

The University of Tennessee Health Science Center

ASSURANCES OF COMPLIANCE WITH FEDERAL REGULATIONS

Effective Date: March 1990

Revised Date: May 2002

As a recipient of federal funds for various research and educational activities, UT Health Science Center is required to file certain Assurances indicating compliance with specific federal regulations. In order to insure that these Assurances are current, filed in a timely manner, and made available to appropriate individuals, the Office of Research Administration is designated as the office responsible for assuring preparation and filing of all Assurances and Certifications, and maintenance of the official copy of record, when applicable.

Included under this policy are all Assurances and Certifications of compliance with regulations and as set forth in the attached Summary.

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UT Health Science Center
SUMMARY OF
DEPARTMENT OF HEALTH AND HUMAN SERVICES ASSURANCES

June 1990

Revised December 2001; March 2010

Applicants for federal grants, loans, contracts, property, discounts, or other financial assistance extended by the Department of Health and Human Services, as well as other federal agencies, are required to submit certain assurances certifying and declaring that they are in compliance with federal regulations, policies, guidelines, and requirements, including 45 CFR use of federal funds for federally assisted projects. For any grant or contract proposal submitted to a federal agency, UTHSC must certify that the assurances and certifications have been filed. The Office of Research Administration is responsible for assuring preparation, filing and maintenance of all assurances and certifications.

I. ASSURANCES

1. Civil Rights Assurance, HHS-441
2. Human Subjects (IRB) Application Materials and DHHS Assurance Form 596
3. Laboratory Animals Used in Research
4. Rehabilitation Act (Handicapped), HHS-641
5. Scientific Integrity (Misconduct), HHS-6315
6. Sex Discrimination, HEW-639A

II. CERTIFICATIONS

- a. Department and Suspension
- b. Drug Free
- c. Federal Debt - Certification of Non-delinquency
- d. Institutional Eligibility
- e. Lobbying

ASSURANCES

1. CIVIL RIGHTS

FORM PHS 441 - Assurance of compliance with Title VI of the Civil Rights Act of 1964.

Officer designated to coordinate efforts to comply with Civil Rights Act: Affirmative Action Director

Signed by: Chancellor

Official Custodian: Research Administration

Copies: Equity and Diversity

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State Agency Compliance

Tennessee Public Chapter 502 requires that effective January 1, 1994, the State Department of Audit will monitor compliance with Title VI by all state agencies.

University-wide Coordinator: Assistant Vice President, Personnel Services

Campus Coordinator: Equity & Diversity Director

Official Custodian: Research Administration

Copies: Equity and Diversity

2. HUMAN SUBJECTS

The PHS Office for Protection from Research Risks (OPRR) requires that all research activities involving human subjects be approved by an Institutional Review Board (IRB) in accordance with Section 474 of the PHS Act as implemented by Title 45, Part 46 of the CFR (45CFR 46 - as revised).

The UTHSC Assurance, Number is FWA00002301. A separate committee reviews research activities involving human subjects at the UT Medical Center at Knoxville and the College of Medicine, Chattanooga Unit, but the same Assurance Number applies to the both entities.

UTHSC:

Officer designated to coordinate efforts to comply: Institutional Review Board Chair

Signed by: Vice Chancellor for Research

Official Custodian: Research Administration

Copies: Institutional Review Board Chair

UT Medical Center at Knoxville:

Officer designated to coordinate efforts to comply: Institutional Review Board Chair
Signed by: Vice Chancellor for Research
Official Custodian: Research Administration

UT College of Medicine, Chattanooga Unit:

Officer designated to coordinate efforts to comply: Institutional Review Board Chair
Signed by: Vice Chancellor for Research
Official Custodian: Research Administration

3. LABORATORY ANIMALS USED IN RESEARCH

The OPRR requires that all activities which involve the use of laboratory animals in research be approved by an institutional Animal Care and Use Committee and that the institution file an Assurance that all such activities have been approved by that committee. UTHSC is fully accredited by the American Association for the Accreditation of Laboratory Animal Care (AAALAC) as a Category 1 institution. UTHSC maintains a current Assurance on file with OPRR (A-3325-01). The University of Tennessee Medical Center at Knoxville is AAALAC accredited and has a separate review committee and a separate assurance number (A 3121-01).

Officer designated to coordinate efforts of compliance: Chair, Department of Comparative Medicine

Signed by: Vice Chancellor for Research

Official Custodian: Research Administration

Copies: Chair, Department of Comparative Medicine, Animal Care and Use Committee Chair

The Animal and Plant Health Inspection Service, U.S. Department of Agriculture (USDA) requires that all institutions which use laboratory animals in research be registered with them and comply with the Animal Welfare Act. The University of Tennessee Health Science Center, has a separate registration with USDA under #63-R-107-01. The Animal Welfare Act requires that all research animal protocols have been approved by an Animal Care and Use Committee appointed by the Institutional Official (the Chancellor) or his designee.

Officer designated to coordinate efforts of compliance: Chair, Department of Comparative Medicine

Signed by: Vice Chancellor for Research

Official Custodian: Research Administration

Copies: Chair, Department of Comparative Medicine, Animal Care and Use Committee Chair

4. REHABILITATION (HANDICAPPED)

FORM PHS 641 - Assurance of compliance with Section 504 of the Rehabilitation Act of 1973, as amended.

Officer designated to coordinate the efforts to comply with the PHS regulations:
Affirmative Action Director

Signed by: Chancellor
Official Custodian: Research Administration
Copies: Equity and Diversity

5. SCIENTIFIC MISCONDUCT

Assurance that an administrative review process has been established and that the reporting requirements of the published scientific misconduct regulations will be followed. Effective January 1, 1990, all institutions must have on file a PHS Form 6315 certifying compliance with federal requirements.

Officer designated to coordinate UTHSC review process: Vice Chancellor for Research

Signed by: UT System

Official Custodian: UT System Associate Vice President for Research

Copies, UTHSC: Deans and Research Administration

6. SEX DISCRIMINATION

FORM 639A - Assurance of compliance with Title IX of the Education Amendments of 1972 and the regulation issued by the Department of Health, Education and Welfare in implementation thereof.

Officer designated to coordinate the efforts of compliance: Equity & Diversity Director

Signed by: Chancellor

Official Custodian: Research Administration

Copies: Equity & Diversity

CERTIFICATIONS

The following additional certifications are required although at present no assurance form is filed. On grant applications, these are indicated by checking the appropriate boxes on the "check-list" page of the application (PHS398). These certifications are verified by the signature of the official signing for the applicant organization on the face page of the application. The UTHSC certifications cover also the UT Medical Center at Knoxville.

a. Debarment/Suspension:

Certification that neither the institution nor its principals are presently debarred, suspended, proposed for debarment, declared ineligible or voluntarily excluded from covered transactions by any federal department or agency.

Officer designated to coordinate efforts of compliance: Vice Chancellor for Administration

b. Drug-Free Workplace:

Certification of compliance with the Drug-Free Workplace Act of 1988 (PL100-690) and Drug-Free Schools and Communities Act Amendments of 1989 (PL101-226). Effective October 1, 1990, all institutions must certify to the adoption and

implementation of a program to prevent illicit use of drugs and abuse of alcohol by students and employees. Certification for all UT units will be handled centrally from Knoxville.

Officer designated to coordinate efforts to assure compliance: Vice Chancellor for University Relations

c. Federal Debt - Certification of Non-delinquency:

Certification that the institution is not delinquent on any federal debt as required in OMB Circular A-129 (Rev. 11/15/88).

Officer designated to assure non-delinquency: Assistant Vice President, Business & Finance

d. Institutional Eligibility:

Certification that UTHSC satisfies the definition of an eligible Institution of Higher Education and Postsecondary Vocational Institution, as set forth in the Higher Education Act of 1965 as amended, for purposes of eligibility to apply for postsecondary education Federal assistance programs under Title II, IV, VII and VIII administered by the U.S. Department of Education.

Officer designated to apply for eligibility certification: University Relations Vice Chancellor

Signed by: Chancellor

Official custodian: Research Administration

Copies: Financial Aid, Vice Chancellor for Univ. Relations; Asst. Vice President, Bus. & Finance

e. Lobbying:

Certification that this institution or its employees are not using federal funds to influence certain federal contracting and financial transactions as defined in PL 101-121, Section 319, October 23, 1989.

Officer designated to assure compliance: Assistant Vice President, Business and Finance