which would reduce potential risks was not chosen for use, please provide a rationale.
   * Describe procedures of the proposed research designed to protect against or minimize the potential risk. Assess the effectiveness of these procedures.

|  |  |  |
| --- | --- | --- |
| a. | **Students will be used as subjects.**  *(If using college or K-12 students – the risk is that they may feel coerced to participate; therefore, you will need to state this as a risk and how you plan to address this risk.)*  Rationale for using students as subjects: Explain why you specifically need students for your study? Does it relate to your topic? Are you using them because they are a convenient population?  Describe and assess potential risk: This section only focuses on the risk of being a student. Will students feel pressured to participate even if they don’t’ want to because the researcher is a classmate or friend? Will students feel pressured to participate because the faculty advisor is also their instructor for a class? Will student-athletes feel pressured to participate because their coach approved of them participating in the study. These are the types of concerns we are looking at in this section.  Describe measures to minimize and address risk: Make sure to include a statement here and in the Informed Consent that clearly states students may choose not to participate and are free to withdraw from participation at any time without fear of prejudice from Wayne State College or the researchers for this study. There are many ways to write this statement, but this examples provides the minimal information necessary. | \_\_\_ Yes \_\_\_ No |
| b. | **Experimental drugs will be used.**  Rationale for using experimental drugs:  Describe and assess potential risk:  Describe measures to minimize and address risk: | \_\_\_ Yes \_\_\_ No |
| c. | **Potential for medical problems exists.**  *(Must include referral in consent form.)*  Describe and assess potential risk: This section should address all possible issues that would require more than a band-aid for treatment.  Describe measures to minimize and address risk: For any study involving physical activity, one way you should be reducing the risk for medical problems is to have each participant fill out a health history questionnaire and review it to ensure it is safe for each person to perform the physical activity required in the study. Another way to reduce the risk is to recruit participants who are conditioned to perform the same type and intensity of activity you need for your study. Another way to address the risks would be to have individuals who are trained in first aid and CPR on site for all data collection sessions. When performing strength and conditioning activities, having a certified strength coach on site would work well too. This section must include a statement of referral to Student Health (for WSC students) or another medical facility for non-WSC students. If you are specifically recruiting WSC Athletes, you need to include a referral to the WSC Athletic Training Room along with Student Health. Make sure to include the contact information/phone number for the referring facility. You must provide this information up front in the Informed Consent for all subjects; do not wait to provide it till after something happens. | \_\_\_ Yes \_\_\_ No |
| d. | **Non-English speaking subjects will participate.**  Rationale for using non-English speaking subjects:  Describe and assess potential risk:  Describe measures to minimize and address risk: | \_\_\_ Yes \_\_\_ No |
| e. | **Minors (less than 18 years of age) will participate.**  Rationale for using minors:  Describe and assess potential risk:  Describe measures to minimize and address risk: | \_\_\_ Yes \_\_\_ No |
| f. | **Mentally disabled subjects will participate.**  Rationale for using mentally disabled subjects:  Describe and assess potential risk:  Describe measures to minimize and address risk: | \_\_\_ Yes \_\_\_ No |
| g. | **Incarcerated subjects will participate.**  Rationale for using incarcerated subjects:  Describe and assess potential risk:  Describe measures to minimize and address risk: | \_\_\_ Yes \_\_\_ No |
| h. | **Participants may experience physical discomfort.**  *(Must include referral in consent form.)*  Describe and assess potential risk: Do not repeat risks from section C-medical problems in this section. An example here might include the uncomfortable pinching that occurs as a part of conducting skin fold measurements. This pinching does not create a medical risk, but it is uncomfortable for the subject.  Describe measures to minimize and address risk: You must include a statement here that you are in fact going to include a referral to a specific medical facility, with the contact information/phone number, in your consent form. | \_\_\_ Yes \_\_\_ No |
| i. | **Participants may experience mental discomfort.**  *(Must include referral in consent form.)*  Describe and assess potential risk:  Describe measures to minimize and address risk: This section must include a statement of referral to the WSC Counseling Center (for WSC students) or another mental health facility (for non-WSC students). Make sure to include the contact information/telephone number for all facilities listed. You must provide the information up front in the Informed Consent for all participants. Don’t wait till something happens to provide the referral information. | \_\_\_ Yes \_\_\_ No |
| j. | **Electrical equipment will be used.**  Rationale for using electrical equipment:  Describe and assess potential risk: Make sure to include all equipment that is plugged into an electrical outlet or runs on batteries and it applied directly to the participant in order to collect data at any point during the study.  Describe measures to minimize and address risk: One way to reduce the risk is to ensure that all operators are fully trained on how to use the equipment safely, ensure the equipment is operated according to manufacturer guidelines, and ensure the equipment it checked and calibrated prior to each use. | \_\_\_ Yes \_\_\_ No |
| k. | **Mechanical equipment will be used.**  Rationale for using mechanical equipment:  Describe and assess potential risk: This includes all equipment with moving parts that is applied directly to each participant to collect data.  Describe measures to minimize and address risk: See the comments for electrical equipment as they apply here as well. | \_\_\_ Yes \_\_\_ No |
| l. | **Deception will be used.**  *(Debriefing statement is required).*  Rationale for using deception:  Describe and assess potential risk:  Describe measures to minimize and address risk: | \_\_\_ Yes \_\_\_ No |
| m. | **Participants will be photographed or recorded (audio or video).**  Rationale for using photographs or recordings (audio or video: Clarify which type of recording(s) you will use. Make sure to use correct terminology for recording medium.  Describe and assess potential risk: One of the risks should include if the person can be identified on the recording.  Describe measures to minimize and address risk: In audio recordings, a good way to protect subject identities is to avoid recording the subject’s name and any personally identifiable information. | \_\_\_ Yes \_\_\_ No |
| n. | **Internet survey will be used (see Internet Research Policy).** This document is still in development. Meanwhile, consider how personally identifiable information could be hacked during transmission or information could be sent to incorrect locations/e-mails. Make sure to include information about the method of transferring the information (i.e. Survey Monkey, WSC E-mail, etc.) and the security in place to protect that information from getting into the wrong hands.  Rationale for using internet survey:  Describe and assess potential risk:  Describe measures to minimize and address risk: | \_\_\_ Yes \_\_\_ No |

1. **Benefit Assessment**

a) Describe the benefits to the subjects. This addresses the specific benefits for each subject who participates in your study. Remember, these people are not reading your literature review or (most likely) attending your final presentation. This is just what they personally get out of being a subject. Many times there are no benefits to being a research subject. Benefits could include learning how to perform a specific fitness test, getting some health aspect measured, being able to share their experiences and/or feelings about a topic, or just knowing they contributed to the research process (like doing a good deed).

b) Describe the significance of the study and contributions to the general knowledge in the field of inquiry. How will the results of this study add to what is already known about your research topic?

**Section C: Managing and Storing Raw Data**

Describe procedures and recording and storing data and the final disposition of raw data or coding identifiers.

*For IRB purposes, Raw Data is any source material that can be linked to a specific individual. Raw data includes but is not limited to video files, audio files, transcriptions, questionnaires, surveys, numeric data, health history questionnaires, and coding identifiers. All forms of raw data that pertain to your study must be clearly addressed in this section.*

*Raw data containing Personally Identifiable Information (PII) about participants must not be accessible to parties who are not involved in the study. Paper files and USB drives identifying participants should be kept in locked locations, in an advisor’s office, such as file cabinet drawers. Computer files containing PII (other than USB drives) should only be kept in a WSC password-protected location.*

*The American Psychological Association protocol calls for raw data to be kept for a minimum of five years after completion of the study.*

1. Identify the raw data associated with your study.
2. How will the raw data be recorded? (Be sure to address how confidentiality will be maintained.)

Make sure to include the medium on which the data will be recorded. Clearly explain how you will protect each subject’s personal information. One way is to assigned random numbers to subjects and use these rather than using their names on all documents. Another way is to simply not collect any personally identifiable information. Reminder, subject information cannot be both confidential and anonymous. The type of study you are conducting will influence whether your subjects are confidential or anonymous and how you will maintain that. Additionally, identify who will have access to subject information. Also, make sure to read the directions in italics to this section because it provides additional information you will need to complete this section.

1. Where will the raw data be stored? How long?

If you use coding identifiers in C.2. you must address where those will be stored here. Hint, they need to be stored separate from the rest of the data. All raw data should be stored for a minimum of 5 years (see directions above).

1. How will you dispose of the raw data?

Be specific here. Will you shred paper documents in the campus secure shredding bins? Will you delete computer files? Will you smash the USB drive? Make sure to clearly state (specify the documents) how you will dispose of all documents, files, and records that have identifiable subject data.

**Section D. Consent Form**

Whenever possible, obtain informed consent (a signed form) from all participants. In online surveys, include a statement stating that completing the survey implies consent, following the Elements of Informed Consent below. Always use plain language. Avoid technical terms or discipline jargon. An example of a consent form is available in “Guidelines for Researchers.”

Include in your informed consent (please check as you complete): Make sure you actually check each line as you complete it when creating your Informed Consent form. If an item does not apply to your study, enter “n/a” in the blank rather than leaving it blank. Each item checked here must be included in your Consent Form. A majority of these are going to be requirements for just about every study conducted on this campus.

\_\_\_\_ 1. Explanation of the purpose of the study, description of procedures to be followed. This needs to match what you provided in section A of the proposal form.

\_\_\_\_ 2. Identification of individuals performing the procedures and their credentials.

\_\_\_\_ 3. Description of possible immediate and long-term discomforts, hazards and risks. This needs to match what you provided in section B1 of the proposal form.

\_\_\_\_ 4. Description of any benefits to participants or potential benefits to society. This needs to match what you provided in B2 of the proposal form.

\_\_\_\_ 5. Offer to answer any questions concerning the procedures at any time.

\_\_\_\_ 6. A statement that participants are free to withdraw consent and to discontinue participation at any time without prejudice to their future relations with WSC, their professors, or the principal investigator. The list included in this statement may vary to match the possible subject relationships, but the full statement needs to be included.

\_\_\_\_ 7. Assurance that the identities of the participants will not be disclosed without the participant’s consent.

\_\_\_\_ 8. If a mental or physical risk is identified, include appropriate healthcare professional referral information (such as WSC Counseling Center or WSC Student Health or non-student community resources). This should also be addressed in section B of the proposal form.

\_\_\_\_ 9. If subject is photographed or recorded (audio or video), consent must contain statement to be initialized by subjects.

\_\_\_\_ 10. Notification that if the participants are minors (less than 18 years of age), one parent or legal guardian must sign the consent form). This should match what you provided in section A.3.f. of the proposal form.

\_\_\_\_ 11. Faculty and staff provide each participant with the name and telephone number of the principal investigator. Graduate students must provide each participant with the name and telephone number of the principle investigator and research advisor. Undergraduate students must provide each participant with the name and e-mail address of the principle investigator and the name and telephone number of the research advisor.

**Section E. Materials and Apparatus**

To this document, **attach** copies of all written materials to which subjects will be exposed including questionnaires, survey, instructions, cover letters, consent/assent forms, debriefing statements (required when deception is part of study), etc.

Make sure you do provide all supporting documents. This includes all forms of communication (typed, verbal, e-mail, photos, videos, etc.) that subjects will be exposed to at any point in the research process. It is better to include too much rather than not enough. Make sure wording on all documents and in all locations within each document is consistent. The research proposal cannot be reviewed until all documentation is provided.

If applicable, **attach** Human Performance Lab protocols, documentation of agreement from individuals or organizations that are cooperating with you to recruit subjects (i.e. school districts, team coaches), and/or letters of participation from outside organizations working with you.

Human Performance Lab protocols are not a repeat of what was entered in A.3. on this form. This is where, if you indicated in A.3. that you are requiring subjects to complete a 1RM for bench press, you provide the step-by-step directions on how you will actually perform the 1RM bench press test. If you are having subjects warm up prior to testing, you would state this in A.3., and then you would provide the detailed warm-up (exercise, exercise order, distance/time/repetitions). If you are completing a PAP protocol, you would provide the detailed protocol here.

If you are specifically recruiting athletes only, you must provide a signed letter of agreement from the sport coach with your proposal submission. Recruiting subjects who happen to be athletes for a study where being an athlete is not part of the inclusion criteria, does not require a letter.

If you are conducting research during class time, you must provide a signed letter of agreement from the instructor with your proposal submission. Just advertising and recruiting during class, but conducting the data collection outside of class does not require a letter.

**Section F. IRB Review Level**

The Federal government requires that copies of ALL research proposals involving human subjects be on file with the Institutional Review Board. Certain types of research may be exempt from full IRB review or qualify for expedited review. Exempt status does not relieve the researcher from the obligation to obtain consent from the subjects, their representatives, or cooperating organizations.

To help determine the level of review, please see “Guidelines for Researchers.”

Please check the level of review you are requesting:

\_\_\_ Exempt \_\_\_ Expedited \_\_\_ Full

Revised December 2017