The Centers for Disease Control and Prevention (CDC[1]) has issued the **"Distinguishing Public Health Research and Public Health Nonresearch"** Policy

1. **Reason for Issue**: This policy strengthens CDC's longstanding guidelines on distinguishing research from nonresearch activities and will support continuing excellence in public health service, including surveillance, program evaluation, and public health response activities.

2. **Summary of Policy:** CDC has an ethical and legal obligation to ensure that individuals are protected in all public health research activities it conducts. All CDC activities must be reviewed to determine whether they are research involving human participants. When an activity is classified as research involving human participants, CDC and its collaborators will comply with Title 45, Code of Federal Regulations, Part 46 in assuring human research protections. The policy specifically addresses:

   - Guidelines for compliance
   - Definitions of research and nonresearch activities and examples of different categories of each
   - Responsibilities of investigators, supervisors, and other stakeholders necessary to support the program

3. **Related Issues:** CDC Policy, Human Research Protections

4. **Responsible Officials:** Office of the Associate Director for Science

5. **Material Superseded**: None

6. **Recertification:** This document is scheduled for recertification on or before the last working day of July 2015.

7. **Point of Contact:** Tom Jones, Policy Analyst, Management Analysis and Services Office 404-498-1516.

   To go directly to the policy, click on the link below or enter the following URL into the location line of your browser.

   http://aops-mas-iis.cdc.gov/policy/Doc/policy557.pdf

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[1] References to CDC also apply to the Agency for Toxic Substances and Disease Registry (ATSDR)

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DISTINGUISHING PUBLIC HEALTH RESEARCH AND PUBLIC HEALTH NONRESEARCH

SECTIONS

1. PURPOSE AND SCOPE

The Centers for Disease Control and Prevention (CDC)[1] is committed to protecting the rights and welfare of individuals who participate in all public health activities. In the conduct of public health research, CDC follows the Code of Federal Regulations, Title 45, Part 46, which codifies regulations for the protection of human research participants.

This policy sets forth CDC guidelines on the definition of public health research conducted by CDC staff irrespective of the funding source, whether provided by CDC or by another entity. Under federal regulations (45 CFR part 46), the determination of what is research and whether the federal regulations are applicable lies with CDC and, ultimately, with the Office for Human Research Protections (OHRP) at the U.S. Department of Health and Human Resources (HHS). Thus, this document is intended to apply to CDC activities and CDC-supported activities carried out by state and local health departments and other institutions that conduct collaborative research with CDC. The policy is intended to ensure both the protection of human research participants and the effective practice of public health.

2. BACKGROUND

In 1974, the Department of Health and Human Services (at that time, the Department of Health, Education and Welfare) developed regulations to assure the protection of human research participants from research risks. These regulations were developed to address ethical issues raised in connection with biomedical or behavioral research involving human research participants. These regulations, referred to as 45 CFR part 46, have been revised several times.

The practice of public health poses several challenges in implementing 45 CFR part 46. Some public health activities can unambiguously be classified as either research or nonresearch. For other activities the classification is more difficult, because 45 CFR part 46 does not directly address many public health activities. In addition, the statutory authority of state and local health departments to conduct public health activities using methods similar to those used by researchers is not recognized in the regulations. Appropriate protections applicable for activities occurring at the boundary between public

1 References to CDC also apply to the Agency for Toxic Substances and Disease Registry (ATSDR).

health nonresearch and public health research are not readily interpretable from the regulations.

The regulations state that "research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge" (45 CFR 46.102(d). Obtaining and analyzing data are essential to the usual practice of public health. For many public health practice activities, data are systematically collected and analyzed. Scientific methods are used in both public health research as well as public health practice activities. Knowledge is generated in both cases. Furthermore, the extent to which knowledge is generalizable might not differ greatly in research and nonresearch. Thus, nonresearch and research activities cannot be easily defined by the methods they employ. Three public health activities – surveillance, emergency response, and evaluation – are particularly susceptible to the quandary over whether the activity is research or nonresearch.

The word “designed” in the regulatory definition of research is key for classifying public health activities as either research or nonresearch. The major difference between research and nonresearch lies in the *purpose* of the activity. The purpose of research is to generate or contribute to generalizable knowledge. The purpose of nonresearch in public health is to prevent or control disease or injury and improve health, or to improve a public health program or service. Knowledge might be gained in any public health endeavor designed to prevent disease or injury or to improve a program or service. In some cases, that knowledge might be generalizable, but the purpose of the endeavor is to benefit clients participating in a public health program or a population by controlling a health problem in the population from which the information is gathered.

Classifying an activity as research does not automatically lead to review by an institutional review board (IRB) for the protection of human research participants. Once an activity is classified as research, three additional determinations must be made:

1. Is the activity research involving human participants?
2. If the activity is nonexempt research involving human participants, which institutions are engaged in research and are required to certify IRB approval?
3. If the activity is research involving human participants, does the research meet the criteria for exemption from 45 CFR part 46?

This policy deals only with the first determination of whether a public health activity is research or nonresearch. Activities that are determined to be research are further addressed in CDC’s Policy on Human Research Protections (CDC-SA-2010-01).

3. POLICY

CDC has an ethical and legal obligation to ensure that individuals are protected in all public health research activities it conducts. All CDC activities must be reviewed to determine whether they are research involving human participants. When an activity is classified as research involving human participants, CDC and its collaborators will comply with 45 CFR part 46 in assuring human research protections.

Some surveillance projects, emergency responses, and evaluations are research involving human participants; others are not. Each project must be reviewed on a case-by-case basis. Although general guidance can be provided to assist in classifying these activities as either research or nonresearch, no one criterion can be applied universally. The ultimate decision regarding classification lies in the purpose of the project. If the purpose is to develop or contribute to generalizable knowledge, the project is research. If

the purpose is to prevent or control disease or injury or to improve a public health program, and no research is intended at the present time, the project is nonresearch. If the purpose changes to developing or contributing to generalizable knowledge, then the project becomes research.

4. GUIDELINES FOR COMPLIANCE

A. General

The Associate Director for Science (ADS) in each National Center (NC) has been given the responsibility to determine whether a project constitutes research involving human participants. This authority may be redelegated at the discretion of the ADS. If the ADS is unclear about classifying a project, the ADS should consult with the chief of CDC's HRPO. This determination is made by examining the purpose of the project. What is the purpose for which the project was designed?

General Attributes of Public Health Research – The purpose of the activity is to develop or contribute to generalizable knowledge to improve public health practice; intended benefits of the project can include study participants, but always extend beyond the study participants, usually to society; and data collected exceed requirements for care of the study participants or extend beyond the scope of the activity. Generalizable knowledge means new information that has relevance beyond the population or program from which it was collected, or information that is added to the scientific literature. Knowledge that can be generalized is collected under systematic procedures that reduce bias, allowing the knowledge to be applied to populations and settings different from the ones from which it was collected. Generalizable, for purposes of implementing the definition of research, does not refer to the statistical concept of population estimation, or sampling, which is collecting information from selected individuals in order to understand health in the population from which the sample came. Holding public health activities to a standard of studying every case in order to classify an activity as nonresearch is not practical or reasonable, nor is it necessary for nonresearch activities.

General Attributes of Nonresearch – The purpose of the activity is to identify and control a health problem or improve a public health program or service; intended benefits of the project are primarily or exclusively for the participants (or clients) or the participants' community; data collected are needed to assess or improve the program or service, the health of the participants or the participants' community; knowledge that is generated does not extend beyond the scope of the activity; and project activities are not experimental.

Other attributes, such as publication of findings, statutory authority (see discussion in next section), methodological design, selection of participants, and hypothesis testing or generating, do not differentiate research from nonresearch, because these types of attributes can be shared by both research and nonresearch activities.

A nonresearch activity can develop or contribute to generalizable knowledge after the project is undertaken even though generating this knowledge was not part of the original purpose. In this case, because the purpose was not to develop or contribute to generalizable knowledge, the project is not classified as research at the outset. However, if subsequent analysis of identifiable private information is undertaken to develop or contribute to generalizable knowledge, the analysis constitutes human research that now requires further consideration under 45 CFR part 46.

If a project includes multiple components and at least one of those components is designed to develop or contribute to generalizable knowledge, then the entire project is classified as research unless the components are separable.

B. Public Health Surveillance

Public health surveillance is a series of ongoing systematic activities, including collection, analysis, and interpretation of health-related data essential to planning, implementing, and evaluating public health practice closely integrated to the dissemination of data to those who need to know and linked to prevention and control. Public health surveillance is predicated on the need to address a defined public health problem or question and aimed at the use of data to guide efforts to protect and promote population health. Surveillance systems can be either research or nonresearch, depending whether the purpose is to identify and control a health problem or to contribute to knowledge beyond the system's participants, to society.

Surveillance systems are likely to be nonresearch when they involve the regular, ongoing collection and analysis of health-related data conducted to monitor the frequency of occurrence and distribution of disease or a health condition in the population. Data generated by these systems are used to manage public health programs. They have in place the ability to invoke public health mechanisms to prevent or control disease or injury in response to an event. Thus, the purpose of these surveillance systems is to prevent or control disease or injury in a defined population by producing information about the population from whom the data were collected.

These nonresearch attributes of surveillance are generally found in state statute or regulation where the intent of the activity, its purposes, and uses of the data are specified. Surveillance systems that most easily fit into this category are systems in which the data, such as disease or event reports, are limited to describing the occurrence of a health-related problem. Subjects are rarely selected according to a design; rather, observed cases are entered into the surveillance system as they are identified. Hypothesis testing is rarely part of the system, although often a system can be hypothesis-generating.

Surveillance systems are likely to be research when they involve the collection and analysis of health-related data conducted either to generate knowledge that is applicable to populations and settings other than the ones from which the data were collected or to contribute to new knowledge about the health condition. The information gained from the data collection system might be used to invoke public health mechanisms to prevent or control disease or injury, but this is not a purpose of the project. Thus, the purpose of these surveillance systems is to develop or contribute to generalizable knowledge. Surveillance systems most easily fit into this category if they entail longitudinal data collection systems (such as follow-up surveys and registries) that allow for hypothesis testing; if the scope of the data is broad and includes more information than occurrence of a health-related problem; if analytic analyses can be conducted; and if cases are identified in order to be included in subsequent studies.

In general, disease reporting, monitoring requirements and other data collection activities conducted under state statute or under recognized public health authority are nonresearch. Disease or event reporting activities are not research. Disease or event reporting, for these purposes, is defined narrowly to include the reporting of the specific health condition or disease; demographic information; and accepted, known risk factors as specified in state statutes or regulations. When reporting systems collect data beyond standard reporting information, the reporting activity is not automatically considered to be

nonresearch. Collection of data that would allow etiologic analysis is likely to be research if its purpose is to develop or contribute to generalizable knowledge.

If other activities are added to a surveillance project with the specific purpose of developing or contributing to generalizable knowledge, these additional activities are considered to be research. It becomes important to distinguish between event reporting activities that are nonresearch and uses of the reported data that can be either nonresearch or research.

Sometimes, CDC funds state and local health departments to establish surveillance systems with dual intentions on the part of CDC: to build state capacity in disease reporting and for CDC to generate new knowledge. Disease reporting activities conducted at the state level are generally nonresearch. However, if these are aggregated and analyzed at the national level to generate new knowledge, then those activities would constitute research at the national level, but might or might not be research at the state level. If the states' purpose for data collection is solely to identify and control a health problem, their activity would be considered nonresearch. If states are participating beyond merely providing the data, they might be considered as engaged in the research. Institutions providing information to state health departments would not be considered engaged in the research (OHRP, 2008).

Some surveillance projects do not fit easily into the categories described above. For these projects, the purpose and elements of the project must be examined carefully.

C. Emergency Response

Emergency response activities tend to be nonresearch because these projects are undertaken to identify, characterize, and solve an immediate health problem and the knowledge gained will directly benefit those participants involved in the investigation or their communities. However, an emergency response might have a research component if, for example, samples are stored for future use intended to generate generalizable knowledge or additional analyses are conducted beyond those needed to solve the immediate health problem. For emergency responses, whenever a systematic investigation of a non-standard intervention or a systematic comparison of standard interventions occurs, the activity is research.

When unapproved drugs or devices are used or drugs or devices are used for unapproved purposes, their use might either fall under an Emergency Use Authorization (EUA) or under FDA regulations. Decision-making about these activities is particularly complicated, as they might or might not meet the definition of research at 45 CFR 46.102(d) and they might or might not meet the definition of clinical investigation at 21 CFR 56.102(c). Careful consideration and consultation with the Center ADS and the manager of HRPO is warranted in these situations.

D. Evaluation

The terms "evaluation" and "program evaluation" are used interchangeably. Yet, there are subtle differences between the two terms (see definitions and reference provided above). Evaluation is a broad term that refers to the systematic use of scientific methods to measure efficacy, implementation, utility, and other characteristics of a program or its components. Evaluations might or might not be research. Program evaluations are a subset of evaluations. As defined here program evaluations are generally nonresearch.

When the purpose of an evaluation is to test a new, modified, or previously untested intervention, service, or program to determine whether it is effective, the evaluation is research. The systematic comparison of standard or nonstandard interventions in an experimental-type design is research. In these cases, the knowledge gained is applicable beyond the individual, specific program. Thus, the purpose is to generate new knowledge or contribute to the knowledge in the scientific literature. Further, it is intended to apply the knowledge to other sites or populations.

When the purpose is to assess the success of an established program in achieving its objectives in a specific population and the information gained from the evaluation will be used to provide feedback to that program, the evaluation, referred to as program evaluation, is nonresearch. In the nonresearch scenario, the evaluation is used as a management tool to monitor and improve the program. The evaluation activity is often a component of the regular, ongoing program. Information learned from the evaluation has immediate benefit for the program or the clients receiving the services or interventions. Interventions and services that are evaluated are never experimental or new; they are known (either from empirical data or through consensus) to be effective.

Sometimes, the term "formative evaluation" is used to describe data collection activities that occur before the implementation of an intervention, service, or program. Whether the "formative evaluation" is research or nonresearch depends on its purpose. If the evaluation is conducted before implementing a new, modified, or previously untested intervention, the evaluation is part of the overall research project. If the evaluation is conducted to provide information on how to tailor a proven-effective intervention, service, or program in a specific setting or context, the evaluation is not research.

Evaluations of programs that CDC funds to all state health departments, and in which evaluation is one component, are not research. These evaluation activities are on-going and generally involve the collection of minimal, standard data elements across all sites. The data are generally used at both the local and national levels as a management tool. Sometimes, data from these evaluation activities will be aggregated at CDC and used for other purposes. Depending on the purpose, subsequent use of the data might constitute research.

In some cases, program activities and evaluation activities are separable. For example, interventions or services are being provided; they have a history of being provided and there is an intention to continue to provide them. An evaluation is conducted to determine the efficacy of these program activities. In another example, a public health department, under its public health authority, might provide an untested intervention in an outbreak situation. An evaluation component is added. In both of these examples, because the intervention and evaluation activities are undertaken with different purposes and are separable, the intervention activities are not research but the evaluation activities are research.

5. EXAMPLES

Examples are provided below of CDC surveillance, emergency responses, and evaluation activities that are nonresearch and research.

A. Surveillance

(1) Nonresearch

National Notifiable Diseases Surveillance System (NNDSS) – States and territories have asked CDC to act as a common data collection point for data on nationally notifiable diseases. A notifiable disease is considered by the Council of State and Territorial Epidemiologists to be a condition for which regular, frequent, and timely information about individual cases is necessary at the national level for the prevention and control of disease. NNDSS data are collected and published weekly in the Morbidity and Mortality Weekly Report and annually in the Summary of Notifiable Diseases, United States. The NNDSS is essential to the day to day practice of public health. The purpose of the surveillance system is to provide CDC and state and local health officials with information to prevent, detect, and control outbreaks of disease. The NNDSS is also used to measure the impact of programs such as immunization. The intended benefits resulting from the NNDSS are for the residents of the states and local areas who contribute data to the system.

Diabetes Surveillance

A national diabetes surveillance system is compiled using public use data from several national surveys. Data from the surveillance system are used to describe the burden of diabetes and its complications on a national and state level. The purpose of the surveillance system is to provide information for the development and improvement of national and state public health programs and services for the prevention and control of diabetes. The intended benefits are for those who have diabetes or those who are at risk of developing diabetes.

(2) Research

A Sentinel Surveillance System for Lassa Fever in the Republic of Guinea – Four study sites were selected to identify and describe cases of Lassa fever. Cases were identified from hospital and outpatient admissions. The purpose of the project was to generate baseline information on the Lassa virus and human clinical Lassa fever in the Republic of Guinea. No public health interventions were planned as part of this project; there was no direct benefit for study participants. Thus, the purpose was to contribute to the generalizable knowledge of Lassa fever.

Developmental Disabilities in Very Low Birthweight Children: Linkage of the Georgia Very Low Birthweight Study and the Metropolitan Atlanta Developmental Disabilities Surveillance Program – The Metropolitan Atlanta Developmental Disabilities Surveillance Program, an ongoing CDC surveillance program to monitor trends in the occurrence of selected developmental disabilities in children living in the metropolitan Atlanta area, and the Georgia Very Low Birthweight Study, conducted in the 1980s to investigate the environmental and other risk factors for very low birthweight were linked for specific investigations of adverse developmental outcomes. Linkage of these primary files provides a unique opportunity to assist efforts to assess the occurrence of selected developmental disabilities in metropolitan Atlanta children and to identify causes of these

conditions without the additional time and resource expenditure of additional field data collection. For these investigations involving secondary analyses of the linked primary data sets, no individuals were contacted; only information available from the linkage was used. The purpose of the project was to estimate the prevalence of cerebral palsy, intellectual disability, and hearing and visual impairments and to identify pre- and perinatal medical and sociodemographic risk factors for these disabilities in a population-based cohort of very low birthweight children in Atlanta. The purpose was to generate generalizable knowledge about developmental disabilities.

B. Emergency Responses

(1) Nonresearch

Outbreak of Gastroenteritis – Three days after a cruise ship left Los Angeles, California for several ports in Mexico, CDC was notified that 24 of 1,899 passengers and 6 of 670 crew had presented to the ship's infirmary with gastrointestinal illness. The purpose of the investigation was to determine the cause and extent of the outbreak and to prevent and control gastrointestinal illness among the ship's passengers and crew. Although this type of investigation is often undertaken after the outbreak has occurred and, therefore, information gained is likely to benefit the ship's next set of passengers and crew, the purpose of the investigation is to assist in preventing and controlling the current gastroenteritis outbreak.

Recall Peanut Butter Containing Products Due to Salmonella –CDC collaborated with several state and local health departments and the Food and Drug Administration to investigate an outbreak of infections caused by salmonella. When the outbreak was first detected, the source was not immediately apparent. After several weeks of detailed case interviews, investigations of local clusters of illness, and joint epidemiologic efforts across states the source was identified as peanut butter and peanut paste made at a processing plant in Blakely, Georgia. The purpose of the investigation was to identify the source of the outbreak and prevent and control the enterocolitis outbreak caused by the contaminated products.

(2) Research

Childhood Exposure to Nicotine-Containing Products in Rhode Island – Between January 1, 1995, and June 30, 1996, 90 cases of childhood exposure to nicotine-containing products were reported to the Rhode Island Poison Control Center. No known population-based investigation has been conducted to determine risk factors associated with childhood exposure to nicotine-containing products. The purpose of the investigation was to determine risk factors associated with childhood exposure to nicotine-containing products, and to develop appropriate control measures. Although there might be some benefit to the 90 children exposed in Rhode Island, the benefits from this study extend beyond the study participants to the population of children who are at risk of exposure to nicotine-containing products. In addition, there was no immediate health problem to be controlled. Thus, the purpose of the investigation was to generate generalizable knowledge about the risk factors associated with childhood exposure to nicotine-containing products.

Azithromycin Used as Prophylaxis Against the Spread of Illness Due to *Mycoplasma pneumoniae* in the Setting of an Outbreak – During the first week of freshman entering a post-high school academic institution, a cluster of respiratory illness was recognized by the infirmary staff. Early serologic testing suggested *Mycoplasma pneumoniae* as the etiologic agent. About four weeks later 42% of the freshman and 17% of the upperclassmen reported a respiratory illness; 50% of those tested had serologic evidence of *Mycoplasma pneumoniae* infection. The lower attack rate among upperclassmen was likely a consequence of their returning to campus 15 days after the freshmen arrived. A trial of chemoprophylaxis with azithromycin was proposed. Highly effective control measures in the setting of an outbreak have not been described. There is limited information about the role of antimicrobials in controlling an epidemic of *Mycoplasma pneumoniae*. Thus, the purpose of the investigation was to generate generalizable knowledge about the efficacy of azithromycin to prevent the spread of *Mycoplasma pneumoniae* in an outbreak situation.

C. *Program Evaluation*

(1) Nonresearch

Evaluation of School-based HIV Prevention Program – As part of the evaluation of the school-based HIV prevention program in Denver public schools, principals, teachers, staff in contact with students, students, and parents were interviewed. HIV program efforts in policy awareness, staff development, curriculum implementation, and status of students receiving HIV prevention education were assessed.

The purpose of the program evaluation was to provide information to Denver public schools that will be used to improve their school-based HIV prevention programs. The results from the evaluation were used to assess the success of the interventions in a specific population (Denver public school children) and to refine the interventions in that population.

IMPACT Progress Reports – The Office on Smoking and Health awarded to health departments in 32 states and the District of Columbia cooperative agreements to build capacity to conduct tobacco use prevention and control programs. These cooperative agreements are part of CDC's Initiatives to Mobilize for the Prevention and Control of Tobacco Use (IMPACT), which is a nationwide effort to establish comprehensive, coordinated tobacco use prevention programs. Evaluation of IMPACT requires awardees to submit semi-annual progress reports. Information in the evaluation reports includes staffing, coalition composition and efforts, status of a state tobacco control plan, development of a resource center, training efforts, community outreach and mobilization, and participation in CDC national campaigns.

The purpose of these program evaluations is to assess the success of tobacco use prevention and control programs within each state. The information gained from the evaluation is used to improve these programs. In addition, the information is used nationally to evaluate the success of the IMPACT program.

(2) Research

Evaluation of Community Based Organization Intervention to Reduce Sexually Transmitted Disease (STD) Rates Among STD Patients in Miami – Male STD patients were randomly assigned to either the standard HIV prevention counseling or intensive

counseling comprised of four sessions of HIV counseling from a community based organization. STD clinic records were reviewed to determine whether there was a difference in return rates of patients with new STDs between the study groups, testing the two interventions. The objective of the intervention and evaluation is to determine whether intensive counseling reduces the acquisition of new STDs among high risk people attending a STD clinic. The purpose of the project was to evaluate a new intervention for reducing the transmission of STDs. Knowledge gained from this evaluation would be generalized to reducing incidence of sexually transmitted diseases at other sites.

A Comprehensive Evaluation for Project DIRECT (Diabetes Intervention: Reaching and Educating Communities Together) – Project DIRECT is a community diabetes demonstration project targeting African American adults residing in Raleigh, North Carolina. The project is three-tiered and addresses diabetes care, community screening for persons at high risk for developing diabetes, and population based approaches to increase physical activity and reduce dietary fat intake (two risk factors for diabetes). The goals of the community project are to reduce preventable complications of diabetes via a health systems approach; increase the proportion of persons at risk for diabetes who are screened; and increase the proportion who participate in regular, vigorous, physical activity and eat a reduced- fat diet. Baseline and follow-up population-based surveys are planned to evaluate the community intervention. The purpose of this project is to evaluate new and innovative interventions to prevent diabetes and its complications. Knowledge gained from this project will be used to develop similar intervention projects in other communities.

6. RESPONSIBILITIES

All persons covered by this policy are responsible for being familiar with human research regulations, this policy, and related policies and practices as they relate to their official duties. The full set of responsibilities is listed in CDC's Policy on Human Research Protections (CDC-SA-2010-01). Specific responsibilities related to distinguishing research from nonresearch are listed here.

A. Investigators

1. Submit proposed activities for human research review under NC procedures, including research/nonresearch determinations and exempt/nonexempt human research. Ensure that the design of proposed activities conforms to acceptable scientific, ethical, and legal requirements. Determine that the resources necessary to protect participants are present before conducting the research activity. Declare competing interests.
2. For nonexempt human research or clinical investigations conducted by CDC, obtain IRB approval prior to CDC's conducting the activity. This approval must generally be obtained before involving human participants, unless CDC undertakes collaboration on a project that has previously been approved by one or more other IRBs.
3. Ensure appropriate protections, such as for privacy and confidentiality, when research is not covered by human research regulations (e.g., because it is exempt or because CDC is not engaged).

B. Supervisors

This includes employees with responsibility for administrative supervision, such as team leaders, branch chiefs, division directors, and NC directors.

1. Ensure that each human research activity has adequate resources, such as enrollment capacity, time for completion, and qualified staff.
2. Ensure appropriate protections, such as for privacy and confidentiality, when activities are not covered by human research regulations (e.g., because it is exempt research).

C. Associate Directors for Science

This includes Associate Directors for Science or equivalent scientific oversight roles at branch, division, and NC levels.

1. Provide guidance to and mentor investigators and supervisors on scientific, ethical, legal, and policy-related practices for human research.
2. Perform timely regulatory, ethical, and scientific reviews when routing proposals, including categorizing research, involvement of human participants, agency engagement, regulatory exemptions, routing to CDC or non-CDC IRB, and related reviews. Ensure that the research uses procedures consistent with sound research design sufficient to yield the expected knowledge and that each protocol has sufficient resources. Determine that the resources necessary to protect participants are present before permitting the research activity. Assess investigators' competing interests.
3. As a condition for clearing information products, ensure appropriate compliance with scientific, ethical, legal, and policy-related requirements. Require that research-related information products that are submitted for clearance have been derived from research that complies with human research ethics and regulations.
4. Ensure appropriate protections, such as for privacy and confidentiality, when activities are not covered by human research regulations (e.g., because it is exempt research).

D. Human Research Protection Coordinators

This includes Human Research Protection Coordinators or equivalent human research analyst roles at branch, division, and NC levels.

1. Provide guidance to investigators and supervisors on scientific, ethical, legal, and policy-related practices for human research.
2. Perform timely regulatory and ethical reviews when routing proposals, including categorizing research, involvement of human participants, agency engagement, regulatory exemptions, routing to CDC or non-CDC IRB, and related reviews.
3. Ensure appropriate protections, such as for privacy and confidentiality, when research is not covered by human research regulations (e.g., because it is exempt or because CDC is not engaged).
4. Demonstrate that research-related information products that are submitted for clearance have been derived from research that complies with human research ethics and regulations.

E. Institutional official

The designated Signatory Official on CDC's FWA is authorized to do the following:

1. Exercise the responsibility of the CDC Director, under 45 CFR 46.103(c), to provide formal, legally binding assurance regarding compliance with requirements set forth in the policy; the authority and responsibility for assuring CDC-wide compliance with all applicable laws, regulations, policies, and standards regarding the protecting the rights

and welfare of human participants of research that is conducted or supported by CDC; and to serve as the institutional official for purposes of compliance with 45 CFR part 46 and 21 CFR parts 50 and 56.

2. Set the tone for the agency by promoting an institutional culture of respect and conscience, so that the ethical conduct of human research is supported at the highest levels of the organization.
3. Ensure that investigators fulfill their scientific, ethical, legal, and policy-related responsibilities.
4. Provide investigators with ways to obtain answers to questions, express concerns, and convey suggestions regarding the HRPP to someone outside of the IRB.
5. Encourage all staff involved in the conduct or oversight of human research to participate in ongoing education activities.
6. Ensure appropriate protections, such as for privacy and confidentiality, when research is not covered by human research regulations (e.g., because it is exempt or because CDC is not engaged).
7. Require that research-related information products that are submitted for clearance have been derived from research that complies with human research ethics and regulations.

F. Procurement and Grants Office

The CDC Procurement and Grants Office shall ensure that no funds are disbursed to an awardee in support of nonexempt human research, whether through an assistance mechanism or an acquisition mechanism, unless each awardee that will become engaged in nonexempt human research holds a valid federalwide assurance with OHRP and certifies that the research has been reviewed and approved by an IRB provided for in the approved assurance and will be subject to continuing review by the IRB.

7. REFERENCES

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8. ACRONYMS AND DEFINITIONS

Emergency response – A public health activity undertaken in an urgent or emergency situation, usually because of an identified or suspected imminent health threat to the population, but sometimes because the public and/or government authorities perceive an imminent threat that demands immediate action. The primary purpose of the activity is to document the existence and magnitude of a public health problem in the community and to implement appropriate measures to address the problem (Langmuir, 1980).

Evaluation – The systematic application of scientific and statistical procedures for measuring program conceptualization, design, implementation, and utility; making comparisons based on these measurements; and the use of the resulting information to optimize program outcomes (Rossi and Freeman, 1993; Fink, 1993).

HHS – U.S. Department of Health and Human Services

Human subject or participant – A living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information. (See 45 CFR 46.102(f).)

Longitudinal data collection system – A system that collects information regarding numerous discrete events on individuals over time.

Program evaluation – An essential organizational activity in public health using a systematic approach to improve and account for public health actions (Centers for Disease Control and Prevention, 1999).

Research – A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. (See 45 CFR 46.102(d).)

Surveillance – The ongoing systematic collection, analysis and interpretation of health data, essential to the planning, implementation and evaluation of public health practice, closely integrated to the dissemination of these data to those who need to know and linked to prevention and control.