

# B-WELL-Mom Study Eligibility

## 1. Purpose

- a. Identify women that are eligible to participate in B-WELL-Mom Study and insure that women have active asthma (not a prior history only) or no history
  - i. No History of asthma: target 75 each site
  - ii. Not Well Controlled asthma in the 12 months prior to pregnancy: target 100 each site
  - iii. Well Controlled asthma in the 12 months prior to pregnancy: target 100 each site
- b. Track the number of people approached that were:
  - i. Eligible but refused to participate
  - ii. Eligible willing to participate
  - iii. Ineligible
- c. Describe reasons for refusals and ineligibility

## 2. Initial eligibility

- Age  $\geq 18$  Years
- $< 14$  weeks, 0 days gestation
- English or Spanish speaker
- No diagnosis of HIV, MS, Lupus, or Rheumatoid Arthritis

## 3. Patient eligibility - General

- Able to schedule baseline visit  $< 14$  weeks, 0 days gestation.  
*Goal is to get as early as possible to better approximate pre-pregnancy lung function*
- Singleton  
*If unknown but otherwise eligible, enroll and we will withdraw twins later.*
- Plan to deliver at study site hospital
  - i. No plan to move out of the area (will stay with the practice throughout)
  - ii. Plan to keep the baby
- Willing to give blood

## 4. Patient eligibility - Asthma

- a. History of asthma
  - i. Has a doctor ever told you that you have/had asthma, even as a child?
    - NO (possible no asthma group)
    - YES (possible asthma group)
  - ii. Have you ever used any asthma medication (including a rescue inhaler or medicine before you exercise, etc.)?
    - NO
    - YES

Women who answer:

NO-NO to i and ii above are eligible for the 'no asthma group'

NO-YES to i and ii above are ineligible for the study (past medication)

YES-NO to i and ii above skip to question on symptoms (3 iv)

YES-YES to i and ii above continue

iii. Have you used any asthma medication (including a rescue inhaler or medicine before you exercise, etc.) in the past year?

NO

YES

iv. Have you had any asthma symptoms during the past year (difficulty breathing, coughing, wheezing, etc.)?

NO

YES

Women who answer:

NO-NO to iii and iv above are ineligible for the study (no current asthma)

Skip-NO to iii and iv above are ineligible for the study (no current asthma)

YES-NO to iii and iv or NO/Skip-YES to iii and iv above eligible for asthma group. Final group assignment to be determined at enrollment visit.

YES-YES to iii and iv above are eligible for the study (asthma group)

5. Eligible:

No

Yes – control group

Yes – asthmatic group

6. Agree to participate (proceed to consent, schedule baseline visit)

Yes

No → Why?

Not interested in taking part in research.

Does not have time.

Thought study was too burdensome.

Wanted more time to think about participating.

Wanted to speak to partner or family about participating.

Other \_\_\_\_\_