Retrospective Study on the Use, Efficiency, and Safety of the at-home Mosie Kit

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Funded by Mosie Baby
Protocol Number: MOSIE-001
Short Name: Mosie Kit Survey
Version Number: 1; this is the first version of the protocol.
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CONFIDENTIALITY STATEMENT

Table of Contents

Statement of Compliance

The trial will be conducted in accordance with International Council on Harmonisation Good Clinical Practice (ICH GCP) and applicable United States (US) Code of Federal Regulations (CFR); specifically the United States (US) Code of Federal Regulations (CFR) applicable to clinical studies (45 CFR Part 46, 21 CFR Part 50, 21 CFR Part 56, 21 CFR Part 312, and/or 21 CFR Part 812). The Principal Investigator will assure that no deviation from, or changes to the protocol will take place without prior documented approval from the Institutional Review Board (IRB), and the Investigational Device Exemption (IDE) sponsor, if applicable, except where necessary to eliminate an immediate hazard(s) to the trial participants. All personnel involved in the conduct of this study have completed Human Subjects Protection and ICH GCP Training.

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the IRB for review and approval. Approval of both the protocol and the consent form(s) must be obtained before any participant is consented. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. All changes to the consent form(s) will be IRB approved; a determination will be made regarding whether a new consent needs to be obtained from participants who provided consent, using a previously approved consent form.

Investigator's Signature

The signature below constitutes the approval of this protocol and provides the necessary assurances that this study will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable US federal regulations and ICH guidelines, as described in the *Statement of Compliance* above.

Principal Investigator or Clinical Site Investigator:

Signature:_____ Date: _____/_____/2020
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1 PROTOCOL SUMMARY

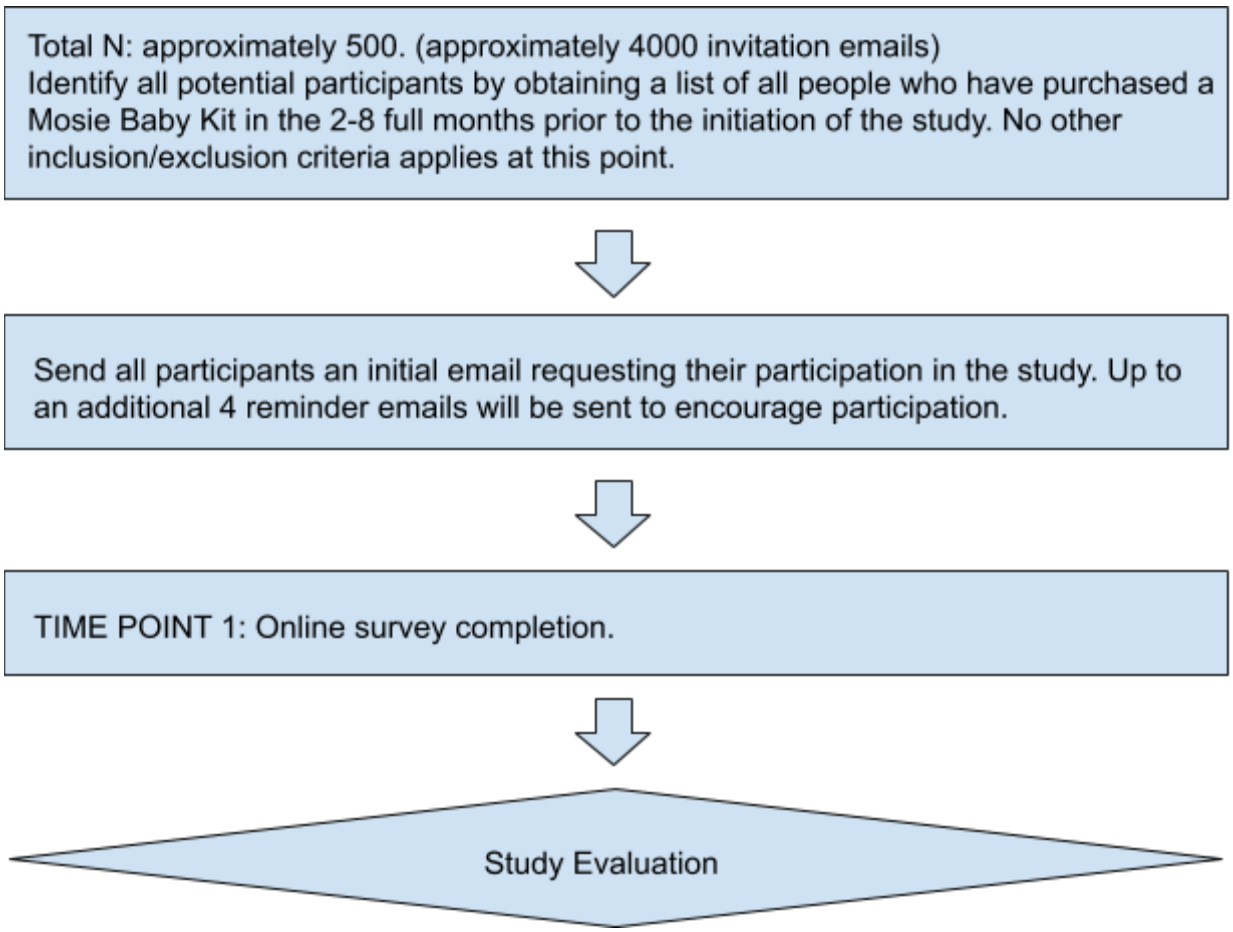
1.1 Synopsis

Title:	Retrospective Study on the Use, Efficiency and Safety of the at-home insemination Mosie Kit
Study Description:	This study examines the experience of people who have selected to use the at-home insemination Mosie Kit to understand the user's experience, the perceived safety and the efficiency. People who have recently purchased and voluntarily selected to use the Mosie Kit will be invited to complete a one-time online anonymous survey. The results of the survey will be analyzed to understand their experiences.
Objectives*:	The primary objective is to understand how many people end up pregnant by using the at-home insemination Mosie Kit during up to 6 cycles of voluntary use and how many people get pregnant using the Mosie Kit without using sex because they are either single, in a same-sex relationship, or in an unconsumated mariage due to infertility problems. The secondary objectives are to understand perceived safety and ease of use of the at-home Mosie Kit.The tertiary objective will be to examine pregnancy outcome in relationship to self-reported reason for infertility. Additionally, since COVID-19 has recently affected everyone, its effect on family expansion plans and stress will also be examined.
Endpoints*:	The specific study endpoints include pregnancy rates after up to 6 cycles of at-home intracervical insemination (ICI), perceived ease of use, perceived safety, and the relationship of infertility source with pregnancy outcome rates, stress related to COVID-19 and its impact on family expansion plans.
Study Population:	The sample will be drawn from all people who have purchased an at-home Mosie Kit in the past 2-8 full months prior to the study commencement. The approximate sample size will be 500 but all will be invited to participate.

	Both females and males will be included in the study. It is expected that the age range of the participants will vary from approximately 21 - 50 years of age. The participants will have a history of fertility problems, specifically problems getting pregnant. Otherwise, the participants should be in overall good health. No other health conditions are being used as exclusion criteria for participation in the study. Participants may be located anywhere in the world as this study will be conducted using an online web-based survey.
Phase* or Stage:	This is a post-market retrospective study to examine the experience people have with using the Mosie Kit for at-home insemination.
Description of Sites/Facilities Enrolling Participants:	No sites or facilities will be used in this study. Participants will be existing Mosie Baby Clients who have purchased a Mosie Kit in the prior 8 months. Participants may reside anywhere in the world.
Description of Study Intervention/Experimental Manipulation:	This is a retrospective study. Participants completing the study survey will have voluntarily purchased a Mosie Kit in the prior 8 months. Each participant will be asked to complete one study survey. Each participant will receive up to 5 email invitations to participate in the study. The study survey will be administered anonymously online on an individual basis.
Study Duration* :	It is estimated that participants will complete the retrospective study survey within one month of receipt of the initial email requesting their participation.However, the study might continue until sufficient surveys are collected.
Participant Duration:	Participants will be able to complete all study related questions in less than 25 minutes (approximately 10-20 minutes).

1.2 Schema

Following is the flow of this study.



1.3 Schedule of Activities

This study consists of completion of a one-time online survey. The following type of information is contained within this one-time survey:

- Informed consent
- Demographics (includes gender, sexual identification, type of relationship. race, ethnicity, household income and age. No identifying information will be requested)
- Fertility history and diagnosis if any
- Mosie Kit use and experience
- Post-Mosie Kit use pregnancy success rate
- Perceived safety
- Perceived ease of use
- Effect of COVID-19 on family expansion plans
- Effect of COVID-19 on stress

2 INTRODUCTION

2.1 Study Rationale

At-home intracervical insemination (ICI), folklorickly known as the “turkey-baster” method, has been used for decades to increase likelihood of pregnancy. This method works by depositing semen close to or at the cervix. While there are several devices such as over the counter syringes and silicone caps, the creator of the Mosie Baby syringe believes it is designed to be more ergonomic and compatible with a woman’s body, easy and safe to use, and results in depositing the semen at or near the cervix opening. The Mosie Kit provides people with an at-home intracervical insemination option which could be used before resorting to more invasive and expensive options such as Intrauterine Insemination (IUI) or in vitro fertilization. There is vast evidence of Mosie’s success in the form of happy users who have conceived. There is a desire to learn more about the safety, useability and experience of using the Mosie kit.

This retrospective study will examine the experience of people who have voluntarily chosen to purchase and use the Mosie Kit. The Mosie Kit consists of 2 syringes and a semen collection cup Understanding the safety, useability and experience of using the Mosie Kit will provide additional information about the nature of using intracervical insemination as a viable method for getting pregnant. The information gained will increase understanding of how viable the Mosie Kit is as a first step in trying to conceive and how it is perceived by the people who have chosen to use it.

2.2 Background

Infertility is defined as not being able to get pregnant after one year of unprotected sex. About 6% of married and overall 12% of women ages 15 to 44 have infertility issues. Infertility issues can be of male or female origin. According to the CDC, in 35% of the infertility cases a male factor was found along with a female factor and in 8% of the cases the only identifiable cause was a male factor. Fertility is affected by multiple factors, one of which is the female’s age. For this reason it is recommended that people anatomically female under the age of 35 seek help after one year of trying to conceive while those over the age of 35 should seek help after 6 months. One of the first options available is artificial insemination.

The first documented case of artificial insemination was done in the 1770s by John Hunger in London (Obmelet & Robays 2015). Subsequently J. Mario Sims reported his findings in the mid-1880s. Sims describes 55 inseminations. Unfortunately since he believed ovulation occurred during meneses, only one pregnancy was reported (Obmelet & Robays 2015). Research has come a long way since the early 18th century. Artificial insemination is now a much more frequent occurrence. Initially used by couples with male infertility (low sperm count and inherited Y-chromosome disease), later for couples with physiological and psychological dysfunction, such as retrograde ejaculation, vaginismus, hypospadias and impotence, and now

is very commonly used by people with no male partner (both single and those in lesbian relationships).

Since Dr. Sherman's sperm freezing success in 1953 with a subsequent live birth, collecting and using sperm for insemination in humans was made possible. However, it would be more than a decade before it became legally possible as it was initially ruled as contrary to public policy and good morals. In the 1960s and 70s, sperm selection and washing techniques led to Intrauterine insemination (IUI) which placed the sperm even further into the woman's body by putting it directly into the uterus. By the 1970s sperm banks in the US became popular. Also in the 1970s, Steptoe and Edwards introduced the world to In-Vitro Fertilization (IVF). More recently, techniques such as intratubal insemination, and intraperitoneal insemination have been added to the available conception methods. During the last decades the popularity of Intrauterine Insemination (IUI) increased because it was safer, painless, and more cost-effective. Additionally, more information has become available about sperm selection techniques and now there is a greater understanding of many of the causes of infertility.

The most popular method of insemination is to use the husband's sperm (Artificial Insemination by Homologous or Husband (AIH)). In some cases anonymous donor sperm is used. Intracervical (ICI) or intravaginal insemination (IVI) are terms used interchangeably to describe the insemination technique colloquially known as the "turkey baster method". This method consists of placing the semen into the vagina at or near the cervix. In the United States, IUI is the most frequently doctor assisted technique. Some researchers have examined the success rates of each technique. ICI/IVI has been found to have a per cycle pregnancy rate of 10-15% while IUI has been found to be slightly higher up to 10-35%. Meanwhile techniques such as IVF can be as high as 31% in people under 35 years of age and as low as 3% for those above 43 according to the CDC.

Getting pregnant using IUI can cost $250-500 per insemination before accounting for the cost of the testing and other imaging done as part of the process. IVF is even more expensive and invasive. According to Katz et al. 2011, the median per-person cost of IVF was approximately $24,373 (for just IVF) to $38,015 (for IVF-donor egg). Voorhis et al. 1997 found ICI to cost $7.800-10,300 while Assisted Reproductive Therapy (ART) cost $37,00 - 76,000. The cost difference between IVI/ICI, IUI and ART therapies such as IVF is significant. This makes cost a consideration for people attempting to conceive.

The good news is a number of studies such as Cohlen and Ombelet 2014 and Banerjee and Singla 2017, demonstrate the viability of using IVI/ICI as a means of AIH. The benefits of ICI is that it can be done in the privacy of the home, is relatively low cost, and over a 6 cycle time frame seems to have comparable rates to its more expensive counterparts.

Cohlen and Ombelet 2014 showed that for many couples with cervical factor infertility, psychological sexual dysfunction, physiological dysfunction, unexplained infertility and mild to moderate male subfertility using artificial insemination with a husband's sperm (AIH) was a

preferred treatment option. Banerjee and Singla (2017), tested couples with unconsummated marriages due to vaginismus, erectile dysfunction and premature ejaculation. They found 69% of couples ages 20-32, 43% ages 33-36, and 25% over 36 years old conceived using IVI. This is comparable to the expected 10-35% pregnancy rate of IUI.

Additionally, Kop et al. 2018 conducted a literature review to determine if there was a difference between pregnancy rates and live births of IUI versus ICI. They reported that out of six trials totalling 708 women. They concluded that there was not enough evidence to determine that IUI resulted in more live births or pregnancies than ICI.

Carroll and Palmer (2001) conducted a prospective randomized cross over control study on 62 single fertile women choosing to use donor sperm. They had a total of 189 cycles (94 IUI and 95 ICI). The resulting pregnancy rate was 15% and 9% respectively (p=0.04) which indicated that IUI was more effective than ICI. On the other hand, Hogerzeil et al. (1988) studied 53 women who either had at home ICI (n=29) or in clinic ICI (n=24). In the first 6 cycles 13 pregnancies resulted in the home ICI group while only 11 pregnancies resulted in the clinic group. Additionally, they followed 138 couples who did not meet the inclusion criteria. Of these 45 had opted for at home insemination and 20 of them ended up with a pregnancy.

In conclusion, there is a lot of room to learn more about the pregnancy rates of ICI and the experience of at-home artificial insemination. With 12% of women of child bearing age experiencing infertility there is an important contribution to be made to the fertility field. Using the Mosie Baby at-home artificial insemination kit is a low cost option that could potentially be a first line alternative for many people seeking to conceive. Therefore, it is important to understand the experience and pregnancy rates of people who have chosen to use the Mosie Kit to get pregnant at home. This study will provide valuable information for the fertility industry as a whole, as well as, will provide information for a follow up study where people choosing to use the Mosie Kit will be prospectively followed to capture their data in real time. Together these studies will provide a better understanding of at-home insemination success, safety and perception.

2.3 Risk/Benefit Assessment

2.3.1 Known Potential Risks

Since this is a retrospective study and the participants will have already used the Mosie Kit, there is no potential additional physical risk from participating in the study. In some cases, because fertility is a sensitive issue, some people might become a bit emotional in recalling unsuccessful attempts to get pregnant. Otherwise, there are no known additional risks for participating in this study.

This retrospective study will be conducted as an anonymous one-time self-report survey that will contain no personal information that will allow the participant to be identified. This is done to

reduce the risk of the information being associated with the individual providing the information. This also ensures there are no immediate or long-term risks associated with participation.

2.3.2 Known Potential Benefits

The potential benefit of this study is mostly for people seeking to perform at-home intracervical insemination in the future using the Mosie Kit. Each Mosie Kit provides syringes for two inseminations to occur within a cycle at the cost of about $89. This is less than 20% of the cost of IUI which can range between $500-1500/ procedure before labs, ultrasounds, and additional expenses, and around 5% once all costs are added up. The study will provide valuable information to people trying to conceive about the efficiency of using the Mosie Kit for ICI, how that efficiency might compare to the effectiveness of IUI, and how the cost of each compares. This will help the user decide whether the Mosie Kit is the right conception tool for them. The study will also provide valuable information about the safety and usability of the kit. The research will let Mosie know if they have successfully communicated how to use the kit, if the instructions are clear or if any changes are needed, and whether anything else should be considered in future design changes. The study might also provide information on the timing of the insemination that might lead to a positive pregnancy outcome. Additionally, this knowledge might provide Mosie Baby with information to help it position itself better in the market..

The participant themselves will only benefit by having been able to share their experience about the Mosie Kit. While they might receive a discount code towards the purchase of a future Mosie Kit, this is not considered a benefit but a thank you for participation. Note the discount code will be a standard code used for other marketing purposes in order to ensure there is no way for Mosie staff to know if the participant obtained it for completing the survey or obtained it via other marketing avenues. The participant may feel good because they shared their experience and provided input into the Mosie Kit which will in turn help others.

The information obtained through this study will allow Mosie Baby to enhance or clarify the instructions provided with the Mosie Kit and will be considered in future production of the Mosie Kit.

2.3.3 Assessment of Potential Risks and Benefits

As stated previously there is minimal risk to the subject because this a retrospective observational study of the subject's previously chosen voluntary behavior to purchase and use the Mosie Kit. There are also minimal to no benefits to the participants for completing the survey except for their personal satisfaction of having shared and contributed to the research via their experience(s). The benefit will mainly be for people who will use the Mosie Kit in the future and who will benefit by being able to try the Mosie Kit before they resort to more expensive and invasive methods of getting pregnant. It is believed that the good of many and future possibility of having an acceptable method of artificial insemination at home outweighs the risk of participation in the study.

3 OBJECTIVES AND ENDPOINTS

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS	PUTATIVE MECHANISMS OF ACTION
Primary			
The primary objective is to understand the outcome of using the at-home intracervical insemination Mosie kit, i.e. pregnancy rate after its use.	The primary endpoints is: Pregnancy Rate after up to 6 cycles. Another primary end point is to understand the rates of pregnancy in people who desire to get pregnant without intercourse (i.e. both single and those in LGBTQ relationships.	The ultimate objective of using the Mosie Kit is to end up pregnant. Thus pregnancy rate is a primary endpoint. Specifically, pregnancy rate in up to 6 (six) cycles will be examined as it is the typical standard timeframe for attempting to get pregnant using IVI or IUI before seeking an alternative method. People who have no known fertility issue who are trying to conceive without intercourse such as those who are in LGBTQ relationships or those who are not in any relationship at all will likely have higher pregnancy rates than those with known fertility issues of female origin. Women in LGBTQ relationships wishing to conceive might also have a higher pregnancy rate than those in heterosexual relationships where infertility might be caused by things like low sperm count, sperm motility issues or erectile dysfunction (ED).	The Mosie Kit is intended to be used to deposit semen at or near the cervix where the sperm will have an increased likelihood of entering the uterus and pairing up with the ovum resulting in a pregnancy. Pregnancy rates increase when sperm reaches the ovum and fertilizes it. In people with no known fertility issues, the Mosie kit deposits the semen where it is able to fertilize the ovum. People without infertility issues who want to get pregnant without sex by using the Mosie Baby are also more likely than people with known fertility issues to get pregnant.

Secondary			
The secondary objective(s) are to understand the user's experience with the Mosie Kit and it's safety.	Secondary endpoints are: perceived ease of use and perceived safety.	The perceived ease of use is being examined as a secondary endpoint because being able to follow the instructions and use the kit as designed will directly affect whether the semen is deposited at or near the cervix having a direct effect on the results. Perceived ease of use is viewed as a mediating variable. Finally, perceived safety of the Mosie Kit will be examined. It is expected to be a moderating variable.	In order for the delivery of sperm at or near the cervix, the user needs to maximize the sperm drawn up into the Mosie syringe, insert it into the vagina, and deposit the sperm at or near the cervix. Because the Mosie syringe is inserted into the vagina, it is important to understand any perceived issues or concerns related to safety and use of the syringe.
Tertiary/Exploratory			
The tertiary objective will be to examine the pregnancy rate of people with different self-reported sources of infertility. Given the Pandemic, exploratory effect of COVID-19 on family planning, stress and pregnancy results will be examined.	Because the reason for a person's or couple's infertility might affect pregnancy rates, the reason for the infertility will also be examined. This will provide information as to whether the Mosie Kit is more effective given a specific source of infertility. The pandemic has caused an overall increase in stress, higher stress can affect fertility.	The source of infertility may play a mediating role in a successful pregnancy. For example, it might be more likely that a couple with a woman with no known infertility issue using Mosie might be more likely to get pregnant than a woman with a specific known infertility issue. Stress can play a mediating role in pregnancy. Concern over future stability and	Women who do not have a fertility issue might be more likely to get pregnant when the sperm is successfully deposited at or near the cervix. For example, this would help if the infertility was rooted in Erectile Dysfunction (ED). Stress hormones can affect pregnancy outcome. Stressful and uncertain times make people more

	Additionally, family planning may be affected.	uncertainty can affect family planning.	prone to put off expanding their families.

4 STUDY DESIGN

4.1 Overall Design

This is a post-market retrospective cross-sectional observational study of people using the Mosie Kit for at-home insemination. The goal of the study is to understand the pregnancy rate resulting from using the Mosie Kit of people with known fertility issues or those wishing to conceive without intercourse due to medical reasons such as vaginismus or being in a LGBTQ relationship desiring a child.

This study uses a convenience sample of people who purchased the Mosie Kit in the past 8 complete months prior to the commencement of the study. The complete known list of people will be invited to participate in the study. For the primary hypothesis 1, all study participants will be treated as one group initially. Subsequently, the study participants may be divided into groups according to their age, the type of relationships (heterosexual or LGBTQ), and/or source of infertility to examine the hypothesis as it relates to these subgroups if sufficient sample size indicates this is appropriate; this analysis corresponds to the tertiary hypothesis.

> Primary hypothesis 1: Pregnancy rates using the at-home insemination Mosie Kit to deposit semen near or at the cervix (i.e. intracervical insemination) are equivalent or better than traditional in doctor's office intrauterine insemination.

Given the participants can either be people with fertility issues or people in LGBTQ relationships without known problems conceiving or single women wishing to conceive, another primary hypothesis that will be examined is the difference of pregnancy rates in each of these groups. Specifically, the primary hypothesis related to this is as follows:

> Primary Hypothesis 2: Pregnancy rates of LGBTQ people or single women using the Mosie Kit where the female has no know fertility issues will be higher than that of heterosexual people with a known fertility cause or those that are designated as having an unexplained fertility issue.

The secondary hypothesis will examine the use of the Mose Kit and its safety as perceived and reported by the study participants. For these hypotheses the participants will be examined as one group as well as categorized by age group and type of relationship. Specifically, the secondary hypothesis will be as follows:

> Secondary Hypothesis 1: The participants perceived the Mosie Kit to be easy to use for its intended purpose.

Secondary Hypothesis 2: The participants were able to use the Mosie Kit as instructed using the instructions contained in the kit.

Secondary Hypothesis 3: The participants reported they used the kit as intended, specifically, using it within 24 hours of initial signs of ovulation and again 24-48 hours after ovulation was confirmed or expected.

Secondary Hypothesis 4: Participants reported they perceived the Mosie Kit to be a safe way to conceive.

Secondary Hypothesis 5: The majority of participants indicate they have little to no safety concerns related to using the Mosie Kit.

The tertiary hypothesis for this study dives further into the primary hypothesis by breaking out the participants into groups based on their type of relationship and the source of their infertility to examine their cohort specific pregnancy rates.

Tertiary Hypothesis 1: There will be higher pregnancy rates when using the Mosie Kit when the source of infertility is male-based than when infertility is female-based.

Tertiary Hypothesis 2: There is a difference in pregnancy rates of people or couples with known fertility issues depending on the source of their infertility. Specifically, the following sources of infertility will be examined if sufficient data is available.

- PCOS
- Endometriosis
- Low AMH or low ovarian reserve
- Low sperm count
- Sperm motility issues
- Unexplained infertility
- Erectile dysfunction
- Performance issues or sexual anxiety, or inability to orgasm with partner.
- Vaginismus or vulvodynia
- Tilted uterus
- Multiple uterus/cervix
- Loss of a fallopian tube

Tertiary Hypothesis 3: There will be a difference between individuals who perform 2 insemination instances as described in the instructions and those that follow a different schedule or dosage number.

Additionally since we are in the midst of a pandemic with COVID-19, exploratory analysis will be conducted on the stress levels and its impact on family expansion plans.

Tertiary Hypothesis 4: COVID-19 has affected people's family expansion plans.

Tertiary Hypothesis 5: There will be a decrease in pregnancy rates in those using the Mosie Kit during the Months of March - June.

This study does not use randomization. While no control group will be examined for the study, determining the result of some of the hypotheses is based on using the reported pregnancy rate of IUI in the literature. Specifically, the reported rate of pregnancy with IUI is as high as 20% in one cycle according to the American Pregnancy Association. According to the CDC, it can range between 10-35% across 6 cycles.

4.2 Scientific Rationale for Study Design

The retrospective cross-sectional study design was selected because the desire is to examine the pregnancy rates and perception of useability and safety of the Mosie Kit. Since this is a post-market study, the use of an existing group of participants who voluntarily purchased and used the Mosie Kit exists and provides an excellent group of participants to study. The past experiences of these participants will provide valuable information for future participants on the success rate of at-home insemination, information as to the ease of use of the instructions included in the kit, ease of use of the kit, and perceived safety.

The rationale for examining the participants first as a complete cohort and then stratified by type of relationship, infertility source, and age group is that the primary hypotheses relate to overall pregnancy rates using the at-home insemination Mosie Kit and the rate of pregnancy in women without a known fertility cause wanting to get pregnant without intercorse. The type of relationship is also important because a woman in an LGBTQ relationship without fertility issues is more likely to easily get pregnant than a heterosexual female with fertility issues once the semen is deposited at or near the cervix. While there might be LGBTQ women that also have a known cause of fertility, they will be examined by type or relationship as well as by infertility source. Likewise, single women will be categorized by their known infertility source or as not having a known fertility issue. It is important to study the difference between the two groups and explore the impact on the overall pregnancy rate of Mosie Kit users.

Additional hypotheses aim to examine more specifics related to each stratification. For example, age is known to affect fertility rates. Women ages 20-30 are more likely to get pregnant than those in their 40s. The source of infertility may also indicate underlying biological or physical issues that might mediate the pregnancy rates causing different rates of success in each of the groups. All the information obtained through this study will be used to benefit people who are trying to get pregnant and are experiencing infertility issues. Specifically, the study will examine the viability and success rate of at-home insemination.

Another benefit of conducting a retrospective study is being able to examine the natural use of the Mosie Kit. While instructions are provided as to how and when to use the Mosie Kit for

insemination, it is known that there will be a variation of use among study participants. This might affect the pregnancy outcome. Therefore, one of the tertiary hypotheses will collect information related to timing and dosing (with dosing being the instance of insemination). This is important because the results will help provide information that will help ensure future studies have clearer instructions and so that all users regardless of study participation optimize the use of the Mosie Kit in order to get pregnant.

4.3 Justification for Intervention

This is a retrospective cross-sectional study of existing users of the Mosie Kit. Participants will be recruited via email. Specifically, it is planned that participants will receive up to 5 email invitations to participate in the study, however more emails might be used to recruit sufficient participants.. The email will direct them to the study survey where they will read the consent form and choose to participate in the study. The email will contain a link to the survey. If they elect to participate, they will complete the study survey and submit it online. Participation consists of completing a 10-20 minute survey. This is a one time survey. Since no identifying information will be collected, there will be no possibility of follow up.

There is no intervention. This study merely looks at the past experience of using the Mosie Kit. It is important to know the success rates of pregnancy with at-home insemination kits, and understand the usability and safety as there are individuals and couples using these types of options on a regular basis as a means to get pregnant. For people who suffer from infertility, having this information will help them choose whether ICI is right for them and whether the Mosie Kit should be chosen for this method. Additionally, since age is a factor in pregnancy success and risks increase with age, there is a need to understand the success of at home ICI so recommendations can be made as to whether to use ICI and how long to use it before seeking other methods of conception. This study aims to address some of these issues.

4.4 End-of-Study Definition

It is expected that the study will be completed within 30 days of the initial email. This will provide participants with an opportunity to find 10-20 minutes to participate in the study during a 30 day window. Participants will receive up to three additional reminder emails at least 7 days apart and one final email 2 days prior to study close. Participants who choose to participate in the study will be considered to have completed the study upon submission of the complete survey. If sufficient participants have not completed the survey, the study timeframe may be expanded at the discretion of the PI.

5 STUDY POPULATION

The study population will consist of all individuals who have purchased the Mosie Kit in the past 2-8 complete months prior to study initiation. All qualifying individuals will receive an invitation to participate. These individuals will typically be of child-bearing age, both females and males, and generally ages ranging 18-50 years old.

It is assumed that purchasing the Mosie Kit means the kit will be used as intended for at-home insemination. One of the inclusion criteria is to have previously used the kit. Therefore, the initial list of study participants will be drawn from people who have placed a purchase order within the prior 8 complete months; complete months are used with the expectation that the Mosie Kit would be used within the month post-purchase. If the study duration is expanded, additional potential participants will be invited who have purchased the kit at least 2 full months prior to being invited to participate in the study.

5.1 Inclusion Criteria

In order to be included in the study, the following inclusion criteria will be used.

Inclusion Criteria:

- Provide implicit consent by filling out and submitting the survey.
- Used a Mosie Kit to conceive during at least one cycle.
- At least 18 years old.
- Has an active email on file (presumed or they would not have received an invitation to participate. This information will not be verified as there is a desire to keep the survey completely anonymous.)

5.2 Exclusion Criteria

The following exclusion criteria will be used.

- Never used a Mosie Kit

5.3 Lifestyle Considerations

There are no exclusions due to lifestyle considerations as this is a one time cross-sectional survey of past experiences.

5.4 Screen Failures

Participants who are consented to participate in the study, and who do not meet one or more criteria required for participation in the trial during the screening procedures, are considered screen failures. If an individual identifies their age as less than 18 years old or as not having used the Mosie Kit which will be the first 2 questions, then the survey will automatically end. These participants will be designated as screen failures. Screen failures will not be rescreened or included in the study in the future as this study is expected to have a very short duration (approximately 30 days).

5.5 Strategies for Recruitment and Retention

Recruitment of participants will be conducted via a direct email campaign. Participants will receive multiple emails requesting their participation in the study. Specifically they will receive emails according to the following schedule:

	Email Content	Expected Date
Initial Email	Initial Invitation to participate	Day 0
Second Email	Reminder of invitation to participate	Day 7
Third Email	Reminder of invitation to participate	Day14
Fourth Email	Last week to participate survey	Day 21
Fifth Email	Final email - 2 days left to complete survey	Day 28

If the study duration is expanded, a weekly email and a reminder a couple of days prior to the new deadline will be sent.

Typical response rates vary between 5-30% for email surveys. The rate of response is higher when people have a connection with the company or product. They also go up with repeated reminders and incentives to participate. A good survey response rate is about 50%.

Participants who complete the survey will receive a code to purchase a future Mosie Kit at a discount. This discount code will also be a code used in other marketing efforts in order to help reduce the likelihood a participant's status of participating in the study will remain masked.

The expected response rate for this study is between 30-50%.This response rate is expected because the potential participants will have all previously purchased a Mosie Kit. Additionally, the Mosie Newsletter has about a 20% open rate so it is expected that participation might be slightly higher than this.

Because participants will only be selected from people who have previously purchased a Mosie Kit there will be a limit in the mix of people available for selection for study participation. This means the results might not be generalizable to the public in general, nonetheless it is a representative sample of the people who would do at-home insemination.

6 STUDY INTERVENTION(S) OR EXPERIMENTAL MANIPULATION(S)

6.1 Study Intervention(s) or Experimental Manipulation(s) Administration

6.1.1 Study Intervention or Experimental Manipulation Description

This is a cross-sectional retrospective observational study of people who have selected to voluntarily purchase and use the Mosie Baby at-home insemination kit. No additional intervention or manipulation is planned for this study.

6.1.2 Administration and/or Dosing

This study retrospectively examines the administration and dosing of semen during insemination in the home environment by using the Mosie Kit. The recommended dosing of semen to produce a positive pregnancy outcome is at least 2 times in a cycle. With the first dose preferably administered within 24 hours of the first signs of ovulation and the second one between 24-48 hours post ovulation confirmation. Since this study is retrospective, it will not influence dosing, but merely will collect information on the dosing frequency and timing.

6.2 Fidelity

While this study will look backwards onto how the Mosie Kit was used and resulting pregnancy rates, it also affords the opportunity to examine variations in timing of the insemination with respect to ovulation as well as the frequency of insemination within a cycle. The study will not influence how the Mosei Kit was used, but it is hoped that the information gathered will add understanding to whether timing and frequency might have played a role in pregnancy results. It is important to study how people use Mosie because timing and dosage might impact the pregnancy rate. It is also important to understand the variations in use.

6.2.1 Interventionist Training and Tracking

No intervention will be performed.

6.3 Measures to Minimize Bias: Randomization and Blinding

This study will not have any masking or randomization. It is a retrospective study. Participant selection bias will be minimized by including all people who have purchased a Mosie Kit in the prior 2-8 whole months.

6.4 Study Intervention/Experimental Manipulation Adherence

This study does not have an intervention. However data will be collected on the self-administered intervention that will be examined retrospectively. The data will allow determination as to whether the minimum intervention was followed, i.e. administration of two

at-home insemination instances one within 24 hours of initial signs of ovulation and one at 24-48 hours after confirmed ovulation.

6.5 Concomitant Therapy

N/A

6.5.1 Rescue Therapy

N/A

7 STUDY INTERVENTION/EXPERIMENTAL MANIPULATION DISCONTINUATION AND PARTICIPANT DISCONTINUATION/WITHDRAWAL

7.1 Discontinuation of Study Intervention/Experimental Manipulation

N/A

7.2 Participant Discontinuation/Withdrawal from the Study

Participants may choose to leave the survey at any time without submitting the completed survey. There will be no way to know which participant did not complete the survey or why the survey was not completed. There will be no way to follow up with the participant to request continued participation as the survey will not contain any identifying information.

There will be no replacement participants. Any incomplete surveys will be discarded automatically by the system. They will not be available for use in the final analysis.

7.3 Lost to Follow-Up

N/A

8 STUDY ASSESSMENTS AND PROCEDURES

8.1 Endpoint and Other Non-Safety Assessments

The only assessment for this study will be one online survey which can be completed in approximately 10-20 minutes. The survey will collect demographics information, relationship status, infertility history, experience using the Mosie Kit and perceptions related to its use and safety.

8.2 Safety Assessment

Since there is no intervention there will be no safety assessments related to the survey however, questions about the perceived safety of using the Mosie Kit Syringe will be asked.

8.3 Adverse Events and Serious Adverse Events

This retrospective study does not expect there to be any adverse events reported due to participating in the survey. It does however ask questions about any infections that might have occurred during the prior 7 months. While these infections might be completely unrelated to using the Mosie syringe, the response will be evaluated and examined as a percentage of respondents and cycles. It is one of the goals of this study to find out if there might be any adverse events due to the use of the Mosie Kit.

Nonetheless, the definitions and classification for adverse events are outlined below.

8.3.1 Definition of an Adverse Event

This protocol uses the definition of adverse event from 21 CFR 312.32 (a): any untoward medical occurrence associated with the use of an intervention in humans, whether or not considered intervention-related. However, as a cross-sectional study, only retrospective information will be available if provided by the Participant.

8.3.2 Definition of Serious Adverse Events

According to the FDA a serious adverse event is one that results in death, disability, require and intervention to prevent a disability or permanent damage, birth defect or hospitalization. ER visits without hospitalization are individually evaluated for their severity to determine if they are a serious adverse event.

8.3.3 Classification of an Adverse Event

8.3.3.1. Severity of Event

For adverse events (AEs) not included in the protocol defined grading system, the following guidelines will be used to describe severity.

- **Mild** – Events require minimal or no treatment and do not interfere with the participant's daily activities.
- **Moderate** – Events result in a low level of inconvenience or concern with the therapeutic measures. Moderate events may cause some interference with functioning.
- **Severe** – Events interrupt a participant's usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually potentially life-threatening or incapacitating. Of note, the term "severe" does not necessarily equate to "serious".

8.3.3.2. Relationship to Study Intervention/Experimental Manipulation

All adverse events (AEs) will have their relationship to study procedures, including the intervention, assessed by an appropriately-trained clinician based on temporal relationship and his/her clinical judgment. The degree of certainty about causality will be graded using the categories below.

- **Definitely Related** – There is clear evidence to suggest a causal relationship, and other possible contributing factors can be ruled out. The clinical event, including an abnormal laboratory test result, occurs in a plausible time relationship to study procedures administration and cannot be explained by concurrent disease or other drugs or chemicals. The response to withdrawal of the study procedures should be clinically plausible. The event must be pharmacologically or phenomenologically definitive.
- **Probably Related** – There is evidence to suggest a causal relationship, and the influence of other factors is unlikely. The clinical event, including an abnormal laboratory test result, occurs within a reasonable time after administration of the study procedures, is unlikely to be attributed to concurrent disease or other drugs or chemicals, and follows a clinically reasonable response on withdrawal.
- **Potentially Related** – There is some evidence to suggest a causal relationship (e.g., the event occurred within a reasonable time after administration of study procedures). However, other factors may have contributed to the event (e.g., the participant's clinical condition, other concomitant events). Although an AE may rate only as "possibly related" soon after discovery, it can be flagged as requiring more information and later be upgraded to "probably related" or "definitely related", as appropriate.
- **Unlikely to be related** – A clinical event, including an abnormal laboratory test result, whose temporal relationship to study procedures administration makes a causal relationship improbable (e.g., the event did not occur within a reasonable time after administration of the study procedures) and in which other drugs or chemicals or underlying disease provides plausible explanations (e.g., the participant's clinical condition, other concomitant treatments).
- **Not Related** – The AE is completely independent of study procedures administration, and/or evidence exists that the event is definitely related to another etiology. There must be an alternative, definitive etiology documented by the clinician.

8.3.3.3. Expectedness

There are no expected adverse events for this study.

8.3.4 Time Period and frequency of Event Assessment and Follow-up

This retrospective study will only capture past self-reported vaginal infections. There will be no way to tell if it was a potentially related adverse event of the Mosie Kit use in a one time survey. No additional follow-up will be conducted. No identifying information will be collected to allow follow up.

8.3.5 Adverse Event Reporting

Adverse Events will be captured via the survey but will have occurred in the past. Due to the nature of this study, it will not be possible to follow-up with participants reporting these AEs.

8.3.6 Serious Adverse Event Reporting

It is unlikely that there will be any SAEs related to the Mosie Kit. Even if a participant reveals an SAE, because identifying information will not be collected, it will be impossible to follow up.

8.3.7 Reporting Events to Participants

N/A

8.3.8 Events of Special Interest

Only the events associated with the use of the Mosie Kit will be captured via the survey. If there are any concerns of special interest, the information will be shared immediately with Mosie. This complete study is expected to take approximately 30 days. At the latest, the information will be reviewed for any special items of interest within 2 weeks of the study completion.

8.3.9 Reporting Pregnancy

Pregnancy status will be obtained during the survey. It is not used as an exclusion factor. It is used as an outcome measure.

8.4 Unanticipated Problems

Given the nature of a cross-sectional one-time survey no unanticipated events are expected.

9 STATISTICAL CONSIDERATIONS

9.1 Statistical Hypotheses and General Statistical Approach

The primary objective is to understand the outcome of using the Mosie kit for Intracervical insemination, i.e. pregnancy rate after its use. Specifically the hypothesis is as follows.

> **Primary hypothesis 1:** Pregnancy rates using the at-home insemination Mosie Kit to deposit semen near or at the cervix (i.e. intracervical insemination) are equivalent or better than traditional in doctor's office intrauterine insemination (IUI). Conversely the null hypothesis is that the pregnancy rates using the at-home insemination Mosie Kit to deposit semen near or at the cervix do not have higher rates of pregnancy than in doctor's office IUI.
>
> Analysis: Comparison of total rates of pregnancy using the Mosie Kit to the 10-20% rate reported for IUI by the American Pregnancy Association.
>
> **Primary Hypothesis 2:** Pregnancy rates of LGBTQ couples or single women using the Mosie Kit where the female has no know fertility issues will be higher than that of heterosexual couples with a known fertility cause or those that are designated as having an unexplained fertility issue. The alternative hypothesis is that people with no known

fertility issues using the Mosie Kit will have less pregnancies than heterosexual couples with known fertility issues.

Analysis: Rate of pregnancy using the Mosie Kit will be obtained for the following groups: LGBTQ couples where carrying female has no known fertility issues, LGBTQ couples where carrying female has a known fertility issue, Heterosexual people with no known fertility issue, Heterosexual people with a known fertility issue, Single females with no known fertility issue and Single females with a known fertility issue. The rates of each group will be analyzed using descriptive statistics and the aggregate of the 3 groups with fertility issues will be compared with the aggregate of the 3 groups without fertility issues. An ANOVA will be used to compare the differences between groups.

Secondary Hypothesis 1: The participants perceived the Mosie Kit to be easy to use for its intended purpose. The alternative hypothesis is that the participants perceive the Mosie Kit to be difficult to use for its intended purpose.

Analysis: Descriptive statistics surrounding the ease of use on a 5-point likert (very easy to very difficult) will be analyzed on five different aspects of use. Specifically, the steps of using the Mosie Kit (collecting a sperm sample, drawing up the sample in the Mosie syringe, inserting the syringe, and depositing the sperm at or near the cervix) and overall ease of use will be examined. Additionally questions related to use such as comfort, ease and safety of the process, enjoyable and intuitiveness of use (able to use it without instructions) will allow the user to rate their experience from Strongly agree to strongly disagree (5 point scale). The data will be plotted and examined as part of the analysis.

Secondary Hypothesis 2: The participants were able to use the Mosie Kit as instructed using the instructions contained in the kit. The alternative hypothesis is that the participants were not able to use the kit using the instructions contained in the kit.

Analysis: Descriptive analysis of perceived overall success rate will be analyzed. Additionally, descriptive analysis of the frequency of each expected behavior related to use of the kit will be examined.

Secondary Hypothesis 3: The participants reported they used the kit as intended, specifically, using it within 24 hours of initial signs of ovulation and again 24-48 hours after ovulation was confirmed or expected. The alternative hypothesis is that the participants report they did not use the kit as intended with respect to timing (within 24 hours of initial signs of ovulation and again 24-48 hours post ovulation).

Analysis: Frequency rates related to timing of insemination at all reported cycles will be analyzed. The data will be reported in both total number of attempts at each time point as well as percentage of attempts at each time point in comparison with total cycles where the Mosie Kit was used. T-tests will also be used in this analysis. Additionally,

amount of time lying after insemination and position of lying will be analysed using descriptive statistics and correlations with pregnancy rate.

Secondary Hypothesis 4: Participants reported they perceived the Mosie Kit to be a safe way to conceive. The alternative hypothesis is that participants did not perceive the Mosie Kit to be a safe way to conceive.

Analysis: Descriptive statistics will be used to analyze perceived safety. Qualitative analysis will be used on any comments made related to safety. Rates of vaginal infections will be analyzed using descriptive statistics.

Secondary Hypothesis 5: The majority of participants indicate they have little to no safety concerns related to using the Mosie Kit. Alternative hypothesis is the majority of participants will be very concerned or extremely concerned about the safety of using the Mosie Kit.

Analysis: Descriptive statistics of self-reported level of concern. Additionally, safety measures such as hand washing, disposing of the syringe after use, and reading the instructions will be examined using descriptive statistics.

Tertiary Hypothesis 1: There will be higher pregnancy rates when using the Mosie Kit when the source of infertility is male-based than when it is female-based. The alternative hypothesis is there will be lower pregnancy rates when using the Mosie Kit when the source of infertility is male-based than when it is female-based.

Analysis: In addition to the descriptive statistics a t-test will be run to examine this hypothesis.

Tertiary Hypothesis 2: There is a difference in pregnancy rates of people with known fertility issues depending on the source of their infertility. Specifically, the following sources of infertility will be examined if sufficient data is available.

- PCOS
- Endometriosis
- Low AMH or low ovarian reserve
- Low sperm count
- Sperm motility issues
- Unexplained infertility
- Erectile dysfunction
- Performance issues or sexual anxiety, or inability to orgasm with partner.
- Vaginismus or vulvodynia
- Tilted uterus
- Multiple uterus/cervix
- Loss of a fallopian tube

The alternative hypothesis is that there will be no difference in the fertility rates associated with different sources of infertility.

Analysis: Descriptive statistics, t-test, correlations and multiple ANOVAs will be used to examine this hypothesis.

Tertiary Hypothesis 3: There will be a difference between individuals who perform 2 insemination instances as described in the instructions and those that follow a different schedule or dosage number. The alternate hypothesis is that there will be no difference between the individuals that perform the minimum 2 insemination instances and those that follow difference dosage schedule.

Analysis: Descriptive statistics of pregnancy rates for groups with 1, 2, 3 and 4 or more inseminations per cycle will be used. These rates will then be compared to determine if there is a difference.

Tertiary Hypothesis 4: COVID-19 has affected people's family expansion plans. The alternate hypothesis is that COVID-19 has had no effect on people's family expansion plans.

Analysis: Descriptive analysis and a t-test will be conducted to examine this hypothesis.

Tertiary Hypothesis 5: There will be a decrease in pregnancy rates in those using the Mosie Kit during the Months of March - June.

Analysis: Descriptive statistics, graphing, ANOVA and multiple regression analysis will be used to examine this hypothesis.

Additional Analysis will also be conducted to explore why people might choose to use the Mosie Kit, how they actually use it, additional things they do when using the Mosie Kit to complement the experience, and whether they think their health care provider should recommend Mose as an conception option. Most of this analysis will be achieved using descriptive statistics, correlations, and t-tests.

9.2 Sample Size Determination

The desired final sample size for this study is 500 completed surveys. This will produce a 95% confidence interval with +/- 4.4% within larger populations. In order to obtain that rate of respondents, the study will invite about 50% people who have ordered a Mosie Kit in the prior 2-8 months to the study start date. It is expected that approximately 4000 people will be invited to participate. By inviting 4000 potential participants, it is expected that with a response rate of 15% approximately 600 will complete the survey. Currently Mosie has about a 20% open rate on their general emails. For this reason, all people who purchased a kit within the last 2-8 months will be invited to participate.

According to the sample size tables, a response rate of 384 is sufficient to provide a 95% confidence interval with a 5% margin of error rate. While the total number of respondents can not be controlled, every effort will be made via the reminder emails to obtain at least 500 participants but no less than 384.

9.3 Populations for Analyses

The population to be analyzed include any one using the Mosie Kit in the full 2-8 months prior to study commencement. Respondents can be male or female. Overall the data will be analyzed as a whole and stratified by sex (having ovaries and a uterus as indication of being a female), age and type of relationship .

9.4 Statistical Analyses

9.4.1 General Approach

Statistical analysis will commence with descriptive statistics for each survey question and plotting of the individual data into scatter plots to understand the data distribution.If any information suggests corrective procedures should be employed, the appropriate transformation or non-parametric test will be used.

Categorical values will be reported using descriptive statistics and frequency of occurrence. Key categorical values will also be converted into a percentage of total responses in order to allow an understanding of the prevalence of the response in the sample. For continuous variables, the means with standard deviations, median and range will be reported.

Qualitative data is only expected as a response to two questions, an open ended safety question and an additional comments question.The responses will be evaluated and categorized. Then the frequency of each category will be provided.

For inferential tests such as t-tests and ANOVAs, a p-value of 0.05 and a confidence interval of 95% will be used for statistical significance. The type of hypothesis will determine whether the specific tests will be one-tailed or two-tailed. Hypothesis seeking to understand whether there is or is not a difference will use a two-tailed test while those seeking a greater than or less than relationship will use a one-tailed test. Correlations among some of the variables will also be examined as appropriate.

Statistical analysis process for each hypothesis has already been described in section 9.1. No baseline analysis is used for cross-sectional studies. No interim analyses are planned for cross-sectional one survey studies.

9.4.2 Sub-Group Analyses

All endpoints (primary, secondary and tertiary) will be analyzed based on age, sex, race.ethnicity, SES, relationship preference, male/femaile infertility issues. Only aggregate

information will be used in the final analysis. No tabulation of individual participant data will be used in reporting findings.

9.4.3 Exploratory Analyses

Additional exploratory data analysis will be conducted to examine the main characteristics of the data. This analysis will be done using descriptive statistics, scatter plots, and odds ratio. If the exploratory analysis warrants the testing of new hypotheses, t-test or ANOVA may be used for further analysis.

Exploratory modeling will be conducted to examine multiple variables and their relationship to the pregnancy outcome. This will include the source of infertility, age, number of inseminations, number of cycles, lying time, and type of relationship. The model will use correlations and goodness of fit tests in its analysis.

1 0 SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

10.1 Regulatory, Ethical, and Study Oversight Considerations

10.1.1 Informed Consent Process

Upon receiving the invitation email, the potential participant will select to follow the study link. In the study web page, the user will be provided with information related to the study and consent to participate in the study. They will be informed that if they choose to respond to the questions and submit their responses, they are providing consent. They will agree to participate in the research by selecting “Yes” to “Do you agree to participate in this study?”. No signature will be collected as the intent is for the study to be completely anonymous.

Waiver of signed consent was selected for this study in order to be able to ensure the anonymity of the participant in this cross-sectional post-elective-intervention study. Since participants previously elected to use the Mosie Kit and now are selecting to share their experiences and perceptions about it, they need only share these experiences; there is no reason to collect any identifying information for this one time survey.

10.1.1.1 Consent/assent and Other Informational Documents Provided to participants

A consent form describing in detail the study procedure and risks will be displayed to the participant upon access to the study website using the link provided in the email. Each participant will be able to read and provide consent. The participant may print the displayed consent. Additionally, the email will contain a link to a Frequently Asked Question Document where the participant can learn more about the study.

10.1.1.2 Consent Procedures and Documentation

After reading the consent form, the participant can elect to proceed to the survey or conclude the survey. The only documentation collected about the consent is whether or not the participant elected to respond to the questions. A consent is not required for participation in this study. Answering the questions and submitting the responses provides consent. Only completed surveys that are submitted will end up in the database.

10.1.2 Study Discontinuation and Closure

It is not expected that the study will end prematurely. The expected total duration of study data collection is approximately 30 days. However, if the minimum number of surveys are not collected within the 30 day time-frame, the study will continue collecting data for up to 90 days. Since this is a one-time anonymous survey there is no reason to follow up with the participant. There is also no way to follow up with any given participant should there be a desire to do so since the surveys will be responded to completely anonymously.

Should there be any reason to discontinue the study prematurely, the PI will advise the study Sponsor and the institutional review board (IRB) of this occurrence. Circumstances that might warrant termination or suspension might include:

- Difficulties with the data capture/survey technology
- Difficulties with participant recruitment
- Data that are not sufficiently complete and/or evaluable
- Determination of a need to prematurely complete the study as determined by the PI, Sponsor, IRB or regulatory agency.

The study may resume once concerns about data quality and data security are addressed, and satisfying any requirements of the Sponsor, IRB, or regulatory agency.

The study may be terminated prematurely if sufficient surveys are completed prior to the 30 days of data collection. This will be done at the discretion of the Primary Investigator (PI).

10.1.3 Confidentiality and Privacy

Participation in this study is completely anonymous. Participants will receive an invitation email with a generic link to the study website. Once informed about the study and its participation, the participant can respond to the survey questions without entering any identifiable information. The PI deemed the value of obtaining any identifying information was inferior to protecting the participant's privacy and that it was unnecessary for this study. Therefore, no identifying information will be collected. There will be no identifiers that can link directly back to an individual. While information about race, gender, and age will be collected, it will not be possible to point the information back to any given individual.

Invitations to participate will be sent out by the Sponsor company. The full list of those emails will never be released to the PI. This will help keep the information from being able to be linked back to the group of emails sent.

The final database will be an anonymous database that will be the property of the Sponsor. There is currently no intent to share the results of that study beyond this research. There is an intent to publish the findings of the study as a journal article and for information on the Sponsor's company website, but this information will be limited to aggregate results and to discussions related to the findings. The Sponsor might also use aggregate data or results in future marketing materials.

10.1.4 Future Use of Stored Specimens and Data

Specimens are not part of this study. Therefore no storage of specimens is required.

Data collected for this study will be analyzed and stored as an anonymous de-identified database in the possession of the PI and at Mose Baby. The archived data will be stored for use by Mosie Baby. No one will be given access to the raw study data without the written consent of the PI or Mosie Baby.

10.1.5 Key Roles and Study Governance

Principal Investigator:

Karina Loyo, Ph.D., MBA, CCDM
Clinical Research Consultant
307 Champions Drive, Georgetown, TX 78628
512-563-1393
karina@drkarina.com

This one time survey does not require a medical monitor or safety oversight as no interventions are occurring.

10.1.6 Safety Oversight

Safety oversight is provided by the Institutional Review Board (IRB) who is responsible for independently reviewing this study to ensure protection of human subjects. This study will seek exempt approval Category2(i) since the research is an observation of public behavior and the information obtained is recorded in such a manner that the identity of the human subjects cannot be readily ascertained, directly or through identifiers linked to the subject..

10.1.7 Clinical Monitoring

N/A

10.1.8 Quality Assurance and Quality Control

This one time survey does not require clinical monitoring or an external QA process. Quality Assurance is conducted to ensure the quality of data is complete and that appropriate documentation is in place to support and conduct the study.

Quality Control (QC) Procedures will be implemented as follows:

- **Informed Consent** - PI and Sponsor will both review the documentation of the consenting process. This review will be conducted in compliance with GCP, accuracy and completeness. Feedback will be provided to the PI and Sponsor in order to ensure proper consenting procedures are followed. The Institutional Review Board will also review and provide feedback on this process.
- **Source Documents and the electronic data** - The electronic data capture will constitute the source documents for this study. The data will be entered by the participant directly into the final study database.
- **Intervention fidelity** - This is a retrospective observational study of people using the Mosie Kit. Part of data collection will include information about the use of the kit and how it was used. This information will be used to determine whether the person used the kit as intended thus confirming the intervention fidelity occurred voluntarily prior to participation in the study.
- **Protocol Deviations** - There is no directed intervention for this study. Therefore, protocol deviations with respect to an intervention are not expected. If any deviations occur with relation to how the data is collected or the participants recruited, that will be collected as part of the study documentation.

There is no expectation that independent monitoring would be necessary. However, if it is required, the necessary arrangements will be made.

10.1.9 Data Handling and Record Keeping

The following section pertains to data handling and record keeping. It is described in accordance with GCP standards.

10.1.9.1 Data Collection and Management Responsibilities

Google forms will be used to collect this one time survey. The only data quality checks that will be included in the survey will be those that are implemented via the appropriate selection of the type of field in order to ensure the appropriate data is entered into the field and edit checks to ensure all questions are filled in.

The online Google Form and resulting excel sheet will constitute the source data for this study. No external records or information will be combined with the survey data. Only the PI and the Sponsor will have access to download the data.

Data standards will be implemented for the study. Descriptive field names will be used for each field. All data collection is the responsibility of the PI. The PI is responsible for ensuring the accuracy and completeness of the data.

10.1.9.2 Study Records Retention

Study documents will be retained for a minimum of 3 years. No records will be destroyed without the written consent of the Sponsor. It is the responsibility of the Sponsor to inform the PI when these documents are no longer needed.

10.1.10 PROTOCOL DEVIATIONS

This protocol defines a protocol deviation as any noncompliance with the clinical trial protocol and International Council on Harmonization Good Clinical Practices (ICH GCP). The non compliance may be either on the part of the participant or the investigator. Since this is a one-time survey, no deviations are expected. If any deviations do occur, they will be documented and corrective action plans will be implemented promptly.

10.1.11 Publication and Data Sharing Policy

This study will result in data that is proprietary to the Sponsor. As such, this data will be held privately and will only be shared at the discretion of the Sponsor.

The trial will be registered with and the results of the analysis will be submitted to ClinicalTrials.gov. In addition, every attempt will be made to publish results in a peer-reviewed journal(s). Aggregate data may also be shared in any format by the Sponsor.

10.1.12 Conflict of Interest Policy

The independence of this study from any actual or perceived influence, is critical. In order to ensure the integrity of this research, any conflict of interest of persons who have a role in the design, conduct, analysis, publication or any aspect related to the trial will be disclosed and managed. The PI reports that this study is a work for hire by the Sponsor. There is no other known conflict of interest.

10.2 Additional Considerations

No additional considerations.

10.3 Abbreviations and Special Terms

Below is a list of abbreviation or special terms used in this study protocol.

AE	Adverse Event
ANCOVA	Analysis of Covariance
CFR	Code of Federal Regulations
CRF	Case Report Form

eCRF	Electronic Case Report Forms
FDA	Food and Drug Administration
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act
ICH	International Council on Harmonisation
IDE	Investigational Device Exemption
IRB	Institutional Review Board
ITT	Intention-To-Treat
LSMEANS	Least-squares Means
NIH	National Institutes of Health
NIH IC	NIH Institute or Center
OHRP	Office for Human Research Protections
PI	Principal Investigator
QA	Quality Assurance
QC	Quality Control
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SOP	Standard Operating Procedure
UP	Unanticipated Problem
US	United States

10.4 Protocol Amendment History

*The table below is intended to capture changes of IRB-approved versions of the protocol, including a description of the change and rationale. A **Summary of Changes** table for the current amendment is located in the **Protocol Title Page**.*

Version	Date	Description of Change	Brief Rationale

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Appendix A:
Online Survey Tool and Consent Form
(Google Form)

This section shows what the Google Form will look like to the study participant. These are the questions the participant will be asked.

The first page of the study contains the consent form and the question that confirms the participant's agreement to participate.

There is skip logic for certain sections. For example, if the participant selects one cycle of using Mosie, the information related to cycles 2-6 will be skipped. If the participant selects that she is pregnant the questions related to the pregnancy will be asked, otherwise they will be skipped. If a donor was used, the questions related to producing a sperm sample will be skipped.

Note: Final language and questions might be tweaked or revised at any time to increase clarity.

Mosie Kit Survey

The Mosie Kit Survey: Retrospective Study on the Use, Efficiency, and Safety of the Mosie Kit.

Thank you so much for being a part of the Mosie Community!

We are conducting a retrospective study, which will help us understand how effectively Mosie is being used and help us make improvements to the instructions, design, and user experience. Your participation will help improve future Mosie users experiences with the Mosie Kit.

Your privacy is important to us and all answers will be anonymous. The data will only be used for research purposes.

Participation is voluntary. Please refer to our Survey FAQs <LINK> if you have any questions.

If you agree to participate in this study, you will be asked questions about the process of using the Mosie Kit and its results. At the completion of the survey you will receive a code for 15% off a future purchase.

Responding "Yes" below, completing and submitting the study survey indicates your consent to participate. Your information will only be included if you hit submit at the end of the survey.

Should you have any questions about the research, the survey or the consent form, please contact Karina Loyo, PhD, MBA, CCDM at 512-563-1393 or karina@drkarina.com.

* Required

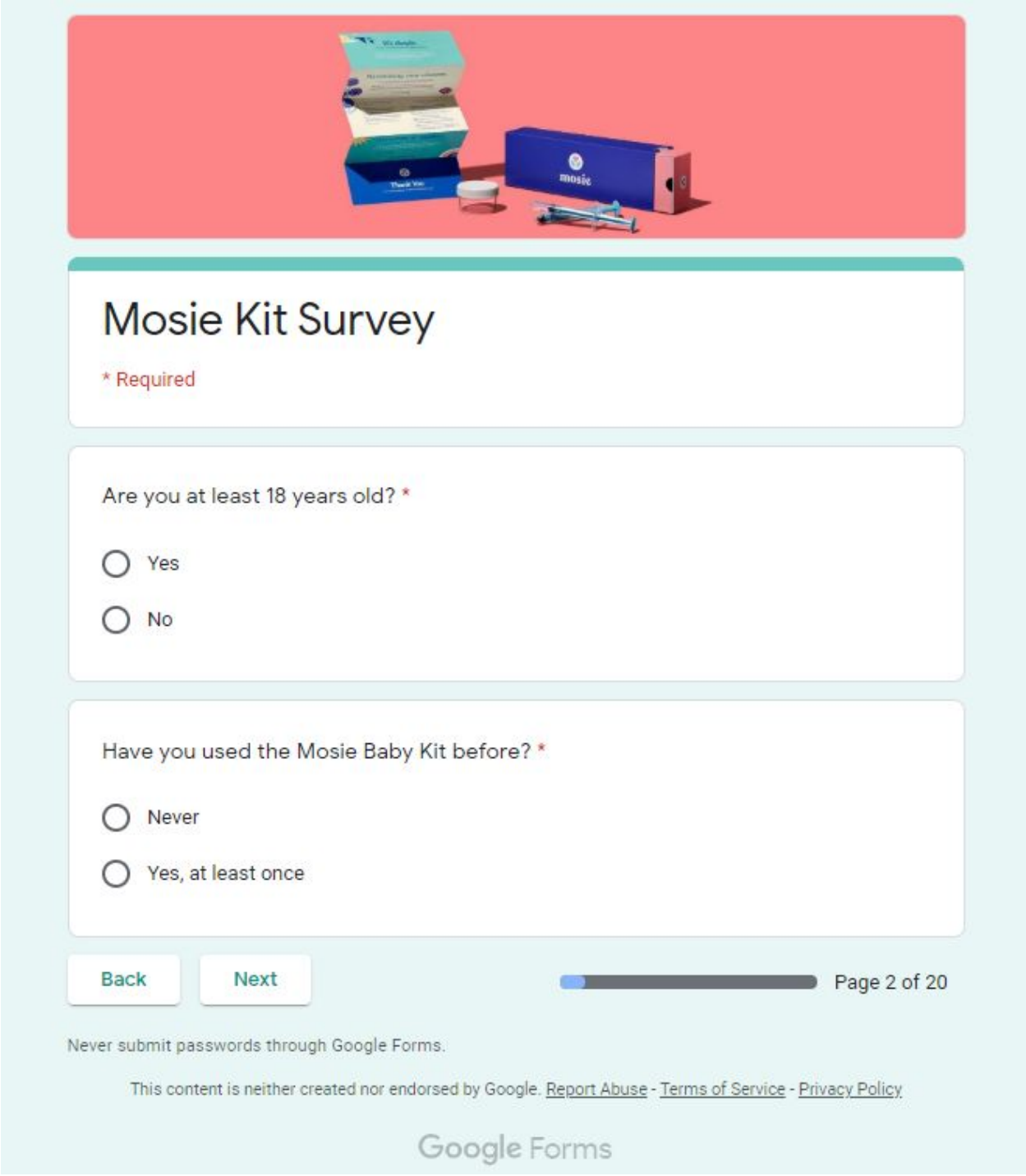
Do you agree to participate in this study? *

- ◯ Yes
- ◯ No

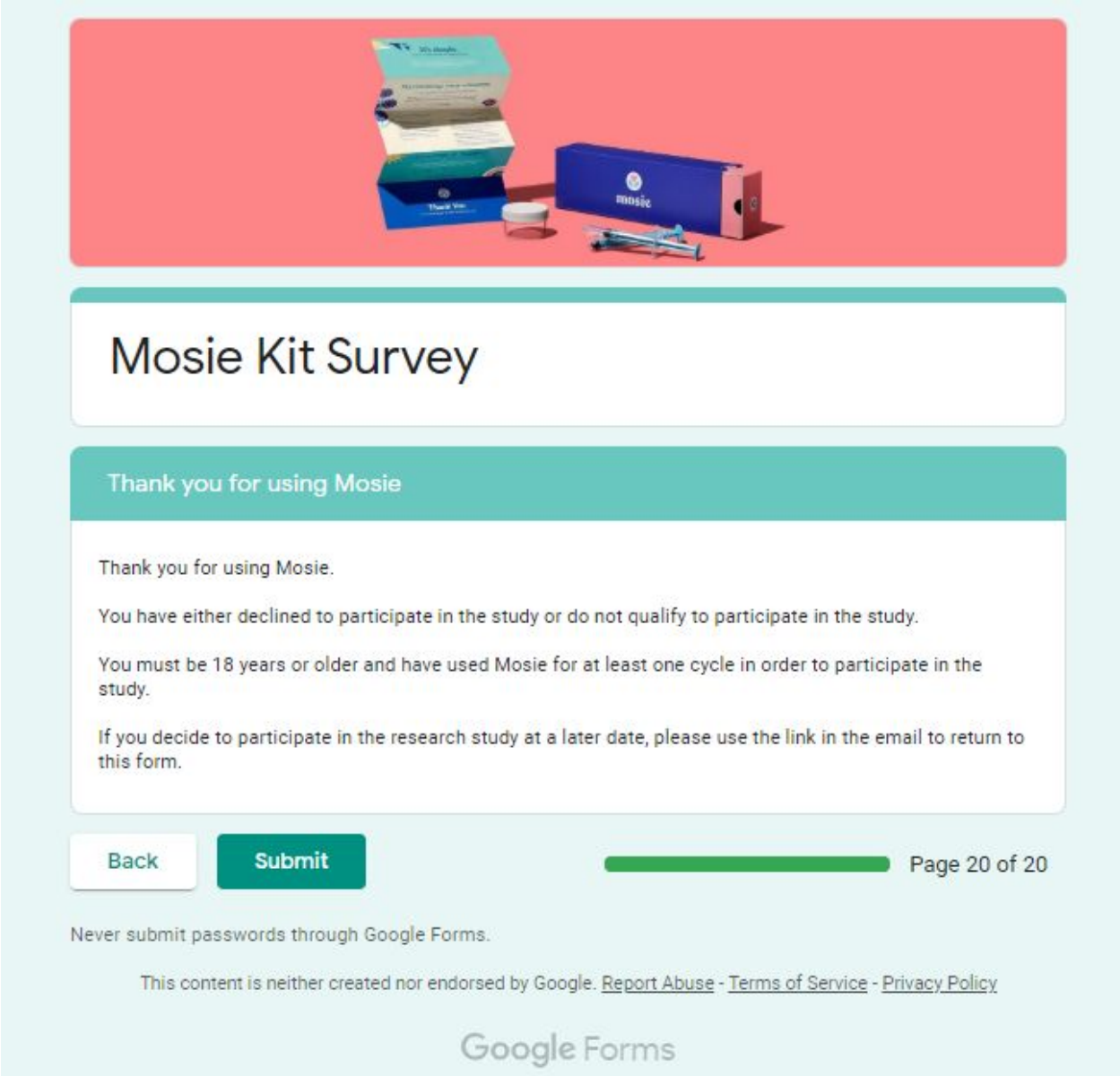
Next

Page 1 of 20

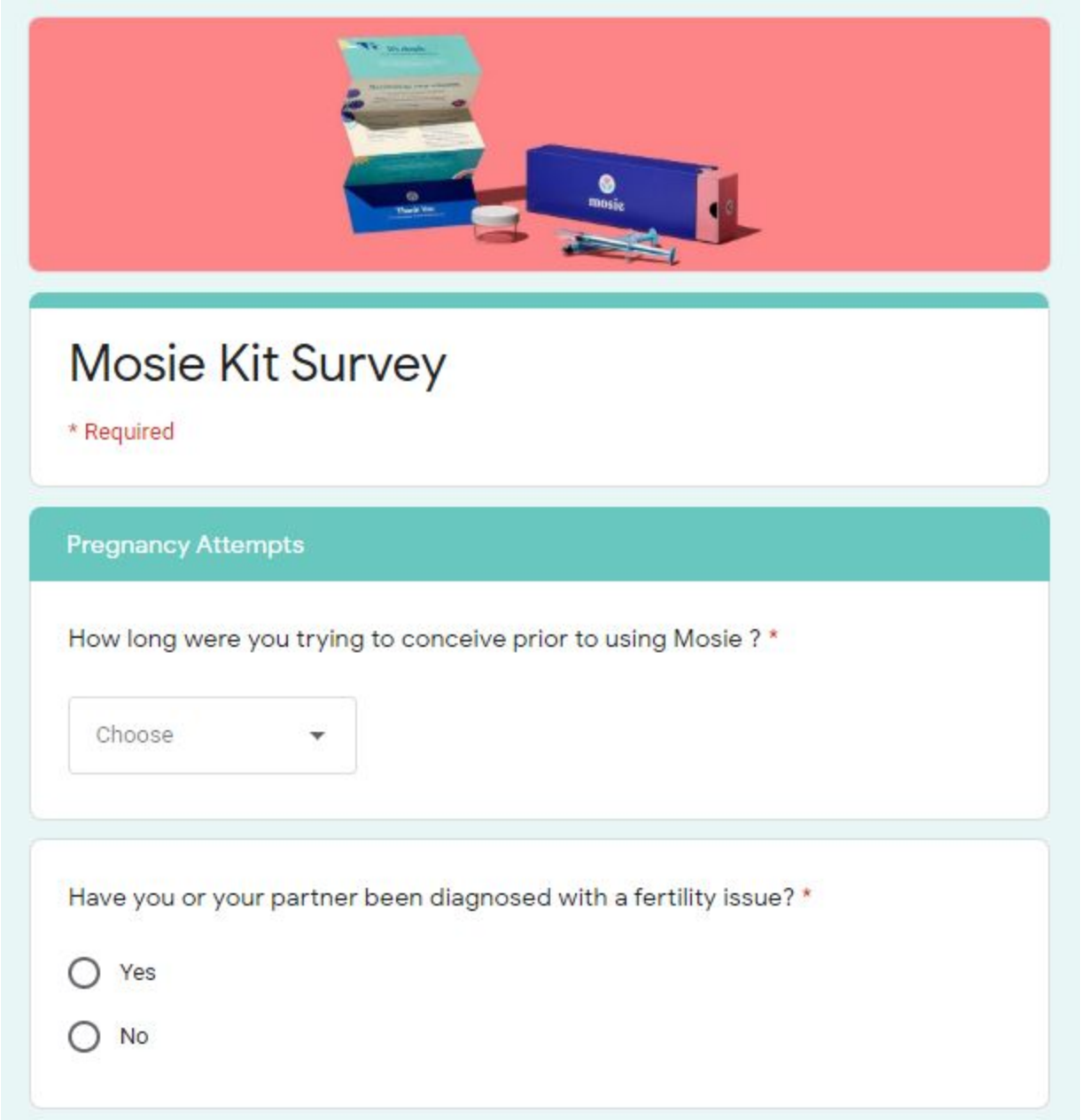
This is the inclusion/exclusion form.



If Participant selected to not participate in the study, he/she will see this screen next. If the participant said he/she is not 18 or older or has not used Mosie this screen will be displayed.



Qualifying participants will continue the survey on this page.



Which of these diagnoses or issues do you believe are contributing to your infertility? *

- [ ] Not applicable
- [ ] PCOS
- [ ] Endometriosis
- [ ] Low AMH or low ovarian reserve
- [ ] Low Sperm count
- [ ] Sperm motility issues
- [ ] Erectile Dysfunction
- [ ] Performance issues or sexual anxiety, or inability to orgasm with partner
- [ ] Vaginismus or vulvodynia
- [ ] Tilted Uterus
- [ ] Multiple uterus/cervix
- [ ] Unexplained infertility
- [ ] Have only one functioning fallopian tube
- [ ] Other: _____

What other methods have you tried that were unsuccessful? *

- [ ] No other methods attempted
- [ ] Male/Female intercourse
- [ ] IVI or syringe other than Mosie
- [ ] IUI
- [ ] Femara
- [ ] Clomid
- [ ] IVF
- [ ] Cervical Cap
- [ ] Other: _____

Please select the best answer for each. *

	None	1	2	3 or more
How many pregnancies have you had?	○	○	○	○
How many live births have you had?	○	○	○	○
How many pregnancies have you had that were prematurely terminated (ex. abortion, miscarriage, still birth)?	○	○	○	○
How many DNCs have you had?	○	○	○	○

Back Next

Page 3 of 20

Mosie Kit Survey

* Required

Your First Experience with the Mosie Kit

For each cycle (up to 6 cycles) report the date of the cycle and how frequently the Mosie syringe was used.

What month did this cycle start? *

Choose

When did you use your Mosie syringes and how many did you use during each time period listed below? *

	0	1	2	3+
24-48 hours prior to ovulation	○	○	○	○
within 24 hours of ovulation	○	○	○	○
24-48 hours after ovulation	○	○	○	○
48+ hours after ovulation	○	○	○	○

Did you use Mosie for another cycle?

- ○ Yes
- ○ No

Back Next

Page 4 of 20

Mosie Kit Survey

* Required

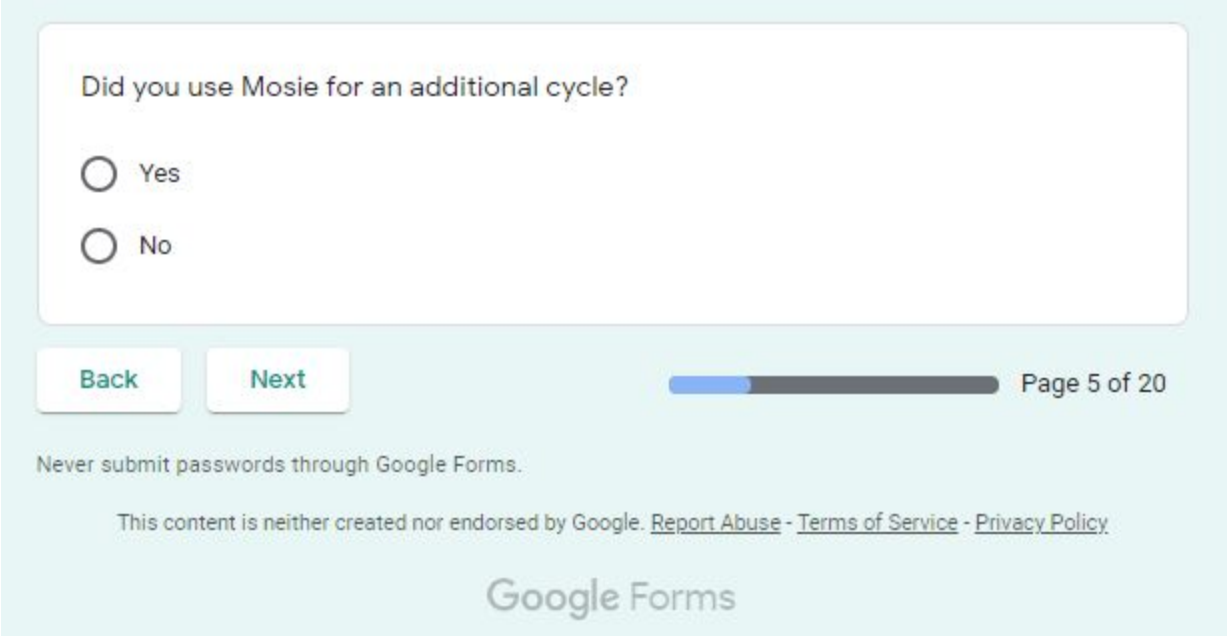
2nd Cycle with the Mosie Kit

What month did this cycle start?

Choose

When did you use your Mosie syringes and how many did you use during each time period listed below? *

	0	1	2	2+
24-48 hours prior to ovulation	○	○	○	○
within 24 hours of ovulation	○	○	○	○
24-48 hours after ovulation	○	○	○	○
48+ hours after ovulation	○	○	○	○


Did you use Mosie for an additional cycle?
Yes
No
Back
Next
Page 5 of 20
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Mosie Kit Survey

* Required

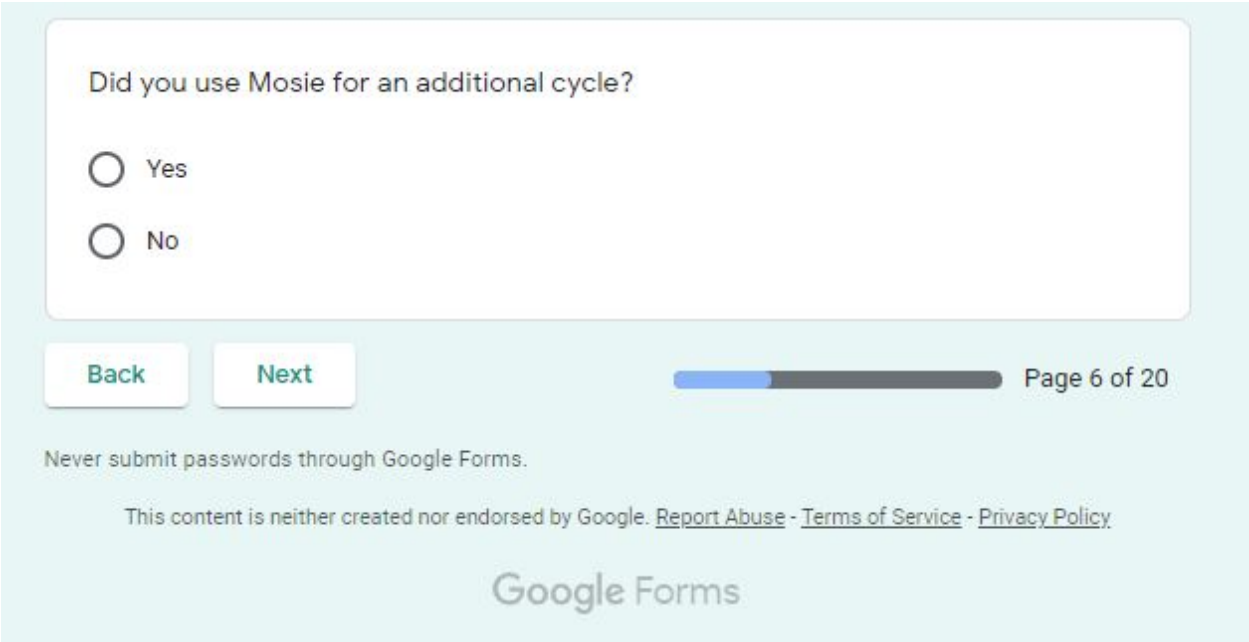
3rd cycle with the Mosie Kit

What month did this cycle start?

Choose

When did you use your Mosie syringes and how many did you use during each time period listed below? *

	0	1	2	2+
24-48 hours prior to ovulation	○	○	○	○
within 24 hours of ovulation	○	○	○	○
24-48 hours after ovulation	○	○	○	○
48+ hours after ovulation	○	○	○	○


Did you use Mosie for an additional cycle?
Yes
No
Back
Next
Page 6 of 20
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Mosie Kit Survey

* Required

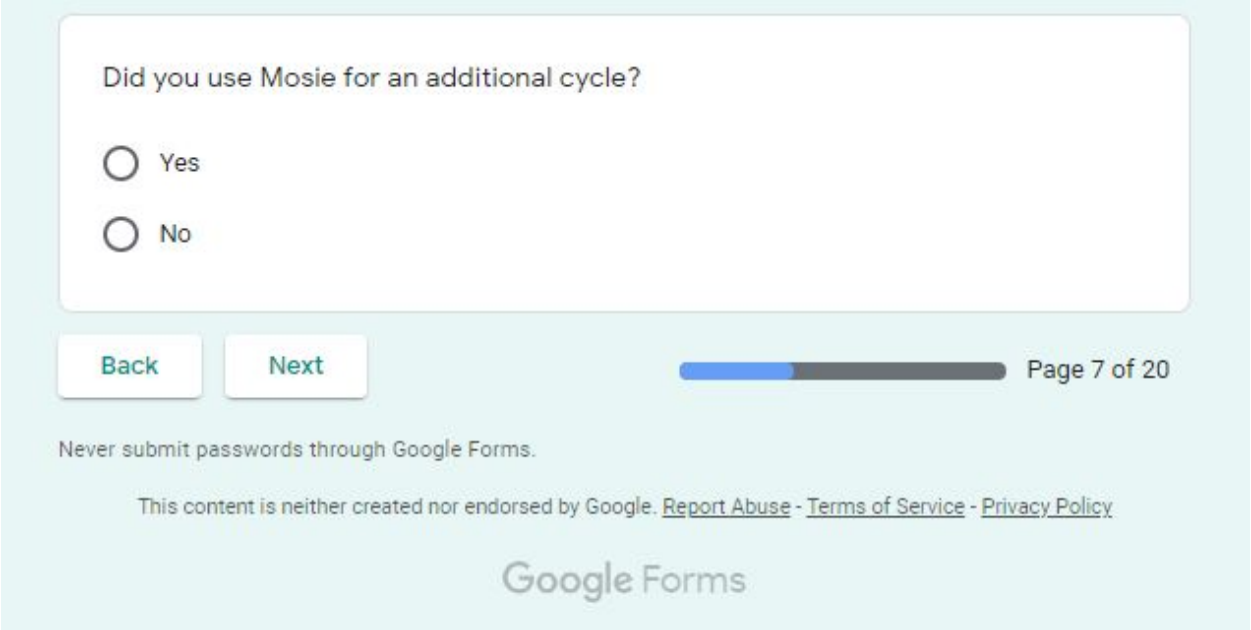
4th Cycle with the Mosie Kit

What month did this cycle start?

Choose

When did you use your Mosie syringes and how many did you use during each time period listed below? *

	0	1	2	2+
24-48 hours prior to ovulation	○	○	○	○
within 24 hours of ovulation	○	○	○	○
24-48 hours after ovulation	○	○	○	○
48+ hours after ovulation	○	○	○	○


Did you use Mosie for an additional cycle?
Yes
No
Back
Next
Page 7 of 20
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Mosie Kit Survey

* Required

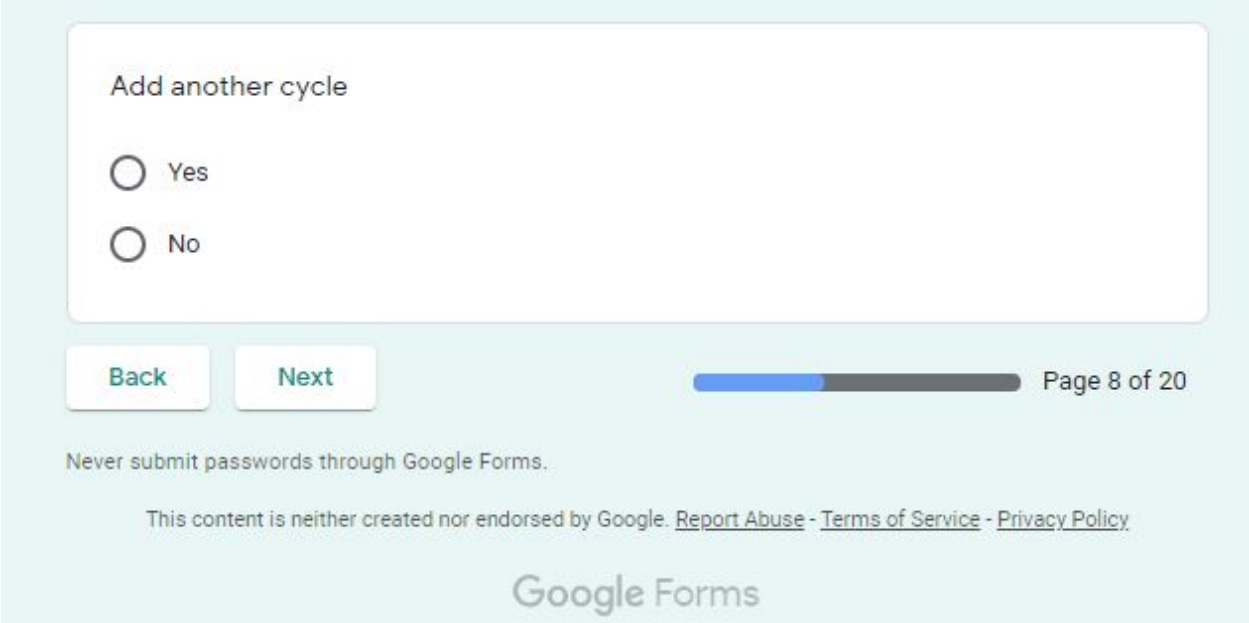
5th Cycle with Mosie Kit

What month did this cycle start?

Choose

When did you use your Mosie syringes and how many did you use during each time period listed below? *

	0	1	2	2+
24-48 hours prior to ovulation	○	○	○	○
within 24 hours of ovulation	○	○	○	○
24-48 hours after ovulation	○	○	○	○
48+ hours after ovulation	○	○	○	○


Add another cycle
Yes
No
Back
Next
Page 8 of 20
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Mosie Kit Survey

* Required

6th Cycle with Mosie Kit

What month did this cycle start?

Choose

When did you use your Mosie syringes and how many did you use during each time period listed below? *

	0	1	2	2+
24-48 hours prior to ovulation	○	○	○	○
within 24 hours of ovulation	○	○	○	○
24-48 hours after ovulation	○	○	○	○
48+ hours after ovulation	○	○	○	○

Back Next

Page 9 of 20

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Mosie Kit Survey

* Required

How did you or your partner time your ovulation? (Select all that apply.) *

- [ ] Count days in cycle
- [ ] Track vaginal or cervical fluids
- [ ] Tracking changes in the cervix
- [ ] Use ovulation predictor kit
- [ ] Use an app to estimate ovulation
- [ ] Basal Body Temperature
- [ ] Wearable device
- [ ] Did not time ovulation

Did using Mosie result in a pregnancy? *

- ( ) Yes
- ( ) No

Back Next Page 10 of 20

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Mosie Kit Survey

* Required

Pregnancy Info

If yes, after how many Mosie cycles did you get pregnant? *

Choose

If yes, what is your expected due date or the baby's birth date?

Date

mm/dd/yyyy

Back Next

Page 11 of 20

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Mosie Kit Survey

* Required

How would you rate the Mosie Kit on each of the following? *

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
Comfortable	○	○	○	○	○
Intuitive (able to use it without instructions)	○	○	○	○	○
Easy process	○	○	○	○	○
Safe process	○	○	○	○	○
Enjoyable	○	○	○	○	○

How easy was it to do each of the following with the Mosie Kit? *

	Very Easy	Easy	Neutral	Difficult	Very Difficult
To collect the semen/sperm sample in the cup?	○	○	○	○	○
To draw up the semen/sperm in the syringe?	○	○	○	○	○
Insert the Mosie syringe into the vagina up to the handles?	○	○	○	○	○
To deposit the semen/sperm at or near the cervix using the syringe?	○	○	○	○	○
My overall impression on the ease of use	○	○	○	○	○

Back Next

Page 12 of 20

Mosie Kit Survey

* Required

Using Mosie

Which of the following did you do when preparing to use the Mosie Kit? (select all that apply) *

- [ ] Read the instructions
- [ ] Wash my hands
- [ ] My partner washed their hands
- [ ] Washed the penis
- [ ] Thawed out donor sperm from sperm bank
- [ ] Pulled the syringe plunger back and forth to confirm it was functioning.
- [ ] Prepared all items and have them handy ready to use.
- [ ] Use a sperm friendly-lubricant.

Did the person being inseminated do or receive any of the following (select all that apply)? *

- [ ] Lie down in a comfortable position.
- [ ] Relax
- [ ] Receive oral sex
- [ ] Stimulate clitoris
- [ ] Use any vibratory or non-vibratory stimulation device intravaginally
- [ ] Have an orgasm
- [ ] Other: _____

Overall, how well were you able to use the Mosie syringe to inseminate yourself or your partner? *

- ◯ Very Able
- ◯ Able
- ◯ Not Very Able
- ◯ Not Able at All

How long did you remain laying down after using the Mosie syringe? *

- ◯ Less than 15 minutes
- ◯ 15 - 30 minutes
- ◯ 31-45 minutes
- ◯ More than 45 minutes

Which best describes your lying position? *

- ◯ On my stomach
- ◯ On my side
- ◯ On my back
- ◯ On my back with my hips elevated by a pillow
- ◯ Other: _____

Did you dispose of the syringe after using it one time? *

- ◯ Yes
- ◯ No

What type of sample did you use? *

- ◯ Donor sperm from a sperm bank (frozen)
- ◯ Partner's sperm
- ◯ Other known source of sperm (ex. friend, acquaintance or hired)

What percentage of the semen would you say you were able to successfully draw up into the syringe from the cup? *

- ◯ Less thank 50%
- ◯ 51% - 70%
- ◯ 71% - 80%
- ◯ 81% - 90%
- ◯ 90% - 95%
- ◯ 96% - 100%

Back Next Page 13 of 20

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Mosie Kit Survey

* Required

Sperm Collection Process

How easy was it for you or your partner or known donor to deposit the sample into the cup? *

- ◯ Very Difficult
- ◯ Difficult
- ◯ Easy
- ◯ Very Easy

How stressful was the experience for your partner or donor to produce a semen sample at home (view point of the person providing the sperm)? *

- ◯ Not Stressful at all
- ◯ A Little Stressful
- ◯ Moderately Stressful
- ◯ Very Stressful
- ◯ Extremely Stressful

Have you or your partner had to produce a semen sample at a doctors office? *

- ○ Yes
- ○ No

To what degree do you agree or disagree with the following statement:
Producing a sample at home was a lot less stressful than at the doctor's office. *

- ○ Strongly Agree
- ○ Agree
- ○ Neutral
- ○ Disagree
- ○ Strongly DIsagree

Back Next Page 14 of 20

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Mosie Kit Survey

* Required

Choosing Mosie

Why did you choose the Mosie Kit (select all that apply)? *

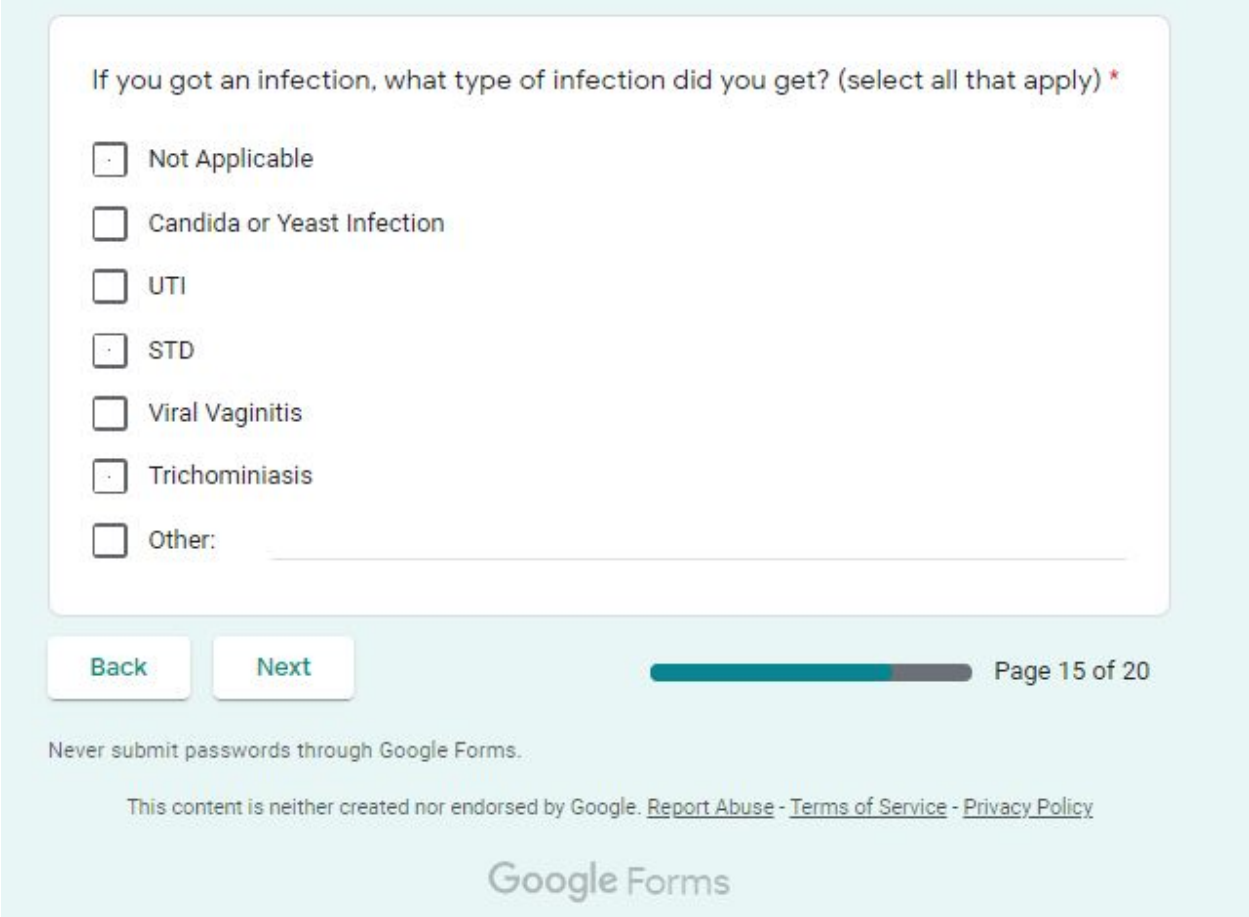
- [ ] Cost
- [ ] Covenience
- [ ] Ability to control the process
- [ ] Ability to do it myself or with my partner
- [ ] Privacy
- [ ] Ability to do it at home
- [ ] The supportive Mosie Community
- [ ] Other: _____

How would you rate your level of concern over the safety of using the Mosie Kit? *

- ◯ Not concerned at all
- ◯ A little concerned
- ◯ Somewhat concerned
- ◯ Very concerned
- ◯ Extremely concerned

If you or your partner had a vaginal infection in the last 7 months, what did you do to help resolve the infection? (Please answer this on behalf of the person using Mosie to conceive.) *

- ◯ Not Applicable: Did not have any vaginal infections
- ◯ Nothing, it resolved on its own
- ◯ Douche or wash
- ◯ Used over the counter (OTC) medications
- ◯ Used prescription medication


If you got an infection, what type of infection did you get? (select all that apply) *
Not Applicable
Candida or Yeast Infection
UTI
STD
Viral Vaginitis
Trichominiasis
Other:
Back
Next
Page 15 of 20
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Mosie Kit Survey

* Required

Please indicate to what extent you agree or disagree with the following statements.

I wish my doctor would have recommended Mosie to me. *

- ◯ Strongly agree
- ◯ Agree
- ◯ Neutral
- ◯ Disagree
- ◯ Strongly disagree

I wish doctors would recommend Mosie to other people in my/our situation. *

- ◯ Strongly agree
- ◯ Agree
- ◯ Neutral
- ◯ Disagree
- ◯ Strongly disagree

My doctor had no concerns about me doing at home insemination. *

- ◯ I did not talk to my doctor
- ◯ Strongly agree
- ◯ Agree
- ◯ Neutral
- ◯ Disagree
- ◯ Strongly disagree

My doctor was concerned that my diagnosis would not allow at-home insemination to be successful. *

- ◯ I did not talk to my doctor
- ◯ Strongly agree
- ◯ Agree
- ◯ Neutral
- ◯ Disagree
- ◯ Strongly disagree

If your doctor had any concerns over using Mosie, would you please share them below?

Your answer

I would recommend Mosie to other people in my same situation. *

- ○ Strongly agree
- ○ Agree
- ○ Neutral
- ○ Disagree
- ○ Strongly disagree

Overall how many stars would you give Mosie?

Choose

Back Next

Page 16 of 20

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Mosie Kit Survey

* Required

Which of the following are reasons for using the Mosie Kit? *

- [ ] Home Insemination
- [ ] Medication delivery
- [ ] Pleasure
- [ ] Delivery of semen at or near the cervix
- [ ] To ensure a pregnancy occurs every time

How many cycles do you believe you should try Mosie to get pregnant before you contact your physician to try another method? *

Choose

Were the instructions clear and easy to follow? *

- ○ Very easy
- ○ Easy
- ○ Neither easy nor difficult
- ○ Difficult
- ○ Very difficult

Back Next Page 17 of 20

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Mosie Kit Survey

* Required

About you

Who was the person who was inseminated with Mosie? *

- ◯ Me
- ◯ My partner
- ◯ Both my partner and me
- ◯ A surrogate

What year were you born in? *

Your answer

What is your race/ethnicity? *

- [ ] Multiracial or Multiethnic
- [ ] Black or African American
- [ ] Hispanic or Latinx
- [ ] White
- [ ] Native American or Alaska Native
- [ ] Native Hawaiian or other Pacific Islander
- [ ] Asian American
- [ ] Indian American
- [ ] Other

What is your approximate household income? *

Choose

How would you describe yourself? *

- ◯ Woman
- ◯ Man
- ◯ Transgender
- ◯ Non-binary
- ◯ Prefer not to say
- ◯ Other: _____

Which best describes your relationship status while trying to conceive? *

- ◯ Heterosexual Relationship
- ◯ Single/Not in a relationship
- ◯ LGBTQ Relationship
- ◯ Other: _____

Are you married? *

- ◯ Yes
- ◯ No

Has COVID-19 affected your family building plans? *

- ◯ Yes
- ◯ No

If yes, please share how it has affected your family building plans.

Your answer

Is there anything else you would like to share with us?

Your answer

Back Next Page 18 of 20

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Mosie Kit Survey

Submit your survey responses

Thank you for sharing your experience with us!

Your anonymous answers will help us help others as they embark on their journey with Mosie.

Please hit submit below. The discount code will appear on the next page.

Back Submit

Page 20 of 20

Mosie Kit Survey

THANK YOU! We so appreciate you!

Use code WARMHUGS for 15% off your next purchase.

If you did conceive with the Mosie Kit, we'd love to celebrate your joyful news and send you a special baby gift. Email us at bigfatpositive@mosiebaby.com to share your news!

If you're still on your journey to conceive, we are sending you big hugs! We want to help and support you as best we can, no matter the path taken, we are here for you! If you have any questions or if you're interested in sharing your current journey to conceive with the Mosie Community, email us at mosie@mosiebaby.com. Fingers crossed for you!

Our thanks and best wishes to you!
Team Mosie Baby

Appendix B:
Frequently Asked Questions

The frequently asked questions will be hosted by Mosie Baby on their website. There will be a hyperlink within the survey tool on the consent form allowing participants to be able to access the frequently asked questions at any time.

The following page shows the text of the FAQ.

Frequently Asked Questions

Study Name: **Retrospective Study on the Use, Efficiency, and Safety of the at-home Mosie Kit**
Short Study Name: **Mosie Kit Survey**
Principal Investigator: Karina Loyo, Ph.D., MBA, CCDM
Contact Information: 512-630-0990 or karina@drkarina.com

Why am I being asked to participate in this study?
You are being asked to participate because we are interested in learning about your experience using the Mosie Kit for at-home insemination. Since you have purchased at least one kit, we hope that you have had an opportunity to use it and can share your experience.

How long will the survey take?
It is expected that most people will be able to complete the survey in about 15-30 minutes.

Do I have to participate?
No. Participation is optional, although we would really appreciate your help! The feedback you provide is crucial for us to improve the experience for others in the future.

Will the survey be anonymous or will I have to identify myself?
The survey is completely anonymous. While we will ask some questions about your demographics (ex. race, age, income, preferred relationship), nothing will be able to identify you as the person submitting the responses. In fact, Mosie will be sending the invitations, but our external primary investigator will be the one receiving the results in a completely separate database that can never be linked.

Do you want both of us to participate by filling out a survey? Or do you have a preference about who fills it out?
We would prefer to have the person who was inseminated respond to the survey. But if they are not able to fill it out, you are welcome to fill it out on their behalf.

Can I forward the link to a friend?
Please only forward to friends who have used the Mosie syringe. One of the reasons we are using a general link is to allow you to share it if you desire and the other is to make sure we keep your responses anonymous.

I noticed the survey is being conducted in a google form. Is my data safe?
Yes. The information you provide is transmitted safely into our Principal Investigator's custody. Access to it is password protected. The only person who will be able to access the survey data during the data collection period will be the principal investigator, who does not have access to the email list.

Is the Principal Investigator an employee of Mosie Baby?
No, the Principal Investigator is an independent consultant hired by Mosie Baby to conduct the research.

Will I be compensated for my time?
There is no cash compensation for participating in the study. However, in appreciation for sharing your experience and your time, Mosie will provide you with a discount code to be used on your next purchase. Using this discount code will not identify you as having participated in the study as we have used it before in a prior marketing campaign. We selected this code because it will help keep your participation anonymous.

What do you hope to learn from our responses?
We hope to learn about your experience using the Mosie Kit. We are studying how well people understand our instructions and the effectiveness of doing at-home insemination with Mosie Baby.

Are there any risks involved in participating in the study?
There are no known risks for participating in the study. You will be asked about your conception history which can be a trigger for some folks, and if this is too much, please know you do not have to complete the survey and can exit at any time. Please know that by exiting the survey your answers will not be submitted at all.

Why is Mosie Baby doing this study?
Mosie Baby cares about its community and wants to continuously improve to meet your fertility needs for at-home insemination. This study will provide us some valuable information about the product and your experience.

How is this clinical research study different from a marketing survey?
Marketing surveys focus on people's purchasing behaviors. This clinical research study focuses on your experience with Mosie and the experience of others like you. The purpose is to understand your interaction with and use of the kit, the ease of use, identify any concerns over safety, understand the rates of pregnancy, and what if anything people are doing that could be beneficial when doing at-home insemination.

Additionally, this study has been reviewed by an Independent Review Board who has determined that the study has been designed to protect your rights as a participant and will in no way endanger you. The study is also registered with clinicaltrials.gov.

Will the results be published?
We do plan to analyze and publish the results. We hope that the information we gain will not only be valuable for Mosie, but also to the whole fertility industry. There is very little research on the effectiveness of at-home insemination so this study will definitely add to the general knowledge about its effectiveness.

Can I withdraw at any time?
Yes. You have the right not to participate and the right to withdraw at any time. One of the reasons the google forms was selected is that if you choose to end your participation before submitting the survey, none of the data will be posted into the database. If you choose to stop mid-survey you can close your browser and no data will be recorded.

What happens if I stop the survey somewhere in the middle?
Only completed surveys where the user clicks the Submit button at the end of the survey end up posting to the study database. Be sure to click submit when you are done to send the information to the database.

Can I get my name taken off the list of reminders as I already completed the survey or decided not to participate?
Absolutely, please send an email to mosie@mosiebaby.com to be taken off the list. In the email simply include the title: Remove from SURVEY list.

There is no need to provide any additional information. That way, we won't know if you participated or not. Note: This will not take you off Mosie's regular mailing list, that takes a separate request.

How many surveys do you hope to get?
We hope to get around 500 completed surveys. This will allow us to analyze the data and have strong significance in our findings.

How long do you think it will take to get all those surveys?
Our Mosie community is very engaged. We strongly believe we can have all the needed surveys within 30 days. However, if more time is needed, we can continue to receive responses.

What if I have additional questions about this survey? Is there anyone I can call?
Yes. You can call the Principal investigator directly, her contact information is at the top of this page as well as below.

Karina Loyo, Ph.D., MBA, CCDM
512-630-0990
karina@drkarina.com

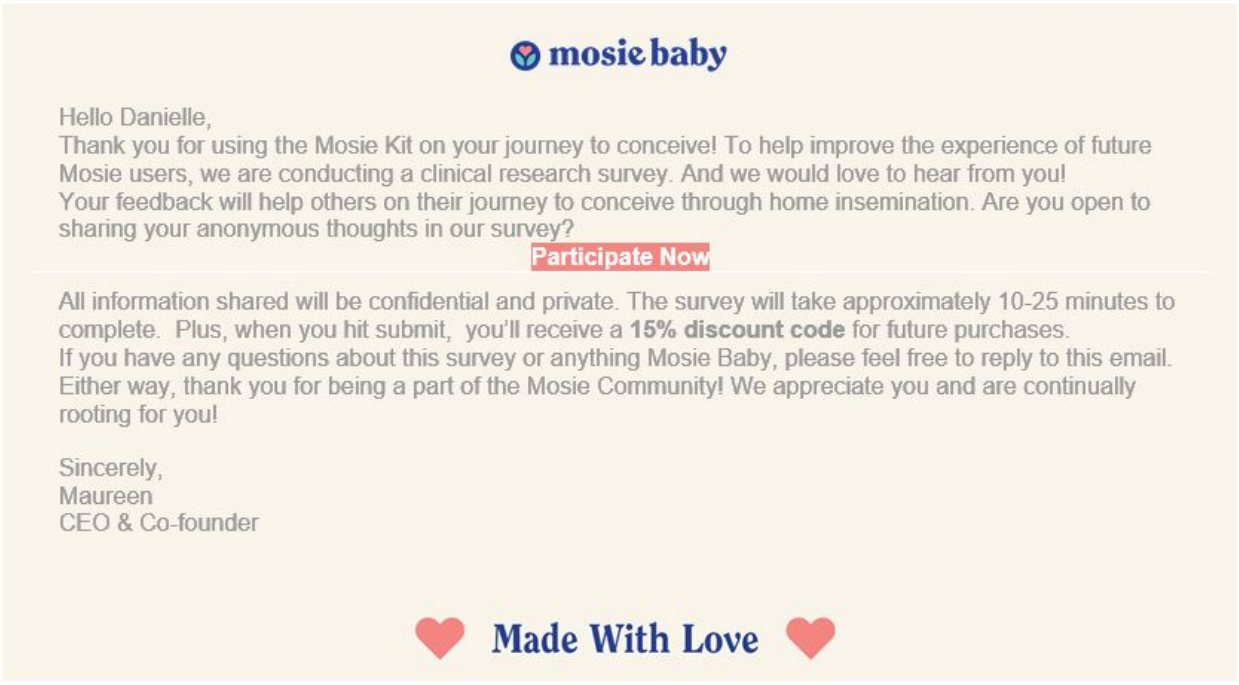
Appendix C:
Participant Recruitment Emails

This section contains samples of the participant recruitment emails.

Note: These are samples. Final language and appearance might be tweaked.

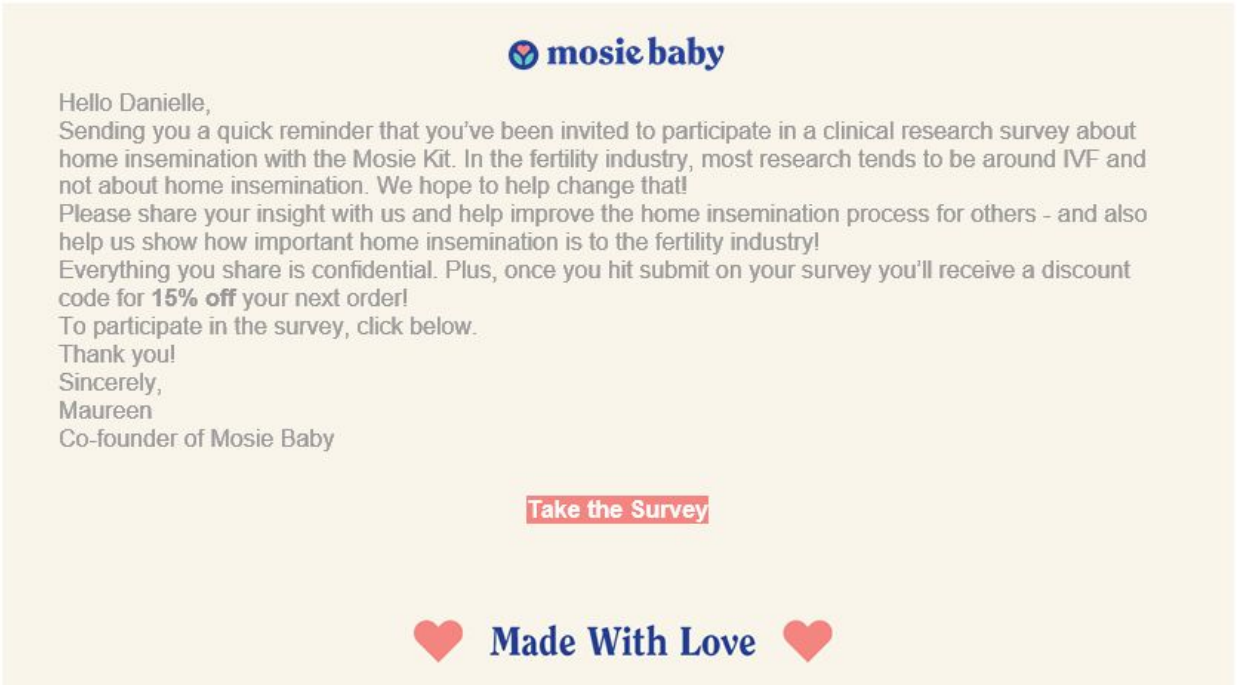
Initial Email

From: Mosie Baby <mosie@mosiebaby.com>
Subject: [PREVIEW] Tell us what you really think
Date: July 30, 2020 at 2:18:03 PM CDT
To: Danielle <mo@mosiebaby.com>



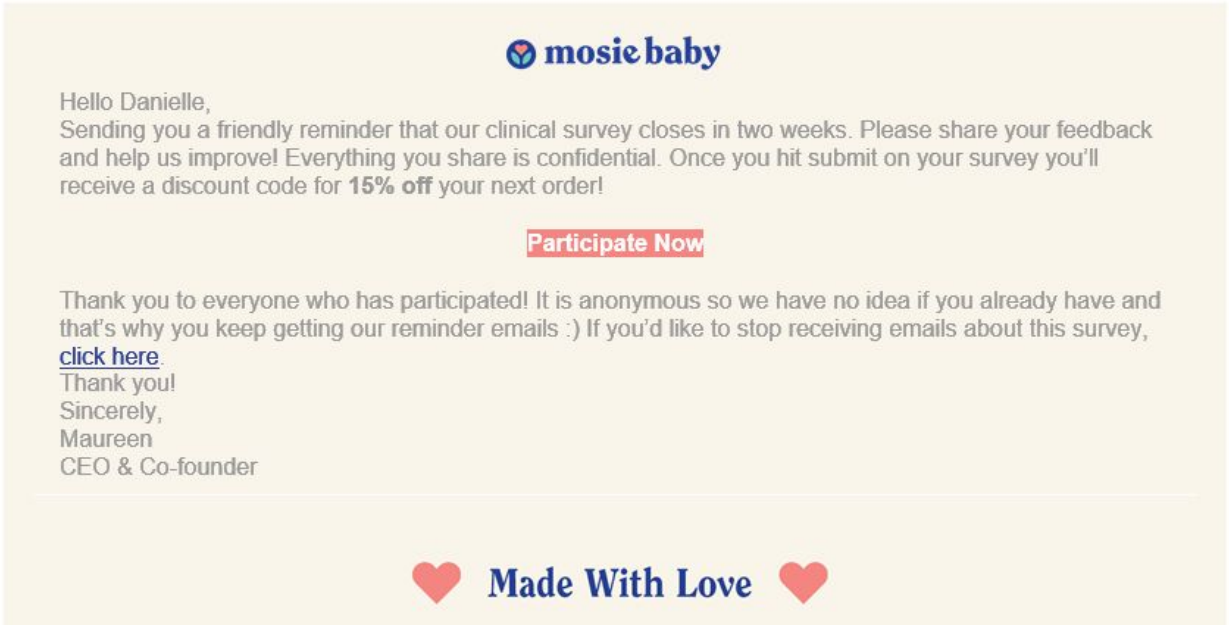
Second email (approximately 1 week later)

From: Mosie Baby <mosie@mosiebaby.com>
Subject: [PREVIEW] Help Us Make Mosie Baby Even Better!
Date: July 30, 2020 at 2:21:11 PM CDT
To: Danielle <mo@mosiebaby.com>



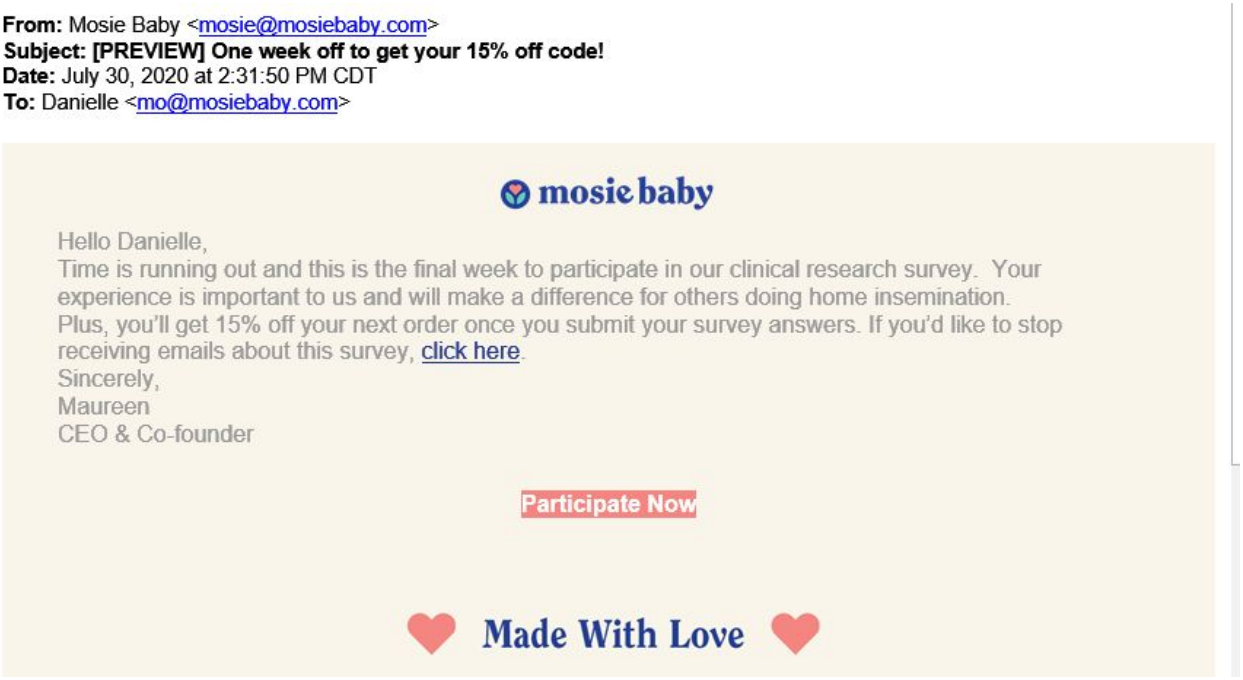
Third Email (approximately 2 weeks after initial email)

From: Mosie Baby <mosie@mosiebaby.com>
Subject: [PREVIEW] Two weeks left to share your feedback privately
Date: July 30, 2020 at 2:39:12 PM CDT
To: Danielle <mo@mosiebaby.com>



Fourth email (third week)

From: Mosie Baby <mosie@mosiebaby.com>
Subject: [PREVIEW] One week off to get your 15% off code!
Date: July 30, 2020 at 2:31:50 PM CDT
To: Danielle <mo@mosiebaby.com>



Final email reminder (approximately 24 hours prior to study close)

From: Mosie Baby <mosie@mosiebaby.com>
Subject: [PREVIEW] LAST CHANCE for 15% off!
Date: July 30, 2020 at 2:34:45 PM CDT
To: Danielle <mo@mosiebaby.com>