**POLICY**

It is the policy of the Upstate Carolina NCORP (UC-NCORP), Inc. to conduct their activities in accordance with the public policy requirements, objectives and appropriation mandates (listed in Exhibit 4 table) stated in the NIH Grants Policy Statement per the US Department of Health and Human Services, Section 4.1.

UC-NCORP is responsible for: 1) establishing and maintaining (See the included UC-NCORP Master Required Assurances Table for the level of assurances required by UC-NCORP, participating communities, and contracted PIs and staff) the necessary processes to monitor its compliance and that of its employees, community participants, and contractors with these requirements; 2) taking appropriate action to meet the stated objectives; and, 3) informing NIH of any problems or concerns.

UC-NCORP currently only participates in research conducted primarily on adult subjects. UC-NCORP is not a member of Children’s Oncology Group (COG), however, UC-NCORP can access these studies for adolescents and young adult (AYA) subjects through CTSU.

Some individual policies are covered in more detail in the UC-NCORP Policy Manual. The public policy requirements, objectives, and appropriation mandates are covered collectively as noted below:

1. Seat Belt Use (Section 4.1.28): The use of seat belts is required while UC-NCORP employees or members who are operating a vehicle, whether rented or personally owned, or a front seat or back seat passenger while traveling for any attendance to research base meetings, UC-NCORP business meetings, site visits to communities or any other travel related to UC-NCORP activities.
2. Smoke-Free or Tobacco-Free Workplace (Section 4.1.29): UC-NCORP provides a smoke-free and tobacco-free workplace in order to promote the nonuse of tobacco products, in addition to electronic cigarettes. A tobacco-free environment will promote healthy lifestyles throughout UC-NCORP communities, by encouraging individuals, especially UC-NCORP Operations Center employees, to refrain from the use of tobacco products. The workplace is defined as the space including private offices and conference rooms, corridors, stairways, restrooms, other public spaces which includes any rented vehicle for UC-NCORP activities.
3. Drug-Free Workplace (Section 4.1.7): UC-NCORP will maintain a drug-free workplace in accordance with The Drug-Free Workplace Act of 1988 (41 U.S.C. § 701 et seq.) as required of any organization receiving grants from any Federal agency. By signing the NCORP application, the Authorized Organization Representative (AOR) or UC-NCORP Principal Investigator (PI) agrees that UC-NCORP will provide a drug-free workplace and will comply with the requirement to notify NIH if an employee is convicted of violating a criminal drug statute. Any non-compliance will be reported to the Administrator who in return will notify the PIs. Failure to comply with these requirements may be cause for debarment. Government wide requirements for Drug-Free Workplace for Financial Assistance is found in 2 CFR 182; HHS implementing regulations are set forth in 2 CFR 382.400. UC-NCORP will comply with the requirements in Subpart B of Part 382.
4. Standards of Conduct (Section 4.1.30): UC-NCORP does not allow employees, consultants, members of the UC-NCORP Leadership Council, and others who may be involved in grant-supported activities to use their positions for purposes that are, or give the appearance of being, motivated by a desire for private financial gain for themselves or others, such as those with whom they have family business or other ties. Any of these outside activities, relationships or financial interests are not allowed. The PIs will be notified of any UC-NCORP employee or member found to violate these standards of conduct. UC-NCORP membership or participation will be terminated upon discovery of misconduct.
5. Certification of Filing and Payment of Taxes (Section 4.2.2):None of the funds appropriated or otherwise made available by the governing appropriation Federal Debt Collection Procedures Act (Act) may be used to enter into a contract in an amount greater than $5,000,000 or to award a grant in excess of such amount unless UC-NCORP certifies in writing to NIH that, to the best of its knowledge and belief, Spartanburg Regional Healthcare System District, Inc. has filed all tax returns (990) required during the 3 years preceding the certification, has not been convicted of a criminal offense under the Internal Revenue Code of 1986, and has not more than 90 days prior to certification, been notified of any unpaid Federal tax assessment for which the liability remains unsatisfied, unless the assessment is the subject of an installment agreement or offer in compromise that has been approved by the Internal Revenue Service (IRS) and is not in default, or the assessment is the subject of a non-frivolous administrative or judicial proceeding. Form 990 is the return of an organization exempt from income tax filed by the tax-exempt organizations to provide the IRS with the information required by section 501(c) of the Internal Revenue Code. UC-NCORP will verify unpaid Federal tax assessments by reviewing the System for Award Management (SAM) on at least a yearly basis or more often if needed.
6. Federal Funding Accountability and Transparency Act or FFATA (Section 4.1.8): The FFATA of 2006 requires full disclosure of all entities and organizations receiving Federal funds including grants, contracts, loans and other assistance and payments through a single publicly accessible Web site, USASpending.gov. The Web site includes information on each Federal financial assistance award and contract over $25,000, including such information as:
   1. The name of the entity receiving the award
   2. The amount of the award
   3. Information on the award including Federal Award Identification Number (FAIN), transaction type, funding agency, etc.
   4. The location of the entity receiving the award
   5. A unique identifier of the entity receiving the award; and
   6. Names and compensation of highly-compensated officers (as applicable)

Compliance of this law is primarily the responsibility of the Federal agency. However, two elements of the law require information to be collected and reported by UC-NCORP: 1) Information on executive compensation when not already reported through the Central Contractor Registry; and 2) similar information on sub-awards/sub-contracts/consortiums over $25,000. This requirement is being implemented in accordance with Office of Management and Budget (OMB) Interim Final Guidance, Federal Register Volume 75, Number 177, September 14, 2010. Full text of the award term is available at 2 CFR 170.

UC-NCORP will collect and report all applicable information.

1. Non-delinquency on Federal Debt (Section 4.1.21): The Federal Debt Collection Procedures Act of 1990 (Act), 28 U.S.C. 3201(e), provides that an organization or individual that is indebted to the United States, and has a judgment lien filed against it, is ineligible to receive a Federal grant. NIH cannot award a grant unless the Authorized Organization Representative (UC-NCORP Principal Investigator) of the applicant organization (UC-NCORP) certifies, by means of his/her signature on the application, that the organization or individual is not delinquent in repaying any Federal debt. If the applicant discloses delinquency on a debt owed to the Federal government, NIH may not award the grant until the debt is satisfied or satisfactory arrangements are made with the agency to which the debt is owed. In addition, once the debt is repaid or a satisfactory arrangement made, NIH will take that delinquency into account when determining whether the applicant would be a responsible NIH grant recipient.

UC-NCORP will confirm the PIs have no Federal debt prior to the AOR signing the NCORP application. The UC-NCORP Leadership Council will be notified of any offense to determine the plan of action.

Anyone who has been judged to be in default on a Federal debt and who has had a judgment lien filed against him or her will not be listed as a participant in the UC-NCORP NCORP application until the judgment is paid in full or is otherwise satisfied. No funds may be used for or re-budgeted following an award to pay such an individual. NIH will disallow costs charged to awards that provide funds to individuals in violation of this ACT.

These requirements apply to all types of organizations and awards.

1. Inclusion of Women/Minorities as Subjects in Clinical Research and Reporting Sex/Gender, Racial, and Ethnic Participation (Section 4.1.15.8): NIH-conducted and –supported Clinical research must conform to the *NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research* in accordance with Public Health Service Act sec. 492B, 42 U.S.C. sec 289a-2. The policy requires that women and members of minority groups and their subpopulation be included in NIH-conducted or supported clinical research. UC-NCORP communities/affiliates are made aware of offering women and minorities the opportunity to participate in clinical research is a requirement.

UC-NCORP must collect and provide annual report information on sex/gender, race, and ethnicity in clinical research studies to NCI on a regular basis. The Office of Management and Budget (OMB) minimum standards for maintaining, collecting, and presenting data on race and ethnicity for all grant projects are described in OMB Directive No. 15. The standards include five racial categories: American Indian or Alaskan Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White. There are two categories for ethnicity: “Hispanic or Latino” and “Not Hispanic or Latino.”

1. Lobbying – Appropriation Prohibition (Section 4.2.6): NIH appropriated funds may not be used, other than for normal and recognized executive-legislative relationships for publicity or propaganda purposes, for the preparation, distribution, or use of a kit, pamphlet, booklet, publication, electronic communication, radio, television, or video presentation designed to support or defeat the enactment of legislation before the Congress or any State or local legislature or legislative body except in presentation to the Congress or any State legislature or local legislature itself or designed to support or defeat any proposed or pending regulation administrative action, or order issued by the executive branch of any State of local government, except in presentation to the executive branch of any State of local government itself. No part of any governing appropriation Act shall be used to pay the salary or expenses of any grant (NCORP) or contract recipient (UC-NCORP), or agent acting for such recipient, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive Order proposed or pending before the Congress or any State government, State legislature or local legislature or legislative body other than for normal and recognized executive-legislative relationships or participation by an agency or officer of a State, local or tribal government in policymaking and administrative processes within the executive branch of that government. No part of any governing appropriation Act shall be used for any activity to advocate or promote any proposed, pending or future Federal, State or local tax increase, or any proposed, pending, or future requirement or restriction on any legal consumer product, including its sale or marketing, including but not limited to the advocacy or promotion of gun control, except as described above.

UC-NCORP members and employees are prohibited to lobby for inappropriate relationships while involved in UC-NCORP activities.

1. Limited English Proficiency (Section 4.1.2.5): Executive Order 13166, August 11, 2000, requires recipients receiving Federal financial assistance to take steps to ensure that people with limited English proficiency can meaningfully access health and social services. Investigators within each UC-NCORP community provides language assistance for people with limited English proficiency to ensure effective communication between the provider (investigator) and the patient to facilitate participation in, and meaningful access to, services. Several NCTN and NCORP research bases provide clinical trial material and/or consent forms in designated foreign languages. UC-NCORP member affiliate have translational services available.
2. Salary Cap/Salary Limitation (Section 4.2.10): None of the funds appropriated in the governing appropriation Act for NIH (the Act), shall be used to pay the salary of an individual through a grant or other extramural mechanism at a rate in excess of that prescribed in the Act. Applications and proposals with categorical direct cost budgets reflecting direct salaries of individuals in excess of the rate prescribed in the Act will be adjusted in accordance with the legislative salary limitation. Current and historical information on the applicable salary cap for each fiscal year is on the OER Salary Cap Summary webpage.

UC-NCORP will review the salary cap to verify the salaries of the PIs and Co-PIs are within allowed range.

1. Text Messaging While Driving (Section 4.1.31): Executive Order 13513 requires each Federal agency to encourage contractors, subcontractors, and grant and cooperative agreement recipients and sub-recipients to adopt and enforce policies that ban texting while driving company-rented vehicles or while driving personally owned vehicles when on official UC-NCORP business.

To further the requirement of encouraging such policies, the NIH encourages recipients to consider new rules and programs, reevaluate existing programs to prohibit text messaging while driving, and conduct education, awareness, and other outreach for employees about the risks associated with texting while driving. These initiatives should encourage voluntary compliance with the recipient agency’s text messaging policy while off duty.

The following definitions apply:

1. “Texting” or “Text Messaging” means reading from or entering data into any handheld or other electronic device, including for the purpose of Short Message Service (SMS) texting, e-mailing, instant messaging, obtaining navigational information, or engaging in any other form of electronic data retrieval or electronic data communication.
2. “Driving” means operating a motor vehicle on an active roadway with the motor running, including while temporarily stationary because of traffic, a traffic light or stop sign or otherwise. It does not include operating a motor vehicle with or without the motor running when one has pulled over to the side of, or off, an active roadway and has halted in a location where one can safely remain stationary.
3. UC-NCORP will educate employees, contractors, and governing bodies of text messaging restrictions.
4. Research Misconduct (Section 4.1.27): Title 42 CFR 93, PHS Policies on **Research Misconduct**, Subpart C, “Responsibilities of Institutions” specifies recipient responsibilities to have written policies and procedures for addressing allegations of **research misconduct**, to file an Assurance of Compliance with the HHS Office of Research Integrity (ORI), and take all reasonable and practical steps to foster research integrity. **Research misconduct** is defined as the fabrication, falsification or plagiarism in proposing, performing or reviewing research, or in reporting research results. The HHS ORI has the responsibility for addressing research integrity and misconduct, monitors institutional investigations of research misconduct and facilitates the responsible conduct of research through education, preventive, and regulatory activities.

To be eligible for PHS funding UC-NCORP must have an assurance on file with ORI stating that is has developed and will comply with an administrative process for responding to allegation of **research misconduct** in PHS-supported research that complies with 42 CFR 93. UC-NCORP establishes an assurance when an official signs the face-page of the grant application for or when UC-NCORP files a separate assurance form. Once established, UC-NCORP maintains their assurance by filing the Annual Report on Possible Research Misconduct (between January 1 and March 1 each year), submitting their policy for responding to allegations of research misconduct for review when requested by ORI, revising their policy when requested by ORI to bring the policy into compliance with the PHS regulation, and complying with the PHS regulation.

As stated throughout the National Institutes of Health Grants Policy Statement (NIHGPS), UC-NCORP has the primary responsibility for ensuring that it is conducting its NIH-funded project in accordance with the approved application and budget and the terms and conditions of the award. UC-NCORP must carry out its responsibilities with extra care where research misconduct has been found or where a **research misconduct** investigation has been initiated, as specified in 42 CFR 93, Subpart C. UC-NCORP must report promptly to ORI any decision to initiate an investigation of research misconduct.

The regulations specify the timing of an institutional investigation, related reporting to ORI, notice to the respondent, custody of records, documentation, opportunity for respondent to comment on the report, and the components on a final UC-NCORP investigative report.

If a misconduct investigation is initiated, UC-NCORP must take any necessary steps, in addition to its normal and ongoing responsibilities under the grant, to protect the scientific integrity of the project, protect human subjects, provide reports to ORI, and ensure the proper expenditure of funds and continuation of the project during the investigation, if appropriate. The UC-NCORP staff will notify the UC-NCORP Leadership Council of any misconduct discovered so appropriate plan of action can be determined. ORI staff members are available to help UC-NCORP with investigating and reporting on research misconduct, and Institute or Center staff members are available to provide technical assistance and to work with UC-NCORP to protect funded projects from the adverse effects of **research misconduct**.

UC-NCORP is responsible for the actions of its employees, investigators, affiliate staff and other research collaborators, including third parties, involved in the project. When UC-NCORP finds **research misconduct** by anyone working on an NIH grant-support project, whether at UC-NCORP or at a third-party organization, UC-NCORP must assess the effect of that finding on the ability to continue that project, as originally approved by NIH, and must promptly obtain NIH approval of any intended change of Program Director/Principal Investigator (PD/PI) or other senior/key personnel or change of scope. UC-NCORP’s failure to comply with the terms and conditions of award, including confirmed instances of **research misconduct**, may cause NIH to take one or more enforcement actions including disallowance of costs, withholding of further awards, suspension or termination. These actions are described in Administrative Requirements (Section 14.11).

1. Controlled Substances (Section 4.1.5): If controlled substances are proposed to be administered as part of a research protocol or if research is to be conducted on the drugs themselves, UC-NCORP will notify investigator conducting the research to ensure that the DEA requirements, including registration, inspection, and certification, as applicable, are met. Regional DEA offices can supply forms and information concerning the type of registration required for a particular substance for research use. The main registration office in Washington, DC may be reached at 800-882-9539. Information also is available from the National Institute on Drug Abuse at 301-443-6300.
2. Data and Safety Monitoring (Section 4.1.15.6): The NIH policy for data and safety monitoring requires oversight and monitoring of all NIH-conducted or –supported human biomedical and behavioral intervention studies (clinical trials) to ensure the safety of participants and the validity and integrity of the data. The NIH policies on data and safety monitoring specify that the level and frequency of monitoring should be commensurate with the risks, nature, and complexity of the clinical trial, and are in addition to any monitoring requirements imposed by FDA or the *NIH Guidelines for Research Involving Recombinant DNA Molecules (“NIH Guidelines”)*. There are a number of options for monitoring clinical trials including, but not limited to, monitoring by a/an:
   1. PD/PI (required);
   2. IRB (required);
   3. Independent individual/safety officer;
   4. Designated medical monitor;
   5. Internal committee or board with explicit guidelines;
   6. DSMB (required for multi-site trials).

A detailed monitoring plan must be included as part of the research protocol, be submitted to the local IRB at UC-NCORP communities or the NCI CIRB, and be reviewed and approved by the NIH awarding Institute or Center prior to the accrual of human subjects. The reporting requirements for adverse events will be specified, which are in addition to the annual report to the IRB or NCI CIRB. The clinical trial monitoring function is above and beyond that traditionally provided by local IRBs or NCI CIRB; however, the local IRB or NCI CIRB must be cognizant of the procedures used by clinical trials monitoring entities and the monitor must provide periodic reports to investigators for transmittal to the local IRB or NCI CIRB.

Timely summary reports of adverse events for clinical trials will be prepared and distributed among sites and IRBs/NCI CIRBs of participating sites. The frequency of summary reports will depend on the nature of the trial.

All multi-site clinical trials with Data and Safety Monitoring Boards (DSMBs) are expected to forward summary reports of adverse events to individual IRBs/NCI CIRBs so they can address reports related to the site for which they have responsibility.

1. Dissemination of False or Deliberately Misleading Information (Section 4.2.3): None of the funds made available in the governing appropriations Act may be used to disseminate information that is deliberately false or misleading. UC-NCORP provides education to member investigators to the requirement to not communicate false or misleading information.
2. Acknowledgment of Federal Funding (Section 4.2.1): UC-NCORP and Affiliates must acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid invitations, and other documents describing projects or programs funded in whole or in part with Federal money. Recipients are required to state (1) the percentage and dollar amounts of the total program or project costs financed with Federal money and (2) the percentage and dollar amount of the total costs financed by nongovernmental sources.
3. Certificates of Confidentiality (Section 4.1.4.1): Section 301(d) of the PHS Act, as amended by Section 2012 of the 21st Century Cures Act, P.L. 114-255, states that the Secretary shall issue Certificates of Confidentiality (Certificates) to NIH funded investigators or institutions engaged in biomedical, behavioral, clinical, or other research activities in which identifiable, sensitive information is collected. All recipients who conduct biomedical, behavioral, clinical, or other research that collects or uses identifiable, sensitive information, are covered by a new NIH Policy ([NOT-OD-17-109](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html)), and are deemed to be issued a Certificate. Recipients are therefore required to protect the privacy of individuals who are subjects of such research in accordance with subsection 301(d) of the Public Health Service Act. Institutions and their investigators are responsible for determining whether research they conduct is subject to the new Policy. Certificates issued in this manner will not be issued as a separate document.

NIH considers research in which identifiable, sensitive information is collected or used, to include:

* Human subjects research as defined in the Federal Policy for the Protection of Human Subjects (45 CFR 46), including exempt research except for human subjects research that is determined to be exempt from all or some of the requirements of 45 CFR 46 if the information obtained is recorded in such a manner that human subjects cannot be identified or the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
* Research involving the collection or use of biospecimens that are identifiable to an individual or for which there is at least a very small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to deduce the identity of an individual;
* Research that involves the generation of individual level, human genomic data from biospecimens, or the use of such data, regardless of whether the data is recorded in such a manner that human subjects can be identified or the identity of the human subjects can readily be ascertained as defined in the Federal Policy for the Protection of Human Subjects (45 CFR 46); or
* Any other research that involves information about an individual for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual, as defined in subsection 301(d) of the Public Health Service Act.

Disclosure is permitted only when:

* Required by Federal, State, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act, or state laws requiring the reporting of communicable diseases to State and local health departments), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding;
* Necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual;
* Made with the consent of the individual to whom the information, document, or biospecimen pertains; or
* Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.
* For studies in which informed consent is sought, NIH expects investigators to inform research participants of the protections and the limits to protections provided by a Certificate issued by the Policy.

1. Section 301(d) of the PHS Act provides that the Secretary may authorize people engaged in biomedical, behavioral, clinical or other research activities to protect the privacy of research subjects by withholding the names and other identifying characteristics of those subjects from individuals not engaged in the research. The National Clinical Trials Network (NCTN)and the NCI Community Oncology Research Program (NCORP) research bases have Certificates of Confidentiality (CoC). UC-NCORP communities provide research subject protection under the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, 42 CFR Parts 160 and 164, and under Section 543 of the PHS Act by protecting identifiable health information from forced disclosure (e.g., by court order). UC-NCORP protects research subject information by having a HIPAA compliant database.
2. Human Subjects Protection (Section 4.1.15): The HHS regulations for the protection of human subjects, in 45 CFR 46, implement Section 491 (a) of the PHS Act and provide a framework, based on established, internationally recognized ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the NIH or other HHS components.

The HHS regulations stipulate that UC-NCORP bears ultimate responsibility for safeguarding the rights and welfare of human subjects in HHS-supported activities (46.101a and 46.1-3a). Each UC-NCORP community institution “engaged” in human subjects research obtains a Federalwide Assurance (FWA) with the HHS Office for Human Research Protections (OHRP), and establishes appropriate policies and procedures for the protection of human subjects. The UC-NCORP community institutions are engaged in research since their employees obtain individually identifiable private information about human subjects for research purposes. UC-NCORP receives a direct HHS award and distributes the funds to UC-NCORP community institutions to conduct human subjects research. OHRP guidance states that institutions adopt clear procedures under which the local IRB determines whether proposed research is exempt from human subjects regulations. NIH will make a final determination as to whether proposed activities are covered by the regulations or are in an exempt category, based on the information provided in the Research Plan. Research involving human subjects may be only conducted under an HHS award if the organization has a current OHRP approved FWA and provides certification that an IRB registered under the specific Assurance has reviewed and approved the proposed activity in accordance with the HHS regulations.

UC-NCORP verifies that each community institution/affiliate maintains a current OHRP approved FWA through the OHRP website. UC-NCORP maintains a database where all initial IRB approvals for all clinical trials open in any UC-NCORP community/affiliate are kept on file for reference. In addition, the yearly renewals for these clinical trials are maintained. The majority of clinical trials are approved through the NCI Central Institutional Review Board (CIRB). Any remaining clinical trials not approved through the NCI CIRB are approved via the local IRB who adheres to HHS regulations assuring human subjects protection.

Federalwide Assurance (FWA) Requirements (Section 4.1.15.1): The FWA commits the institution to compliance with the requirements set forth in 45 CFR 46, and the Terms of Assurance. Each UC-NCORP community “engaged” in HHS supported human subjects research must be covered by an FWA approved by OHRP. UC-NCORP community IRBs are registered with OHRP before the IRB is designated on an FWA as reviewing proposed research for UC-NCORP. UC-NCORP verifies FWA status for each community or institution on at least a yearly basis or more often if needed.

Certification of IRB Approval (Section 4.1.15.2): UC-NCORP must provide a certification to NIH that the research application has been approved by an appropriate IRB, consistent with 45 CFR 46 and OHRP guidance. IRB approval must have been granted within 12 months before the budget period start date to be valid. NIH requires the date of final IRB approval; conditional IRB approval is not sufficient. UC-NCORP has the initial NCORP application and the RPPR yearly progress reports reviewed by Spartanburg Regional Healthcare System District, Inc. IRB. This approval is submitted to the Grants Management Specialist.

Reporting to Funding Agency and OHRP (Section 4.1.15.3): Under the HHS regulations, UC-NCORP must have written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the NIH of any unanticipated problem involving risks to subjects or others or any serious or continuing noncompliance with 45 CFR 46 or IRB requirements (45 CFR 46.103b5). Any UC-NCORP local community IRB suspension or termination of approval must include a statement of reasons for the IRB’s action and must be reported promptly to the investigator, appropriate institutional officials, and NIH (45 CFR 46.113). UC-NCORP community institutions/affiliates must also file incident reports with OHRP of unanticipated problems involving risks to subjects or others, serious or continuing non-compliance with 45 CFR 46 or with the requirements or determinations of the IRB, and suspension or termination of IRB approval.

OHRP Oversight (Section 4.1.15.4): OHRP has regulatory responsibility for oversight of UC-NCORP compliance with the HHS human subjects regulations. In carrying out this responsibility, OHRP evaluates all written allegations or indications of non-compliance with the HHS regulations it receives from any source. All compliance oversight evaluations are predicated on the HHS regulations and UC-NCORP’s assurance of compliance. Any corrective actions imposed as a result of a compliance oversight evaluation are intended to remedy identified non-compliance and prevent reoccurrence. Because each case is different, OHRP tailors corrective actions to foster the best interest of human research subjects and, to the extent possible, of the organization, research community, and HHS. Most compliance oversight evaluations and resultant corrective actions are resolved at the OHRP level. However, OHRP may recommend actions to be taken by other HHS officials. UC-NCORP UC-NCORP Leadership Council will be notified by the Administrative Office staff with discovery of oversight non-compliance in order that appropriate action can be taken by the UC-NCORP Leadership Council.

Education in the Protection of Human Research Participants (Section 4.1.15.5): Before funds are awarded for competing application involving human subjects, UC-NCORP must submit documentation that all senior/key personnel involved in human subjects research have received training in the protection of human subjects. Senior/key personnel include all individuals responsible for the design or conduct of the study, including senior/key personnel of consortium participants or alternate performance sites if they are participating in research that involves human subjects. This documentation is included in the cover letter signed by the Authorized Organization Representative (AOR) that accompanies the description of other support, IRB approval, and other information submitted prior to funding in accordance with Just-in-Time procedures. UC-NCORP maintains individual file on senior/key personnel that includes human subjects training certification. For non-competing continuation awards, the description of education for new senior/key personnel should be part of the progress report submitted as a prerequisite to award. UC-NCORP and member affiliate institutions utilize the Collaborative Institutional Training Initiative (CITI) Program for all human subject and GCP training.

Additional information about this education requirement is available on the NIH Web site at: <http://-grants.nih.gov/grants/policy/hs_educ_faq.htm>.

1. The United States Hotel and Motel Fire Safety Act of 1990 (Section 14.6.1): This act (PL101-391) was passed into law by Congress to save lives and protect property by promoting fire and life safety in hotels, motels and other places of public accommodation. It states that federally funded meetings and conferences cannot be held in properties that do not comply with the law. PL101-391 is applicable to all places of public accommodation, and requires that such properties are equipped with:
   1. Hard-wired, single-station smoke detectors in each guestroom in accordance with the National Fire Protection Association (NFPA) standard 72;
   2. An automatic sprinkler system, with a sprinkler head in each guest room in compliance with NFPA standards 13 and 13R. Properties three stories or lower in height are exempt from the sprinkler requirement.

The United States Fire Administration (USFA) is charged with carrying out the Federal Emergency Management Agency’s (FEMA) responsibilities with respect to the Hotel and Motel Fire Safety Act of 1990.

UC-NCORP verifies with hotels, motels and conference centers their compliance with the requirements of the Hotel and Motel Fire and Safety Act of 1990 prior to conferences and/or meetings and relays information to the UC-NCORP Leadership Council for approval of conference or meeting.

1. Health and Safety Regulations and Guidelines (Section 4.1.12): UC-NCORP is responsible for meeting applicable Federal, State, and local health and safety standards and for establishing and implementing necessary measures to minimize their employees’ risk of injury or illness in activities related to NIH grants.
2. Financial Conflict of Interest (Section 4.1.10): NIH requires UC-NCORP and its investigators to comply with the requirements of 42 CFR 50, Subpart F, “Responsibility of Applications for Promoting Objectivity in Research for which PHS Funding is Sought.” A Final Rule amending the 1995 PHS regulation (and the companion regulation at 45 CFR 94, “Responsible Prospective Contractors,” imposing similar requirements for research contracts) was published on August 25, 2011 in the Federal Register (<http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf)>.

The requirements under the 2011 revised regulation promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct or reporting of research funded under PHS grants or cooperative agreements will be free from bias by any conflicting financial interest of an Investigator, defined as the PD/PI and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of research funded by PHS or proposed for such funding, which may include, for example, collaborators or consultants. When submitting the NCORP grant application, the signature of the AOR certifies UC-NCORP’s compliance with the requirements of 42 CFR 50, Subpart F, including that:

* 1. There is in effect at UC-NCORP an up-to-date, written and enforced administrative process to identify and manage Financial Conflicts of Interest (FCOI) with respect to all research projects for which NIH funding is sought or received;
  2. UC-NCORP promotes and enforces Investigator compliance with the regulation’s requirements including those pertaining to disclosure of Significant Financial Interests;
  3. UC-NCORP identifies and manages FCOIs for Council members and applicable staff and provides initial and ongoing FCOI report to the NIH consistent with this subpart;
  4. When requested, UC-NCORP promptly makes information available to the NIH/HHS relating to any UC-NCORP Council member disclosure of financial interests and UC-NCORP’s review of, and response to, such disclosure, whether or not the disclosure resulted in UC-NCORP’s determination of and FCOI;
  5. UC-NCORP shall fully comply with the requirements of the regulation.

When UC-NCORP determines that an FCOI exists, the UC-NCORP Leadership Council is informed and UC-NCORP reports to the NIH awarding Institute or Center through the submission of an initial and annual FCOI report using the eRA Commons FCOI Module. The initial FCOI report will include the following information:

* Grant number and PD/PI or Contact PD/PI if the grant is awarded under the multiple PI model;
* Name of PD/PI with the FCOI;
* Name of the entity with which the PD/PI has an FCOI;
* Nature of the FCOI (e.g., consulting fees, honoraria, paid authorship, equity interest, intellectual property rights and interests, and reimbursed or sponsored travel);
* Value of the financial interest $0-4,999; $5,000-9,999; $10,000-19,999; amounts between $20,000-100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000 or a statement that a value cannot be readily determined;
* A description how the financial interest relates to the NIH-funded research and the basis for UC-NCORP’s determination that the financial interest conflicts with such research; and
* Key elements of UC-NCORP’s management plan, including:

1. Role and principal duties of the conflicted PD/PI in the research project;
2. Conditions of the management plan;
3. How the management plan is designed to safeguard objectivity in the research project;
4. Confirmation of the PD/PI’s agreement to the management plan;
5. How the management plan will be monitored to ensure PD/PI compliance; and
6. Other information as needed.

The annual FCOI report is submitted to the NIH through the eRA Commons FCOI Module each year within a competitive segment or until UC-NCORP reports that the FCOI no longer exists. The annual FCOI report includes the following information:

* Status of the FCOI
* Changes to the management plan, if applicable

UC-NCORP will make certain information available concerning identified FCOI held by senior/key personnel as defined in the regulation via a publicly accessible Web site or by a written response to any requestor within five business days of a request, and update such information as specified in the regulation.

UC-NCORP requires each Investigator (including sub-recipient Investigators, if applicable) to complete training prior to engaging in NIH-supported research and at least every three years with copies of training completion sent to UC-NCORP, and immediately under the designated circumstances:

* UC-NCORP or UC-NCORP community institution FCOI policies change in a manner that affects Investigator requirement
* An Investigator is new to an institution
* UC-NCORP community institution finds an Investigator noncompliant with UC-NCORP’s FCOI policy or management plan.

As described in the regulation, examples of how FCOIs might be addressed include, but are not limited to, the following:

* Public disclosure of FCOI (e.g., when presenting or publishing the research);
* Disclosure of FCOI directly to human subjects research participants;
* Monitoring of research by independent reviewer(s);
* Modification of the research plan;
* Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
* Reduction or elimination of Significant Financial Interests (e.g., sale of an equity interest)
* Severance of relationships that create financial conflicts.

The information above is only a sample of the regulatory requirements found in 42 CFR 50, Subpart F. Applicants and recipients must review the regulation in its entirety to ensure compliance with all of the requirements.

1. The Fly America Act (49 U.S.C. 40118) generally provides that foreign air travel funded by Federal government money may only be conducted on U.S. flag air carriers. A “U.S. flag air carrier” is an air carrier that holds a certificate under 49 U.S.C. 41102 but does not include a foreign air carrier operating under a permit. UC-NCORP Travel Policy prohibits the use of non-US flag carriers.
2. Federal Information Security Management Act (Section 4.1.9): All information systems, electronic or hard copy which contain Federal data need to be protected from unauthorized access. This also applies to information associated with NIH grants and contracts. Congress and the Office of Management and Budget (OMB) have instituted laws, policies and directives that govern the creation and implementation of federal information security practices that pertain specifically to grants and contracts. The current regulations are pursuant to the Federal Information Security Management Act (FISMA), 44 U.S.C. 3541 et seq. The applicability of FISMA to NIH recipients (UC-NCORP) applies only when recipients collect, store, process, transmit or use information on behalf of HHS or any of its component organizations.

Spartanburg Regional Healthcare System District, Inc (SRHS) on behalf of UC-NCORP, SRHS IT Security verifies that all systems meet the requirements of FISMA and all new systems are verified prior to implementation.

1. Age Discrimination Act of 1975 (Section 4.1.2.4): The Age Discrimination Act of 1975 prohibits discrimination on the basis of age in any program or activity receiving Federal financial assistance. The HHS implementing regulations are codified as 45 CFR 91. UC-NCORP does not discriminate on the basis of age.
2. Civil Rights Act of 1964 (Section 4.1.2.1): Title VI of the Civil Rights Act of 1964 provides that no person in the United States shall, on the grounds of race, color or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. The HHS implementing regulation are codified at 45 CFR 80. UC-NCORP does not exclude participation, deny benefits or discriminate based on race, color or national origin in the NCORP.
3. Confidentiality of Patient Records: Health Insurance Portability and Accountability Act (Section 4.1.4.3): HHS issued the final version of the “Standards for Privacy of Individually Identifiable Health Information” – the Privacy Rule – on August 14, 2002. The Privacy Rule is a Federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information. It is administered and enforced by OCR, HHS. Those entities required to comply with the Privacy Rule (classified under the rule as “covered entities”) had until April 14, 2003 to do so (with the exception of small health plans which have an extra year to comply).

Decision about applicability and implementation of the Privacy Rule reside with the researcher and UC-NCORP or the UC-NCORP community institution. The OCR Website (<http://www.hhs.gov/ocr/)> provides information on the Privacy Rule, including the complete text of the regulation and set of decision tools for determining whether a particular entity is subject to the rule. An educational booklet, Protecting Health Information in Research: Understanding the HIPAA Privacy Rule, is available through OCR’s Web site and also at http://privacyruleandresearch.nih.gov/. That Web site also includes other educational materials including information specific to grants.

UC-NCORP creates HIPAA forms for each clinical trial available through NCI, in order to make sure that UC-NCORP institutions comply with the Privacy Rule.

1. Debarment and Suspension (Section 4.1.6): HHS regulations published in 2 CFR 376 implement the government-wide debarment and suspension system guidance (2 CFR 180) for HHS’ non-procurement programs and activities. “Non-procurement transactions” include, among other things, grants, cooperative agreements, etc. NIH implements the HHS Debarment and Suspension regulations as a term and condition of award. Accordingly, recipients of NIH grants (UC-NCORP), are required to determine whether it or any of its principals (as defined in 2 CFR 180.995 and 2 CFR 376.995) is excluded or disqualified from participating in a covered transaction (i.e., grant or cooperative agreement) prior to entering into the covered transaction, i.e., prior to the drawdown of funds which signals acceptance of the grant award. Recipients may decide the method and frequency by which this determination is made and may check excluded parties in the System for Award Management (SAM), although checking SAM is not required.

Prior to the drawdown of funds for each grant award, recipients must report to the funding Institute or Center if the recipient or any of its principals:

* Are presently excluded or disqualified;
* Have been convicted within the preceding three years of any of the offenses listed in 2 CFR 180.800(a) or had a civil judgment for one of those offenses within that time period;
* Are presently indicted for or otherwise criminally or civilly charged by a governmental entity (Federal, State or local) with commission of any of the offenses listed in 2 CFR 180.800(a); or
* Have had one or more public transactions (Federal, State or local) terminated within the preceding three years for cause or default.

Disclosure of unfavorable information by recipients under this requirement will not necessarily cause NIH to deny participation in the grant. NIH will consider the information when determining whether to enter into the covered transaction. NIH will also consider any additional information or explanation that recipients elect to submit with the disclosed information. However, if it is later determined that a recipient failed to disclose information that it knew at the time it accepted the NIH grant award, NIH may a) terminate the transaction for material failure to comply with the terms and conditions of the award or b) pursue any other available remedies, including suspension and debarment.

UC-NCORP must immediately report to the NIH funding Institute or Center if at any time during the project period, including periods of no-cost extension, they discover that they a) failed to disclose information prior to the drawdown of funds or b) due to changed circumstances the recipient or any of its principals for the grant now meet the reporting criteria.

“Lower tier” transactions (e.g., consortiums, subcontracts, consultants, collaborators, and contractors that require the provision of goods or services that will equal or exceed $25,000) also are subject to the HHS regulations. Prior to entering into a lower tier covered transaction with a participant (as defined in 2 CFR 180.980), recipients must verify that the person (as defined in 2 CFR 180.985) is not excluded or disqualified. UC-NCORP may not enter into any transaction with a person who is disqualified from that transaction unless an exception under the disqualifying statue, Executive Order, or regulation has been obtained from HHS.

UC-NCORP must require participants at the next lower tier to a) comply with the HHS Debarment and Suspension regulations as a condition of participation in the transaction and b) pass the requirement to comply with the HHS Debarment and Suspension regulations to each person involved in the covered transaction at the next lower tier. Likewise, before entering into such a transaction lower tier participants and contractors under grants (where the contract requires the provision of goods and services that will equal or exceed $25,000) must report to the recipient if it or any participants are presently excluded or disqualified.

Organizations or individuals that are suspended, debarred or voluntarily excluded from eligibility cannot receive NIH grants, be paid from NIH grant funds, whether under a primary or lower-tier transaction or otherwise participate during the period of suspension, debarment or exclusion. Because individuals who have been disbarred, suspended, declared ineligible or voluntarily exclude from covered transactions may not receive Federal funds for a specified period of time,

charges made to the NIH grants for such individuals (e.g., salary) are unallowable.

The Administrator and Grants Management have access to SAM and will check at least yearly or more often as needed the status of UC-NCORP investigators, contractors, and vendors. If any of the investigators, contractors, and vendors are excluded or disqualified, the UC-NCORP UC-NCORP Leadership Council are notified promptly in order to determine the plan of action.

1. Educational Amendments of 1972 (Section 4.1.2.2): Title IX of the Educational Amendments of 1972 provides that no person in the United States shall, on the basis of sex, be excluded from participation in, be denied the benefits of or be subjected to discrimination under any education program or activity receiving Federal financial assistance. The HHS implementing regulation are codified at 45 CFR 86. UC-NCORP does not exclude, deny or discriminate on the basis of sex.
2. Rehabilitation Act of 1973 (Section 4.1.2.3): Section 504 of the Rehabilitation Act of 1973, amended, provides that no otherwise qualified handicapped individual in the United States shall, solely by reason of the physical or mental impairment, be excluded from participation in, be denied the benefits of or be subjected to discrimination under any program or activity receiving Federal financial assistance. These requirements pertain to the provision of benefits or services as well as to employment. The HHS implementing regulations are codified at 45 CFR Part 84 and 85. UC-NCORP does not exclude participation, deny benefits or discriminate to handicapped individuals solely on their impairment.
3. Lobbying (Section 4.1.17): Recipients of Federal grants are prohibited by 31 U.S.C. 1352, “Limitation on use of appropriated funds to influence certain Federal contracting and financial transactions,” from using appropriated Federal funds to pay any person for influencing or attempting to influence any officer or employee of an agency, a Member of Congress, an officer or employee of Congress or an employee of a Member of Congress with respect to the award, continuation, renewal, amendment or modification of any of these instruments. These requirements are implemented for HHS in 45 CFR 93, which also describes types of activities, such as legislative liaison activities and professional and technical services, which are not subject to this prohibition under certain circumstances.

Applicants for NIH awards are required to certify and disclose that they:

* Have not made, and will not make, such prohibited payment;
* Used or will not use non-appropriated funds if they have made or agreed to make such payment; and
* Will include these requirements in consortium agreements and contracts under grants that will exceed $100,000 and obtain necessary certification from those consortium participants and contractors.

Certifications and disclosures must be filed at time prescribed in the regulations base on the expected total costs.

The signature of the Authorized Organizational Representative (AOR) on the application serves as the required certification of compliance for UC-NCORP. UC-NCORP establishes membership agreements with each community organization, in addition, each UC-NCORP investigator agrees to the UC-NCORP Bylaws. UC-NCORP Operations Center educates the PIs, Co-PIs, and YIs of prohibited lobbying for Federal grants.

1. Trafficking in Persons (Section 4.1.32): This government-wide award term implements Section 106(g) of the Trafficking Victims Protection Act (TVPA) of 2000, as amended (22 U.S.C. 7104), located at 2 CFR 175. This is implemented in accordance with OMB Interim Final Guidance, Federal Register Volume 72, No. 218, November 13, 2007. A Final Notice is expected to be issued in the future; however, HHS agencies have implemented this award term based on the Interim Final Guidance.

In accordance with the statutory requirement, in each agency award under which funding is provided to a private entity, section 106(g) of the TVPA, as amended, requires the agency to include a condition that authorizes the agency to terminate the award, without penalty, if the recipient or a sub-recipient –

* 1. Engages in severe forms of trafficking in persons during the period of time that the award is in effect;
  2. Procures a commercial sex act during the period of time that the award is in effect; or
  3. Uses forced labor in the performance of the award or sub-awards under the award.

Full text of the award term is provided at 2 CFR 175.15.

UC-NCORP discourages the activities listed above related to trafficking in persons.

**ASSOCIATED FORMS:**

1004F NIH Grant Policy Statement Affiliate Assurances Form

**COMMITTEE APPROVAL:**

Policy and Procedure Committee

**UC-NCORP Master Required Assurances Table**

**Public Policy Requirements, Objectives and Appropriation Mandate**

This table is used to ensure compliance with NIH required Assurances, are implemented and addressed throughout all of UC-NCORP’s research, Federal grant and business operations.

|  | **Assurances** | **Reference** | **Recipient**  **(UC-NCORP)** | **Sub-award/Consortium**  **Participant (Affiliate Sites)** | **Contractor Under Grant (PIs, staff under agreements)** | **Attestation**  **(Yes/No & Initial)** |
| --- | --- | --- | --- | --- | --- | --- |
|  | Seat Belt Use | NIH GPS Section 4.1.28 | Y | NA\* | NA\* |  |
|  | Smoke-Free/Tobacco-Free Workplace | NIH GPS Section 4.1.29 | Y | Y | Y |  |
|  | Drug-Free Workplace | NIH GPS Section 4.1.7 | Y | Y | Y |  |
|  | Standards of Conduct | NIH GPS Section 4.1.30 | Y | Y | Y |  |
|  | Certification of Filing & Payment of Taxes | NIH GPS Section 4.2.2 | Y | NA | NA |  |
|  | Federal Funding Accountability & Transparency Act (FFATA) | NIH GPS Sections 4.1.8 and 8.4.1.5.5 | Y | NA | NA |  |
|  | Non-delinquency on Federal Debt | NIH GPS Section 4.1.21 | Y | NA | NA |  |
|  | Inclusion of Women/Minorities as Subjects in Clinical Research and Reporting Sex/Gender, Racial and Ethnic Participation | NIH GPS Section 4.1.15.8 | Y | y | Y |  |
|  | Lobbying-Appropriation Prohibition | NIH GPS Section 4.2.6 | y | y | Y |  |
|  | Limited English Proficiency | NIH GPS Section 4.1.2.5 | y | y | Y |  |
|  | Salary Cap/ Salary Limitation | NIH GPS Section 4.2.10 | Y | NA | NA |  |
|  | Text Messaging While Driving | NIH GPS Section 4.1.31 | Y | NA\* | NA\* |  |
|  | Research Misconduct | NIH GPS Section 4.1.27 | Y | Y | Y |  |
|  | Inclusion of Children as Subjects in Clinical Research | NIH GPS Section 4.1.15.7 | NA | NA | NA |  |
|  | Controlled Substances | NIH GPS Section 4.1.5 | Y | Y | Y |  |
|  | Data and Safety Monitoring | NIH GPS Section 4.1.15.6 | Y | Y | Y |  |
|  | Dissemination of False or Deliberately Misleading Information (Appropriation Mandate) | NIH GPS Section 4.2.3 | Y | Y | Y |  |
|  | Acknowledgment of Federal Funding (Appropriation Mandate) | NIH GPS Section 4.2.1 | Y | Y | Y |  |
|  | Certificates of Confidentiality | NIH GPS Section 4.1.4.1 | Y | Y | Y |  |
|  | Clinical Trials.gov | NIH GPS Section 4.1.3 | Y | Y | Y |  |
|  | Humans Subjects Protections | NIH GPS Section 4.1.15 | Y | Y | Y |  |
|  | Hotel and Motel Fire Safety Act of 1990 | NIH GPS Section 14.6.1 | Y | NA | NA |  |
|  | Health and Safety Regulations and Guidelines | NIH GPS Section 4.1.12 | Y | NA | NA |  |
|  | Financial Conflict of Interest | NIH GPS Section 4.1.10 | Y | Y | Y |  |
|  | Federal Information System Security Management Act | NIH GPS Section 4.1.9 | Y | Y | Y |  |
|  | Age Discrimination Act of 1975 | NIH GPS Section 4.1.2.4 | Y | Y | Y |  |
| **27.** | Civil Rights Act of 1964 (Title VI) | NIH GPS Section 4.1.2.1 | Y | Y | Y |  |
| **28.** | Health Insurance Portability and Accountability Act (HIPAA) | NIH GPS Section 4.1.4.3 | Y | Y | Y |  |
| **29.** | Debarment and Suspension | NIH GPS Section 4.1.6 | Y | Y | Y |  |
| **30.** | Education Amendments of 1972 (Title IX) | NIH GPS Section 4.1.2.2 | Y | Y | Y |  |
| **31.** | Rehabilitation Act of 1973 (section 504) | NIH GPS Section 4.1.2.3 7 10.10.1 | Y | Y | Y |  |
| **32.** | Lobbying (Federalwide Certification) | NIH GPS Section 4.1.17 | Y | Y | Y |  |
| **33.** | Trafficking in Persons | NIH GPS Section 4.1.32 | Y | NA\* | NA\* |  |

NA: A designation of NA in this table indicates that a particular requirement does not apply to an otherwise eligible recipient, consortium participant, or contractor or may not apply because the type of activity covered is one not normally performed by such an entity.

“Y” for Yes

NA\*: Designation of NA\* in this table indicates that UC-NCORP Consortium Policy covers the community site and staff under agreement.

**The Sections that are not applicable to UC-NCORP are:**

* Military Recruiting and ROTC Program Access to Institutions of Higher Education (Section 4.1.19)
* Labor Standards under Federally Assisted Construction (Section 105.3)
* Flood Disaster Protection Act of 1973 – Flood Insurance (Section 10.10.1)
* National Environmental Policy Act of 1969 (Section 4.1.20)
* Intergovernmental Review of Federal Programs under Executive Order (Section10.10.1)
* Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 (Section 10.10.1)
* President’s Emergency Plan for AIDS Relief (Section 4.1.22)
* National Historic Preservation Act of 1966 – Archaeological and Historic Preservation Act of 1974 (Section 10.10.1)
* Lead-Based Paint Poisoning Prevention Act (Section 10.10.1)
* Investigational New Drug Applications/Investigational Device Exceptions (Section 4.1.16)
* Metric System (Section 4.1.18)
* Pro-Children Act of 1994 (Section 4.1.23)
* Safe Drinking Water Act (Section 10.10.1)
* Restriction on Distribution of Sterile Needles (Section 4.2.9)
* Select Agents (Section 4.1.24.1.1)
* USA Patriot Act (Section 4.1.33)
* U.S Flag Air Carriers (Section 7.9.1)
* Restriction on Abortions and Exceptions (Sections 4.2.8 and 4.2.8.1)
* Wild and Scenic Rivers Act of 1968 (Section 10.10.1)
* Protection of Wetlands (Section 10.10.1)
* Promotion or Legalization of Controlled Substances (Section 4.2.7)
* Public Health Security and Bio-terrorism Preparedness and Response Act (Section 4.1.24.1.1)
* Research Involving Recombinant or Synthetic Nucleic Acid Molecules (Section 4.1.26)
* Reporting and Assurance Requirements for Institutions Receiving Awards for Training of Graduate Students for Doctoral Degrees (Section 4.1.25)
* Inclusion of Children as Subjects in Clinical Research (Section 4.1.15.7)
* Copeland Act (Section 10.10.1)
* Conservation of Petroleum and Natural Gas (Section 10.10.1)
* Dual Use Research of Concern (Section 4.1.24.1)
* Davis-Bacon Act (Section 10.10.1)
* Confidentiality of Alcohol and Drug Abuse Patient/Client Records (Section 4.1.4.2)
* Architectural Barriers Act of 1968 (Section 10.10)
* Animal Welfare (Section 4.1.1)
* Coastal Zone Management Act of 1972 (Section10.10)
* Clean Air and Clean Water Act (Section 10.10.1)
* Earthquake Hazards Reduction Act of 1977 and Seismic Safety of Federal and Federally Assisted or Regulated New Building Construction (Section 10.10)
* Gun Control (Section 4.2.4)
* Fly America Act (Section 4.1.11)
* Human Fetal Tissue Research (Section 4.1.14)
* Human Stem Cell Research (Section 4.1.13)
* Human Embryo Research and Cloning Ban (Section 4.2.5)
* Endangered Species Act of 1973 (Section 10.10.1)
* Equal Employment Opportunity (Section 10.5)

Reference: NIH Grants Policy Statement, Section 4.1