Columbia University Human Subjects Protocol Data Sheet

Protocol: IRB-AAAA5282(Y2M00)  Protocol Status: Approved  Effective Date: 01/01/2001
Renewal  Expiration Date: 12/31/2007

Originating Department: MSPH DEAN'S OFFICE (475-00-47500)
Submit To: Medical Center
Title: MTCT-Plus Initiative

Sponsor Protocol Version#:  Abbreviated title: MTCT Plus Initiative

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

Personnel Staff

<table>
<thead>
<tr>
<th>Name/Phone</th>
<th>Role</th>
<th>COI-Date</th>
<th>Courses</th>
<th>Dept</th>
<th>Edit/View</th>
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<tbody>
<tr>
<td>Allan Rosenfield, Principal Investigator (ar32) 212-305-3929 Professor</td>
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<td>1. HS GCP - Epid. &amp; Soc. Behav. - 09/28/2000</td>
<td>475</td>
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<td>2. HIPAA - 03/22/2005</td>
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<td>Jessica Arrighi, Initiator (jaw83) (212) 342-0535 Admin Coord</td>
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<tr>
<td>Wafaa El-sadr, Co-Investigator (wme1) 212 939 2936 Prof Clin/ Assoc Attend</td>
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<td>1. HS GCP - Patient/Clinical - 03/19/2001</td>
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<td>2. HIPAA - 01/02/2004</td>
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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?
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  Date: 00/00/0000  NOT YET SIGNED
Electronic Signature: Wafaa El-sadr (527) - Co-Investigator  Date: 00/00/0000  NOT YET SIGNED