SAN ANTONIO SAN ANTONIO SAN ANTONIO METROPOLITAN HEALTH DISTRICT CITY COUNCIL AGENDA MEMORANDUM.

TO:

Mayor and City Council

FROM:

Fernando A. Guerra, MD, MPH, Director of Health

SUBJECT:

ORDINANCE ACCEPTING FUNDS FROM THE UNIVERSITY OF TEXAS

HEALTH SCIENCE CENTER

DATE:

March 31, 2005

SUMMARY AND RECOMMENDATIONS

This ordinance authorizes the Interim City Manager to accept and execute a subaward agreement totaling \$37,672.00 from the University of Texas Health Science Center (UTHSCSA) for the San Antonio Metropolitan Health District (SAMHD) to participate in the San Antonio Center for the Study of Stillbirth Project for the period August 1, 2004 through July 31, 2005. This ordinance will also establish a fund, adopt the project budget, and approve the personnel complement.

Staff recommends approval.

BACKGROUND INFORMATION

The University of Texas Health Science Center (UTHSCSA) was granted an award through a Cooperative Clinical Research Agreement from the National Institutes of Health (NIH) for a project entitled "San Antonio Center for the Study of Stillbirth". The objective of the NIH Stillbirth Research Agreement is to (1) develop a standard stillbirth postmortem protocol, to include review of clinical history, protocols for autopsies and pathologic examinations of the fetus and placenta, other postmortem tests to illuminate genetic, maternal, and other environmental influences, and (2) obtain a geographic population-based determination of the incidence of fetal deaths at 20 weeks gestation or greater, their causes, and risk factors. This will involve a geographic population-based study of stillbirths enrolled at the time of demise.

The SAMHD provides extensive outreach, recruitment, case management and health education interventions to women and families in order to reduce the incidence of infant mortality and low birth weights in target communities. Through the services currently offered and the data collected, participation in the UTHSCSA Study of Stillbirth would be of great value to the overall project objectives. Therefore, UTHSCSA has offered a subaward agreement to SAMHD for the SAMHD to participate in the San Antonio Center for the Study of Stillbirth project.

This will be a five (5) year project encompassing 500 patients nationwide. The SAMHD is responsible for enrolling 100 of these patients. The study developed protocols and started enrollment in late 2004. Patients that have experienced a stillbirth will be interviewed, have lab work done, medical records reviewed, and placentas collected for diagnostic data.

The personnel complement for this program will be one (1) part time position: Special Projects Coordinator (See Attachment I). This person, currently employed in the SAMHD, will coordinate all aspects of the project, sharing epidemiologic data pertinent to the project and providing appropriate support as needed when the project protocol is complete.

POLICY ANALYSIS

This ordinance follows past City policy of fostering the development and maintenance of cooperative relationships with academic institutions that can yield insight and interventions for the benefit of the community.

FISCAL IMPACT

This UTHSCSA subaward agreement provides \$37,672.00 in funding for the SAMHD to participate in the project. Acceptance of this grant will place no demands on the City General Fund.

COORDINATION

The City Attorney's Office and the Human Resources Department, Risk Management Division, have reviewed all attached professional services agreements with partner organizations.

SUPPLEMENTARY COMMENTS

Costs which were incurred by SAMHD since August 1, 2004 shall be retroactively reimbursed to the City on behalf of SAMHD under this subaward agreement.

Provisions of the Ethics Ordinance do not apply.

Attachments: Attachment I: Project Budget and Personnel Complement

Attachment II: UTHSCSA Subaward Agreement

Fernando A. Guerra, MD, MPH

Director of Health

Frances A. Gonzalez

Assistant City Manager

J. Rolando Bono

Interim City Manager

AN ORDINANCE

AUTHORIZING THE **ACCEPTANCE OF FUNDS** TOTALING \$37,672.00 FROM THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO (UTHSCSA) FOR THE PARTICIPATION OF THE SAN ANTONIO METROPOLITAN HEALTH DISTRICT IN THE SAN ANTONIO CENTER FOR THE STUDY OF STILLBIRTH PROJECT FOR THE PERIOD AUGUST 1, 2004 THROUGH JULY 31, 2005; AUTHORIZING THE EXECUTION OF A SUBAWARD AGREEMENT WITH UTHSCSA; ADOPTING THE PROJECT BUDGET; AND APPROVING THE PERSONNEL COMPLEMENT.

WHEREAS, the San Antonio Metropolitan Health District (SAMHD) delivers various comprehensive public health services to protect the health of all residents within the jurisdiction of the District; and

WHEREAS, the SAMHD provides extensive outreach, recruitment, case management and health education interventions to women and families in order to reduce the incidence of infant mortality and low birth weights in target communities; and

WHEREAS, the University of Texas Health Science Center at San Antonio (UTHSCSA) has offered a subaward agreement totaling \$37,672.00 for the SAMHD to participate in the San Antonio Center for the Study of Stillbirth project for the period August 1, 2004 through July 31, 2005 to develop a standard stillbirth postmortem protocol and to obtain a geographic population-based determination of the incidence of fetal deaths at 20 weeks gestation or greater; and

WHEREAS, costs which were incurred by SAMHD since August 1, 2004 may be retroactively reimbursed to the City of San Antonio on behalf of the SAMHD under this subaward agreement; and

WHEREAS, it is now necessary to authorize the acceptance and execution of the subaward agreement from UTHSCSA, adopt the project budget, and approve the personnel complement; NOW THEREFORE:

BE IT ORDAINED BY THE CITY COUNCIL OF THE CITY OF SAN ANTONIO:

SECTION 1. The Interim City Manager, or his designee, is authorized to accept and execute a subaward agreement totaling \$37,672.00 from the University of Texas Health Science Center at San Antonio (UTHSCSA) for the SAMHD to participate in the San Antonio Center for the Study of Stillbirth Project for the period August 1, 2004 through July 31, 2005. A copy of said agreement is set out in Attachment II and incorporated herein for all purposes.

SECTION 2. SAP Fund No. 26012000, Funds Center 3606800000, Cost Center 3606800002, Internal Order 136000000268 are hereby designated for use in accounting for the fiscal transactions of this project. Funds are hereby appropriated for the budget period August 1, 2004 through July 31, 2005.

SECTION 3. The sum of \$37,672.00 is hereby appropriated in the above-designated fund and the budget set out in Attachment I is approved and adopted for entry on the City books.

SECTION 4. The one (1) personnel position set out in Attachment I is hereby authorized for the activity shown thereon.

SECTION 5. The Director of Finance may, subject to concurrence by the Interim City Manager or the Interim City Manager's designee, correct allocation to specific fund numbers, account numbers, and internal order numbers as necessary to carry out the purpose of this ordinance.

SECTION 6. Should the grant awarded be in an amount other than that budgeted for, or should the grant contain terms and conditions different than those currently existing, acceptance of the grant, budget and corresponding personnel complement will be subject to subsequent City Council ordinance.

SECTION 7.	This ordinance shall be effect	ctive on and after the tenth da	y after passage hereof.
PASSED AND	APPROVED this	day of March, 2005.	
		MAYOR	
ATTEST:			

APPROVED AS TO FORM: ______City Attorney

City Clerk

Attachment I UTHSCSA San Antonio Center for the Study of Stillbirth Fund 26012000

Funds Center 3606800000 Functional Area 360050000020010

Budget for Period: 08/01/2004 to 07/31/2005

ESTIMATED REVENUES	SAP-GL NO.	_	URRENT MOUNT
UTHSCSA Subaward Agreement Total Estimated Revenues	4501160	<u> </u>	37,672 37,672
1 otta 135timated 146 (citaes		*_	57,072

APPROPRIATIONS

UTHSCSA San Antonio Center for the Study of Stillbirth

Cost Center: 3606800002 Internal Order: 136000000268

Regular Salaries & Wages 510	22,903
Language Skill Pay 510)1050 250
Retirement Benefits - Soc. Sec. 510	3005 1,745
Retirement Benefits - TMRS 510	2,603
Group Health Insurance 540	2,270
Life Insurance 510	34
Travel - Official 520	07010 4,508
Indirect Cost 540	06530 3,359
Total Appropriations	\$ 37,672

		CURRENT
	PERSONNEL COMPLEMENT	POSITIONS
	Cost Center: 3606800002	
	Internal Order: 136000000268	
Class No.		
	Title	
0870	Special Project Coordinator (.5 FTE)	1
	Total Personnel:	1

Subaw	ard Agreement		
Institution/Organization ("UNIVERSITY")	Institution/Organization ("COLLABORATOR")		
Name: The University of Texas Health Science Center at San Antonio Address:7703 Floyd Curl Drive, MC 7828 San Antonio, TX 78229-3900	me: The City of San Antonio on behalf of the San Antonio Metropolitan Health District dress: 332 W. Commerce, Suite 307 San Antonio, TX 78205		
	EIN No. 1-740662070		
Prime Award No. 5 U10 HD045955-02	Subaward No. 119856/119249		
Awarding Agency US DHHS/National Institutes of Health	CFDA No. 93.865		
Subaward Period of Performance 8/1/04 – 7/31/05	Amount Funded This Action Est. Total (if incrementally funded) \$ 37,672		
Project Title San Antonio Center for the Study of Stillbirt	h		
Reporting Requirements [Check here if applicable 🗵 See			
Terms and Conditions 1) University hereby awards a cost reimbursable Subaward, as described above, to Collaborator. The statement of work and budget for the Subaward are (check one): as specified in Collaborator's proposal dated; or ⊠ as shown in Attachment 5. In its performance of the Subaward work, Collaborator shall be an independent entity and not an employee or agent of University. 2) University shall reimburse Collaborator not more often than monthly for allocable costs. All invoices shall be submitted using Collaborator's standard invoice, but at a minimum shall include current and cumulative costs (including cost sharing), Subaward number, and certification as to truth and accuracy of invoice. <i>Invoices that do not reference University's Subaward number shall be returned to</i>			
Collaborator. Invoices and questions concerning invoice receipt or payment should be directed to the appropriate party's Financial Contact, as shown in Attachment 3. 3) A final statement of cumulative costs incurred, including cost sharing, marked "FINAL" must be submitted to University's Financial Contact NOT LATER THAN sixty (60) days after Subaward end date. The final statement of costs shall constitute Collaborator's final financial report. 4) All payments shall be considered provisional and subject to adjustment within the total estimated cost in the event such adjustment is necessary as a result of an adverse audit finding against the Collaborator. 5) Matters concerning the technical performance of this Subaward should be directed to the appropriate party's Project Director, as shown in Attachment 3. Technical reports are required as shown above, "Reporting Requirements."			
6) Matters concerning the request or negotiation of any changes in the terms, conditions, or amounts cited in this Subaward agreement should be directed to the appropriate party's Administrative Contact, as shown in Attachment 3. Any such changes made to this Subaward agreement require the written approval of each party's Authorized Official, as shown in Attachment 3. 7) Each party shall be responsible for its negligent acts or omissions and the negligent acts or omissions of its employees, officers, or directors, to the extent allowed by law. 8) Either party may terminate this Agreement with thirty days' written notice to the other party's Administrative Contact, as shown in Attachment 3. University shall pay Collaborator for termination costs as allowable under OMB Circular A-21or A-122, as applicable. 9) No-cost extensions require the approval of the University. Any requests for a no-cost extension should be addressed to and received by the Administrative Contact as shown in Attachment 3, not less than thirty days prior to the desired effective date of the requested change. 10) The Subaward is subject to the terms and conditions of the Prime Award and other special terms and conditions, as identified in Attachment 2. 11) By signing below Collaborator makes the certifications and assurances shown in Attachments 1 and 2.			
By an Authorized Official of UNIVERSITY:	By an Authorized Official of COLLABORATOR:		
Jane A. Youngers, Director (date) Office of Grants Management	(date)		

Attachment 1 Subaward Agreement

By signing the Subaward Agreement, the authorized official of COLLABORATOR certifies, to the best of his/her knowledge and belief, that:

Certification Regarding Lobbying

- 1) No Federal appropriated funds have been paid or will be paid, by or on behalf of the Collaborator, 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.
- 2) If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or intending 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 Collaborator shall complete and submit Standard Form –LLL, "Disclosure Form to Report Lobbying," to the University.
- 3) The Collaborator 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 13.52, 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.

Debarment, Suspension, and Other Responsibility Matters

Collaborator certifies by signing this Subaward Agreement that neither it nor its principals are presently debarred, suspended, proposed for debarment, declared ineligible or voluntarily excluded from participation in this transaction by any federal department or agency

OMB Circular A-133 Assurance

Collaborator assures University that it complies with A-133 and that it will notify University of completion of required audits and of any adverse findings which impact this subaward.

Attachment 2 Subaward Agreement NIH

Agency-Specific Certifications/Assurances

1. The following assurances/certifications are made and verified by Collaborator's Authorized Official on the face page of this Subaward. Descriptions of individual assurances/certifications are provided in Section III of the PHS 398. 1) Human Subjects; 2) Research Using Human Embryonic Stem Cells; 3) Research on Transportation of Human Fetal Tissue; 4) Women and Minority Inclusion Policy; 5) Inclusion of Children Policy; 6) Vertebrate Animals; 7) Debarment and Suspension; 8) Drug-Free Workplace; 9) Lobbying; 10) Non-Delinquency on Federal Debt; 11)Research Misconduct; 12) Civil Rights (Form HHS 441 or HHS 690); 13) Handicapped Individuals (Form HHS 641 or HHS 690); 14) Sex Discrimination (Form HHS 639-A or HHS 690); 15) Age Discrimination (Form HHS 680 or HHS 690); 16) Recombinant DNA and Human Gene Transfer Research; 17) Financial Conflict of Interest.

General terms and conditions:

- 1. The restrictions on the expenditure of federal funds in appropriations acts are applicable to this subaward to the extent those restrictions are pertinent.
- 2. 45 CFR Part 74 or 45 CFR Part 92 as applicable. [This is the CFR governing NIH.]
- 3. The NIH Grants Policy Statement, including addenda, in effect as of the beginning date of the period of performance and found at http://grants.nih.gov/grants/policy/policy.htm, except for the payment mechanism and final reporting requirements are replaced with Reporting Requirements and Terms and Conditions on the front page of this agreement.
- 4. The Terms and Conditions of the prime aware attached to the Subaward Agreement as Attachment 6.
- 5. Collaborator assures, by signing this Subaward Agreement, that all Collaborator's personnel who are responsible for the design and conduct of projects involving human research participants have successfully completed their institutional training in accordance with the NIH Guide, Notice OD-00-039.

Special terms and conditions: [Institutions may include the following optional clauses.]

- 1. Copyrights
 - Collaborator \square grants / \boxtimes shall grant (check one) to University an irrevocable, royalty-free, non-transferable, non-exclusive right and license to use, reproduce, make derivative works, display, and perform publicly any copyrights or copyrighted material (including any computer software and its documentation and/or databases) first developed and delivered under this Subaward Agreement solely for the purpose of and only to the extent required to meet University's obligations to the Federal Government under its Prime Award.
- 2. Data Rights
 - Collaborator grants to University the right to use data created in the performance of this Subaward Agreement solely for the purpose of and only to the extent required to meet University's obligations to the Federal Government under its Prime Award.

Attachment 3 Subaward Agreement

	University Contacts		Collaborator Contacts
Administrativ		Administrat	ive Contact
Name: Address:	Jane A. Youngers Director, Office of Grants Management The University of Texas Health Science Center at San Antonio 7703 Floyd Curl Drive, MC 7828 San Antonio, TX 78229-3900	Name: Address:	Sharon Shumpert Health Start Program Manager 1325 N. Flores Street, Suite 104 San Antonio, TX 78212
Telephone: Fax: Email:	210.567.2340 210.567.2344 grants@uthscsa.edu	Telephone: Fax: Email:	210.299.5035 210.299.5051 sshumpert@sanantonio.gov
Principal Inv	estigator	Project Director	
Name: Address:	Donald J. Dudley, M.D. Department of Obstetrics/Gynecology The University of Texas Health Science Center at San Antonio 7703 Floyd Curl Drive San Antonio, TX 78229-3900	Name: Address:	Fernando A. Guerra, MD, MPH, FAAP Director of Health San Antonio Metropolitan Health District 332 W. Commerce, Suite 307 San Antonio, TX 78205
Telephone: Fax: Email:	210.567.5035 210.567.3013 dudleyd@uthscsa.edu	Telephone: Fax: Email:	210.207.8731 210.207.8999 fguerra@sanantonio.gov
Financial Co	ntact	Financial C	ontact
Name: Address:	Accounting Group Supervisor Office of Accounting The University of Texas Health Science Center at San Antonio 7703 Floyd Curl Drive, MC 7966 San Antonio, TX 78229-3900	Name: Address:	Ramon Sanchez Administrative Services Manager San Antonio Metropolitan Health District 332 W. Commerce, Suite 307 San Antonio, TX 78205
Telephone: Fax: Email:	210.567.6085 210.567.2566 not available	Telephone: Fax: Email:	210.207.8721 210.207.6359 raymonds@sananatonio.gov
Authorized C	Official:	Authorized	Official:
Name: Address:	Jane A. Youngers Director, Office of Grants Management The University of Texas Health Science Center at San Antonio 7703 Floyd Curl Drive, MC 7828 San Antonio, TX 78229-3900	Name: Address:	Frances A. Gonzalez Assistant City Manager City of San Antonio 100 Military Plaza San Antonio, TX 78207
Telephone: Fax: Email:	210.567.2340 210.567.2344 grants@uthscsa.edu	Telephone: Fax: Email:	210.207.2200 210.207.4122 francesg@sanantonio.gov

ATTACHMENT 4 SUBAWARD AGREEMENT

Reporting Requirements

(as modified by The University of Texas Health Science Center at San Antonio)

- 1. Subawardee shall submit reports to University's Project Director, as stated in Attachment 3, in such form and content as University's Project Director may reasonably request.
- 2. Final Statement of Cumulative Costs. Pursuant to Item 3 of Terms and Conditions, a final statement of cumulative costs incurred, including cost sharing, marked "FINAL," must be submitted to University's Financial Contact NOT LATER THAN sixty (60) days after subaward end date. The final statement of costs shall constitute Collaborator's final financial report.

University reserves the right to reject any final statement of cumulative costs incurred received after sixty (60) days after subaward end date.

ATTACHMENT 5 STATEMENT OF WORK AND BUDGET

Paola Tovar-Kurth, R.N., Research Nurse Study Coordinator (50% effort) will coordinate all aspects of the study. She will share Epidemiologic data pertinent to the study and provide appropriate support as needed by Dr. Donald Dudley when the study protocol is complete. Because the Study Protocol has not yet been finalized, other reports or requirements may be required as may be reasonably requested by Dr. Dudley and appropriate within the scope of the budget.

This budget is a reasonable effort of anticipated costs; budget category adjustments are allowable as long as the total amount is not exceeded.

Salary, Paola Tovar-Kurth, 50% effort Employee Benefits Total Salary-related Costs	\$22,903 6,902 \$29,805
Travel	<u>4,508</u>
Total Direct Costs	\$34,313
Indirect Costs @9.79%	_3,359
TOTAL	\$37,672

ATTACHMENT 6 PRIME AWARD

COOPERATIVE CLINICAL RESEARCH AGREEMENT Issue Date:07/31/2004 Department of Health and Human Services

National Institutes of Health

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Grant Number: 5 U10 HD045955-02

Principal Investigator: DUDLEY, DONALD J MD

Project Title: San Antonio Center for the Study of Stillbirth

DIRECTOR OF GRANTS MANAGEMENT UNIVERSITY OF TEXAS HLTH SCIENCE CTR AT SAN ANTONIO 7703 FLOYD CURL DR/MSC 7828 SAN ANTONIO, TX 782293900 UNITED STATES

Award e-mailed to: nihgrants@uthscsa.edu

Budget Period: 08/01/2004 - 07/31/2005 Project Period: 09/26/2003 - 07/31/2008

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of \$___(see ''Award Calculation'' in Section I) to UNIVERSITY OF TEXAS HLTH SCI CTR SAN ANT in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 31 USC 6305 & 6306 and is subject to terms and conditions referenced below.

Acceptance of this award including the Terms and Conditions is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Award recipients are responsible for reporting inventions derived or reduced to practice in the performance of work under this grant. Rights to inventions vest with the grantee organization provided certain requirements are met and there is acknowledgement of NIH support. In addition, recipients must ensure that patent and license activities are consistent with their responsibility to make unique research resources developed under this award available to the scientific community, in accordance with NIH policy. For additional information, please visit http://www.iedison.gov.

If you have any questions about this award, please contact the individual(s) referenced in the information below.

Sincerely yours,
CHRIS ROBEY
Grants Management Officer
NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

See additional information below

SECTION I - AWARD DATA - 5 U10 HD045955-02

AWARD CALCULATION (U.S. Dollars):

Salaries and Wages
Fringe Benefits
Personnel Costs
Supplies
Travel Costs
Other Costs
Consortium/Contractual Cost
Federal Direct Costs
Federal F&A Costs
APPROVED BUDGET
TOTAL FEDERAL AWARD AMOUNT

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project, is as follows.

03

04

05

FISCAL INFORMATION: CFDA Number 93.865 EIN: 1741586031A3

Document Number: UHD045955A

IC/ CAN / FY2004 / FY2005 / FY2006 / FY2007 HD/8421368/ 395,982/ 407,862/ 420,097/ 432,700

NIH ADMINISTRATIVE DATA:

PCC: PP -MW / OC: 41.4P /Processed: ROBEYC 040729 0407

SECTION II - PAYMENT/HOTLINE INFORMATION - 5 U10 HD045955-02

For Payment and HHS Office of Inspector General Hotline Information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III - TERMS AND CONDITIONS - 5 U10 HD045955-02

This award is based on the application submitted to, and as approved by, the NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

- a. The grant program legislation and program regulation cited in this Notice of Grant Award.
- b. The restrictions on the expenditure of federal funds in appropriations acts, to the extent those restrictions are pertinent to the award.
- c. 45 CFR Part 74 or 45 CFR Part 92 as applicable.
- d. The NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period. e. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(see NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

This grant is awarded under the terms and conditions of the Federal Demonstration Partnership Phase IV.

Carry over of an unobligated balance into the next budget period requires Grants Management Officer prior approval.

Treatment of Program Income: Additional Costs

SECTION IV- ADDITIONAL TERMS AND CONDITIONS - 5 U10 HD045955-02

The requested budget was considered and did not raise any concerns regarding a potential change in scope. Therefore, categorical amounts reflect the direct and facilities and administrative cost levels previously recommended for the current year.

The grantee institution bears ultimate responsibility for protecting human subjects under this award, including human subjects at all participating and consortium sites, and for ensuring that a Federal-wide assurance approved by OHRP and certification of IRB review and approval have been obtained before human subjects research can be conducted at each site. The documentation of these assurances should be kept on file at the grantee institution. If requested, this documentation should be submitted to the awarding component.

RESTRICTION: The present award is being made without a currently valid certification of Institutional Review Board (IRB) approval for this project with the following restriction: Only activities that are clearly severable and independent from activities that involve human subjects may be conducted under this award until the project has received IRB approval consistent with 45 CFR Part 46 and certification of IRB approval has been submitted to and accepted by NICHD.

No funds may be drawn down from the payment system and no obligations may be made against Federal funds for research involving human subjects by the grantee or any other site engaged in such research for any period not covered by an OHRP-approved Assurance and IRB approval consistent with 45 CFR Part 46.

Failure to comply with the above requirements may result in suspension and/or termination of this award, withholding of support, audit disallowances, and/or other appropriate action.

See the NIH Grants Policy Statement, December 2003, (http://grants2.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part5.htm) for specific requirements related to the protection of human subjects, which are applicable to and a term and condition of this award.

RESTRICTION: Funds awarded for capitation costs \$240,608 total costs (\$164,800 Direct Costs + \$75,808 Facilitates and Administrative Costs) are restricted and may not be used for any purpose. Once protocols are developed and costs are determined, these funds will be released accordingly.

Funds associated with capitation costs are awarded in the "other expenses" category. Therefore, costs requested in the "other expensed" category have been rebudgeted to the "supplies" category.

This award includes funds awarded for consortium activity with San Antonio Metropolitan Health District in the amount of \$37,672 (\$34,313 direct costs + \$3,359 facilities and administrative costs). Consortiums are to be established and administered as described in the NIH Grants Policy Statement (NIH GPS). The referenced section of the NIH Grants Policy Statement is available at http://grants1.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part12.htm#_Toc5 4600251

Human Subjects: The National Institute of Child Health and Human Development (NICHD) recognizes that investigators are submitting applications to conduct exciting and important research of interest to NICHD. NICHD has oversight responsibilities to ensure compliance with government regulations and to ensure the safety of human subjects in research. The following web site contains information regarding your institutional responsibilities and compliance issues that should be reviewed throughout the duration of your NIH-supported project. DHHS Web Site for Human Subjects: http://ohrp.osophs.dhhs.gov/index.htm.

Beginning December 2002, NIH changed the notification of Non-Competing Grant Progress Reports from a hard copy mailing of preprinted electronic PHS 2590 and PHS 416 face pages to an electronic notification. The website of Non-competing Progress Report due date information is at: http://era.nih.gov/userreports/pr_due.cfm

All publications, posters, oral presentations at scientific meetings, seminars, and any other forum in which results of this NICHD-supported research are presented must include a formal acknowledgement of NICHD support, citing the NIH grant number as identified on this award document.

Grantees may submit prior approval requests for NIH grants and cooperative agreements via e-mail as detailed in the NIH Guide announcement OD-00-009. The announcement can be found at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-009.html.

Prior approval requests for this grant should be directed to the Grants Management Specialist listed below.

Direct inquiries regarding scientific programmatic issues to the program official listed below.

Direct inquiries regarding fiscal and administrative matters to the grants management specialist listed below.

MARIAN WILLINGER, Program Official

Phone: (301) 496-5575 Email: willingm@mail.nih.gov Fax: (301) 496-3790

Cheryl A Nathaniel, Grants Specialist

Phone: (301) 435-7006 Email: cn15b@nih.gov Fax: (301) 480-4782