

LCCS POLICY 176

Human Subject Research

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| See new Policy #: | |

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| Scope: | All LCCS staff & Substitute Care Providers |
| Responsibility: | Executive Director, All Administrative staff |
| Purpose: | To provide guidelines for staff & Substitute Care Providers' participation in human subject research studies/projects. |
| Legal Cite: | OAC 5101:2-5-13 (A) (21); OAC 5101: 2-33-21 |

POLICY STATEMENT

In the interest of gaining knowledge LCCS supports human subject research under the conditions addressed in this policy.

PROCEDURE - including required timeframes and documentation

Staff or substitute care providers participation in human subject research studies/projects requires the informed, written consent of the Executive Director, who may agree to the dissemination of information to a researcher in the area of child welfare, if the information is determined to be relevant to the researcher, and the results of the research will be beneficial to LCCS. Authorization of the dissemination shall be documented.

No direct access to SACWIS or any other state of Ohio database shall be approved for or granted to, any researcher. LCCS shall disclose only the minimum information needed by the researcher to perform the study, and, prior to disseminating information to any researcher, the PCSA shall require the researcher to sign an agreement which addresses all of the following:

- (1) The researcher shall not disseminate confidential information containing names or data by which any individual or out-of-home care setting could be identified or deductively inferred.
- (2) LCCS will review the research prior to its dissemination or publication to ensure that the research is void of names or data by which any individual or out-of-home care setting could be identified or deductively inferred.

(3) The researcher shall accept liability for unauthorized dissemination of information.

Any researcher, including LCCS staff or substitute care providers who are conducting research, wanting LCCS staff/substitute care providers to participate in human subject research must provide a written description of the proposed research and rationale for participation to the Executive Director to initiate the consent/approval process. The requirement to seek consent also includes situations in which the proposed research would impact the business of the agency, utilize agency materials, equipment and/or staff/substitute care provider time or if the employee/substitute care provider receives any type of agency related compensation, including disability payments.

If the request for consent is initiated by an LCCS employee/substitute care provider who is conducting the research, it must be channeled through the employee's/substitute care providers' chain-of-command. The researcher submitting the consent request must answer any subsequent questions the Executive Director might have once the consent request has been made.

If the employee/substitute care provider receives a request to participate in a human subjects research study/project from a researcher, he/she is to inform the researcher of the process for requesting consent and direct him/her to request same.

The Executive Director will respond, in writing, to any consent request made by a researcher and indicate his/her approval or denial along with any restrictions or other stipulations. As appropriate, the Executive Director will also inform staff/substitute care providers who would be eligible to participate, given his/her approval, restrictions and stipulations.

Approval from the Executive Director for consent must be obtained prior to the initiation of any research activities.

All human subject research studies/projects sent to the Executive Director for consent/approval must meet accepted guidelines/standards and ethical principles set by, at least, the U.S. Department of Health and Human Services, Office for Human Research Protections, Federal Policy for the Protection of Human Subjects (often referred to as the "Common Rule") and The Belmont Report.

At a minimum, any human subject research must embody the following principles:

- Participation by human subjects must always be voluntary;
- Adequate standards of informed consent must always be utilized;
- The privacy of human subjects and the confidentiality of information must be protected.

CASE PRACTICE GUIDES

Children in agency custody will not be involved in human subject research studies/projects under any conditions.

When an individual, agency, or organization is conducting research on the area of child welfare, LCCS shall determine what information is appropriate to make available to the researcher. Information provided by LCCS shall remain the property of LCCS.

RELATED POLICIES and FORMS

LCCS Policy 662 (Treatment of Children by Out-of-Home Caregivers)