Subaward No. GCROE0147C\_PPB CFDA No. 93.262

418681

COP # 30002556

185240

This Agreement is by and between the Oregon Health & Science University at 3181 SW Sam Jackson Park Road, Portland, Oregon (hereinafter referred to as the UNIVERSITY) and the Women's Strength Program of the Portland Police Bureau (hereinafter referred to as SUBAWARDEE). Witnesseth

Whereas, Johns Hopkins University was awarded grant number R01OH009080 from HHS, CDC, and NIOSH, and subsequently awarded UNIVERSITY a subcontract for support of the project entitled "Partnership to Improve Workplace Safety for In-Home Care Workers";

Whereas, the SUBAWARDEE has proposed to collaborate with the UNIVERSITY to complete the work described in the award referenced above;

Whereas, the SUBAWARDEE has skilled personnel and facilities available to undertake such project;

Whereas, the SUBAWARDEE and the UNIVERSITY desire this Agreement and the work to be performed under it to fully comply with applicable administrative requirements and cost principles and all other pertinent Federal laws, rules and regulations;

OMB Circular A-110, A-21 for Educational Institutions

OMB Circular A-110, A-122 for Non-Profit Organizations

OMB Circular A-102, A-87 for State and Local Governments and Indian Tribes

OMB Circular A-110, 45 CFR Part 74, Appendix E for Hospitals

OMB Circular A-110, 48 CFR Subpart 31.2 (Federal Acquisition Regulation), for Commercial/For-Profit Organizations, and Non-Profit Organizations exempt from A-122

Now therefore, the parties agree to the following conditions:

#### Article 1. Scope of Work

Performance of the work shall be as described in Attachment A, which by this reference is made a part of this Agreement.

#### Article 2. Period of Performance

The period of performance for this agreement shall be September 1, 2010 through August 31, 2011.

#### Article 3. Estimated Cost and Expenditure Limitations

The UNIVERSITY shall reimburse the SUBAWARDEE for actual expenses incurred in the performance of this Agreement up to \$10,809 for the budget period of September 1, 2010 through August 31, 2011, unless amended by written mutual agreement.

## Article 4. Terms of Payment

The SUBAWARDEE will submit vouchers to the UNIVERSITY for reimbursement of all allowable direct and indirect costs (as defined per Articles II, III, and IV of the Special Provisions), not more often than monthly, to the

GCROE0147C\_PPB following address:

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Oregon Health & Science University Sponsored Projects Administration 690 SW Bancroft St., L106SPA Portland, Oregon 97239

The vouchers must be in sufficient detail to indicate clearly the nature of all expenses in the format of the approved budget, Attachment B, which, by this reference, is made a part of this Agreement. The vouchers must reference the UNIVERSITY Subaward number.

The final voucher must be submitted no later than 45 days after termination of this Agreement and must be clearly marked "FINAL."

The SUBAWARDEE assures to the UNIVERSITY that all expenditures incurred are in full compliance with OMB Circular A-133 or its own applicable audit regulations. In the event the SUBAWARDEE receives \$500,000 or more in federal funding per year, and the SUBAWARDEE is an entity that complies with OMB Circular A-133 or equivalent guidelines; the SUBAWARDEE shall provide a copy of one of the following: 1) the schedule of findings and questioned costs disclosed in audit finding that relate to this Agreement or 2) the summary schedule of prior audit findings that report the status of any audit findings that relate to this Agreement.

When there are no audit findings related to this Agreement, SUBAWARDEE shall provide the UNIVERSITY with a written statement to confirm there were no findings. Other entities who do not comply with OMB Circular A-133 may be required to provide UNIVERSITY with their most recent audit report or statement of compliance.

Failure to comply with these requirements may result in nonpayment of the voucher.

#### Article 5. Scientific Personnel

The UNIVERSITY's Principal Investigator for grant number R010H009080 is W. Kent Anger, PhD who is responsible for coordinating the research efforts under this project. The UNIVERSITY's Principal Investigator is not authorized to amend or alter this Agreement. Any amendments or alterations must be approved by the written mutual agreement of the parties hereto.

Sara Johnson shall be responsible for the conduct of the research under this Agreement for the SUBAWARDEE. The SUBAWARDEE shall not replace Sara Johnson without prior written approval from the UNIVERSITY.

#### Article 6. Performance Report

The SUBAWARDEE must provide to the UNIVERSITY's Principal Investigator any interim performance report concerning the progress of the work that UNIVERSITY may request and a final performance report within 45 days.

after the end of the performance period.

## Article 7. Termination

This Agreement may be terminated by mutual consent of both parties or by either party upon thirty (30) days notice. This termination must be in writing and delivered by certified mail or in person. Any such termination of this Agreement shall be without prejudice to any obligations or liabilities of either party already accrued prior to such termination. If SUBAWARDEE is located in a foreign country, notice of termination will be delivered via registered mail.

## Article 8. Notices

All notices required to be given under this Agreement shall be in writing and sent to the party as indicated below:

TO UNIVERSITY

Marla Chitsaz, Grants & Contracts Administrator Research Grants & Contracts, Mail Code L106RGC Oregon Health & Science University 3181 SW Sam Jackson Park Road Portland, Oregon 97239-3098 Phone: 503.494.7784 E-Mail: orserv@ohsu.edu

#### TO SUBAWARDEE

#### **Bob Del Gizzi**

Women's Strength Program / Portland Police Bureau 1111 SW Second Avenue Portland, OR 97204 Phone: 503.823.0495 E-Mail: Bob.DelGizzi@portlandoregon.gov

#### Article 9. Terms of Acceptance

By acceptance of funds awarded under this Agreement, SUBAWARDEE acknowledges that it will comply with the following terms and conditions as set forth under "TERMS OF ACCEPTANCE" of the "NOTICE OF GRANT AWARD":

1.42 USC 290

2.42 CFR 52

3. This award is included under Expanded Authorities

4. This award is subject to SNAP.

5. The restrictions on the expenditure of federal funds in appropriations acts, to the extent those restrictions are pertinent to this Agreement.

6. NIH Grants Policy Statement including addenda in effect at the beginning date of this Agreement.

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7. 45 CFR Part 74 or 45 CFR Part 92, as applicable

#### Article 10. Incorporation of Special Provisions

The Special Provisions attached hereto and incorporated herein apply to this Agreement.

THIS AGREEMENT CONSTITUTES THE ENTIRE AGREEMENT BETWEEN UNIVERSITY AND SUBAWARDEE. NO WAIVER, CONSENT, MODIFICATION OR CHANGE OF TERMS OF THIS AGREEMENT SHALL BIND EITHER PARTY UNLESS IN WRITING AND SIGNED BY A DULY AUTHORIZED REPRESENTATIVE OF BOTH ORGANIZATIONS.

Approved and Agreed: **OREGON HEALTH & SCIENCE UNIVERSITY** 

SUBAWARDEE

3.9.1 By:

Jesse Null Grants & Contracts Manager Name/Title:

Date

Date

#### SUBAWARDEE:

By:

Sam Adams Mayor

Date

By:

Date:

LaVonne Griffin-Valade Auditor

Date

APPROVED AS TO FORM Approved as to form: 3/8/2012 CITY ATTORNEY

## Attachment A

# Women's Strength Scope of Work:

The Women's Strength team will work closely with research associates from OHSU and PSU to develop a computer based training module related to the prevention and handling of violent situations for In Home Care Workers. Women's Strength staff members will also conduct in person training seminars based on their existing program. Modifications to the program will be made to meet the specific needs of individuals working in the home-based care environment.

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PHS 398 (Rev. 6/09)

Form Page 4

#### SPECIAL PROVISIONS Revised 05/2011

## I. ALLOWABLE COSTS

This is a cost reimbursement agreement. The amount authorized will cover direct costs of the research and whatever indirect costs are allocable in accordance with OMB Circular A-21 and the NIH Grants Policy Statement in effect as of the beginning date of this Agreement.

# II. FACILITIES & ADMINISTRATIVE COSTS (F&A)

Budgeted indirect costs for the SUBAWARDEE are based on the approved direct costs budgeted using the negotiated indirect cost rate available at the time of award. The amount of indirect costs charged must be based upon actual direct cost expenditures and is limited to the amount awarded. No additional funds will be awarded for indirect costs.

Upon request, the SUBAWARDEE will provide to the UNIVERSITY one copy of its current indirect Cost Rate Agreement with its cognizant audit agency for all indirect costs charged under this Agreement. As new rates are negotiated, the SUBAWARDEE will forward one copy of the new Rate Agreement to the UNIVERSITY.

## III. REBUDGETING OF FUNDS

Rebudgeting between budget categories shall be consistent with 1) NIH policy as stated in NIH Grants Policy Statement, and 2) and applicable Special Conditions of the Prime Award.

SUBAWARDEE may rebudget direct costs in accordance to NIH Grants Policy Statement. Rebudgeting requests which fall outside of the Grants Policy Statement shall be in writing and directed to the UNIVERSITY's contact, as listed under Article 8, Notices. UNIVERSITY shall provide administrative endorsement and shall forward the request to the National Institutes of Health.

### IV. CARRY FORWARD OF FUNDS

Carry forward of an unobligated balance is restricted and req uires prior written approval. SUBAWARDEE shall send a written request to the UNIVE RSITY's Administrative Contact listed in Article 8, Notices.

## V. CONTRACT RELATED INCOME

The SUBAWARDEE is required to maintain such records as may be necessary to comply with the requirements of the NIH Grants Policy Statement and 45 CFR Part 74 or 45 CFR Part 92, as applicable. A ny income generated under this contract shall be used to reduce the expendit uses chargeable to the agreement.

#### VI. EQUIPMENT

SUBAWARDEE shall utilize sound purchasing and inventory procedures and shall maintain adequate records for the purchase, inventory, and disposition of equipment acquired under this agreem ent. Title to equipment shall reside with the SUBAWARDEE; however, the UNIVERSITY maintains the right to require the transfer of equipment, including title, having a unit acquisition cost of \$5,000 or more to the UNIVERSITY or to the Federal Government.

The DHHS Appropriations Act requires that to the greatest extent practicable, all equipment and products purchased with funds made available under this award should be American made.

At the request of the UNIVERSITY or NIH, the SUBAWARDEE shall submit a final report of equipment purchased under the Agreement to the UNIVERSITY individual identified in Article 8 no later than thirty (30) days after such request.

## **VII. INSPECTION**

Designated Representatives of the UNIVERSITY shall have the right to inspect and review the progress of the work performed pursuant to this Agreement. All reasonable facilities, including access to relevant data, test results and computations used or generated under this Agreement shall be made available when such inspections are conducted. Inspections shall be conducted in a manner as to not unduly delay the progress

of the work and the UNIVERSITY shall give the SUBAWARDEE reasonable notice prior to conducting any such inspections.

## VIII. AUDITS

All costs reimbursed for the performance of this Agreement will be subject to audit by the UNIVERSITY's Financial Officer or the Secretary of State Division of Audits and the cognizant Federal Audit Agency. The SUBAWARDEE further agrees to provide the UNIVERSITY with copies of any independent auditors' reports which present instances of noncompliance with federal laws and regulations which bear directly on the performance or administration of this Agreement. In such cases of noncompliance, SUBAWARDEE will provide copies of responses to auditors' reports and a plan for corrective actions. The SUBAWARDEE shall cooperate with UNIVERSITY in resolving questions UNIVERSITY may have concerning the auditors' reports and plan for corrective action.

SUBAWARDEE shall maintain supporting documentation of all charges and expenditures under this Agreement for audit purposes of all invoices submitted to UNIVERSITY for reimbursement. SUBAWARDEE agrees to maintain records reflecting the time and percentage of effort of personnel employed under this Agreement in compliance with applicable Federal regulations. The books, records, and documentation of SUBAWARDEE, insofar as they related to work performed or money received under this Agreement, shall be maintained in conformity with generally accepted accounting principles for a period of three years from the date of final payment. All reports prepared in accord with the requirements of OMB Circular A-133 shall be available for inspection by representatives of UNIVERSITY during normal business hours.

Upon request, the SUBAWARDEE will provide UNIVERSITY with a copy of any audit findings in relation to this Agreement. If there were no audit finding, a statement in writing will be provided by the SUBAWARDEE to the UNIVERSITY or the SUBAWARDEE will provide the UNIVERSITY with an online link to the latest audit report.

#### IX. PUBLICATIONS

All research reports and other publications relating to the work under this Agreement shall bear proper acknowledgment of the support provided by the grant identified in the preamble of this Agreement.

UNIVERSITY recognizes that under Sponsor policy, the results of work performed hereunder must be publishable and agrees that SUBAWARDEE and its employees and students engaged in work under this Subaward are free to present at symposia or professional meetings, and to publish such results. SUBAWARDEE agrees to furnish three copies of proposed manuscripts to UNIVERSITY for review and comment prior to publication and will delay publications for not-to-exceed ninety (90) days for completion of such review.

## X. SUBAWARDS

It is understood that the SUBAWARDEE shall not subaward any of the research effort required under this Agreement without prior written approval of the UNIVERSITY.

If approval is granted, provisions contained here in must be included in any subtier subawards or purchase orders made by the SUBAWARDEE under this Agreement so that such provisions, including sanctions for noncompliance, will be binding upon each subtier SUBAWARDEE or purchase order.

#### **XI. INDEPENDENT CONTRACTOR**

The SUBAWARDEE is an independent contractor. No provision of this Agreement shall be deemed to constitute the SUBAWARDEE or any agent or employee of the SUBAWARDEE as an agent or employee of the UNIVERSITY. The SUBAWARDEE agrees that it has entered into this Agreement and will discharge its obligations, duties, and undertakings and the work pursuant thereto whether requiring professional judgment or otherwise as an independent SUBAWARDEE and without liability on the part of the UNIVERSITY.

#### XII. INDEMNIFICATION

To the extent permitted by state law and subject to the terms and conditions of the Oregon Tort Claims Act

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(ORS 30.260-30.300), and the Oregon Constitution, Article XI, Section 9, the SUBAWARDEE agrees to defend, indemnify, and hold the UNIVERSITY and its officers, employees, and agents, harmless from and against any and all liability, loss expense (including reasonable attorney's fees), or claim for injury or damages arising out of the performance of this Agreement, but only in proportion to and to the extent that such liability, loss, expense, attorney's fees, or claim for injury or damages are caused by or result from the negligent or intentional acts of the SUBAWARDEE.

The UNIVERSITY agrees to defend, indemnify, and hold the SUBAWARDEE and its officers, employees, and agents, harmless from and against any and all liability, loss expense (including reasonable attorney's fees), or claim for injury or damages arising out of the performance of this Agreement, but only in proportion to and to the extent that such liability, loss, expense, attorney's fees, or claim for injury or damages are caused by or result from the negligent or intentional acts of the UNIVERSITY, subject to the terms and conditions of the Oregon Tort Claims Act (ORS 30.260-30.300) and except as otherw ise limited by the Oregon Constitution, Article XI, Section 7.

## **XIII. PATENTS AND INVENTIONS**

SUBAWARDEE and the UNIVERSITY agree that this Agreement shall be governed by public law 98-620, by the government wide regulations issued by the Department of Commerce at 37 CFR Part 401 for patents and inventions arising out of activities assisted by NIH grants, and by NIH's implementing policy, Patent and Invention Policy Statement, NIH Grants Policy Statement, all of which, by reference, are incorporated herein. In accordance with these provisions, SUBAWARDEE and the UNIVERSITY agree to promptly report all inventions made in the course of or under this agreement.

Ownership of and rights to inventions resulting from work performed that are made solely by the SUBAWARDEE, its faculty, administrators, employees and students under this A greement, will be solely owned by the SUBAWARDEE. Ownership of and rights to inventions resulting from work performed that are made solely by the UNIVERSITY, its faculty, administrators, employees and students under this Agreement, will be solely owned by the UNIVERSITY. Ownership of and rights to inventions made jointly by UNIVERSITY and SUBAWARDEE faculty, administrators, employees and students will be jointly determined, subject to NIH's regulations and existing patent I aw. All persons who perform work under this Agreement and who may be reasonably expected to make inventions must be covered by this Agreement. The SUBAWARDEE will submit a final report of inventions no later than thirty (30) days after the expiration of the Agreement to the UNIVERSITY individual identified in Article 8.

#### XIV. COPYRIGHT

Parties are free to arrange for copyright without approval when publications or similar materials are developed from work supported in whole or in part by this Agreement. Per 45 CFR Part 92.34 and the NIH Grants Policy Statement, any copyrighted or copyrightable works developed under this Agreement shall be subject to a royalty-free, non-exclusive, and irrevocable license to the U.S. Government to reproduce them, translate them, publish them, use and dispose of them, and to authorize others to do so.

#### XV. USE OF NAME

Neither party shall use the name of the other party or that party's employees, agents or assigns in any form of advertisement or publicity without first obtaining the other party's written approval for such use.

## **XVI. MODIFICATIONS**

The parties agree that the terms and provisions of this Agreement shall be modified in writing and executed by the parties hereto, to reflect any additional requirements or changes mandated by the NIH as a condition of receiving the grant, or as a result of changes to the guidelines promulgated by the NIH for the participants of consortium grants.

#### XVII. CERTIFICATIONS

SUBAWARDEE certifies compliance with the following rules and regulations.

1. Discrimination/Affirmative Action: The SUBAWARDEE will not discriminate against any employee

or applicant for employment because of race, color, religion, sex, marital status, handicap or national origin. The SUBAWARDEE will take affirmative action to ensure that applicants are employed, and that employees are treated during employment, without regard to their race, color, religion, sex, marital status, handic ap, or national origin. Such action shall include, but not be limited to the following: Employment, upgrading, demotion, or transfer; recruitment or recruitment advertising; layoff or termination, rates of pay or other forms of compensation; and selection for training, including apprenticeship. SUBAWARDEE agrees to maintain and regularly update an Affirmative Action Plan. SUBAWARDEE agrees to post in conspicuous places, available to employees and applicants for employment, notice setting forth the provisions of this nondiscrimination clause. SUBAWARDEE certifies compliance with:

Title VI and VII of the Civil Rights Act of 1964, as amended, 42 U.S.C. 2000d et sed, and Executive Order 11246 (and amendment 11375)

Nondiscrimination under Programs Receiving Federal Assistance... 45 CFR Part 80 Section 504 of the Rehabilitation Act of 1973, as amended: 29 U.S.C. 794 Title IX of the Education Amendments of 1972, as amended: 20 U.S.C. 1681 et seg.

Age Discrimination Act of 1975, as amended: 42 U.S.C. 6101 et seq.

The Americans with Disabilities Act of 1990

Non-Discrimination Action: 41 CFR Part 60

Affirmative Action Compliance: 41 CRF Parts 60-1 and 60-2

Limited English Proficiency: EO 13166

Inclusion of Women and Minorities in Clinical Research: Section 492B of the NIH Act Inclusion of Children as Subjects in Clinical Research: 45 CFR Part 46

- 2. Laboratory Animals: If SUBAWARDEE uses vertebrate animals in its performance of this work, it will comply with the applicable portions of the Animal Welfare Act (7 U.S.C. 2131 et. seg.) and will follow the guidelines prescribed in the Health Research Extension Act of 1985, P.L. 99-158 "Anim als in Research".
- 3. Human Subjects: The SUBAWARDEE agrees that the rights and welfare of human subjects will be protected in accordance with policies established under the Code of Federal Regulations, 45 CFR Parts 160, 162, and 164, 45 CFR Part 46 "Protection of Human Subjects" Part A - Subparts A and B and D, any policies statements issued by DHHS then in effect, and have on file with DHHS an approved General Assurance. The SUBAWARDEE shall bear full responsibility for the proper and safe performance of all work and services involving the use of human subjects under this Agreement.
- 4. Human Subjects Training: If use of human subjects is required in the performance of this Agreement, SUBAWARDEE certifies that key personnel involved in the performance of this Agreement have completed a human subjects training program in accordance with the NIH Guide to Grants and Contracts published June 5, 2000 (revised August 25, 2000).
- 5. Confidentiality: SUBAWARDEE will take appropriate action to protect the privacy and confidentiality of all research subjects. Investigators, Data Safety Monitoring Boards, IRBs and other appropriate entities should ensure that policies and procedures are in place that protect identifying information and that they oversee compliance with those policies and procedures. Policies should be in accordance to Section 301(d) and 543 of the PHS Act.
- 6. Misconduct in Science: SUBAWARDEE certifies that it has established administrative or other policies for dealing with and reporting possible misconduct in science to the extent required by 42 CFR Part 50 Subpart A - Sections 50.101 through 50.105, 45 CRF Part 620, and 45 CFR Part 689.
- 7. Debarment, Suspension: SUBAWARDEE certifies that neither it nor its principals is presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any Federal department or agency (45 CFR Part 76, 48 CFR Subparts 9.4 and 309.4).
- 8. Conflict of Interest: SUBAWARDEE will comply with Federal policies and regulations regarding objectivity in research (42 CFR Part 50, Subpart F). SUBAWARDEE agrees to ensure that standards and procedures are established to protect the design, conduct and reporting of research from conflicting financial interests of investigators. Any incidence of non-compliance with these standards and procedures on the part of investigators involved in activities sponsored by this Agreement shall be reported to the UNIVERSITY.

If SUBAWARDEE determines at any time during the period of performance that one or more investigators participating in the design, conduct, or reporting of research has or may appear to have a significant financial conflict of interest, SUBAWARDEE must inform UNIVERSITY of the existence of this real or apparent significant financial conflict of interest and must provide UNIVERSITY with a copy of the plan to manage that conflict.

If SUBAWARDEE does not have established standards and procedures in place for protecting the design, conduct and reporting of research from conflicting financial interests of investigators, SUBAWARDEE may delegate the responsibility to the UNIVERSITY. If SUBAWARDEE chooses to so delegate these responsibilities to the UNIVERSITY, SUBAWARDEE must indicate this delegation in writing and submit that delegation to UNIVERSITY representative, identified in Article 8, Notices. Upon delegation, SUBAWARDEE agrees that SUBAWARDEE's investigators who are participating in the study will complete

UNIVERSITY's procedures to ensure protection in the design, conduct and r eporting of research from conflicting financial interests.

- Non-Delinquency on Federal Debt: SUBAWARDEE certifies that it is in compliance with the Non-9. Delinquency on Federal Debt criteria, in accordance with the requirements of the NIH Grants Policy Statement.
- Certification Regarding Lobbying: The following is only applicable when the value of the subaward 10. is \$100,000 or greater. SUBAWARDEE certifies to the best of its knowledge and belief that 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 any 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.

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. SUBAWARDEE certifies compliance with the requirements of the NIH Grants Policy Statement (December, 2003).

- 11. Salary Rate Limitations: Pursuant to PL 106-554, funds may not be used to pay the direct salary of any individual through this Agreement at a rate in excess of the Executive Level 1 salary level in effect at the beginning date of this Agreement.
- 12. Drug Free Workplace: SUBAWARDEE certifies compliance with the requirements of the Drug Free Workplace Act of 1988, 45 CFR Part 76 subpart F, and the NIH Grants Policy Statement.
- 13. Pro-Children Act of 1994: SUBAWARDEE certifies compliance with the requirements of PL 103-227, Title X, Part C "Environmental Tobacco Smoke" and with the NIH Grants Policy Statement.
- 14. Clean Air Act of 1970: In compliance with 42 USC 7401 et seq., SUBAWARDEE certifies that it is not listed on the Environmental Protection Agency List of Violating Facilities. In addition, SUBAWARDEE will immediately notify UNIVERSITY of the receipt of any communication from the Environmental Protection Agency indicating that any facility that SUBAWARDEE proposes to use for the performance of this Agreement is under consideration to be listed on the EP A List of Violating Facilities.
- 15. Student Unrest Provisions: SUBAWARDEE shall be responsible for carrying out applicable provisions described in P.L. 93-192 relating to prohibitions on remuneration from funds awarded under this Agreement to any individual who has been engaged or involved in activities described as "student unrest".
- Medicare and Medicaid Anti-Kickback: SUBAWARDEE certifies compliance with 42 U.S.C. 1320a-16. 7b (b).