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RULE SUMMARY

Texas A&M AgriLife Extension Service (AgriLife Extension) will comply with all applicable laws and regulations relating to human subjects in research including 45 C.F.R., Part 46 and 21 C.F.R., Parts 50 and 56. AgriLife Extension assures that all its research involving human subjects will comply with the terms of its Federal-wide Assurance (FWA) for Protection of Human Subjects. This commitment to comply with the Common Rule (46 C.F.R, Part 46, Subpart A) will apply to all non-exempt human subjects research that AgriLife Extension is engaged in that is federally funded.

This rule is required by System Regulation *15.99.01, Use of Human Subjects in Research*, and is developed to ensure compliance with federal and state laws and regulations, and agency procedures applicable to the protection of human research subjects, including the ethical principles and standards of the Belmont Report, April 18, 1979, for the protection of human subjects of research.

PROCEDURES AND RESPONSIBILITIES

1.0 GENERAL

- 1.1 All AgriLife Extension's activities related to human subjects research, regardless of the source of funding, will be guided by ethical principles and guidelines set forth in the Belmont Report the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.
- 1.2 AgriLife Extension will obtain a Federal-wide Assurance (FWA) with the U.S. Department of Health and Human Services' Office of Human Research Protections (OHRP). In accordance with 45 C.F.R. §46.103(b), the AgriLife Extension Director is the official authorized to act for AgriLife Extension and to assume on behalf of AgriLife Extension the obligations imposed under AgriLife Extension's FWA.
- 1.3 All research activities involving human subjects that are overseen and conducted under the auspices of AgriLife Extension, regardless of the location of the research activities, including cooperative research involving more than one institution, must be reviewed and approved by Texas A&M University's (Texas A&M) Institutional Review Board (IRB) prior to initiation of the research to ensure that it is conducted in accordance with applicable laws and regulations, agency and university rules and procedures, and ethical guidelines, including AgriLife Extension's FWA and 45 C.F.R., Part 46 and 21 C.F.R., Parts 50 and 56.
- 1.4 The Texas A&M IRB will register with OHRP and comply with the Common Rule and any other applicable federal or state, laws, regulations, and policies.
- 1.5 In the conduct of cooperative research projects involving more than one institution, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with applicable laws and regulations. Joint review arrangements, where the agency seeks to rely on the review of another qualified IRB, or similar arrangements, must be documented in writing and are subject to approval by Texas A&M IRB.
- 1.6 Texas A&M AgriLife (AgriLife) Ethics and Compliance is the responsible office for compliance associated with AgriLife Extension awards and will closely coordinate with the Texas A&M University Office of Research Compliance and Biosafety, Texas A&M Sponsored Research Services (SRS), the principal investigator (PI), and other appropriate parties in connection with Texas A&M IRB's review and approval.

2.0 PROCEDURES FOR REVIEW AND APPROVAL

- 2.1 AgriLife Extension does not have an internal IRB and designates the Texas A&M IRB for review of all research to which the AgriLife Extension FWA applies as documented in an agreement between AgriLife Extension and Texas A&M that describes the responsibilities of the parties, including the following responsibilities:
- 2.1.1 Texas A&M responsibility to register with OHRP.
 - 2.1.2 Texas A&M responsibility to comply with the Common Rule and any other applicable federal or state, laws, regulations, and policies.
 - 2.1.3 Texas A&M responsibility to document and maintain written IRB policies and procedures reflecting current practices of the IRB in conducting reviews and approval consistent with federal requirements, including those specified in 45 C.F.R., Part 46.
- 2.2 All research conducted under AgriLife Extension, including cooperative research in which human subjects are involved, must be both reviewed and approved by the Texas A&M IRB. For more information regarding the approval process, please refer to the [University Office of Research Compliance and Biosafety website](#).
- 2.3 SRS is responsible for sponsored research administration for AgriLife Extension and will notify AgriLife Ethics and Compliance of all compliance issues for AgriLife Extension involving the use of human subjects in research.
- 2.4 Responsibility for ensuring that all research involving human subjects is submitted to the Texas A&M IRB for review and approval lies with both the PI and unit/department head with support from SRS and AgriLife Ethics and Compliance.
- 2.5 Policies and procedures for criteria, review, and approval by the Texas A&M IRB for research involving human subjects will be conducted in accordance with Texas A&M Rule *15.99.01.M1, Human Subjects in Research*.

3.0 COMPLIANCE

Reports and allegations of noncompliance with applicable laws, policies, regulations, rules, and procedures may be submitted to the, Director for Ethics and Compliance at AgriLife Administrative Services, the [Human Research Protection Program](#) (HRPP) at the Texas A&M Office of Research Compliance and Biosafety, or via the [TAMUS Risk, Fraud, and Misconduct Hotline](#). Any allegation of noncompliance with federal rules on a project with a federal agency-sponsored grant must also be reported to the A&M System chief research compliance officer.

4.0 RECORDKEEPING

Records will be kept in accordance with System Regulation 15.99.01 and AgriLife Extension procedure *61.99.01.X0.01, Retention of State Records*.

RELATED STATUTES, POLICIES, OR REQUIREMENTS

[42 U.S.C §1230d, et seq.](#)

[45 C.F.R., Part 46](#)

21 C.F.R., Parts [50](#), [56](#), [312](#), and [812](#)

[Belmont Report, April 18, 1979](#)

[56 Fed. Reg. 28012, 28022, June 18, 1991, as amended at 70 Fed. Reg. 36328, June 23, 2005](#)

[Texas Government Code §552](#)

[System Regulation 15.99.01, Use of Human Subjects in Research](#)

[System Regulation 61.99.01, Retention of State Records](#)

[University Rule 15.99.01.M1, Human Subjects in Research](#)

[AgriLife Extension Procedure 61.99.01.X0.01, Retention of State Records](#)

CONTACT OFFICE

Questions regarding this rule should be referred to AgriLife Ethics and Compliance at 979-314-3442.

REVISION HISTORY

Approved: March 15, 2013
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