

Title: Effect of a 9-Month Internship Intervention for Military Dependents with ASD

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RESEARCH SUBJECT INFORMATION AND CONSENT FORM

Student Consent

TITLE: Effect of a 9-Month Internship Intervention for Military Dependents with ASD

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ABOUT THIS CONSENT FORM

You are being invited to participate in a research study. **It is important that you carefully think about whether being in this study is right for you and your situation.**

This consent form is meant to assist you in thinking about whether or not you want to be in this study. **Please ask the investigator or the study staff to explain any information in this consent document that is not clear to you.** You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

Your participation is voluntary. You may decide not to participate in this study. If you do participate, you may withdraw from the study at any time. Your decision not to take part or to withdraw will involve no penalty or loss of benefits to which you are otherwise entitled.

AN OVERVIEW OF THE STUDY AND KEY INFORMATION

Why is this study being done?

The purpose of this research study is to find out some of the best ways to help people with autism spectrum disorder (ASD) get and keep a job. We think that a program called “Project SEARCH plus ASD Supports” (PS+ASD) may help people with ASD get a job because it teaches people with ASD about work and the kinds of jobs they might like to do. This study will allow us to learn more about it.

You are being asked to take part in this study because you:

1. Have Autism Spectrum Disorder diagnosis
2. Attend a participating school
3. Are between the ages of 18 and 21 at the time of enrollment. (You may turn 22 before the end of the study, but must be no older than 21 years at the time of enrollment.)

What will happen if I participate?

In this study, you will be asked to do the following things:

1. Meet with us and answer some questions at three different times during the research study.
2. Go to either the PS+ASD program on base at Fort Eustis or go to your high school.
3. Take surveys and answer questions about your support needs, abilities, quality of life, behaviors, and job history.
4. Give permission for the researchers to collect information about your education from your school records.

Here is a description of the two programs and how they are different from each other:

	Program 1: PS+ASD Program	Program 2: School Group
What will I learn?	You will work in a community business at Fort Eustis to find out what you like.	You will follow the schedule your school creates for you.
Who will decide what I am taught?	We will talk to you about what you like and have you try new jobs on base at Fort Eustis.	Your school will decide what is best for you to learn.
How will I be taught?	We will teach you skills by spending time with you and figuring out what help you need at a job.	Your teachers will decide how to teach you information in your classes.
How much time will it take?	This will take one school year.	This might take 2 plus years depending on what you choose to do after the first year in the study.
Will my parents be part of this?	We will speak with your parents about how you are doing in the program.	The school will decide how and when to talk with your parents.
What happens if I don't learn these skills?	If you have trouble learning these skills, we will talk with you about better ways to help you learn.	The school will decide how to help you.
When will you meet with me to ask questions?	We will meet with you, your parents, and your teachers 3; 1. At the very beginning of the school year in September or October. 2. 12 months after beginning the school year in September or October. 3. 18 months after beginning the school year in March or April.	We will meet with you, your parents, and your teachers 3; 1. At the very beginning of the school year in September or October. 2. 12 months after beginning the school year in September or October. 3. 18 months after beginning the school year in March or April.

You will be assigned by chance to either the PS+ASD program or the school group. You will not have a choice of which group you end up in. If you are assigned to the school group, you might be selected to be in the PS+ASD program in the next school year. Your participation in this study will last up to 32 months. A total of about 32 individuals with ASD will participate in this study.

What alternative treatments or procedures are available?

The only alternative to this study is to not take part. In such cases, you will receive your education as usual. If you decide not to take part in the study, but are interested in work experiences like PS+ASD, we will talk to you about other similar programs if there are any by where you live.

What are the risks and benefits of participating?

Risks and Discomforts	Benefits to You and Others
<p>1. Below are some of the most common risks and discomforts:</p> <ul style="list-style-type: none">• There are no risks beyond what you would encounter in a normal high school or work place. These are examples of issues that you may come across: scheduling changes, and stress from peer and/or boss interaction.• Participation in research might involve some loss of privacy. There is a small risk that others may find out about your disability or other identifying information.• The study questionnaires ask questions that are personal in nature and may make you feel uncomfortable. If so, you may skip that question, ask us to stop that line of questioning, or ask us to stop the interview at any time. <p>2. There may be some risks that the investigators do not know about yet, so we will let you know of any new findings.</p>	<p>Taking part in this study will provide you with the opportunity to engage in community-based work experiences that might lead to job while transitioning from high school to adulthood. It may help you get a job more to your liking than if you were not part of the study. It is also possible that you will not get or keep a job.</p> <p>Even though you may not get a job from this study, the information we learn from people in this study may help us design better ways to help people with disabilities get jobs in the future.</p>

DESCRIPTION OF THE STUDY AND YOUR INVOLVEMENT

If you decide to take part in this study, you will be asked to participate in an assessment before being assigned to one of the two training programs at either your high school or the PS+ASD program at Fort Eustis. During this assessment, we will ask some personal information like for your name, address, and date of birth, and then ask you to complete some questionnaires. The questionnaires are; the Support Intensity Scale, The Social Responsiveness Scale, the Behavior Assessment Scale for Children Adolescent Version and the Quality of Life Questionnaire. The assessments will be done by trained staff at the beginning of the study, 12 months after entering the study, and 18 months after entering the study. Assessment information may be collected from students, parents or guardians, and teachers. We will use the information to determine your skills, abilities, and support needs so that we can best match you to internships and determine the level of support you will need during the course of the study. The assessment will occur at a private place and time fitting to you and will take approximately 1.5 hours to complete. There may be questions that cause you discomfort or distress during the assessment. If you feel discomfort or distress, you may skip those questions, ask to stop that line of questioning or ask to stop the interview.

Once in the study, you will receive educational services in one of two programs. The first program is in your high school. The second is a 9-month internship job training program at Fort Eustis Military Base. Project staff will assign you to one of the two programs. Neither you nor your parents will have a choice of the program to which you are assigned. Project staff will make program assignments by chance. If you are in the study, you will have an equal chance of being in either program as anyone else in the study. If you are assigned to the high school group, you may be able to enroll in the 9 month internship in a community business after you spend one school year in the high school group.

Both programs will begin on the first day of school in the fall and last until the last day of school in the spring. Both programs will follow the public schools calendar. You will be required to attend the program when school is in session, and will be off when school is not in session. If you are assigned to the PS+ASD program, you will attend school at a Fort Eustis. You are responsible for finding and arranging your way to and from the community business. If you would like, we will help you learn how to use public transportation before the internship program begins. If you are assigned to the high school program, you will use a school bus or car to get to and from your school. If you are assigned to the high school program, your school day will follow the school's schedule. Your school day in the community business will start and end at the same time as your high school. Once you complete either program, you may choose to graduate from high school if you so desire, provided that you are still of an age to be in high school. If you are too old to continue in high school, you will have to graduate. If you are unsure if you must graduate at the end of this study, please contact your teacher for more information.

As a part of this research study, we will stay in touch with you for a period of 18 months after you enroll in the study. You will take part in assessments and be asked to complete a survey about your job and job training. The assessments and surveys will be collected three different times when you enroll in the study, 12 months after you enroll in the study and 18 months after you enroll in the study.

We will share with you important findings that we learn during this study. These findings may affect your decision whether or not you want to continue to taking part in this study.

WHAT ARE THE COSTS?

The cost for taking part in the high school job training program includes any high school fees you would normally pay to the school. The cost for taking part in the community based job training program include:

1. Getting to and from the business daily
2. Buying appropriate clothing (which may include buying uniforms)
3. Buying lunch if you are not able to bring a lunch from home

Also, part of the cost will be the time you spend in the study itself. The University will not charge you anything for taking part in this study.

WILL I BE PAID TO PARTICIPATE IN THE STUDY?

We will provide you with compensation for your time to complete the interviews and surveys as described below:

Completion of the first surveys at the beginning of the study - \$75.00

Completion of the second surveys 12 months after beginning the study - \$75.00

Completion of the third and final surveys 18 months after beginning the study - \$75.00

Bonus for completing all of the surveys at all three times - \$75.00

Total possible compensation across 18 months - \$300.00

We will offer this compensation to you in the form of a gift card. Please be aware that the investigative team and the University may receive money to conduct this study.

CAN I STOP BEING IN THE STUDY?

You can stop being in this research study at any time. Leaving the study will not affect your education or employment status. Tell the study staff if you are thinking about stopping or decide to stop.

If you decide to withdraw from the study, you will return to the high school program which you would normally attend as long as you are eligible to continue attending that school. If you stop participating in the study and no longer attend program activities you will be considered to have withdrawn from the study. If you withdraw for any reason, after receiving any part of the study activities, you will be asked to be available for follow-up assessment. Specifically, you will be asked to complete all assessments scheduled and to provide all follow-up information.

Your participation in this study may be stopped at any time by the investigator without your consent. The reasons might include:

- the investigator thinks it necessary for your health or safety
- you are found to not be eligible for the study
- the sponsor has stopped the study
- you have not followed study instructions
- administrative reasons require your withdrawal

HOW WILL INFORMATION ABOUT ME BE PROTECTED?

In this study, we will gather information about your job history. Your information will be added with the information from the other people in the study. We will compare the job training programs with each other. We will protect your information by saving it on a password protected encrypted computer.

We will not tell anyone the answers you give us, however, information from the study and the consent form signed by you may be looked at or copies for research or legal purposes by the sponsor of the research or by Virginia Commonwealth University. Personal information about you might be shared with or copied by officials at the Department of Health and Human Services, Department of Defense or other federal regulatory bodies. The name of the group paying for this research is the Congressionally Directed Medical Research Projects (CDMRP).

In the future, identifiers might be removed from the information you provide in this study, and after that removal, the information could be used for other research studies by this study team or another researcher without asking you for additional consent. With your permission we might send reports and other information to other agencies that serve you. We will only do this if you have given us permission by signing the “Parent/Student Permission to Release Information” located in Part B of the application on page 6. If you tell us that you may hurt yourself or someone else, the law says that we must let people in authority know.

We will not give you any individual results from the study. A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Web site at any time.

Certificate of Confidentiality

To help us protect your privacy, we have received a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances: If you or your students tells us you intend to hurt yourself or others, or if we learn about real or suspected abuse.

The paper or computer information we collect in this study includes:

1. Your name
2. Your birthdate
3. Your address
4. Application
5. Assessment forms
6. The Individualized Education Program
7. Interview notes or recordings
8. Photos.

It is possible that others might identify you from this information. We will keep this information in a locked area, or in a password protected encrypted computer. We will erase or destroy all personal information once the study is finished. Access to all data will be limited to study staff. We will collect the information described above from you, your parents or guardians, and teachers.

NATIONAL DATABASE FOR AUTISM RESEARCH:

Our funding agency has requested that we share our data with a national database for researchers called the National Database for Autism Research (NDAR). This database is run by the National Institutes of Health (NIH). The NIH only allows qualified researchers from approved universities have access to the NDAR. The NIH also keeps this database using the most secure technology currently available. Other researchers may access this data for future research, but they will not know your name, where you are from, or any other information they could use to find you.

In order to protect your confidentiality, we will only share your data if you give us permission. We will not share any data that will reveal your identity. We will assign a random number to your data that is different than any other number or code associated with you. You can refuse permission to share your data and continue to be in the study. You can also change your mind about sharing your data at any point until we close the study with our VCU Institutional Review Board. We think they study will be closed by approximately September 30, 2020. In order to let us know that you changed your mind and would like to remove your data, just tell any staff member in the study and we will ensure that your data is pulled from the database.

1. I give permission for my data to be shared to the National Autism Research Database and used for future research. I understand that my data will be confidential. I also understand that I can change my mind by September 30, 2020.

 YES, I give permission for my data, without my name or any other identifiers, to be shared with NDAR. I also understand that I can change my mind and withdraw my data as long as the research study is active at VCU. I understand that information that is already being used by researchers cannot be withdrawn.

 NO, I do not give permission for my data to be shared with NDAR.

VIDEO RECORDINGS AND PHOTOGRAPHS

On occasion, and only with your permission, we collect video recordings and photographs of you. The purpose of these recordings is to show other interested persons how to implement the project on their own. We will play these recordings at conferences and training events to teach others about the research. We will only collect these recordings with your permission. Any student or legally authorized representative who does not give permission will not be recorded. All recordings will be transferred from camera or other portable device to a password protected, encrypted computer. Once that transfer has occurred, all portable recordings will be destroyed. You will have the opportunity to give permission to be recorded or not. You can also change your mind at any time if you decide you no longer want to be recorded. If you change your mind and want previous recordings to be destroyed, please tell us and we will destroy those recordings.

You can decide to be videotaped or photographed if you want. Please put a check mark by the statement that best matches your decision about video and photographing

YES, I consent to be photographed and/or videotaped during this study.

NO, I do not consent to be photographed and/or videotaped during this study.

WHOM SHOULD I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY?

The investigator named below is the best person to contact if you have any questions, complaints, or concerns about your participation in this research:

Carol M. Schall, PhD
Virginia Autism Resource Center
Virginia Commonwealth University
Richmond, VA 23284-2020
(804)828-6979
cmschall@vcu.edu

Paul Wehman
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Box 842011
Richmond, VA 23284-2011
804-828-1852
pwehman@vcu.org

If you have general questions about your rights as a participant in this or any other research, or if you wish to discuss problems, concerns or questions, to obtain information, or to offer input about research, you may contact:

Virginia Commonwealth University Office of Research
800 East Leigh Street, Suite 3000, Box 980568, Richmond, VA 23298
(804) 827-2157; https://research.vcu.edu/human_research/volunteers.htm

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

CONSENT

I have been given the chance to read this consent form. I understand the information about this study. Questions I wanted to ask about the study have been answered. My signature says that I am willing to participate in this study.

Signature Block for Enrolling Adult Participants	
Adult Participant Name (Printed)	
Adult Participant's Signature	Date
Name of Person Conducting Consent Discussion (Printed)	
Signature of Person Conducting Consent Discussion	Date
Principal Investigator Signature (if different from above)	Date