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| --- | --- |
| Provider name/contact information: |  |
| Date of Research Protocol: |  |
| Date approved by Institutional Review Board (IRB) or Research Review Committee (RRC): |  |
| IRB/ RRC Chair signature or indicate signed document attached: |  |
| Date reviewed by LHRC: |  |
| Type of plan: |
|  | [ ]  | New  |  [ ]  | Periodical review |  |  |  |

Date(s):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| Does the protocol involve human research as defined under the human rights regulations? If yes, the Human Research Protocol (HRP) must be submitted to the LHRC for review under chapter 12VAC35-115-130.  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | [ ]  | Yes | [ ]  | No |

 |
| Was there informed consent obtained from the individual or authorized representative prior to participating in the HRP, in accordance with chapter 12VAC35-115-130B1?  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | [ ]  | Yes | [ ]  | No |

 |
| Was there approval from an IRB/ RRC obtained, prior to performing or participating in the HRP, in accordance with chapter 12VAC35-115-130B3? |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | [ ]  | Yes | [ ]  | No |

 |
| Did the LHRC receive notification and a copy of the IRB/ RRC human research protocol approval prior to the individual’s participation in the HRP, in accordance with chapter 12VAC35-115-130B4? Is there a copy of the IRB/ RRC approved human research protocol documentation available for review by the individual or their authorized representative, upon request, in accordance with chapter 12VAC35-115-130B3? |

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|  | [ ]  | Yes | [ ]  | No |

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| [ ]  | Yes | [ ]  | No |

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| Goal(s) of Human Research Protocol | Comments on Individual’s Participation | Outcome: |
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If requested by the LHRC or otherwise required by regulation, indicate date of planned update: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |
| --- | --- |
|  Name of LHRC |  LHRC Chairperson Signature |

Form Last Updated:6/17/2020

Instructions for LHRC Review of Human Research:

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 individuals first and last name *initials* in the space provided on the LHRC Review Request Form. When 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 and give a copy to the provider following the LHRC meeting. 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)**

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

Region 2, Ann Pascoe ann.pascoe@dbhds.virginia.gov

Region 3, Jennifer Kovack jennifer.kovack@dbhds.virginia.gov

Region 4, Sharae Henderson sharae.henderson@dbhds.virginia.gov

Region 5, Reginald Daye reginald.daye@dbhds.virginia.gov

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

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