
Contact information was omitted from the document.

Comments on this document should be directed to Catherine Howard electronically at choward@acf.hhs.gov. If sending a hard copy, please deliver to: Children’s Bureau, Administration on Children, Youth and Families, Administration on Children and Families, U.S. Dept. of Health and Human Services, 1250 Maryland Ave., SW., 8th Floor, Washington, DC 20024.


Reginia H. Ryan,
Director, Executive Secretariat,
Administration on Children, Youth and Families.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Family Violence Prevention and Services/Grants for Battered Women’s Shelters and Related Assistance/Grants to States

Program Office: Administration on Children, Youth and Families (ACYF), Family and Youth Services Bureau (FYSB).


Announcement Title: Family Violence Prevention and Services/Grants for Battered Women’s Shelters and Related Assistance/Grants to States.

CPDA Number: 93.671.

Due Date for Applications: April 6, 2006.

Executive Summary: This announcement governs the proposed award of mandatory grants under the Family Violence Prevention and Services Act (FVPSA) to States (including Territories and Insular Areas). The purpose of these grants is to assist States in establishing, maintaining, and expanding programs and projects to prevent family violence and to provide immediate shelter and related assistance for victims of family violence and their dependents. This announcement sets forth the application requirements, the application process, and other administrative and fiscal requirements for grants in Fiscal Year (FY) 2006.

I. Description


The purpose of this legislation is to assist States and Indian Tribes, Tribal organizations, and non-profit private organizations approved by an Indian Tribe in supporting the establishment, maintenance, and expansion of programs and projects to prevent incidents of family violence and to provide immediate shelter and related assistance for victims of family violence and their dependents.

Background

During FY 2005, 237 grants were made to States and Indian Tribes, Tribal organizations, non-profit private organizations approved by Indian Tribes. The Department of Health and Human Services (HHS) also made 53 family violence prevention grant awards to non-profit State domestic violence coalitions.

In addition, HHS supports the National Resource Center for Domestic Violence (NRC) and four Special Issue Resource Centers (SIRCs). The four SIRCs are the Battered Women’s Justice Project, the Resource Center on Child Custody and Protection, Sacred Circle Resource Center for the Elimination of Domestic Violence Against Native Women, and the Health Resource Center on Domestic Violence. The purpose of NRC and SIRCs is to provide resource information, training, and technical assistance to Federal, State, and Native American agencies, local domestic violence prevention programs, and other professionals who provide services to victims of domestic violence.

In February 1996, HHS funded the National Domestic Violence Hotline (NDVH) to ensure that every woman has access to information and emergency assistance wherever and whenever she needs it. NDVH is a 24-hour, toll-free service that provides crisis assistance, counseling, and local shelter referrals to women across the country. Hotline counselors also are available for non-English speaking persons and for people who are hearing-impaired. The Hotline number is 1–800–799–SAFE (7233); the TTY number for the hearing-impaired is 1–800–787–3224.

General Grant Program Requirements Applicable to States

Definitions

States should use the following definitions in carrying out their programs. The definitions are found in section 320 of FVPSA.

Family Violence: Any act or threatened act of violence, including any forceful detention of an individual, which (a) results or threatens to result in physical injury and (b) is committed by a person against another individual (including an elderly person) to whom such person is or was related by blood or marriage or otherwise legally related or with whom such person is or was lawfully residing.

Shelter: The provision of temporary refuge and related assistance in compliance with applicable State law and regulation governing the provision, on a regular basis, which includes shelter, safe homes, meals, and related assistance to victims of family violence and their dependents.

Related Assistance: The provision of direct assistance to victims of family violence and their dependents for the purpose of preventing further violence, helping such victims to gain access to civil and criminal courts and other community services, facilitating the efforts of such victims to make decisions concerning their lives in the interest of safety, and assisting such victims in healing from the effects of the violence. Related assistance includes:

(a) Prevention services such as outreach and prevention services for victims and their children, assistance for children who witness domestic violence, employment training, parenting and other educational services for victims and their children, preventive health services within domestic violence programs (including
nutrition, disease prevention, exercise, and prevention of substance abuse), domestic violence prevention programs for school-age children, family violence public awareness campaigns, and violence prevention counseling services to abusers;

(b) Counseling with respect to family violence, counseling or other supportive services by peers, individually or in groups, and referral to community social services;

(c) Transportation and technical assistance with respect to obtaining financial assistance under Federal and State programs, and referrals for appropriate health-care services (including alcohol and drug abuse treatment), but shall not include reimbursement for any health-care services;

(d) Legal advocacy to provide victims with information and assistance through the civil and criminal courts, and legal assistance; or

(e) Children’s counseling and support services, and child care services for children who are victims of family violence or the dependents of such victims, and children who witness domestic violence.

Annual State Administrators Grantee Conference

The annual grantees conference for the State FVPSA Administrators is a training and technical assistance activity. A subsequent Program Instruction and/or Information Memorandum will advise the State FVPSA Administrators of the date, time and location of their grantees conference.

Client Confidentiality

FVPSA programs must establish or implement policies and protocols for maintaining the safety and confidentiality of the adult victims and their children of domestic violence, sexual assault, and stalking. It is essential that the confidentiality of individuals receiving FVPSA services be protected. Consequently, when providing statistical data on program activities and program services, individual identifiers of client records will not be used (section 303(a)(2)(E)).

Stop Family Violence Postal Stamp

The U.S. Postal Service was directed by the “Stamp Out Domestic Violence Act of 2001” (the Act), Public Law 107–62, to make available a “semipostal” stamp to provide funding for domestic violence programs. Funds raised in conjunction with sales of the stamp, less reasonable costs, have been transferred to HHS in accordance with the Act for support of services to children and youth affected by domestic violence.

As a result of the transfer of $1.3 million in 2005, a grant offering was made for the development of “Demonstration Programs for The Enhanced Services to Children and Youth Who Have Been Exposed to Domestic Violence.” Sixty-five (65) applications were received and reviewed. Nine (9) grant applications of approximately $130,000 each have been approved and are in the process of being funded. Detailed information on the successful applicants and their programs will be shared with State FVPSA Administrators upon official initiation of the grants.

The Importance of Coordination of Services

The impacts of family and intimate violence include physical injury and death of primary or secondary victims, psychological trauma, isolation from family and friends, harm to children witnessing or experiencing violence in homes in which the violence occurs, increased fear, reduced mobility and employability, homelessness, substance abuse, and a host of other health and related mental health consequences.

Coordination and collaboration among the police, prosecutors, the courts, victim services providers, child welfare and family preservation services, and medical and mental health service providers is needed to provide more responsive and effective services to victims of domestic violence and their families. It is essential that all interested parties are involved in the design and improvement of intervention and prevention activities.

To help bring about a more effective response to the problem of domestic violence, HHS urges the designated State agencies receiving funds under this grant announcement to coordinate activities funded under this grant with other new and existing resources for the prevention of family and intimate violence and related issues.

Documenting Our Work (DOW) Initiative

The need to accurately communicate reliable and appropriate data that captures the impact of domestic violence prevention work and to provide shelters, States and State domestic violence coalitions with tools for self-assessment continues as the DOW Initiative. In conjunction with representatives for State FVPSA programs, State domestic violence coalitions and experts on both data collection and domestic violence prevention issues, the effort to develop informative, succinct and non-burdensome reporting formats will continue with the hope of concluding in this fiscal year. Any changes in informational needs and reporting formats will be accompanied by specifically designated workshops or adjuncts to regularly occurring meetings.

II. Funds Available

For FY 2006, HHS will make available for grants to designated State agencies 70 percent of the amount appropriated under section 310(a)(1) of FVPSA, which is not reserved under section 310(a)(2). In separate announcements, HHS will allocate 10 percent of the foregoing appropriation to the Tribes and Tribal organizations for the establishment and operation of shelters, safe houses, and the provision of related services, and 10 percent to the State Domestic Violence Coalitions to continue their work within the domestic violence community by providing technical assistance and advocacy services among other activities with local domestic violence programs and to encourage appropriate responses to domestic violence within the States.

Five percent of the amount appropriated under section 310(a)(1) of FVPSA, which is not reserved under section 310(a)(2), will be available in FY 2006 to continue the support for the NRC and the four SIRCs. Additional funds appropriated under FVPSA will be used to support other activities, including training and technical assistance, collaborative projects with advocacy organizations and service providers, data collection efforts, public education activities, research and other demonstration projects as well as the ongoing operation of NDVH.

State Allocation

FVPSA grants to the States, the District of Columbia, and the Commonwealth of Puerto Rico are based on a population formula. Each State grant shall be $600,000 with the remaining funds allotted to each State on the same ratio as the population of the State has to the population of all States (section 304(a)(2)). State populations are determined on the basis of the most recent census data available to the Secretary of HHS and, the Secretary shall use for such purpose, if available, the annual current census data produced by the Secretary of Commerce pursuant to section 1818 of Title 13.

For the purpose of computing allocations, the statute provides that Guam, American Samoa, the Virgin Islands, and the Northern Mariana Islands should be treated as States for the purposes of section 304(a)(2).
Islands will each receive grants of not less than one-eighth of one percent of the amounts appropriated (section 304(a)(1)).

Expenditure Period

FVPSA funds may be used for expenditures on and after October 1 of each fiscal year for which they are granted, and will be available for expenditure through September 30 of the following fiscal year, i.e., FY 2006 funds may be used for expenditures from October 1, 2005, through September 30, 2007. Funds will be available for obligations only through September 30, 2006, and must be liquidated by September 30, 2007.

Re-allotted funds, if any, are available for expenditure until the end of the fiscal year following the fiscal year that the funds became available for re-allotment. FY 2006 grant funds that are made available to the States through re-allotment, under section 304(d)(2), must be expended by the State no later than September 30, 2008.

III. Eligibility

“States” as defined in section 320 of FVPSA are eligible to apply for funds. The term “State” means each of the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, American Samoa, the Virgin Islands, and the Commonwealth of the Northern Mariana Islands.

In the past, Guam, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, and American Samoa have applied for funds as a part of their consolidated grant under the Social Services Block grant. These jurisdictions need not submit an application under this Program Announcement if they choose to have their allotment included as part of a consolidated grant application.

Additional Information on Eligibility

D–U–N–S Requirement

All applicants must have a D&B Data Universal Numbering System (D–U–N–S) number. On June 27, 2003, the Office of Management and Budget (OMB) published in the Federal Register a new Federal policy applicable to all Federal grant applicants. The policy requires Federal grant applicants to provide a D–U–N–S number when applying for Federal grants or cooperative agreements on or after October 1, 2003. The D–U–N–S number will be required whether an applicant is submitting a paper application or using the government-wide electronic portal, Grants.gov. A D–U–N–S number will be required for every application for a new award or renewal/continuation of an award, including applications or plans under formula, entitlement, and block grant programs, submitted on or after October 1, 2003.

Please ensure that your organization has a D–U–N–S number. You may acquire a D–U–N–S number at no cost by calling the dedicated toll-free D–U–N–S number request line at 1–866–705–5711 or you may request a number online at http://www.dnb.com.

IV. Application Requirements


Public reporting burden for this collection of information is estimated to average six hours per response, including the time for reviewing instructions, gathering and maintaining the data needed, and reviewing the collection information.

The project description is approved under OMB control number 0970–0280, which expires October 31, 2008. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Form and Content of Application Submission

The State’s application must be submitted by the Chief Executive of the State and signed by the Chief Executive Officer or the Chief Program Official designated as responsible for the administration of FVPSA.

Each application must contain the following information or documentation:

(1) The name of the State agency, the name of the Chief Program Official designated as responsible for the administration of funds under FVPSA and coordination of related programs within the State, and the name of a contact person if different from the Chief Program Official (section 303(a)(2)(D))

(2) A plan describing in detail how the needs of underserved populations will be met, such as populations that are underserved due to ethnic, racial, cultural or language diversity, alienage status, geographic isolation, disability, or age (section 303(a)(2)(C)).

(a) Identify the underserved populations that are being targeted for outreach and services.

(b) In meeting the needs of the underserved population, describe the domestic violence training that will be provided to the individuals who will do the outreach and intervention to these populations. Describe the specific service environment, e.g., new shelters; services for the battered, elderly, women of color, etc.

(c) Describe the public information component of the State’s outreach program; the elements of your program that are used to explain domestic violence, the most effective and safe ways to seek help; tools to identify available resources, etc.

(3) Provide a complete description of the process and procedures used to involve State Domestic Violence Coalitions, knowledgeable individuals, and interested organizations, and assure an equitable distribution of grants and grant funds within the State and between rural and urban areas in the State (sections 303(a)(2)(C) and 311(a)(5)).

(4) Provide a complete description of the process and procedures implemented that allow for the participation of the State domestic violence coalition in planning and monitoring the distribution of grant funds and determining whether a grantee is in compliance with section 303(a)(2) as required by sections 303(a)(2)(C) and 311(a)(5).

(5) Provide a copy of the procedures developed and implemented that assure the confidentiality of records pertaining to any individual provided family violence prevention or treatment services by any program assisted under FVPSA (section 303(a)(2)(E)).

(6) Include a description of how the State plans to use the grant funds; a description of the target population; the number of shelters to be funded; the services the State will provide; and the expected results from the use of the grant funds (section 303(a)(2)).

(7) Provide a copy of the law or procedures that the State has implemented for the eviction of an abusive spouse from a shared household (section 303(a)(2)(F)).

Assurances

Each application must provide the following assurances:

(1) That grant funds under FVPSA will be distributed to local public agencies and non-profit private organizations (including religious and charitable organizations and voluntary associations) for programs and projects within the State to prevent incidents of family violence and to provide immediate shelter and related assistance for victims of family violence and their dependents in order to prevent future violent incidents (section 303(a)(2)(A)).

(2) That not less than 70 percent of the funds distributed shall be used for immediate shelter and related assistance, as defined in section...
320(5)(A), to the victims of family violence and their dependents and not less than 25 percent of the funds distributed shall be used to provide related assistance (section 303(g)).

(3) That not more than 5 percent of the funds will be used for State administrative costs (section 303(a)(2)(B)(ii)).

(4) That in distributing the funds, the States will give special emphasis to the support of community-based projects of demonstrated effectiveness carried out by non-profit, private organizations, particularly for those projects where the primary purpose is to operate shelters for victims of family violence and their dependents and those which provide counseling, advocacy, and self-help services to victims and their children (section 303(a)(2)(B)(ii)).

(5) That grants funded by the States will meet the matching requirements in section 303(f), i.e., not less than 20 percent of the total funds provided for a project under Chapter 110 of Title 42 of the U.S. Code (U.S.C.) with respect to an existing program, and with respect to an entity intending to operate a new program under this title, not less than 35 percent. The local share will be cash or in-kind; and the local share will not include any Federal funds provided under any authority other than this chapter (section 303(f)).

(6) That grant funds made available under this program by the State will not be used as direct payment to any victim or dependent of a victim of family violence (section 303(d)).

(7) That no income eligibility standard will be imposed on individuals receiving assistance or services supported with funds appropriated to carry out FVPSA (section 303(e)).

(8) That the address or location of any shelter-facility assisted under FVPSA will not be made public, except with the written authorization of the person or persons responsible for the operation of such shelter (section 303(a)(2)(B)(ii)).

(9) That all grants, programs or other activities funded by the State in whole or in part with funds made available under FVPSA will prohibit discrimination on the basis of age, handicap, sex, race, color, national origin or religion (section 307).

(10) That funds made available under the FVPSA will be used to supplement and not supplant other Federal, State and local public funds expended to provide services and activities that promote the purposes of the FVPSA (section 303(a)(4)).

V. Approval/Disapproval of a State Application

The Secretary of HHS will approve any application that meets the requirements of FVPSA and this announcement and will not disapprove any such application except after reasonable notice of the Secretary’s intention to disapprove has been provided to the applicant and after a six-month period providing an opportunity for applicant to correct any deficiencies. The notice of intention to disapprove will be provided to the applicant within 45 days of the date of the application.

VI. Reporting Requirements

Performance Reports

Section 303(a)(4) requires that States file a performance report with HHS describing the activities carried out, and inclusion of an assessment of the effectiveness of those activities in achieving the purposes of the grant. Section 303(a)(5) requires that the State file a report that contains a description of the activities carried out with funds expended for State administrative costs. A section of this performance report must be completed by each grantee or sub-grantee that performed the direct services contemplated in the State’s application certifying performance of such services. State grantees should compile performance reports into a comprehensive report for submission. The Performance Report should include the following data elements as well as narrative examples of success stories about the services provided. The Performance Report should include the following data elements:

Funding—The total amount of the FVPSA grant funds awarded. The percentage of FVPSA funds as to total funding. The percentage of FVPSA funding used for shelters, and the percentage of funding used for related services and assistance.

Shelters—The total number of shelters and shelter programs (safe homes/motels, etc.) assisted by FVPSA program funding. Data elements should include:

- The number of women sheltered.
- The number of shelters in the State.
- The number of safe houses and shelter alternatives in the State.
- The number of non-shelter programs in the State.
- The number of young children sheltered (birth–12 years of age).
- The number of teenagers and young adults sheltered (13–18 years of age).
- The number of men sheltered.
- The number of elderly sheltered (55+ years of age).
The number of elderly provided
non-shelter services.

The average length of shelter stay.

The number of women, children, teens, and others that were turned away because shelter was unavailable.

The number of women, children, teens, and others that were referred to other shelters due to a lack of space.

Types of individuals served (including special populations)—Record information by numbers and percentages against the total population served. Individuals and special populations served should include:

- Racial identification;
- Language (other than English);
- Geographically isolated from shelter (urban or rural);
- Persons with disabilities; and
- Other special needs populations.

Related services and assistance—List the types of related services and assistance provided to victims and their family members by indicating the number of women, children and men that have received services. Services and assistance may include, but are not limited to, the following:

- Individual counseling;
- Group counseling;
- Crisis intervention/hotline;
- Information and referral;
- Batterer support services;
- Legal advocacy services;
- Transportation;
- Services to teenagers;
- Emergency child care;
- Training and technical assistance;
- Housing advocacy; and
- Other innovative program activities.

Volunteers—List the total number of volunteers and hours worked.

Service referrals—List the number of women, children and men referred for the following services: (Note: Please indicate if the individual was identified as a batterer.)

- Alcohol abuse;
- Drug abuse;
- Batterer intervention services;
- Witnessed abuse;
- Emergency medical intervention; and
- Law enforcement intervention.

Narratives of success stories—Provide narratives of success stories of services provided and the positive impact on the lives of children and families. Examples may include the following:

- An explanation of the activities carried out including an assessment of the major activities supported by the family violence funds, what particular priorities within the State were addressed and what special emphases were placed on these activities;
- A description of the specific services and facilities that your agency funded, contracted with, or otherwise used in the implementation of your program (e.g., shelters, safe-houses, related assistance, programs for batterers);
- An assessment of the effectiveness of the direct service activities contemplated in the application;
- A description of how the needs of under-served populations, including populations under-served because of ethnic, racial, cultural, language diversity or geographic isolation were addressed;
- A description and assessment of the prevention activities supported during the program year, e.g., community education events, and public awareness efforts; and
- A discussion of exceptional issues or problems arising, but not addressed in the application.

Performance Reports for the States are due on an annual basis at the end of the calendar year (December 29).

Performance Reports should be sent to:

Family and Youth Services Bureau, Administration on Children, Youth and Families, Administration on Children and Families, Attention: William D. Riley, 1250 Maryland Avenue, SW, Room 8238, Washington, DC 20024.

Please note that section 303(a)(4) of FVPSA requires HHS to suspend funding for an approved application if any State applicant fails to submit an annual Performance Report or if the funds are expended for purposes other than those set forth under this announcement.

Financial Status Reports


Completed reports may be mailed to:


Grantees have the option to submit their reports online through the Online Data Collection (OLDC) system at the following address: https://extranet.acf.hhs.gov/ssi.

Failure to submit reports on time may be a basis for withholding grant funds, suspension or termination of the grant. All funds reported as unobligated after the obligation period will be recouped.

VII. Administrative and National Policy Requirements

States will comply with the applicable HHS recordkeeping and reporting requirements and general requirements for the administration of grants under 45 CFR part 92.

Direct Federal grants, sub-award funds, or contracts under this ACF program shall not be used to support inherently religious activities such as religious instruction, worship, or proselytization. Therefore, organizations must take steps to separate, in time or location, their inherently religious activities from the services funded under this program. Regulations pertaining to the Equal Treatment for Faith-Based Organizations, which includes the prohibition against Federal funding of inherently religious activities, can be found at the HHS Web site at http://www.os.dhhs.gov/fbci/waisgate21.pdf.


VIII. Other Information

FOR FURTHER INFORMATION CONTACT: William D. Riley at (202) 401–5529 or e-mail at WRiley@acf.hhs.gov, or Sunni Knight at (202) 401–5319 or e-mail at GKnight@acf.hhs.gov.


Joan E. Ohl,
Commissioner, Administration on Children, Youth and Families.

Appendices—Required Certifications:
A. Anti-Lobbying and Disclosure
B. Environmental Tobacco Smoke
C. Drug-Free Workplace Requirements

Appendix A: Certification Regarding Lobbying

Certification for Contracts, Grants, Loans, and Cooperative Agreements

The undersigned certifies to the best of his or her knowledge and belief, that:

(1) No Federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of an agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement.

(2) If any funds other than Federal appropriated funds have been paid or will be
paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement, the undersigned shall complete and submit Standard Form—LLL, “Disclosure Form to Report Lobbying,” in accordance with its instructions.

(3) The undersigned shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans, and cooperative agreements) and that all subrecipients shall certify and disclose accordingly. This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by section 1352, title 31, U.S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.

Statement for Loan Guarantees and Loan Insurance

The undersigned states, to the best of his or her knowledge and belief, that:

If any funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this commitment providing for the United States to insure or guarantee a loan, the undersigned shall complete and submit Standard Form—LLL, “Disclosure Form to Report Lobbying,” in accordance with its instructions. Submission of this statement is a prerequisite for making or entering into this transaction imposed by section 1352, title 31, U.S. Code. Any person who fails to file the required statement shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.

Signature

Title

Organization

Appendix B: Certification Regarding Environmental Tobacco Smoke

Public Law 103227, Part C Environmental Tobacco Smoke Prohibition Act of 1994 (Act), requires that smoking not be permitted in any portion of any indoor routinely owned or leased or contracted for by an entity and used routinely or regularly for provision of health, day care, education, or library services to children under the age of 18, if the services are funded by Federal programs either directly or through State or local governments, by Federal grant, contract, loan, or loan guarantee. The law does not apply to children’s services provided in private residences, facilities funded solely by Medicare or Medicaid funds, and portions of facilities used for inpatient drug or alcohol treatment. Failure to comply with the provisions of the law may result in the imposition of a civil monetary penalty of up to $1,000 per day and/or the imposition of an administrative compliance order on the responsible entity. By signing and submitting this application the applicant/grantee certifies that it will comply with the requirements of the Act.

The applicant/grantee further agrees that it will require the language of this certification be included in any subawards which contain provisions for the children’s services and that all subgrantees shall certify accordingly.

Appendix C: Certification Regarding Drug-Free Workplace Requirements

This certification is required by the regulations implementing the Drug-Free Workplace Act of 1988: 45 CFR part 76, subpart, F. Sections 76.630(c) and (d)(2) and 76.645(a)(1) and (b) provide that a Federal agency may designate a central receipt point for STATE-WIDE AND STATE AGENCY-WIDE certifications, and for notification of criminal drug convictions. For the Department of Health and Human Services, the central pint is: Division of Grants Management and Oversight, Office of Management and Acquisition, Department of Health and Human Services, Room 517–D, 200 Independence Avenue, SW., Washington, DC 20201.

Certification Regarding Drug-Free Workplace Requirements (Instruments for Certification)

1. By signing and/or submitting this application or grant agreement, the grantee is providing the certification set out below.

2. The certification set out below is a material representation of fact upon which reliance is placed when the agency awards the grant. If it is later determined that the grantee knowingly rendered a false certification, or otherwise violates the requirements of the Drug-Free Workplace Act, the agency, in addition to any other remedies available to the Federal Government, may take action authorized under the Drug-Free Workplace Act.

3. For grantees other than individuals, Alternate I applies.

4. For grantees who are individuals, Alternate II applies.

5. Workplaces under grants, for grantees other than individuals, need not be identified on the certification. If known, they may be identified in the grant application. If the grantee does not identify the workplaces at the time of application, or upon award, if there is no application, the grantee must keep the identity of the workplace(s) on file in its office and make the information available for Federal inspection. Failure to identify all known workplaces constitutes a violation of the grantee’s drug-free workplace requirements.

6. Workplace identifications must include the actual address of buildings (or parts of buildings) or other sites where work under the grant takes place. Categorical descriptions may be used (e.g., all vehicles of a mass transit authority or State highway department while in operation, State employees in each local unemployment office, performers in concert halls or radio studios).

7. If the workplace identified to the agency changes during the performance of the grant, the grantee shall inform the agency of the change(s), if it previously identified the workplaces in question (see paragraph five).

8. Definitions of terms in the Nonprocurement Suspension and Debarment common rule and Drug-Free Workplace common rule apply to this certification.

Grantees’ attention is called, in particular, to the following definitions from these rules: Controlled substance means a controlled substance in Schedules I through V of the Controlled Substances Act (21 U.S.C. 812) and as further defined by regulation (21 CFR 1308.11 through 1308.15); Conviction means a finding of guilt (including a plea of nolo contendere) or imposition of sentence, or both, by any judicial body charged with the responsibility to determine violations of the Federal or State criminal drug statutes; Criminal drug statute means a Federal or non-Federal criminal statute involving the manufacture, distribution, dispensing, use, or possession of any controlled substance; Employee means the employee of a grantee directly engaged in the performance of work under a grant, including: (i) All direct charge employees; (ii) All indirect charge employees unless their impact or involvement is insignificant to the performance of the grant; and, (iii) Temporary personnel and consultants who are directly engaged in the performance of work under the grant and who are on the grantee’s payroll. This definition does not include workers not on the payroll of the grantee (e.g., volunteers, even if used to meet a matching requirement; consultants or independent contractors not on the grantee’s payroll; or employees of subrecipients or subcontractors in covered workplaces).

Certification Regarding Drug-Free Workplace Requirements

Alternate I. (Grantees Other Than Individuals)

The grantee certifies that it will or will continue to provide a drug-free workplace by:

(a) Publishing a statement notifying employees that the unlawful manufacture, distribution, dispensing, possession, or use of a controlled substance is prohibited in the grantee’s workplace and specifying the actions that will be taken against employees for violation of such prohibition;

(b) Establishing an ongoing drug-free awareness program to inform employees about—

(1) The dangers of drug abuse in the workplace;

(2) The grantee’s policy of maintaining a drug-free workplace;

(3) Any available drug counseling, rehabilitation, and employee assistance programs; and

(4) The penalties that may be imposed upon employees for drug abuse violations occurring in the workplace;

(c) Making it a requirement that each employee to be engaged in the performance
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Industry Exchange Workshop on Food and Drug Administration Clinical Trial Requirements; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA), Baltimore District, in cooperation with the Society of Clinical Research Associates (SoCRA), is announcing a workshop on FDA clinical trial statutory and regulatory requirements. This 2-day workshop for the clinical research community targets sponsors, monitors, clinical investigators, institutional review boards, and those who interact with them for the purpose of conducting FDA regulated clinical research. The workshop will include both industry and FDA perspectives on proper conduct of clinical trials regulated by FDA.

Date and Time: The public workshop is scheduled for Wednesday, May 17, 2006, from 8:30 a.m. to 5 p.m. and Thursday, May 18, 2006, from 8:30 a.m. to 4 p.m.

Location: The public workshop will be held at the Radisson Plaza Lord Baltimore, 20 West Baltimore St., Baltimore, MD 21201, 410–539–8400, FAX: 410–625–1060.


Registration: Send registration information (including name, title, firm name, address, telephone, and fax number) and the registration fee of $550 (member), $625 (nonmember), or $500 (Government employee nonmember). (The registration fee for nonmembers includes a 1-year membership.) The registration fee includes a 1-year membership.) The registration fee for FDA employees is waived. Make the registration fee payable to SoCRA, P.O. Box 101, Furlong, PA 18925. To register via the Internet go to http://www.socra.org/FDA_Conference.htm. (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the Federal Register).

The registrar will also accept payment by major credit cards. For more information on the meeting, or for questions on registration, contact 800–SoCRA92 (800–762–7292), or 215–822–8644, or e-mail: socramail@aol.com. Attendees are responsible for their own accommodations. To make reservations at the Radisson Plaza Lord Baltimore hotel at the reduced conference rate, contact the Radisson Plaza Lord Baltimore hotel (see LOCATION) before April 17, 2006. The registration fee will be used to offset the expenses of hosting the conference, including meals, refreshments, meeting rooms, and materials.

Space is limited, therefore interested parties are encouraged to register early. Limited onsite registration may be available. Please arrive early to ensure prompt registration. If you need special accommodations due to a disability, please contact Marie Falcone (see CONTACT) at least 7 days in advance of the workshop.

SUPPLEMENTARY INFORMATION: The workshop on FDA clinical trials statutory and regulatory requirements helps fulfill the Department of Health and Human Services and FDA’s important mission to protect the public health by educating researchers on proper conduct of clinical trials. Topics for discussion at the workshop include the following: (1) FDA regulation of the conduct of clinical research; (2) Medical device, drug, biological product and food aspects of clinical research; (3) Investigator initiated research; (4) Preinvestigational new drug application meetings and FDA meeting process; (5) Informed consent requirements; (6) Ethics in subject enrollment; (7) FDA regulation of institutional review boards; (8) Electronic records requirements; (9) Adverse event reporting; (10) How FDA conducts bioresearch inspections; and (11) What happens after the FDA inspection.

FDA has made education of the research community a high priority to ensure the quality of clinical data and protect research subjects. The workshop helps to implement the objectives of section 903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393) and the FDA Plan for Statutory Compliance, which includes working more closely with stakeholders and ensuring access to needed scientific and technical expertise. The workshop also furthers the goals of the Small Business Regulatory Enforcement Fairness Act (Public Law 104–121) by providing outreach activities by Government agencies directed to small businesses.

Check if there are workplaces on file that are not identified here.

Alternate II. (Grantees Who Are Individuals)

(a) The grantee certifies that, as a condition of the grant, he or she will not engage in the unlawful manufacture, distribution, dispensing, possession, or use of a controlled substance in any activity with the grant;

(b) If convicted of a criminal drug offense resulting from a violation occurring during the conduct of any grant activity, he or she will report the conviction, in writing, within 10 calendar days of the conviction, to every grant officer or other designee, unless the Federal agency designates a central point for the receipt of such notices. When notice is made to such a central point, it shall include the identification number(s) of each affected grant.

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