Supplemental material - Study Protocol

- Selection of patients, including both eligibility and ineligibility criteria

Study Procedures:

Women who present to a UTMB RMCHP clinic for care during our recruitment period and indicate that they wish to participate will be approached by study personnel. The research assistant (RA) will give a brief verbal description of the research and goals. Patients will then be asked if they would like to participate in the study by completing an anonymous survey in the waiting area that will take approximately 15 minutes to complete. Completion of the survey will imply agreement to participate and as a result, study participants will not complete a consent form. However, patients who are less than 18 years old will require verbal parental consent prior to survey completion.

The survey will be available in both English and Spanish. It will be explained that participation is completely voluntary and that refusal to participate will involve no penalty or loss of benefits to which she is otherwise entitled (i.e. that her decision to decline participation will not affect the care she receives at UTMB). A visual aid illustrating what cosmetic contact lenses (CCL) are will be available to participants who are unfamiliar with the concept.

Survey questions were adapted from other national surveys, and are validated questions, with the exception of some questions on breast cancer DNA testing. The survey will include questions about participants' demographics, perceived neighborhood characteristics, parity and fecundity, current pregnancy status, vaccination status of themselves and one child, preventive health care characteristics, relationship stress, feelings of discrimination, depressive symptoms, history of cancer, feelings about cancer and fetal screening, sexual behavior, usual place of health care, health care access for STIs, use of cosmetic contact lenses, and hygiene or morbidity related to cosmetic contact lenses use.

Criteria for Inclusion of Subjects:

Pregnant or non-pregnant women (of any race or age) who present to a UTMB RMCHP clinic for care.

Criteria for Exclusion of Subjects:

Males. Women < 18 years of age who do not obtain verbal parental consent.

Recruitment Methods and Consenting Process:

Patients will be informed that a study is being conducted by one of the following means:

A. Paper survey:

1. Front desk personnel will distribute a copy of the Fast Fact Sheet and questionnaire to patients with their intake paperwork, and front desk personnel will inform the patient of the optional study with the following instructions.

"Included in the paperwork that you have just been provided is information for an optional research survey. The survey is voluntary and if completed you will return the survey to the research assistant and they will give you a small gift. If you have any questions, please ask for the research assistant."

2. A sign/banner, available in English and Spanish translations, will be posted at or near the check-in window informing patients of the study.

B. Tablet Survey:

1. Clinic census reports will be generated daily and referenced by the research assistant (RA). After a patient has indicated to clinic personnel that they wish to participate, the RA will call the patient to the back area. In this private area, the RA will 1) distribute the study Fast Fact Sheet, 2) answer any questions the patient may have about the study, and 3) ask the patient if she would like to participate by completing the survey in the waiting area before she is seen by the provider.

Patients who agree to complete the one-time, anonymous survey will be offered the use of a tablet so that they can access the online SurveyMonkey questionnaire. Patients may also choose to use their personal smart phones to access the online questionnaire. Completion of the survey will imply consent. Thus, written consent will not be obtained. However, patients who are <18 years old will require verbal parental consent prior to survey completion.

Participants will be offered a small gift, valued at approximately $5 as compensation for their time and participation. Gifts will include general and baby-related items such as the following: socks, bottles, Onesies, rattles, pacifiers, brushes, ear buds, flash drives, etc.

The participants will be instructed to return the paper survey or tablet to the research assistant at which time the gift will be distributed.

Personal identifiers will not be collected on the survey. However, to ensure that patients presenting to the clinics only complete one survey during the recruitment period, study recruiters will be required to maintain a separate recruitment database that contains the date patients were approached, their survey status (completed or declined), name, and unit history number. This information will be collected from the daily clinic census report. (The census report will be limited to non-clinical information only. For example, reason for visit will not be on the report.) For each subsequent day of recruitment, study recruiters will compare the clinic census report to the names and unit history numbers of those entered in the recruitment database. Patients with appointments for that day who have already completed the survey or previously declined participation will not be approached a second time. This methodology will 1) ensure that patients do not complete more than one questionnaire during the recruitment period, and 2) allow us to collect demographic information on patients who decline participation, which will give us greater insight to the population being sampled. The recruitment database will be kept separate from survey responses and the analysis database at all times and will only be available to research staff."

- Schema and treatment plan, including administration schedule

Not applicable.

- Rules for dose modification

Not applicable.

- Measurement of treatment effect including response criteria, definitions of response and survival, and methods of measurement

Not applicable.

- Reasons for early cessation of trial therapy

Not applicable.

- Objectives and entire statistical section (including endpoints)

All analyses will take place using SAS statistical software version 9.3 or 9.4, or other statistical software. Descriptive analyses will include chi-squared and Fisher's exact (when applicable) tests for categorical variables and t-tests for continuous variables. Regression models, including logistic regression or other types of regression analyses will be used to assess factors associated with outcomes, as appropriate. All data will be reported in aggregate, and no identifying information will be released during dissemination of study results.