

## Texas A&M AgriLife Research Rules

### 15.99.01.A1 | Human Subjects in Research

*Approved: March 15, 2013*

*Revised: October 3, 2014*

*Next Scheduled Review: October 3, 2019*



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#### **RULE STATEMENT**

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In accordance with The Texas A&M University System (System) Regulation 15.99.01, *Use of Human Subjects in Research*, Texas A&M AgriLife Research (AgriLife Research) will comply with all applicable laws and regulations relating to human subjects in research. AgriLife Research is committed to the protection of human subjects in research conducted by the agency including cooperative research, regardless of the source of funding or whether or not the research is sponsored.

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#### **REASON FOR RULE**

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This rule is required by System Regulation 15.99.01, and is developed to ensure compliance with all applicable ethical principles and standards of the Belmont Report, April 18, 1979, the Code of Federal Regulations, 45 CFR 46 and all other applicable laws and regulations regarding human subjects in research. Additionally, this document establishes formal procedures and guidelines to ensure protection of human subjects in agency research as well as cooperative research.

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#### **PROCEDURES AND RESPONSIBILITIES**

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##### 1.0 GENERAL

- 1.1 In accordance with System Regulation 15.99.01, *Use of Human Subjects in Research*, AgriLife Research will comply with all applicable standards and ethical procedures including the Belmont Report, April 18, 1979, and the Code of Federal Regulations, 45 CFR 46.
- 1.2 Safeguarding methods for individual rights in research will be consistent regardless of location and regardless of the source of funding or whether the research is funded or unfunded.
- 1.3 Texas A&M AgriLife (AgriLife) Risk and Compliance is the responsible office for compliance associated with AgriLife Research awards, and will closely coordinate with the Texas A&M University (TAMU) Office of Research Compliance and Biosafety, System Sponsored Research Services (SRS), the principal investigator (PI), and other appropriate parties in the coordination of Institutional Review Board (IRB) approval.

##### 2.0 PROCEDURES FOR REVIEW AND APPROVAL

- 2.1 All research conducted under AgriLife Research, including cooperative research in which human subjects are involved, must be both reviewed and approved by the TAMU IRB. For more information regarding the approval process, please refer to the [TAMU Office of Research Compliance and Biosafety Web site](#).
- 2.2 SRS is responsible for sponsored research administration for AgriLife Research, and will notify AgriLife Risk and Compliance of all compliance issues for AgriLife Research involving the use of human subjects in research.
- 2.3 Responsibility for ensuring that all research involving human subjects is submitted to the TAMU IRB for review and approval lies with both the PI and unit/department head in coordination with SRS, and AgriLife Risk and Compliance.

2.4 Policies and procedures for criteria, review, and approval by the TAMU IRB for research involving human subjects will be conducted in accordance with TAMU Rule 15.99.01.M1.

### 3.0 COMPLIANCE

Reports and allegations of noncompliance with applicable laws, policies, regulations, rules, and procedures may be submitted to the, Assistant Director for Risk and Compliance at AgriLife Administrative Services, the Human Subjects Protection Program (HSPP) at the TAMU Office of Research Compliance and Biosafety, or via the [TAMUS Risk, Fraud, and Misconduct Hotline](#).

### 4.0 RECORDKEEPING

Records will be kept in accordance with System Regulation 15.99.01 and AgriLife Research procedure 61.99.01.A1.01, *Retention of State Records*.

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## **RELATED STATUTES, POLICIES, OR REQUIREMENTS**

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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*

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

[AgriLife Research Procedure 61.99.01.A1.01](#), *Retention of State Records*

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## **CONTACT OFFICE**

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For additional questions, contact AgriLife Risk and Compliance at 979-845-7879.