

October 23, 2020

Principal Investigator: Dallas Elgin, PhD

Sponsor: Administration of Children and Families

Protocol Number: ACF-01

Study Title: "Human Services Programs in Rural Contexts Study"

Dear Dr. Elgin:

The above-referenced study has been determined by Michael Aldridge, PhD to be exempt according to 45 CFR 46.104:

Exempt Category #5

Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

In addition, the informed consent was reviewed as part of the exempt application.

RESPONSIBILITIES OF PRINCIPAL INVESTIGATOR:

- (1) Submit for review by IntegReview all modifications to the protocol or consent form(s), when applicable, if planned changes to an exempt study might make that study non-exempt from human subject's research, prior to the implementation of the change;
- (2) Protect the confidentiality of all personally identifiable information collected and train your staff and collaborators on policies and procedures for ensuring confidentiality of this information;

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Tel. 512.326.3001 Local Fax. 512.697.0085 http://www.integreview.com





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If you have any questions please feel free to contact our office at 512-326-3001.

Sincerely, Victoria Govea, CCRP Director of Operations

Electronically signed by Victoria Govea, CCRP on 10/26/2020 10:13:28 AM

Note: Electronic signature above is a Part 11 compliant signature produced via IRBManager.