

## **Guidance on the Local Human Rights Committee Review Requirements under 12VAC35-115-130.Research.**

### **Purpose:**

In Virginia, 12VAC35-115-130 is a state law that addresses the protection of human research subjects. This law is vital for researchers, institutions, and Institutional Review Boards (IRBs) involved in conducting research involving human participants. Thus, this guidance has two aims:

1. To provide a clear set of instructions to the research community (i.e., principal investigator, research coordinators, and other research personnel) involved in conducting human subject research under the licensure of Virginia Commonwealth University's inpatient psychiatric units.
2. To explain how 12VAC35-115-130 relates to the Institutional Review Board (IRB) process and the ethical considerations that researchers must uphold when conducting human subject research.

### **Background:**

The state law is designed to protect the rights, safety, and welfare of human research subjects involved in studies conducted under the auspices of the Commonwealth of Virginia via the oversight of a local human rights committee review (LHRC).

Researchers, IRBs, and institutions involved in human subject research in Virginia must adhere to the provisions outlined in 12VAC35-115-130 to ensure ethical conduct and compliance with state regulations related to human subjects research.

### **Applicable:**

12VAC35-115-130. Research. Virginia administrative code applies to all individuals who are receiving services from a public or private provider of services operated, licensed, or funded by the Department of Behavioral Health and Developmental Services (DBHDS), **except** those operated by the Department of Corrections. At Virginia Commonwealth University, the following inpatient units impacted by this administrative code are as follows:

- Children's Hospital of Richmond at VCU, Virginia Treatment Center for Children
- VCU Medical Center North Hospital Psychiatric Inpatient Units

### **Guidance:**

*Local Human Rights Committee*

The LHRC in Virginia reviews human subject research to ensure the protection and welfare of individuals with intellectual and developmental disabilities who may be considered vulnerable populations. Here's how and when the LHRC typically reviews human subject research:

1. Scope of Review:

Section 37.2-400 of the Code of Virginia requires the State DBHDS Board to promulgate these regulations to further define and to protect the rights of individuals receiving services from providers of mental health, developmental, and substance abuse services in the Commonwealth of Virginia. The LHRC reviews research studies carried out within DBHDS-licensed facilities as part of this process.

2. Prior to Research Initiation (i.e., Starting Research Activities):

Researchers planning to conduct human subject research involving individuals receiving services from providers of mental health, developmental, and substance abuse services licensed by the DBHDS must submit their research protocols to the committee for review and approval. This process typically occurs before the research begins at the research site but after the IRB of Record issues IRB approval.

3. Evaluation of Ethical Considerations:

The LHRC assesses the research proposal based on 12VAC35-115-10. Code of Virginia which authorizes these regulations to further define and protect the rights of individuals receiving services from providers of mental health, developmental, or substance abuse services in Virginia.

4. Ongoing Monitoring:

The LHRC may continue to monitor the research throughout its duration to ensure that the researchers adhere to the approved protocol and that the rights and welfare of the participants are upheld.

5. Reporting Adverse Events:

Researchers are obligated to promptly report any adverse events or unanticipated problems that may occur during the course of the research. The LHRC may review and provide guidance on addressing and preventing such occurrences in the future.

## 6. Collaboration with Institutional Review Boards (IRBs):

LHRC may work in conjunction with the IRBs of the institutions or organizations conducting the research to ensure a comprehensive review process and compliance with relevant regulations and ethical guidelines. However, LHRCs are independent of the IRB of Record and are managed under the authority of the Virginia Department of Behavioral Health and Developmental Services.

For more information on the LHRCs point of contact and meeting dates, please go to the Department of Behavioral Health and Developmental Services [website](#).

The Local Human Rights Committee in Virginia is crucial in safeguarding the rights and welfare of individuals with intellectual and developmental disabilities who reside in certain facilities. By reviewing and approving research protocols involving this vulnerable population, the LHRC helps ensure that research conducted within its jurisdiction adheres to ethical standards and promotes the well-being of human subjects. Researchers should collaborate closely with the LHRC and any applicable IRBs to facilitate the ethical and regulatory review of their human subject research endeavors.

### **Definitions:**

1. The Local Human Rights Committees: LHRCs are independent committees that consist of people who are not affiliated with the facility/organization conducting the research and represent consumer, family, advocacy and external health providers.