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**Instructions for LHRC Review of Human Research:**

Applicable Definitions (12VAC35-115-30):

"**Human research**" means any systematic investigation, including research development, testing, and evaluation, utilizing human subjects, that is designed to develop or contribute to generalized knowledge. Human research shall not include research exempt from federal research regulations pursuant to 45 CFR 46.101(b).

"**Informed consent**" means the voluntary written agreement of an individual, or that individual's authorized representative, to surgery, electroconvulsive treatment, use of psychotropic medications, or any other treatment or service that poses a risk of harm greater than that ordinarily encountered in daily life or for participation in human research. To be voluntary, informed consent must be given freely and without undue inducement; any element of force, fraud, deceit, or duress; or any form of constraint or coercion.

The provider is responsible for notifying the Office of Human Rights concerning participation by individuals in any human research project in accordance with 12VAC35-115-130. Upon request, the assigned Advocate will review with the provider regulatory requirements for the Human Research review/update, provide a copy of the corresponding LHRC Review Form, and provide information about upcoming scheduled LHRC meetings in the region.

Providers are responsible for ensuring the protection of individuals PHI by using an “Individual Identifier”, listed as the individual’s first and last name *initials* in the space provided on the LHRC Review Request Form. **All documents submitted for review should be appropriately \**redacted* by the provider (\*removal of or unreadable Personal Identified Information (PII) or Protected Health Information (PHI).** When PII or PHI is necessary to the review process, the LHRC will conduct the review with the provider and all parties involved in Executive Closed session.

The LHRC Chairperson will sign the LHRC Review Request Form (electronic signature is acceptable) and give a copy to the provider following the LHRC meeting. The final signed version should be maintained in the individual's services record. When applicable, the date for an update of the research project will be listed on the LHRC Review Request Form and reflected in the LHRC meeting minutes. The provider Director or designee is responsible for compliance with this request, in accordance with the corresponding Human Rights Regulations. Providers may direct questions regarding this process to the assigned Advocate.

**Attachments should include the following (see also 12VAC35-115-130):**

* **Evidence of informed consent for individuals impacted**
* **Evidence of review and approval from an institutional review board or research review committee (either as a separate document or signature on this form)**
* **Provider Human Research Protocol or Policy**

For general questions about the LHRC Review process, contact the OHR Regional Manager in your area:

Region 1: Cassie Purtlebaugh [cassie.purtlebaugh@dbhds.virginia.gov](mailto:cassie.purtlebaugh@dbhds.virginia.gov)

Region 2: Diana Atcha [diana.atcha@dbhds.virginia.gov](mailto:deborah.lochart@dbhds.virginia.gov)

Region 3: Mandy Crowder [mandy.crowder@dbhds.virginia.gov](mailto:mandy.crowder@dbhds.virginia.gov)

Region 4: Andrea Milhouse [andrea.milhouse@dbhds.virginia.gov](mailto:andrea.milhouse@dbhds.virginia.gov)

Region 5: Latoya Wilborne [latoya.wilborne@dbhds.virginia.gov](mailto:latoya.wilborne@dbhds.virginia.gov)

Facilities: Brandon Charles [brandon.charles@dbhds.virginia.gov](mailto:brandon.charles@dbhds.virginia.gov)

For information about LHRC meeting dates, times and locations by Region:

<http://www.dbhds.virginia.gov/quality-management/human-rights>

**Human Research – Notification/Update for LHRC Review**

**Section 1 – To be completed by the Provider**

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| --- | --- |
| Provider Name & Contact Information (*email or phone*): | Type here |
| Does the human research project involve human research as defined under the human rights regulations ([12VAC35-115-130](https://law.lis.virginia.gov/admincode/title12/agency35/chapter115/section30/))? If yes, provider Human Research Protocol/Policy is attached. | Yes  No |
| Date approved by the Institutional Review Board (IRB) or Research Review Committee (RCC): | Click here to select date |
| Type of LHRC Review: | New  Periodic Review |

**Section 2 – To be completed by the LHRC**

|  |  |
| --- | --- |
| Does the human research project involve human research as defined under the human rights regulations ([12VAC35-115-130](https://law.lis.virginia.gov/admincode/title12/agency35/chapter115/section30/))? | Yes  No |
| Does the provider Human Research Protocol/Policy require informed consent as defined under the human rights regulations ([12VAC35-115-130](https://law.lis.virginia.gov/admincode/title12/agency35/chapter115/section30/)) to be obtained from the individual(s) or authorized representative(s*) prior* to participating in the human research project, in accordance with chapter [12VAC35-115-130(B)(1)](https://law.lis.virginia.gov/admincode/title12/agency35/chapter115/section130/)? | Yes  No |
| Does the provider Human Research Protocol/Policy require a copy of the IRB/ RRC approved human research documentation be made available for review by the individual(s) or their authorized representative(s), upon request, in accordance with chapter [12VAC35-115-130(B)(3)](https://law.lis.virginia.gov/admincode/title12/agency35/chapter115/section130/)? | Yes  No |
| Was there approval from an IRB/ RRC obtained, prior to the provider performing or the individual(s) participating in the human research project, in accordance with chapter [12VAC35-115-130(B)(3)](https://law.lis.virginia.gov/admincode/title12/agency35/chapter115/section130/)? | Yes  No  N/A research has not begun |
| Did the LHRC receive notification and a copy of the IRB/ RRC approval prior to the individual’s participation in the human research project, in accordance with chapter [12VAC35-115-130(B)(4)](https://law.lis.virginia.gov/admincode/title12/agency35/chapter115/section130/)? | Yes  No |

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| LHRC Recommendations and Acknowledgments |
| Based on the information provided an authority granted to the LHRC by [12VAC35-115-130](https://law.lis.virginia.gov/admincode/title12/agency35/chapter115/section130/): |
| The LHRC acknowledges that the provider Human Research Protocol/Policy is in compliance with the Human Rights Regulations. |
| The LHRC acknowledges that the provider Human Research Protocol/Policy is being implemented in accordance with the Human Rights Regulations and requests that the provider return for a periodic update on the status of individual(s) participation on: Click here to select date |
| ☐ The LHRC acknowledges that the provider human research protocol is not in compliance with the Human Rights Regulations and requests that the provider present evidence of compliance at the next scheduled meeting on: Click here to select date |

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Name of LHRC LHRC Chairperson Signature Date