

Columbia University Human Subjects Protocol Data Sheet

Protocol: IRB-AAA5282(Y2M00) Renewal

Protocol Status: Approved

**Effective Date: 01/01/2001
Expiration Date: 12/31/2007**

Originating Department: MSPH DEAN'S OFFICE (475-00-47500)
Submitting To: Medical Center
Title: MTCT-Plus Initiative
Sponsor Protocol Version#:
Abbreviated title: MTCT Plus Initiatve

Affiliated Institutions:
Protocol Begin Date: 00/00/0000
Protocol End Date: 00/00/0000
Previous Protocol Number: 14714

Personnel Staff

<u>Name/Phone</u>	<u>Role</u>	<u>COI-Date</u>	<u>Courses</u>	<u>Dept</u>	<u>Edit/ Procedure View</u>	<u>Experience</u>
Allan Rosenfield, (ar32) 212-305-3929 Professor	Principal Investigator	09/26/2006	1. HS GCP - Epid. & Soc. Behav. - 09/28/2000 2. HIPAA - 03/22/2005	475	Edit	

Jessica Arrighi, (jaw83) (212) 342-0535 Admin Coord	Initiator	08/09/2004		478	Edit	
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*Wafaa El-sadr, (wme1) 212 939 2936 Prof Clin/ Assoc Attend	Co-Investigator	11/07/2006	1. HS GCP - Patient/Clinical - 03/19/2001 2. HIPAA - 01/02/2004	527	Edit	
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Renewal

Subject Enrollment Status:
Additional relevant information if needed to further explain Study Status:
Date enrollment began at our site: 00/00/0000
Summary of any recent literature or interim findings:
Changes in the literature since the last renewal application:
List of papers pending or published:
Synopsis of the results to date:
If this renewal includes a modification:
Certificate of Confidentiality (COC) obtained:
If COC obtained, expiration date of Certificate: 00/00/0000

Subjects



Is this a multicenter study?	0
Target accrual at all sites:	0
Number of Subjects accrued to date at all sites:	0
Target accrual at this site:	0
Number accrued to date at this site:	0
Number completed at this site:	0
Number still on study at this site:	0
Number who withdrew of own initiative(including those lost to follow-up):	0
Number removed by researcher:	0
Number of subjects accrued since the last IRB approval:	0
Number anticipated to accrue next approval period:	0
Number of subject complaints at this site:	0

Explain subject complaints:

Explain subjects removed by researcher:

Explain subjects who withdrew of own initiative:

Explain incomplete accrual at our site:

Explain problems meeting anticipated accrual number:

Strategies to remedy these problems:

Have you enrolled subjects using the Short Form Consent Process for Non-English speaking subjects?:
Please indicate the number of subjects enrolled for each language:

Subject justification: Previously Paper Protocol 14714

Subject compensation: Previously Paper Protocol 14714

Compensation justification: Previously Paper Protocol 14714

Consent form waiver/alteration request: Previously Paper Protocol 14714

Recruitment url:

Oversight Monitoring/Renewal
Adverse Event

Summary of all Adverse Events to
date at all sites:

Number of deaths at this site: 0

Has your assessment of risks and
benefits changed since the last
submission?:

If Yes, describe assessment of risks
and benefits:

If there is a Data Safety Monitoring
Committee for this study, is the most
recent report attached?:

Explanation why the most recent
safety monitor report is not attached:

If this is a federally supported or
multi-center study, is the most recent
progress report of this study
attached?:

Explanation why the most recent
report is not attached:

Research

Research procedures:

Research facilities:

Scientific abstract: Previously Paper Protocol 14714

Lay abstract: Previously Paper Protocol 14714

Approval Personnel

Electronic Signature: Allan Rosenfield (475) - Principal Investigator
Electronic Signature: Wafaa El-sadr (527) - Co-Investigator

Date: 00/00/0000 NOT YET SIGNED
Date: 00/00/0000 NOT YET SIGNED