

IRB APPLICATION SHEET

Application must be typed.

According to my understanding of the IRB Guidelines, this application qualifies for the following review:

Exempt _____ Expedited X Full Review _____

If more than one researcher, give information on a separate page for #1-4 for each researcher. Indicate who is Principal Investigator.

1. NAME: _____ HOME PHONE: _____
EMAIL ADDRESS: _____
2. HOME MAILING ADDRESS: _____

3. PLACE OF EMPLOYMENT: _____
4. POSITION OR JOB TITLE: _____ WORK PHONE: _____
5. TITLE OF STUDY: Female Athletes and Performance-Enhancer Usage

6. Study is: (a) Thesis _____ (b) Class Project _____ (c) Other [specify] _____
7. Does your research have a potential or actual financial interest of any kind (e.g., any form of payment for services, equity interests, intellectual property rights, etc.)?
____ Yes. (Please complete the Financial Conflict of Interest form at the end of this IRB application and submit with the application.)
____ No
8. Name of advisor, class professor (If applicable): _____
Dept: _____ Phone: _____
9. Anticipated starting and completion dates: 5/20/2004 to 6/01/2004
10. What is the purpose of the study? The purpose of this study is to determine the major issues that lead to the usage of steroids and other performance-enhancers among high school female athletes in order to identify markers for a behavior change program. The study will include an analysis of some of the internal and external pressures that young women face during the high school years that may contribute to the abuse of these substances.

11. What is the Hypothesis or Research Question? It is hypothesized that performance-enhancer usage among high school female athletes will be primarily due to coaching pressures, peer pressure, and the pressure to win.

12. Explain your qualifications for conducting this research. I am a student in the Health Professions Leadership program at Seton Hall University. I have a degree in Health Science Education and I have completed all of my core requirement courses for my master's degree, including advanced research and statistics courses. I was a high school and collegiate athlete and served as an assistant coach for The College of New Jersey.

13. Explain the rationale and significance of the study. Although alcohol, marijuana, tobacco, and cocaine are the most abused drugs by adolescents, anabolic-androgenic steroids and nutritional supplements are becoming increasingly more popular (Luetskemeier et al., 1995; Tyler, Lauver, & Zitans, 1991). While U.S. prevalence rates for steroid use generally range between 4% and 12% among male adolescents, approximately 2% of female adolescents have been engaging in usage as well (Bahrke et al., 1998). In a 1995 study conducted by Luetskemeier et al., a survey was administered to approximately 2,200 junior and senior high school students in the Salt Lake City, Utah metropolitan area to determine the prevalence of AAS use. Although the proportion of steroid users was greater for boys than for girls, it was found that approximately 1.4% of females participating in strength training activities had used steroids. Of the AAS users, 19% were in the 9th grade, 19% were in the 10th grade, 9.5% were in the 11th grade, and 12.7% were in the 12th grade. It was concluded from this study that athletes participating in sports that require strength (e.g., gymnastics, skiing, hockey, tennis) were most likely to use steroids (Luetskemeier et al., 1995).

In addition, in a 1990 study conducted by Terney and McLain, 2113 high school students were surveyed on their general knowledge about anabolic steroids, awareness of risks and side effects, and usage prevalence of anabolic steroids. Of the 2113 surveyed, 1085 females were users of steroids, with athletes reporting a higher usage than nonathletes. Similarly, in a 2001 study conducted by Metzl et al., middle and high school athletes were surveyed with regard to creatine usage, a nutritional supplement that causes water retention in muscles and increased bursts of energy for workouts or competition (Millman & Ross, 2003). Although the use of creatine is not recommended in people less than 18 years of age, this study found that of 1103 participants surveyed, 5.6% admitted taking creatine. Creatine usage was reported in

every grade from 6 to 12, and out of 492 girls surveyed, 1.8% had taken creatine. It was concluded from this study that despite current recommendations against use in adolescents less than 18 years old, creatine is being used by middle and high school athletes at all grade levels. In fact, the prevalence in grades 11 and 12 is approaching levels consistent with collegiate athletes (Metzl et al., 2001).

All of the above studies indicate that performance-enhancer usage is quite prevalent among female athletes despite the vast amount of knowledge indicating harmful physical and psychological effects. Although some reasons cited include the pressure to win and the desire to improve physical appearance, the question still remains: "Why are female athletes so willing to sacrifice their health for the sake of winning or improving their appearance at all costs?" The purpose of this study is to determine some of the major issues that lead to the usage of performance-enhancers among high school female athletes. It is hypothesized that performance-enhancer usage among high school female athletes will be primarily due to coaching pressures, peer pressure, and the pressure to win.

14. Describe the subjects: Subjects will include female athletes from 5 southern New Jersey high schools.

Age(s) of subjects: 14-18 years

Number of subjects: 500

15. From where and how will potential subjects be identified (e.g., outpatient list, class list, etc.)?

In this study, convenience sampling will be used to identify high school female athletes for participation. Each female athletic team at five southern New Jersey high schools will be given the survey. Samples of convenience frequently allow the investigator the advantage of using intact groups of subjects (i.e. high school female athletic teams). Also, convenience sampling permits the investigator to collect a large amount of information, from a large number of people, and in a relatively small amount of time. Participating individuals must possess the following criteria:

1. must be a varsity female athlete
2. must have participated in their particular sport for at least two years

Participating sport teams must be ranked in the top 10% of the state of New Jersey, a factor which may affect athletic pressures associated with increased steroid or performance-enhancer usage.

How do you have access to this population?

Access to this population will first be obtained by contacting the Athletic Directors in each school meeting the specified criteria. Upon consent and recommendation by Athletic Directors, coaches of the sport teams will be contacted first by phone and then through a formal letter of invitation. Distribution of surveys to the athletes will take place upon receiving consent from the team coaches, the athletes, and the parents of the athletes (if under age 18).

16. Do you have a supervisory and/or professional relationship with the subjects? Yes No ☒ X

If yes, please explain how this relationship will not compromise the voluntariness of the subjects' participation in the study.

17. Will data be collected from or about any of the following protected populations:

- ☒ minors (under 18 years of age; age 14-17)
- ☐ prisoners
- ☐ pregnant women
- ☐ fetuses
- ☐ cognitively impaired persons

For additional requirements regarding these categories of protected subjects, consult and follow the IRB Guidelines.

18. What are your criteria for subject selection? Selection of subjects must be equitable and, in the case of protected populations [see #13 above], should reflect their special needs. IRB Guidelines also require researchers to be sensitive to the use of educationally and economically disadvantaged persons as subjects. If you are excluding women or minorities from your subject pool, you must include a scientific justification for such exclusion.

Participating individuals must possess the following criteria:

1. must be a varsity female athlete
2. must have participated in their particular sport for at least two years

Participating athletes must belong to sport teams that are ranked in the top 10% of the state of New Jersey, a factor which may affect athletic pressures associated with increased steroid or performance-enhancer usage.

19. How will subjects be recruited once they are identified (e.g., mail, phone, classroom presentation)? Include copies of recruitment letters, flyers, or advertisements, or copy of script of oral request at time of recruitment.

Initially, subjects will be recruited by contacting the high school athletic directors and coaches by phone so that I may introduce myself and give a broad overview of the study. Coaches will be informed during this phone conversation of an official letter of invitation detailing the study that will be sent to them shortly afterward. Upon receiving permission from both the athletic director and coaches, consent forms will be sent to the coaches to distribute to the athletes. Once consent forms are signed, team coaches will distribute surveys to the athletes prior to team practices.

20. Where will research be conducted? (Be specific) _____

The sites of this study will include five southern New Jersey high schools possessing state ranked female athletic programs. Specifically, female athletes from Bridgeton High School, Cumberland Regional High School, Millville High School, Vineland High School, and Shalick Regional High School will participate. These settings were chosen based on their excellent programs in women's athletics. Surveys will be distributed prior to team practices, and data will be analyzed and recorded by the researcher.

21. Will deception be used? YES ____ NO X If YES, provide the rationale for the deception:

22. Please explain debriefing procedures, if any, to be used in this study: Subjects will be verbally informed about results obtained after study completion.

23. What methodology will be taken to insure the anonymity of the subjects and the confidentiality of the data (i.e., coding system, how and where data will be stored and secured, how data will be analyzed, who will have access to data, what will happen to data after the study is completed)? Note that researchers should retain all data collected for at least 3 years after project completion.

Subject names will not be identified at any time during the research. Surveys will be administered and returned anonymously. Surveys will be given to the team coaches, who will administer them to the athletes. At no time will subjects be asked to state their name on the questionnaire. All information collected in the study is confidential and will be securely stored in a locked cabinet to which only I will have access. The data provided will be grouped with data others provide for reporting and presentation. No one but the researcher will have access to research records. Data will be stored separately from the consent forms, keeping subject answers confidential.

24. Is a subject follow-up anticipated? YES ____ NO X If Yes, for what reason? _____

25. Describe the design and methodology IN DETAIL (what exactly will be done to the subjects? What measures will be taken?) Describe any equipment that will come in contact with the subject. Brand name and model, as well as description of its function. If electrical equipment is connected directly to the subjects, as with GSR and EFF measures, assurances concerning the safety of the equipment (technician should certify that equipment was checked within the last month) should be included.

High school female athletes will be surveyed in this study in order to gather information to be used for development of strategies for prevention education. The study design will be pre-test only, as subjects will only be surveyed once. The research strategy used in this study will be a self-administered paper-and-pencil survey that will take approximately 15-20 minutes to complete. Administering surveys to groups is relatively low in cost, fast, and may be supervised or unsupervised. Prior to survey distribution, the researcher will verbally explain the purpose and rationale of the study to the athletes, and then pass out the official letter of invitation. Students will be informed that participation is completely voluntary, and will be given the option to leave the classroom before survey administration. Surveys will then be distributed to the athletes, and the researcher will leave the room. Upon completion, students will place their surveys in a locked box with an open slot. Surveys will then be analyzed for tabulation of results. Specifically, means, medians, and standard deviations of responses will be calculated.

ATTACH ADDITIONAL SHEETS IF NECESSARY.

Include the necessary copies of any test instruments, questionnaires, etc.

**DO NOT ATTACH COPIES OF SECTIONS OF GRANT PROPOSALS OR
CLASS PROJECTS TO ANSWER THIS ITEM.**

**Female Athletes and Performance Enhancer Usage
Student-Athlete Survey**

Directions: Please rate the following issues in terms of their importance in leading to steroid/performance-enhancer usage among female athletes. Ratings are on a scale of 1 through 5: **1=very important**

2=important

3=moderately important

4=unimportant

5=most unimportant

****Please circle the number that you feel is most appropriate for each issue.**

Issues Related to Performance-Enhancer Usage	Rating				
The pressure to win	1	2	3	4	5
Peer pressure by teammates	1	2	3	4	5
Pressure by the school to win	1	2	3	4	5
Self-induced competitive pressures	1	2	3	4	5
Conscious or unconscious pressure by coaches	1	2	3	4	5
Issues relating to body image	1	2	3	4	5
Societal pressures (i.e. media, TV advertisements)	1	2	3	4	5
Competitive Level (Group I, II, III, IV)	1	2	3	4	5
Curiosity/Experimentation	1	2	3	4	5

Is there anything that you would add to the above list? If so, please list here.

Additional Comments:

LETTER OF INVITATION

May 20, 2004

Name

Address

Dear :

You have been nominated by your athletic director to participate in a study regarding the assessment of high school female athletes that is being conducted, under the direction of Dr. Genevieve Pinto-Zipp, in fulfillment of degree requirements at Seton Hall University.

The purpose of this study is to determine the major issues that lead to the usage of steroids and other performance-enhancers among high school female athletes. The study will include an analysis of some of the internal and external pressures that young women face during the college years that may contribute to the abuse of these substances.

A review of the literature on this topic suggests that a high number of high school athletes engage in regular use of steroids, with an increasing number of these athletes being women. In addition, it has been found that female athletes are also using performance-enhancers such as creatine for energy boosts and improvement of muscle mass. Due to these findings, it appears that there is a need to find the reasons for the increase in steroid/performance-enhancer usage among women athletes.

In order to gather information for this study, a survey will be distributed to your team members. Your athletes' input would be valuable in this attempt to determine some issues relating to performance-enhancer usage by female athletes. Participation in this research involves one questionnaire, taking approximately 10 minutes to complete. At no

time will team members be asked to describe their own behaviors. Rather, we are interested in their perceptions as female high school athletes. After survey analysis, you and your athletes will be provided a summary of the information generated by all of the participants and a final report at the conclusion of the project, if you so desire.

I hope that you agree that this study has the potential for making a significant contribution to the field of athletics and I anticipate that you will find your involvement in this project both intellectually and professionally satisfying. Within the next week or so, I will be contacting you by telephone to answer any questions that you may have and to ask for your commitment to have your team participate.

In the meantime, if you would like clarification regarding this request or the nature of my study, please do not hesitate to contact me or my advisor, Dr. Genevieve Pinto-Zipp. In addition, it would be greatly appreciated if you would complete the enclosed form, indicating your willingness to participate, and return it to me, in the pre-addressed envelope, by January 25, 2004. Thank you very much for your consideration and commitment.

Sincerely,

Barbara K. Fralinger

INFORMED CONSENT FORM

Dear student-athlete,

My name is Barbara Fralinger and I am a student with the School of Graduate Medical Education at Seton Hall University. I am currently earning my degree in Health Science Education. For my research, I am investigating the perceptions of high school female athletes on the usage of performance-enhancers. I am writing to ask you to participate in this research. Allow me to explain this project to you.

Purpose and Duration of the Research

The purpose of this research is to determine the major issues that lead to the usage of steroids and other performance-enhancers among high school female athletes through use of a survey. The expected duration of your participation will be approximately ten minutes.

Description of Procedures

The procedures of this research involve the distribution of a survey before a team practice session. You will be asked to complete the survey and return it for tabulation of results.

Participation is Voluntary

Your participation is strictly voluntary. You do not have to participate and can decide to stop at anytime - there will be no negative consequences for that decision. I emphasize to you that you will in no way be penalized for not participating or for deciding to stop once you have started.

Protecting Your Identity

You will not be identified at any time during the research. Surveys will be administered and returned anonymously. At no time will you be asked to state your name on the questionnaire.

Data Will Be Kept Confidential

All information collected in the study is confidential and will be securely stored in a locked cabinet to which only I will have access. The data provided will be grouped with data others provide for reporting and presentation. No one but the researcher will have access to research records. Data will be stored separately from the consent forms, keeping subject answers confidential.

There are No Risks or Discomforts

There are no risks to your health from this study at any time.

Benefits for Participating

This study is intended to benefit both female athletes and coaches by providing information about the potential mental, physical, and social factors that can lead to the

abuse of steroids and other performance-enhancers among female athletes. As a result of this research, possible solutions for decreasing performance-enhancer usage among female athletes may be obtained.

Contact Information

If you have any questions regarding this study, you can contact me by calling the Seton Hall University Graduate Medical Education Department at 973-275-2076. I would be happy to answer your questions.

Approval of the Institutional Review Board

This project has been reviewed and approved by the Seton Hall University Institutional Review Board for Human Subjects research. The IRB believes that the research procedures adequately safeguard the subject's privacy, welfare, civil liberties, and rights. The Chairperson of the IRB may be reached at (973) 275-2977 or 313-6314.

Note: For anonymity's sake, the researcher, instead of asking for a signature, can include the following statement in the Informed Consent form: "Consent to participate is indicated by returning the enclosed (questionnaire, test, etc.) to the researcher."

I have read the material above, and any questions I asked have been answered to my satisfaction. I agree to participate in this activity, realizing that I may withdraw without prejudice at any time.

Subject or Authorized Representative

Date

Please sign and return one copy of the above consent form. The other copy is for you to keep. Thank you.

References

- Bahrke, M.S., Yesalis, C.E., & Brower, K.J. (1998). Anabolic-Androgenic Steroid Abuse and Performance-Enhancing Drugs among Adolescents. Child and Adolescent Psychiatric Clinics of North America: Oct; 7(4), 821-838.
- Johnson, M.D. (1990). Anabolic Steroid Use in Adolescent Athletes. Pediatric Clinics of North America: Oct; 37(5), 1111-1123.
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- Pecci, M.A. & Lombardo, J.A. (2000). Performance-Enhancing Supplements. Phys. Med. Rehabil. Clin. N. Am.: 11(4), 949-960.
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Yesalis, C.E. & Bahrke, M.S. (2000). Doping among Adolescent Athletes. Baillieres Best Pract. Res. Clin. Endocrinol. Metab.: Mar; 14(1), 25-35.