

SUBJECT: Policy for Minors in Research

1. PURPOSE:

This SOP establishes the procedures for minors working or volunteering in laboratory and/or medical research in the Minneapolis VAHCS Research Service to ensure that all minors conduct work only under proper supervision and with the consent of a parent or legal guardian.

2. DEFINITIONS:

ACOS/R: Associate Chief of Staff for Research
AO/R: Administrative Officer for Research
PI: Principal Investigator
WOC: Without Compensation Employee
R&D: Research and Development
RDC: Research and Development Committee
SRS: Subcommittee on Research Safety
Minor: Person under the age of legal majority (currently 18 years of age)

3. OVERVIEW:

The R&D Committee and the ACOS/R recognize that opportunity to participate in research is a valuable experience for high school and college students, especially for students with an interest in pursuing medical or scientific research as a future career. While the Minneapolis VAHCS Research Service is generally in favor of supporting opportunities for minors to participate in ongoing research projects, the unique hazards of research work as well as state and Federal rules and regulations require additional restrictions and guidelines.

4. PROCEDURES:

- a) Any participation by a minor in VA research (including work funded by VA, performed under the approval of a VA oversight committee, or conducted on VA grounds) must be individually reviewed and approved by both the RDC and ACOS/R prior to commencement of any work.
- b) To be considered, R&D policy is that minors must be 16 years of age or older.
- c) Each request for participation by a minor must be sponsored by the PI for the study protocol. In cases where a study protocol has multiple PIs, a co-PI may serve as the sponsor, but the PI of record must approve and co-sign all necessary documentation and permissions. The sponsoring PI agrees that:
 - i) He/she will be responsible for training and supervising the minor during the minor's participation in the study protocol;
 - ii) The minor will be under continuous adult supervision whenever he/she is working in secured research areas, working with hazardous or dangerous materials, or working in hazardous or dangerous environments;
 - iii) The minor will not be granted access to electronic individually-identifiable information, including in CPRS or VistA;
 - iv) While the sponsoring PI can delegate training and supervision to another individual on the protocol, any such delegate must be 18 years of age or older, and the sponsoring PI will ultimately remain responsible for the safety and conduct of the minor.

- d) Sequence of events for inclusion of a minor in research at the Minneapolis VAHCS:
 - 1) The sponsoring PI must complete the Minors Working in Medical Research consent form, including a detailed description of work to be performed, and listing all hazards to which the minor may be exposed during participation in the study protocol.
 - 2) The parent(s) or legal guardian(s) of the minor must receive a copy of this consent form and all attachments. The parent(s)/guardian(s) must sign the form to acknowledge the potential risks and indicate permission for the minor to participate in the study.
 - 3) An “Authorization To Provide Medical Care In Case Of Emergency” is required by Minneapolis VAHCS for all minors. This form must be filled out and signed by the parent(s) or legal guardian(s). A copy of this form must be provided to the sponsoring PI.
 - 4) The sponsoring PI will submit the signed, completed consent form (including all attachments) AND a copy of the signed authorization to provide medical care, along with any other documents normally required to add personnel to a study protocol, to the SRS and other appropriate RDC subcommittee(s) for consideration.
 - 5) If approved by SRS and other relevant RDC subcommittee(s), the request for participation will be sent to the RDC and ACOS/R for final approval.
 - 6) No work may be performed by a minor until both RDC and the ACOS/R have reviewed and approved the proposed work, AND the minor has a signed “Authorization To Provide Medical Care In Case Of Emergency” form on file with the VAHCS.
- e) Approval will be granted on a per-study protocol basis. Approval for participation in one specific study does NOT constitute permission for a minor to participate in any other study protocol or procedure, whether conducted by the sponsoring PI or not.
- f) Approval will be granted or denied based upon the specific qualifications of the minor, the hazards identified for the study, and the prior experience of the sponsoring PI. The RDC, RDC subcommittees (IACUC, IRB, and SRS), and ACOS/R each individually reserve the right to decline approval for:
 - i) Any individual minor;
 - ii) Any individual study;
 - iii) Any individual procedure within a given study; or
 - iv) Any participation by minors in a study conducted by a specific PI.
- g) Under no circumstances will the RDC or ACOS/R approve work by a minor, or working conditions for a minor, which are not allowed under State or Federal child labor law regulations. Specifically, minors in Research service may not:
 - i) Be given electronic access to any individually-identifiable information, such as VistA/CPRS, in the performance of their voluntary duties, per VHA Directive 1605.01 § 33.b. Minors may be given verbal or paper individually-identifiable information after the completion of privacy training.
 - ii) Perform any work between the hours of 11 PM to 5 AM on school days for high school students, per 2014 MN Stat § 181A.04;
 - iii) Perform work with explosives, per MN Administrative Rules 5200.0910 and 29 CFR § 570.51;

- iv) Perform any work where exposure to ionizing radiation would exceed 0.5 rem per year, per 29 CFR § 570.57.
- h) The ACOS/R, RDC, and RDC Subcommittees reserve the right to revoke permission for participation of a minor at any time.

5. REFERENCES:

VHA Directive 1605.01 “Privacy and Release of Information” (31 August 2016)
Minors Working in Medical Research consent form (attached) (07/27/2015)
United States Child Labor Regulations, 29 CFR § 570
Minnesota Administrative Rules 5200.0910 (Prohibited Employments of Minors Under 18 Years Old)
2014 Minnesota Statutes 181A.04 (Minimum Age and Maximum Hours)
2014 Minnesota Statutes 645.45(14) (Age of Legal Majority)

6. R&D COMMITTEE APPROVAL: 07 August 2018

7. RECISSIONS: Minneapolis Research Service SOP R&D-015 “Policy for Minors in Research” (01 May 2018)

8. EXPIRATION DATE: N/A

9. FOLLOW-UP RESPONSIBILITY: Research and Development (R&D) Committee

Minors Working in Medical Research – Minneapolis VA Health Care System

This clearance request must be completed for any minor working in Research Service at the Minneapolis VA Health Care System prior to the start of any work (paid or non-paid). Federal, state, and institutional policies do not allow minors to work in, with, or around chemicals, biological agents, radiation, equipment, or animals unless appropriate clearance is granted and health and safety concerns are addressed. No work will be approved that is not allowed under State or Federal regulations.

Principal Investigator (PI):	Email Address:	Phone:
Minor Name:		Birth Date:
Parent or Legal Guardian		Phone (emergency only)
Proposed Start Date:		End Date:
Minor will work in: (Check all that apply)		
<input type="checkbox"/> Human Subjects studies <input type="checkbox"/> BSL-1 Laboratory <input type="checkbox"/> BSL-2 Laboratory <input type="checkbox"/> Animal Laboratory		

Indicate all hazards to which minor will be exposed if participating in this research project:

A. Biological Hazards	<input type="checkbox"/> Yes <input type="checkbox"/> No
Microbiological or viral agents, pathogens, toxins, or select agents as defined in Title 42 Code of Federal Regulations If yes, specify:	
B. Human or Animal Cell/Tissue samples	<input type="checkbox"/> Yes <input type="checkbox"/> No
(Cultures, tissues, blood, other bodily fluids, cell lines, etc.) If yes, specify:	
C. Recombinant DNA	<input type="checkbox"/> Yes <input type="checkbox"/> No
(Deoxyribonucleic acid, including PCR and transgenic organisms) If yes, specify:	
D. Hazardous Chemicals	<input type="checkbox"/> Yes <input type="checkbox"/> No
If yes, specify: <div style="display: flex; justify-content: space-between;"> <div> <input type="checkbox"/> Toxic chemicals (including heavy metals) <input type="checkbox"/> Flammable, explosive* or corrosive chemicals <input type="checkbox"/> Carcinogenic, mutagenic, teratogenic chemicals <input type="checkbox"/> Toxic compressed gases </div> <div> <input type="checkbox"/> Acetylcholinesterase inhibitors/neurotoxins <input type="checkbox"/> Nanomaterials <input type="checkbox"/> Pharmaceuticals (in a non-clinical setting) *Work with explosives <u>will not</u> be allowed (29 CFR § 570.51) </div> </div>	
E. Controlled Substances	<input type="checkbox"/> Yes <input type="checkbox"/> No
If yes, specify:	
F. Radiation	<input type="checkbox"/> Yes <input type="checkbox"/> No
If yes, specify: <div style="display: flex; justify-content: space-between;"> <div> Ionizing: <input type="checkbox"/> Radioactive materials* <input type="checkbox"/> Radiation-generating equipment* *Annual exposure <u>cannot</u> exceed 0.5 rem (29 CFR § 570.57) </div> <div> Non-ionizing: <input type="checkbox"/> Ultraviolet light <input type="checkbox"/> Lasers (class 3b or class 4) <input type="checkbox"/> Radiofrequency or microwave sources </div> </div>	
G. Physical Hazards	<input type="checkbox"/> Yes <input type="checkbox"/> No
If yes, specify:	

The following signatures indicate acknowledgement of the information listed above and are required before minor begins work.

Investigator

Date

Parent or Legal Guardian

Date

Minors Working in Medical Research – Minneapolis VA Health Care System

A detailed description of work to be performed **MUST** be attached to this form and provided to parent/guardian

An authorization to provide medical care in case of emergency is required by VAHCS for all minors

Minors Working in Medical Research – Minneapolis VA Health Care System

Description of Proposed Work

Instructions to PI: In lay language, describe the proposed work to be conducted by the minor named on Page 1 of this form. For each potential hazard identified on Page 1 (A through G), provide a description of the hazard, including enough information of the nature and purpose of the potential dangers for the parent(s) or legal guardian(s) to make an informed decision on behalf of the minor. Attach additional pages if necessary.

Minors Working in Medical Research – Minneapolis VA Health Care System Approval to Conduct Work in Research Service

I am requesting participation of a minor in my VA research project. I agree to act as the sponsoring PI for this individual as outlined in SOP Res Svc-R&D-013 "Policy for Minors in Research," and understand that I will remain responsible for his/her conduct, supervision, and training. I assert that he/she will be under adult supervision when conducting work in secure areas, working with hazardous materials, or working in hazardous environments. I further agree that the minor will not be allowed to perform work for which he/she has not received training, work has not been approved by his/her parent or legal guardian, the R&D Committee, and the ACOS/R, or work that is not allowed for minors under State of Minnesota or Federal regulations.

	Protocol number:
Protocol Title:	

Signed:

Date _____

Approval:

SRS ☐ Approved ☐ Disapproved

R&D ☐ Approved ☐ Disapproved

Chair, SRS
Date

Chair, R&D Committee
Date

ACOS ☐ Approved ☐ Disapproved

Associate Chief of Staff/Research
Date