Annual Report on Human Subjects Research

State Fiscal Year 2020

To the Governor and the General Assembly of Virginia

July 13, 2020
Virginia Department for Aging and Rehabilitative Services
Human Research Review Committee
2020 Annual Report

The Code of Virginia §51.5-132 directs the Department for Aging and Rehabilitative Services' (DARS) Human Research Review Committee (HRRC) to submit to the Governor, the General Assembly, and the DARS Commissioner, at least annually, a report on the human research projects reviewed and approved by the HRRC, including any significant deviations from the research applications as approved by the Committee. The HRRC has internal oversight responsibilities for ensuring protection of the rights and welfare of DARS clients and employees who volunteer to participate in research conducted or authorized by DARS. The DARS Commissioner established the HRRC in August 2000 to review and approve research proposed or authorized by DARS, the Wilson Workforce and Rehabilitation Center (WWRC), Centers for Independent Living and Employment Services Organizations that have a vendor relationship with DARS.


The HRRC conducts three types of reviews: Exempt Review (regulatory oversight not required), Expedited Review (application reviewed and approved by one or more HRRC members) and Full Committee Review (a quorum of members in attendance). There was one (1) new application reviewed during the State Fiscal Year 2020. The HRRC conducted five (5) reviews to previously approved studies, and there were two (2) study closures.

To the best of the Committee's knowledge, the HRRC reviewed all research involving human volunteers conducted or authorized by DARS or the WWRC during SFY 2020. The HRRC has no evidence suggesting that there were any significant deviations from study procedures as approved by the HRRC for the studies reviewed and approved by the DARS HRRC during SFY 2020.

Composition of the HRRC is governed by 22 VAC 30-40-60 and 45 CFR 46.107. As of July 1, 2020, the HRRC had seven members and one alternate.

This document is the HRRC's twentieth Annual Report. I wish to express my appreciation to the members of the HRRC for their commitment to supporting this important endeavor.

Kathryn A. Hayfield
Commissioner
During State Fiscal Year (SFY) 2020, the Virginia Department for Aging and Rehabilitative Service, Human Research Review Committee reviewed eight (8) applications.

SFY 2020 Research Applications

<table>
<thead>
<tr>
<th>Study Title</th>
<th>Principal Investigator</th>
<th>Review Type</th>
<th>Control Number</th>
<th>Expiration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effects of Knowledge Translation Methods on VR Counselors Providing Pre-ETS to Youth with Significant Disabilities 14-16 Years of Age: A Pilot RCT.</td>
<td>Elizabeth Getzel VCU</td>
<td>Expedited</td>
<td>SFY20-001</td>
<td>September 10, 2021</td>
</tr>
</tbody>
</table>

Studies Continued/Amended

<table>
<thead>
<tr>
<th>Study Title</th>
<th>Principal Investigator</th>
<th>Review Type</th>
<th>Control Number</th>
<th>Expiration</th>
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<tbody>
<tr>
<td>Longitudinal Administrative Rehabilitation on Occupational Data Repository (LARDOR)</td>
<td>Robert Schmidt, Ph.D. U of R</td>
<td>Continuing Review / Amended (Uof R Review)</td>
<td>SFY09-001</td>
<td>September 10, 2021</td>
</tr>
<tr>
<td>Assessing Longitudinal Employment Impacts of DRS Service Provision 2</td>
<td>Robert Schmidt, Ph.D. U of R</td>
<td>Continuing Review Amended (Uof R Review)</td>
<td>SFY09-002</td>
<td>September 10, 2021</td>
</tr>
<tr>
<td>Pathways to Careers Initiative</td>
<td>Ms. Gina Livermore Mathematica</td>
<td>Expedited</td>
<td>SFY17-004</td>
<td>September 30, 2020</td>
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<tr>
<td>Effects of a 9-month Internship Intervention for Military Dependents with ASD</td>
<td>Paul Wehman, Ph.D. / Carol M. Schall, Ph.D. VCU</td>
<td>Expedited</td>
<td>SFY17-005</td>
<td>December, 21, 2020</td>
</tr>
</tbody>
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1. The DARS HRRC has in place a Memorandum of Understanding with the University of Richmond Institutional Review Board (IRB) to act as the IRB of record for SFY09-001 and SFY09-002 and the research protocols of Dr. Robert Schmidt.

2. The DARS HRRC has in place a Memorandum of Understanding with the University of Richmond Institutional Review Board (IRB) to act as the IRB of record for SFY09-001 and SFY09-002 and the research protocols of Dr. Robert Schmidt.

**Studies Closed During State Fiscal Year 2020**

<table>
<thead>
<tr>
<th>Effects of a Customized Employment Intervention on the Employment Outcomes of Youth with Intellectual Disabilities and/or Autism Spectrum Disorders</th>
<th>Dr. Katherine Inge VCU</th>
<th>Expedited</th>
<th>SFY17-006</th>
<th>February 18, 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Effect of BST with In Situ Training on the Acquisition of Social Skills for Working Interning Youth and Young Adults with ASD&quot;</td>
<td>Carol M. Schall, Ph.D./ Dr. Yaoying Xu VCU</td>
<td>Expedited</td>
<td>SFY19-002</td>
<td>June 29, 2020</td>
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