

**MTN-034/REACH
Risk Mitigation Plan**

Risk Management is the process of identifying, assessing, responding to, monitoring, and reporting risks. The REACH Risk Management Plan identifies key risks associated with the research study and outlines how they will be managed throughout study implementation. All risks and indicators will be monitored at each site. In addition to the monitoring approach included in the table below, members of the management team and/or protocol chairs may visit the sites to provide further support. These topics will also be discussed on protocol team calls for sites to share best practices. Note: As of March 2020, the COVID-19 pandemic may impact study implementation and achievement of several Risk Mitigation Plan indicators. During the time period while site operations and capacity may be affected by COVID-19, sites will not be required to conduct corrective/responsive actions for unmet indicators outlined in this plan. However, instances of unmet indicators will be discussed on management team calls and a determination will be made as to whether response actions are required given the COVID-19 context.

#	Study Risk	Indicators	Action/Response if Indicators Unmet	Monitoring Approach	Documentation
1.	Inadequate accrual of younger cohort (16-17 years old)	<ul style="list-style-type: none"> • Fewer than 10 participants among younger cohort enrolled within 6 months of accrual initiation, OR • Fewer than 2 of the first 10 enrolled are in the younger cohort <p><i>Note: This metric is no longer relevant as of 19MAR2020 due to completion of accrual.</i></p>	<ol style="list-style-type: none"> 1) Pause enrollment of older population until at least one indicator is met. And site to: <ol style="list-style-type: none"> a) evaluate recruitment strategies e.g. locations, target demographics, recruitment materials b) assess Screen to Enrollment ratio for trends in screen fails c) set targets for improvement within two weeks 2) If site unable to improve accrual rate of younger cohort within two months, shift slots to other sites 	REACH Study Leadership and Management Team review accrual reports via SCHARP ATLAS portal, and discuss outcomes on monthly REACH Management Team calls	<ul style="list-style-type: none"> • REACH Management Team call summaries prepared by FHI 360 • REACH Protocol Chairs contact applicable site Investigator of Record (IoR) with action items and instructions if needed


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2.	Inability to reach overall accrual target	<ul style="list-style-type: none"> Fewer than 50 participants enrolled by January 31st, 2020. <p><i>Note: This metric is no longer relevant as of 19MAR2020 due to completion of accrual.</i></p>	<ol style="list-style-type: none"> Site to review screening pipeline and provide updated monthly accrual plan to the management team for discussion If site unable to meet accrual target based on management team review of accrual plan, shift slots to other sites 	REACH Study Leadership and Management Team review accrual reports via SCHARP ATLAS portal and monthly accrual plans for relevant sites	<ul style="list-style-type: none"> REACH Management Team call summaries prepared by FHI 360 NTF to relevant sites documenting decision to shift accrual slots
3.	Low retention of participants	<ul style="list-style-type: none"> Less than 95% retention at Month 1 visits <p><i>Note: This metric is no longer relevant as of 19MAR2020 due to completion of accrual.</i></p> <ul style="list-style-type: none"> Less than 95% retention across study visits overall based on the Data Summary Report 	<ol style="list-style-type: none"> If retention lower than 95%, site IoR to internally review potential issues and strategies with site team If retention is lower than 90%, site to send a detailed analysis of possible reasons, and methods to improve via a Corrective and Preventive Action (CAPA) plan 	REACH Study Leadership and Management Team review retention reports via SCHARP ATLAS portal, and discuss outcomes on REACH Management Team calls	<ul style="list-style-type: none"> REACH Management Team call summaries prepared by FHI 360 REACH Protocol Chairs contact applicable site IoR with action items and instructions if needed
4.	Low participant adherence to study products	<ul style="list-style-type: none"> ≥30% of drug level feedback across participants at site is in red level (no/very low detection) <p>*Note: indicator to be assessed once 6 participants have been enrolled in each group at site</p> <p>** Note: indicator includes product decline</p>	<ol style="list-style-type: none"> If ≥30% of feedback across participants is in the red level, site IoR to review potential issues and identify adherence support strategies with site team If ≥50% of feedback across participants is in the red level: <ol style="list-style-type: none"> Site to send a detailed analysis of possible reasons, and methods to improve via a Corrective and Preventive Action (CAPA) plan Based on CAPA, site and Management Team to revise adherence tools and/or counseling messages, if needed 	REACH Study Leadership and Management Team review site adherence reports via SCHARP ATLAS portal, and discuss outcomes on REACH Adherence Working Group (AWG) calls	<ul style="list-style-type: none"> REACH AWG call summaries prepared by FHI 360 REACH Protocol Chairs contact applicable site IoR with action items and instructions if needed
		<ul style="list-style-type: none"> Counselor does not maintain fidelity to counseling manual content, per recorded counseling sessions and peer 	<ol style="list-style-type: none"> If fidelity wanes, retrain relevant counselor(s) If no improvement in counseling in the following month, recommend 	Counseling sessions and peer feedback forms reviewed by Sybil Hosek	<ul style="list-style-type: none"> Sybil Hosek communicates and conducts training

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		<p>feedback forms reviewed by Sybil Hosek on a monthly basis</p> <ul style="list-style-type: none"> Fewer than 50% of assigned peer feedback forms completed and uploaded within 1 month of being assigned <p>*Note: indicator to be assessed once 6 participants have been enrolled at site, assuming equitable distribution of participants across counselors</p> <p><i>Note: This metric not relevant as of 08JUN2021 due to cessation of counseling recordings.</i></p>	<p>counselor(s) stop counseling until improvement demonstrated in mock sessions</p> <p>3) If peer feedback forms are not uploaded, site to put a corrective and preventive action (CAPA) in place</p>		directly with applicable counselors
5.	Poor Data Quality	<p>For two consecutive months, one or more of the following occurs on the Cumulative Data Quality Management Report:</p> <ul style="list-style-type: none"> Less than 90% of data entered on time More than 10 queries per 100 pages Less than 80% of queries responded to on time 	<p>1) SCHARP conducts root cause analysis with the site to determine what, if any, action is needed.</p> <p>2) If needed, SCHARP conducts refresher training with site and/or specific staff members until overall data quality improves. Training will be documented per SDMC policy.</p> <p>3) Site to re-assess staffing needs if poor data quality is due to heavy work burden and/or update internal QA/QC procedures as needed</p>	<p>REACH Study Leadership and Management Team review data quality reports via SCHARP ATLAS portal, and discuss outcomes on a quarterly basis during REACH Management Team calls</p> <p>MTN Network Evaluation Committee (NEC) reviews data quality reports on NEC calls and provides additional guidance to protocol team if needed</p>	<ul style="list-style-type: none"> REACH Management Team call summaries prepared by FHI 360 SCHARP CDM contacts applicable site staff with action items, instructions and refresher training if needed
6.	High pregnancy rate	<ul style="list-style-type: none"> 2 or more pregnancies 	<p>1) Site to send a detailed analysis of possible reasons, and methods to improve via a Corrective and Preventive Action (CAPA) plan</p> <p>2) REACH Contraceptive Action Team (CAT) provides additional support to site, including refresher training on LARC methods</p>	<p>Protocol Safety Review Team (PSRT) review pregnancies listed in safety summary reports on monthly PSRT calls</p> <p>Contraceptive Action Team and FHI 360 review</p>	<ul style="list-style-type: none"> PSRT call summaries prepared by MTN Safety Physician CAT provides refresher training if needed (training materials)

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			3) For additional pregnancies, management team to discuss whether further CAPA/action is needed	pregnancy case worksheets as they are submitted	prepared by CAT leadership) <ul style="list-style-type: none"> Finalized pregnancy case worksheet prepared by site staff

The undersigned acknowledge they have reviewed and approved the Risk Management Plan for the REACH study. Changes to this Risk Management Plan will be coordinated with and approved by the undersigned.

Protocol Chair:

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Gonasagrie (Lulu) Nair
 Signer Name: Gonasagrie (Lulu) Nair
 Signing Reason: I approve this document
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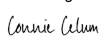
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Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	6/29/2021 2:08:35 PM
Certified Delivered	Security Checked	7/1/2021 1:16:30 AM
Signing Complete	Security Checked	7/1/2021 1:19:56 AM
Completed	Security Checked	7/1/2021 1:19:56 AM
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