

# **Policies and Procedures for the Protection of Human Subjects Participating in Research Programs Conducted or Supported by HRSA**

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## VI. HRSA Contact for Human Subjects Protection

## **I. Purpose**

This directive establishes policies and procedures for ensuring the appropriate implementation of Department of Health and Human Services (HHS) regulations for the protection of human subjects (45 CFR part 46) for research programs conducted or supported by the Health Resources and Services Administration (HRSA).

The purpose of this document is to: (a) provide guidance for compliance with Federal regulations for the protection of human research subjects participating in research that HRSA conducts, supports, and disseminates; (b) affirm HRSA's commitment to protect the rights of all participants in research and delineate various levels of protection applicable to HRSA investigators, supervisors, and other stakeholders; (c) explain how to determine the appropriate procedures to support the human research protections in each HRSA program involving interventions with human subjects to ensure the safety of participants and the integrity of the data; (d) define specific responsibilities and processes for HRSA staff participating in planning, reviewing, executing, or administratively supporting research involving human participants; and (e) explain the exemption process for certain research that is exempt from human subjects research regulatory requirements.

## **II. Scope**

This policy applies to all HRSA research activities that involve human research participants or data use that contains identifiable private information for research conducted or supported by any HRSA Bureau, Office, or program (see Section III for definitions of research, human subject, etc.). The scope of this policy covers all HRSA intramural and extramural research and defines the exemption from regulatory requirements processes applicable to HRSA research activities.

## **III. Definitions**

### **A. Research**

HHS regulations at 45 CFR 46.102(d) defines "research" as a "systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." In the context of this policy, all activities meeting this definition constitute research whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

For the purposes of this policy, “research” should include all HRSA-conducted or supported epidemiological and service utilization studies, surveys, and evaluations involving a systematized collection and analysis of information for the purpose of developing or contributing to generalizable knowledge (i.e., new information that has relevance beyond the population or program from which it was collected). If a HRSA-conducted or supported program includes at least one component that is designed to develop or contribute to generalizable knowledge, then that component must be considered “research” even if the program is not generally considered “research.” The ultimate classification of an activity as “research” depends on the intent of the activity. “Research” would not ordinarily include public or personal health service programs that collect information *solely* to establish eligibility for public health services or benefits, or *solely* to record or evaluate the delivery of such services for internal program purposes. A program would also not be considered “research” if the purpose is to prevent/control disease, improve health, or improve a service or program, where the study would primarily benefit only program participants and any knowledge generated would not extend beyond the scope of the program. However, if the intent of a program (or component of a program) is to produce generalizable knowledge that benefits individuals beyond the program participants, then it would be considered “research.”

## **B. Human Subject**

HHS regulations at 45 CFR 46.102(f) define a “human subject” as a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. For example, human subjects in HRSA-conducted or supported research may include patients, clients, or beneficiaries who receive services, and the providers who deliver services.

## **C. Intervention or Interaction**

An intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulation of the subject or the subject's environment that are performed for research purposes. An interaction includes communication or interpersonal contact between investigator and subject.

## **D. Private Information**

Private information includes information about a behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an

individual and which the individual can reasonably expect, will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.<sup>3</sup>

## **IV. Background/Rationale**

### **A. Basic Ethical Principles for Protecting Human Subjects**

HRSA is committed to the protection of human subjects and their data by subjecting its research programs to the ethical principles defined in The Belmont Report. The ethical principles of respect for persons, beneficence, and justice articulated in The Belmont Report will underlie the conduct of all HRSA research activities involving human subjects. HRSA staff involved in the conduct or oversight of research and demonstration projects should become familiar with the provisions of these regulations, the background of these regulations, and ethical principles governing the conduct of research on human subjects.

The Belmont Report sets forth the following three basic ethical principles underlying the acceptable conduct of research involving human subjects:

#### **1. Respect for persons**

Involves a recognition of the personal dignity and autonomy of individuals, and special protections for those persons with diminished autonomy and underlies the need to obtain informed consent. Potential subjects should be treated as individuals capable of deliberate judgment; they must be given the opportunity to be fully informed about, and to choose voluntarily and without coercion, what will or will not happen to them. At the same time, appropriate protection must be offered to persons with diminished capacity for self-determination.

#### **2. Beneficence**

Entails an obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm. The principle of beneficence underlies the need to engage in a risk/benefit analysis and to minimize risks.

### **3. Justice**

Requires that the benefits and burdens of research be distributed fairly. Participants should be treated fairly. Selection of participants should be equitable so that benefits and burdens are shared fairly at both the individual and societal level.

## **B. HHS Regulations for the Protection of Human Subjects**

All human subjects research activities conducted or supported by HRSA will provide appropriate protections for human subjects, including, among other things, adequate provisions for minimizing risks to subjects, obtaining and documenting the legally effective informed consent of the subjects or the subjects' legally authorized representative, protecting the privacy of subjects, and maintaining the confidentiality of data. All intramural and extramural human subjects research activities conducted or supported by HRSA will provide all basic research participant protections and comply with all applicable ethical guidelines and regulations. HRSA will identify and comply with all regulatory responsibilities related to the protection of human subjects, including:

### **1. The Code of Federal Regulations (CFR)**

Part 46, Title 45 of the CFR, also known as the Common Rule, applies to all research involving human subjects conducted, supported or otherwise subject to regulation by HHS, including research conducted by federal civilian employees or military personnel, and research conducted, supported, or otherwise subject to regulation by the federal government outside the United States.

### **2. Informed Consent**

Participation in any research project must be voluntary. Informed consent must be obtained before individually identifiable private data are to be collected for study purposes, unless informed consent is waived by an institutional review board (IRB) under 45 CFR 46.116(c) or (d). The informed consent must be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative, unless the IRB waives documentation of consent under 45 CFR 46.117(c).

### **3. Federal Wide Assurance (FWA)**

The Federal Wide Assurance (FWA) is an assurance of compliance with the provisions of Title 45 CFR part 46 subparts A-D for the protection of human

subjects in research. Each institution engaged in human subjects research conducted or supported by HRSA must have an approved applicable assurance of compliance on file with the HHS Office for Human Research Protections (OHRP), unless the research is exempt under HHS regulations at 45 CFR 46.101(b). HRSA applied for, and now holds, an OHRP-approved FWA which sets out the responsibilities and procedures that must be followed whenever HRSA staff become engaged in the conduct of non-exempt research involving human subjects.

## **V. HRSA Policy**

### **A. Human Subjects Research at HRSA**

HRSA, through its Bureaus and Offices, administers a variety of service delivery and demonstration programs. While HRSA programs are not generally described as research programs, some HRSA service delivery and demonstration programs (or components of programs) may be designed to contribute to generalizable knowledge, and would be considered “research” as defined by HHS regulations at 45 CFR 46.101(d).

HRSA Bureaus and Offices also administer some specific research programs and a variety of epidemiological and service utilization studies, surveys, and evaluations that may be considered, at least in part, “research.” HRSA policy considers that any activity that involves obtaining private information about living individuals for purposes other than ordinary treatment, prevention, administrative, or project management purposes, may contain a “human subjects research” element. If any program (or component of a program) conforms to the regulatory definition of research involving human subjects, it must comply with an appropriate level of subject-protection procedures and human subjects participating in HRSA-conducted or supported research must be afforded the protections provided for under these regulations.

Please note that if any intervention to be studied or any data-gathering process involves any of the activities below, all procedures required by 45 CFR part 46 must be followed:

- Places any patient, client, beneficiary, subject, or member of the target population at more than minimal risk (including risk of disclosure of identifiable information);
- Involves any significant physical invasion or intrusion on the privacy of participants;
- Utilizes any experimental procedures or investigational drugs or devices; or

- Requires or withholds any accepted treatment for study purposes

HRSA is committed to ensuring that all human subjects participating in any research activities that HRSA conducts or supports (including exempt and non-exempt research activities) are appropriately protected, regardless of whether the research is exempt under HHS regulations at 45 CFR 46.101(b). Thus, this directive charges Associate Administrators and Office Directors to identify all research activities involving human subjects conducted or supported by their units, and ensure that they provide appropriate human subjects protections. In addition, the HRSA Committee for Human Research Protections is available for guidance to Bureaus and Offices as they work to identify research activities involving human subjects and assure adequate human subjects protection.

## **B. Obtaining Human Subjects Protection Clearance**

In all HRSA programs, exempt or not, the confidentiality of client information must be protected by appropriate security procedures. To obtain human subjects protection clearance, the responsible HRSA staff member must adhere to the following guidelines:

### **1. Identify Research Requiring Human Subjects Protection Measures**

Each Bureau and Office will identify all programs and projects that include research involving human subjects. Many surveillance or evaluation activities contain research elements; if an activity contains research involving human subjects, human subjects protection measures must be provided as appropriate to the specific situation involved. If not, no further action is needed with respect to human subjects protection.

### **2. Identify Appropriate Levels of Protection**

Each responsible HRSA staff member will determine the level of protection that is appropriate for each program or project. There are two levels of protection that may apply to research projects involving human subjects:

- a. For *any* activity identified as human subjects research, *basic ethical requirements* for human subjects protections as defined in the Belmont Report apply.
- b. For *some* activities identified as human subjects research, *specific regulatory requirements* for additional protections may also apply, as set forth in 45 CFR part 46. These requirements specify, among other things, that an IRB

approve research protocols, data collection instruments and procedures, and consent forms and consent procedures.

The level of protection to be required for any HRSA research program must be included in grant announcements and contract solicitations, to enable Applicants/Offerors to address human subjects protection issues appropriately. Research activities must be designated in one of the following categories:

- (i) an overt research program, service demonstration, survey, or service utilization study requiring human subjects protections as set forth in 45 CFR part 46; or
- (ii) an overt research program, service demonstration, survey, or service utilization study requiring human subjects protections, which has been determined to be *exempt* under 45 CFR 46.101(b) from the regulatory requirements.

## **C. Exemptions From Human Subjects Protection Requirements under 45 CFR part 46**

### **1. Categories of Exemption**

Research activities involving human subjects that are **exempt** from IRB review are identified in 45 CFR 46.101(b)(1)-(6). Note that institutions and IRBs may not create new categories of exempt research under 45 CFR Part 46. Also note that the exemptions at 45 CFR 46.101(b) do apply to research involving pregnant women, human fetuses, and neonates, but they do not apply to research involving prisoners. In addition, the exemption at 45 CFR 46.101(b)(2) is of limited applicability to research involving children.

There are three of several provisions allowing exemption from regulatory oversight requirements that are most frequently applicable to HRSA programs: the “research involving the use of educational tests, survey procedures, interview procedures or observation of public behavior” exemption of 45 CFR 46.101(b)(2), the “public or anonymous data” exemption of 45 CFR 46.101(b)(4), and the “public benefit and service program” exemption of 45 CFR 46.101(b)(5). Exemptions at HRSA might be observed in extramural and intramural research.

#### **a. Educational Tests, Surveys, Interviews, or Observations Exemption**

Provisions of 45 CFR 46.101(b)(2) permit exemption of research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

#### **b. Public or Anonymous Data Exemption**

Provisions of 45 CFR Part 46.101(b)(4) permit exemption of research involving the collection or study of existing documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available, or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly, or through identifiers linked to the subjects.

#### **c. Public Benefit and Service Program Exemption**

Provisions of 45 CFR Part 46.101(b)(5) permit exemption of research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

Guidance issued by the Office for Protection from Research Risks (the predecessor to OHRP) provides further clarification on this exemption, by listing four criteria which must be satisfied in order for the exemption at 46.101(b)(5) to apply:

(i) The program under study must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services as provided under the Older Americans Act).

(ii) The research or demonstration project must be conducted pursuant to specific federal statutory authority.

(iii) There must be no statutory authority that the project be reviewed by an IRB.

(iv) The project must not involve significant physical invasions or intrusions upon the privacy of participants.

Note that in some circumstances, no exemption from required IRB review can be claimed, even if the project or program might otherwise qualify for the “public benefit and service program” exemption of 45 CFR 46.101(b)(5). Specifically, if any intervention or data-gathering process places any patient, subject, or member of the target population at more than minimal risk (including risk of disclosure of information), involves any significant physical invasion or intrusion on the privacy of participants, utilizes any experimental procedures or investigational drugs or devices, or requires or withholds any accepted treatment for study purposes, all procedures required by 45 CFR part 46 must be followed, including mandatory submission of an appropriate assurance of compliance to OHRP, OHRP’s approval of the assurance, and oversight by a properly constituted IRB.

#### **D. Processes for Human Subjects Protection at HRSA**

The following sections of this policy outline the processes for human subject protections as they relate to extramural and intramural research activities.

##### **1. Process for Extramural Research**

In all research activities involving human subjects, it is HRSA's policy that grantees and contractors will ensure adequate protection of participants in accordance with federal regulations. In all requests, proposals, and applications for research activities involving human subjects, Applicants/Offerors for HRSA funds will be required to develop appropriate procedures for the protection of participants. All grantees and contractors will be required to comply with all applicable laws, regulations, and customary ethical practices for the protection of human subjects.

HRSA requires certification of IRB approval of the proposed research, however documentation of IRB certification may be delayed until after HRSA objective review of an application. Institutions engaged in non-exempt research activities involving human subjects supported by HRSA through grants, contracts, or other mechanisms must have an OHRP-approved FWA. Applicants/Offerors without an FWA will be required to obtain one from OHRP. In addition, grantees and

contractors will develop and implement appropriate procedures as called for in the federal regulations, and submit their project plans to their affiliated IRB for review and approval. Documentation of IRB review and approval must be received by the appropriate HRSA Bureaus and Offices before the funds may be used by the grantee/contractor to initiate human subjects research activities.

## **1.1. Grant or Cooperative Agreement Programs**

### **a. Non-Exempt Research**

#### *i. Competing Applications*

(i) The Project Officer will include language in the funding opportunity announcement (FOA) that Applicants must meet the requirements of 45 CFR part 46. The Project Officer will include the level of protection required (as described in Section V.B.2). Applicants must provide their human subject assurance number (from their FWA) in their application, or if they do not have an FWA they must indicate that they have submitted an application to obtain one from OHRP.

(ii) The Project Officer will check all competing applications to see that required human subjects protection assurance information is included. If it is not included, Applicants with an FWA will be advised to submit the necessary information before the application is formally reviewed. If FWA information has not been received in time for distribution to the reviewers, this will be flagged for the reviewers or review committee.

(iii) The review administrators will instruct the reviewers and/or review committee to identify competing grant applications that have human subjects protection issues that are not adequately addressed.

(iv) The reviewers or review committee will describe any deficiencies in human subject protection in their report, and may make recommendations regarding the design or suggest conditions of award.

(v) The award should not be made until the Applicant provides evidence of having an OHRP-approved FWA, except in rare circumstances where appropriate restrictive language, developed in consultation with HRSA's Human Subjects Protection Administrator, is included as a condition of grant award. If the Applicant does not hold an OHRP-approved FWA, the grants office will notify the Applicant of the need to negotiate an FWA with OHRP, and to submit documentation of this FWA to HRSA.

(vi) When applications involving human subjects research include additional collaborating institutions which do not hold applicable OHRP-approved FWAs, the grants office will notify the Applicant of the need for these collaborating institutions to negotiate FWAs with OHRP. In such cases, appropriate restrictive language, developed in consultation with HRSA's Human Subjects Protection Administrator, should be included as a condition of grant award.

(vii) An Awardee holding an OHRP-approved FWA must provide documentation of IRB review and approval to the Project Officer prior to research activities involving human subjects being initiated. In circumstances where a grant is awarded prior to the Applicant providing documentation of IRB review and approval, appropriate restrictive language, developed in consultation with HRSA's Human Subjects Protection Administrator, must be included as a condition of grant award.

(viii) In all cases, the Project Officer will see that human subjects protection concerns are resolved before research activity involving human subjects is initiated (see Sections IV.A and B).

*ii. Non-Competing Continuing Applications*

(i) Applicants must provide their human subject assurance number (from their FWA), as well as certification of IRB review and approval.

(ii) The Project Officer will check all non-competing continuing applications to see that Applicants have included both their human subjects protection assurance number (from their FWA) and evidence of IRB review and approval. If it is not included, Applicants will be advised to submit the necessary information.

(iii) The Project Officer will identify non-competing continuing grant applications that have human subjects protection issues that are not adequately addressed, and may make recommendations regarding the design or suggest conditions of award.

(iv) In circumstances where a non-competing continuing grant is awarded prior to the Applicant providing documentation of IRB review and approval, appropriate restrictive language, developed in consultation with HRSA's Human Subjects Protection Administrator, must be included as a condition of grant award.

(v) In all cases, the Project Officer will see that human subjects protection concerns are resolved before research activity involving human subjects is initiated (see Sections IV.A and B).

## **b. Exempt Research**

### *i. Competing Applications*

(i) The Project Officer will include language in the funding opportunity announcement (FOA) that Applicants must meet the requirements of 45 CFR part 46. The Project Officer will include the level of protection required (as described in Section V.B.2). For research that is exempt from institutional review, the Project Officer will include a description of the exemption, the conditions under which the exemption applies (as described in Section V.C.1), and, where needed, instructions for addressing human subjects protections if individual proposals do not fall under one of the categories for exemption defined in 45 CFR 46.

(ii) The review administrators will instruct the reviewers and/or review committee to identify grant applications that have human subjects protection issues that are not adequately addressed.

(iii) The reviewers or review committee will describe any deficiencies in human subject protection in their report, and may make recommendations regarding the design or suggest conditions of award.

(iv) In all cases, the Project Officer will see that human subjects protection concerns are resolved before research activity involving human subjects is initiated (see Section IV.A).

(v) For research activities involving human subjects which have been described as exempt, the Applicant may voluntarily choose to obtain an FWA from OHRP and submit the research proposal to an IRB for independent review and confirmation of exempt status.

### *ii. Non-Competing Continuing Applications*

(i) The Project Officer will identify non-competing continuing grant applications that have human subjects protection issues that are not adequately addressed, and may make recommendations regarding the design or suggest conditions of award.

(ii) In all cases, the Project Officer will see that human subjects protection concerns are resolved before research activity involving human subjects is initiated (see Sections IV.A and B).

(iii) For research activities involving human subjects which have been described as exempt, the Applicant may voluntarily choose to obtain an FWA from OHRP and submit the research proposal to an IRB for independent review and confirmation of exempt status.

## **1.2. Contracts**

### **a. Non-Exempt Research**

(i) New contracts: The Contracting Officer's Representative will provide language to include in Request for Proposals (RFP) and Request for Quotes (RFQ), indicating that Offerors must meet the requirements of 45 CFR part 46. The Contracting Officer's Representative will include the level of protection required (as described in Section V.B.2). Offerors must provide their human subject assurance number (from their FWA) in their proposal, or if they do not have an FWA, they must indicate in their proposal that they have submitted an application to obtain one from OHRP.

(ii) When the Offeror proposes to use subcontractors to perform tasks involving human subjects research, the Offeror will provide in their proposal the human subject assurance number from each proposed subcontractor's FWA or will indicate that it will provide the FWA number prior to contract award.

(iii) The Contracting Officer will check all proposals to see that required human subjects protection assurance information is included. A contract may be awarded without discussions and without the possibility of submission of a revised proposal. Because the FWA is a mandatory qualification criterion for non-exempt research, the FWA information must be provided to the Contracting Officer by the time of contract award.

(iv) The Contracting Officer will include human subjects protection considerations as part of the technical evaluation criteria, and will instruct members of the Technical Evaluation Panel to identify proposals that have human subjects protection issues that are not adequately addressed.

(v) The Technical Evaluation Panel's review will identify and/or describe any deficiencies in human subject protection and deduct points for these

deficiencies. The Technical Evaluation Panel will document these deficiencies in their summary review report to the Contracting Officer.

(vi) No contract will be awarded unless the Offeror has provided evidence of having an OHRP-approved FWA. A Contractor holding an OHRP-approved FWA must provide as a contract deliverable documentation of IRB review and approval of the final research protocol to the Contracting Officer's Representative before research activities involving human subjects are initiated.

(vii) At the exercise of each option period in a multiple-year contract, the Contractor must provide their current FWA number to the Contracting Officer. The Contracting Officer may not issue the option without the Contractor's current FWA number. Additionally, if IRB approval was a deliverable in an option period, the Contracting Officer must confirm with the Contracting Officer's Representative that the deliverable of the IRB's approval has been received.

(viii) In all cases, the Contracting Officer's Representative will see that human subjects protection concerns are resolved before research activity involving human subjects is initiated (see Sections IV.A and B), and will contact the Contracting Officer if issues arise.

#### **b. Exempt Research**

(i) New contracts: The Contracting Officer's Representative will provide language to include in the Request for Proposals (RFP) and Request for Quotes (RFQ), indicating that Offerors must meet the requirements of 45 CFR part 46. The Contracting Officer's Representative will include the level of protection required (as described in Section V.B.2). For research that is exempt from institutional review, the Contracting Officer's Representative will include a description of the exemption, the conditions under which the exemption applies (as described in Section V.C.1), and, where needed, instructions for addressing human subjects protections if individual proposals do not meet the criteria for exemption (e.g., an Offeror proposes an approach that involves some risk for participants).

(ii) The Contracting Officer will include human subjects protection considerations as part of the technical evaluation criteria, and will instruct members of the Technical Evaluation Panel to identify proposals that have human subjects protection issues that are not adequately addressed.

(iii) The Technical Evaluation Panel's review will identify and/or describe any deficiencies in human subject protection and deduct points for these deficiencies. The Technical Evaluation Panel will document these deficiencies in their summary review report to the Contracting Officer.

(iv) In all cases, the Contracting Officer's Representative will see that human subjects protection concerns are resolved before research activity involving human subjects is initiated (see Section IV.A), and will contact the Contracting Officer if issues arise.

(v) For research activities involving human subjects that have been described as exempt, the Offeror/Contractor may voluntarily choose to obtain an FWA from OHRP and submit the research proposal to an IRB for independent review and confirmation of exempt status.

## **2. Process for Intramural Research**

### **a. Non-Exempt Research**

HRSA Bureaus and Offices conducting non-exempt research activities involving human subjects will comply with the Statement of Ethical Principles and Terms of Assurance for Protection of Human Subject provisions set forth in the HRSA FWA. The project director or principal investigator must arrange for review of the project by an IRB that is designated in the HRSA FWA.

Under its FWA, HRSA has designated the Centers for Disease Control and Prevention, National Center for Health Statistics (NCHS) IRB to review intramural research proposals in accordance with 45 CFR part 46. Staff support for the IRB is provided by NCHS. The HRSA Human Subjects Protection Administrator is available to coordinate submissions to the NCHS IRB on behalf of all HRSA Bureaus and Offices engaged in intramural research. Bureaus and Offices who submit their applications directly to the NCHS IRB will provide a copy of the IRB approval letter to the HRSA Human Subjects Protection Administrator.

If the project director or principal investigator wishes to use an alternate IRB not designated in HRSA's FWA, the requesting Bureau or Office must obtain a written IRB Authorization Agreement signed by the Signatory Officials from both HRSA and the alternate IRB's sponsoring institution. This agreement must be kept on file at both institutions/organizations and made available upon request.

The project director or principal investigator will see that all human subjects protection concerns are resolved before initiating research activity.

## **b. Exempt Research**

HRSA policy is that investigators do not have the authority to make an independent determination that research involving human subjects is exempt and should consult with the authorities designated in this policy concerning the status of proposed research or changes in ongoing research.

Regardless of any exemption, the responsible HRSA staff member will ensure that the ethical protections outlined in the Belmont Report are applied to all research programs and projects involving human subjects. If the exemption request is not approved, the responsible HRSA staff member will follow the procedures outlined above (in Section V.D.2.a). If unsure about the applicability of any of the exemptions outlined above, contact the HRSA Human Subjects Protection Administrator.

*1. When existing data, which are publicly available or recorded anonymously, are the only data sources to be used, the responsible HRSA staff member should request an exemption under 45 CFR 46.101(b)(4), by submitting documentation to the responsible Associate Administrator or Office Director on how the program or project meets the applicable criteria. The Associate Administrator or Office Director will determine the appropriateness of the exemption by reference to the relevant criteria. The Associate Administrator or Office Director may give final and definitive approval to a request for exemption, and should submit notification of this exempt status to the HRSA Human Subjects Protection Administrator.*

*2. For all other types of exemptions, the responsible HRSA staff member should request an exemption by submitting documentation to the responsible Associate Administrator or Office Director on how the program or project meets the above criteria. Upon examination and endorsement of compliance with HRSA and Department policy by the responsible Associate Administrator or Office Director, the responsible HRSA staff member should submit a request for exemption to the HRSA Committee for Human Research Protections.*

(i) Determination of exemption for intramural research involving human subjects is conducted by the HRSA Committee for Human Research Protections. The responsible HRSA staff member submits an exemption request form (that has been reviewed and approved by the Associate Administrator or Office Director) to the Committee. The requesting Bureau or Office will provide any information required by the Committee in making its determination.

(ii) The HRSA Committee for Human Research Protections will make an exemption determination following guidance and procedures by OHRP. The Committee, by affirmative vote of two-thirds of its members eligible to vote, may determine that the claim of exemption meets the criteria of 45 CFR 46.101(b). Any member of the Committee employed by the proposing Bureau or Office will abstain from voting on any program sponsored by that Bureau or Office. The rationale for approval or disapproval of a request for exemption will be documented and shared with the requesting Bureau or Office. It is important to note that the Secretary of HHS retains final authority as to whether a particular human subjects research study conducted or supported by HHS is exempt from the HHS regulations (45 CFR 46.101(c)).

(iii) The HRSA Human Subjects Protection Administrator will notify the responsible HRSA staff member, as well as the Associate Administrator or Office Director, in writing of the Committee's decision, briefly describing the exemption and the conditions under which the exemption was granted. If the Committee decides that the program or project is not exempt, the responsible HRSA staff member will follow the procedures outlined above (in Section V.D.2.a.) and seek IRB approval.

## **VI. HRSA Contact for Human Subjects Protection**

Lydie A. Lebrun-Harris, PhD, MPH  
HRSA Human Subjects Protection Administrator  
Office of Research and Evaluation  
Office of Planning, Analysis and Evaluation

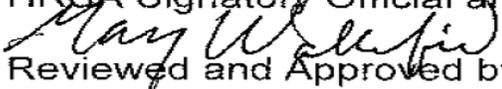
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Signed by



Marcia Brand, PhD

HRSA Signatory Official and Deputy Administrator



Reviewed and Approved by

Mary K. Wakefield, PhD, RN

HRSA Administrator

***This policy was last updated: October 2014***