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| **Annual Report on Human Subjects Research** |
| **State Fiscal Year 2017** |
| **To the Governor and the General Assembly of Virginia**  **July 2017** |

**Virginia Department for Aging and Rehabilitative Services**

**Human Research Review Committee**

**2017 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 to be conducted or authorized by DARS, the Wilson Workforce and Rehabilitation Center (WWRC), and Centers for Independent Living and Employment Services Organizations that have a vendor relationship with DARS.

The HRRC also complies with federal requirements for the *Protection of Human Subjects* (45 CFR 46). The U.S. Department of Health and Human Services approved the HRRC Federal wide Assurance (FWA#00008936) beginning August 15, 2005. The FWA is currently effective through June 23, 2020.

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). Five new applications were reviewed during the State Fiscal Year 2017, and 4 were approved by Expedited Review, 1 by Exempt review. The HRRC also conducted six continuing/amended reviews to previously approved studies, and received two study closures.

To the best of the Committee’s knowledge, all research involving human volunteers conducted or authorized by DARS or the WWRC during SFY 2017 was reviewed by the HRRC. The HRRC has no evidence suggesting that there were any significant deviations from study procedures as approved by the HRRC for the studies that were reviewed and approved by the DARS HRRC during SFY 2017.

Composition of the HRRC is governed by 22 VAC 30-40-60 and 45 CFR 46.107. As of June 30, 2017, the HRRC had seven members and one alternate.

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



James A. Rothrock

Commissioner

During State Fiscal Year (SFY) 2017, the Virginia Department for Aging and Rehabilitative Service, Human Research Review Committee reviewed 12 applications.

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| **SFY 2017 Research Application Requests** | |
| Studies that Received Initial Approval | 5 |
| Studies that were Amended / Continued | 6 |
| Studies that were Closed | 2 |
| Studies that were Cancelled or Withdrawn | 1 |
| **TOTAL** | **14** |

# **Studies Receiving Initial Approval during SFY2017**

| Study Title | Principal Investigator | Type of Review | Control Number | Expiration Date |
| --- | --- | --- | --- | --- |
| The Effect of Occupational Therapy Intervention Group on Travelers with Disabilities | Ms. Courtney Halsey – Mary Baldwin University | Exempted | SFY17-001 | N/A |
| Perceptions of Law Enforcement by Families of Individuals with Disabilities. | Eric S. Snow – Radford University | Expedited | SFY17-002 | PI Withdrew Application  (9/15/2016) |
| Vacant (Proposal not HSR) | Vacant | Vacant | SFY17-003 | N/A |
| Pathways to Careers Initiative | Ms. Gina Livermore - Mathematica | Expedited | SFY17-004 | November 22, 2017 |
| Effects of a 9-month Internship Intervention for Military Dependents with ASD | Paul Wehman, Ph.D. / Carol M. Schall, Ph.D.  VCU | Expedited | SFY17-005 | December, 21, 2017 |
| Effects of a Customized Employment Intervention on the Employment Outcomes of Youth with Intellectual Disabilities and/or Autism Spectrum Disorders | Dr. Katherine Inge -VCU | Expedited | SFY17-006 | February 18, 2018 |

**Studies Continued/Amended**

| Study Title | Principal Investigator | Type of Review | Control Number | Expiration Date |
| --- | --- | --- | --- | --- |
| Vocational Rehabilitation Counselors’ Experiences with Clients who have Autism Spectrum Disorders | Dr. Kim Murza, University of Northern Colorado | Exempted | SFY15-001 | N/A |
| Commonwealth of Virginia State Agency and Provider Survey of Neurobehavioral Services and Support | Dr. Cynthia O ’Donoghue - , James Madison University | Expedited / CR | SFY15-002 | September 30, 2017 |
| Effectiveness of Knowledge Translation Strategies to Promote Supported Employment Knowledge and Outcomes | Katherine J. Inge, PhD  VCU | Expedited  /CR | SFY14-002 | September 30, 2017 |
| Facilitating Employment for Youth with Autism: A Replication Study of an Internship Model to Identify Evidence Based Research Practices | Paul Wehman, Ph.D. / Carol M. Schall, Ph.D.  VCU | Expedited  /CR | SFY13-003 | October 15, 2017 |
| Longitudinal Administrative Rehabilitation on Occupational Data Repository (LARDOR) [[1]](#footnote-1) | Robert Schmidt, Ph.D.  UofR | Continuing/  Amended  (U of R Review) | SFY09-001 | September 10, 2017 |
| Assessing Longitudinal Employment Impacts of DRS Service Provision [[2]](#footnote-2) | Robert Schmidt,  Ph.D.  UofR | Continuing/  Amended  (U of R Review) | SFY09-002 | September 10, 2017 |

**Studies Closed During State Fiscal Year 2017**

| Study Title | Principal Investigator | Control Number | Closure Date | |
| --- | --- | --- | --- | --- |
| The Impacts of Wraparound Supports on the Rehabilitation of Individuals with Disabilities | Kristen Chesser - WWRC | SFY16-001 | | June 16, 2016 |
| The Effects of Occupational Therapy Intervention Group on Travelers with Disabilities | Ms. Courtney C. Halsey – Mary Baldwin University | SFY17-001 | | April 14, 2017 |

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. [↑](#footnote-ref-1)
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. [↑](#footnote-ref-2)