UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: MOMSonLINE2

Company or agency sponsoring the study: None
Names, degrees, and affiliations of the principal investigator and study coordinator (if applicable):

Principal Investigator: Katherine J Gold, MD, MSW, MS, Department of Family Medicine and Department of Obstetrics & Gynecology; University of Michigan
Study Coordinator: Martha Boggs, BS, CCRC, Department of Family Medicine, University of Michigan

1.1 Key Study Information

You may be eligible to take part in a research study. This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or other doctors about joining this study. If you decide to join the study, you will be asked to sign this form (by clicking accept on this webpage at the end) before you can start study-related activities. Before you do, be sure you understand what the research study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about diseases and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

This research is studying what moms who have had the loss of a baby think about participating in a free, anonymous online support group. If you are in the study, we will ask you to sign on to an online support group at least three times a week for six weeks. We will ask you to look at the postings but you do not have to post yourself if you don't want to. We will also ask you to fill out two short surveys and do a phone interview with us to tell us about. This will hopefully lead to better ways to provide support to mothers after a stillbirth or infant death.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, the main risk includes feeling sad or upset as you think about your baby and read postings in the online group.

This study may offer some benefit to you by helping you feel less alone and more supported by other women in the same position as you. For some women, the study may not offer any benefit now but may benefit others in the future by giving moms a way to get continued support.

The time in the study will be six weeks of going online followed by one phone interview scheduled at your convenience.

You can decide not to be in this study. Alternatives to joining this study include continuing with your usual support and your medical team.

Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues in Section 2 of this document.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

We know that losing a baby through stillbirth or early infant death is typically devastating for families. We do not know if internet on-line support for parents helps them manage their grief more easily. We are doing a small 6-week pilot study to see how research participants feel about an internet support site after a stillbirth or infant death and how we can make it better for a much larger future study. This study is too small to look at whether women participating in a group like this feel better at the end than women who don't, but it is important for us to find out if we can recruit women to a program like this and to see what participants like and don't like about the study so we can make it better.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

You must be 18 or older and a woman of color (non-Caucasian) and/or of Hispanic ethnicity. If you are biracial or multiracial you can participate. You must be able to read and write English and have lived in Michigan at the time you delivered your baby.

3.2 How many people are expected to take part in this study?

We estimate up to 75 women will participate.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

We will ask you to join a community group on an existing site called BabyCenter.com. BabyCenter runs hundreds of anonymous community groups including one for people who have had a pregnancy or infant loss.

If you do not already have a BabyCenter account and screen name, you will be asked to create one. You get to pick a screen name so you can be anonymous to others on the support group. We will ask you to share your name, screen name and email address so we can track your usage (how many times you go to the support site and if you post). The study team and the staff at BabyCenter will be the only ones to see this information

It is important for us to know how often people in the study choose to sign on to the support group and what their experiences are. We will ask that you sign in to the BabyCenter site and STAY SIGNED IN by checking a box to keep you signed in on your desktop/laptop computer or any mobile phone apps you use to access the site. The information we will collect includes: when you sign on to the support group, if you post, and if you visit other pages in the group on BabyCenter.com. We will not be tracking information about any other activities on your computer. We ask you to sign on to the BabyCenter support group a minimum of three times a week to read the posts, but it is completely up to you whether you choose to post yourself when you sign on. BabyCenter does have several group moderators who make sure users follow group rules (for example, not selling anything and not being abusive to other users).

The study coordinator will call you after you consent to participate in this study to help answer any questions. She will also call you approximately half way through the study to check in. There will be one final phone call, scheduled at a time that works for you, to complete a phone interview. In the phone interview, we will ask what you thought about the online group and any improvements that can be made. We will text you approximately three times a week to help you remember to sign in to the support group. BabyCenter sends out a "daily digest" email to anyone who participates in their group which simply notifies you of new activity in the group.

We will ask you to fill out an online survey at the beginning and the end of the study. These ask about how you are feeling, a little about the type of loss you had, and your thoughts about social media support and support groups.

The phone interview at the end of the study will be audio recorded. This will then be transcribed. Only the study team members will have access to the audio recording and the recording will be destroyed after it has been transcribed.

How much of my time will be needed to take part in this study?
We expect that you will spend at least 30 minutes each week on the study for the six weeks that you go online. If you choose to spend more time reading on BabyCenter or post responses online, you may, but this is up to you. We estimate the phone calls and online surveys will take less than five minutes each. The phone interview at the end will take 15-30 minutes and will be scheduled at a time which is good for you. The entire study will take 7-8 weeks depending on how quickly we are able to schedule the final phone interview.

4.3 When will my participation in the study be over?
Your participation will end after 6 weeks in the BabyCenter support group and the follow-up phone interview. You can also leave the study at any time without penalty. If you want to stay in the support group after the study ends, you are welcome to do so but we will no longer be tracking your use.

4.4 What will happen with my information used in this study?
Your collected information will be shared with BabyCenter so that they may be able to improve their online support groups as well as to help us run this study. This will be shared anonymously and BabyCenter will not able to link the information we share with them back to you. BabyCenter is a commercial company that has their own privacy policies which applies to the usage of their site.

Your private information may be stripped of information which would identify you (we will assign an anonymous study ID number but not use your name or information about you) and used for future research studies.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

You may feel sad or uncomfortable when you read information about coping with loss or read messages from other parents who have lost a baby. Many mothers have told us that although they do feel sad, they are already thinking about their babies and it can be helpful to have other people who can support them and to know they are not alone. Although you are able to use a screenname and remain anonymous on BabyCenter there is a small risk of loss of confidentiality.

The researchers have tried to minimize these risks by using a site which has experienced moderators and by allowing you to contact the study team if you are uncomfortable. You can choose to sign on at times which are convenient for you as the sites are open 24 hours a day. As with any research study, there may be additional risks that are unknown or unexpected. All of your activity on the study website, your responses to the survey questions and the length of time in which you spend on the support group sites will be protected by a dedicated server within the University of Michigan that is password-protected and has firewalls in place to block access from people who are not on the study team, even if they work at UM.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?
You will be given ways to contact the study team if you have concerns. The team has experience working with families with loss and includes a physician who specializes in this. The team may be able to assist you in finding support options which are closer to where you live, if needed. Should you have any concerns about the moderation of or content found within the group, please reach out to BabyCenter.com .

5.3 If I take part in this study, can I also participate in other studies?
Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?
You may not receive any personal benefits from being in this study. However, many parents report that communication with other parents who lost a baby helps them feel less alone and parents who use these sites have reported they are helpful. Many parents also find it rewarding to support others. This pilot is simply to see if mothers will participate in the groups.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?
Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?
Participating in this study is completely voluntary and you may stop at any time. You may reach out to your medical team to explore other support group options.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?
You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 "Contact Information".

7.2 Could there be any harm to me if I decide to leave the study before it is finished?
No.

7.3 Could the researchers take me out of the study even if I want to continue to participate?
Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?
There are no costs to the study other than the cost of SMS text messages received or sent by your phone or expenses for using email or internet services if you have these. We are providing payments to participants which are meant to help cover any unexpected costs like these. By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?
You will be paid up to $50 for completing all sections of the study. We are testing two possible ways you could earn the $50 and will assign you to one of these two options at random when you sign up for the study. You do not have a choice on which payment option you receive but both groups can earn the same amount of total money. You will be paid only for the parts of the study you complete.

Option one:
-$10 for completing the initial study survey
-$10 for completing the final study survey
-$30 for completing the final phone interview.

Option two:
-$5 for each week (for 6 weeks) that you sign on to the BabyCenter support group at least three times.
-$20 for completing the final phone interview.

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8.3 Who could profit or financially benefit from the study results?
The research team has no financial interest or benefits from this study. You will not receive any proceeds, profits, or other benefits from any commercial product that may result from this study in the future. BabyCenter.com is a commercial site which does include advertisements on their site. However,

they will not get any direct financial benefits from this study and they are providing their assistance to help the study free of charge.

The company whose product is being studied: BabyCenter

9. CONFIDENTIALITY OF SUBJECT RECORDS

The information below describes how the confidentiality of your research records will be protected in this study.

9.1 How will the researchers protect my information?
Any information about you, including this signed virtual consent form, will be stored on a password-protected hard drive which is on a secure server at the University of Michigan. This server is also protected by firewalls to restrict network access to the servers. Only study team members have access to this data. When you access the study website, content is transmitted securely using the Transport Layer Security (TLS) protocol, the same protocol used to protect financial and other personal information when transmitted from a web site to a user's browser. This prevents anyone else on the network from intercepting and viewing the content that is being provided by or to you.

BabyCenter.com can tell when registered users go to their site and what they do on the site as long as they are logged in when visiting the site. They have their own privacy policies for how they protect and use this data. For this study, the study team will let BabyCenter know the screen names of our study participants and then BabyCenter will let the team know when you go to their site and if you post. The study team will not share personal information about you or your loss with BabyCenter.

A description of this clinical trial will be available on http://www.clinicaltrials.gov/. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

9.2 What information about me could be seen by the researchers or by other people? Why? Who might see it?
Signing this form gives the researchers your permission to obtain, use, and share information about you specifically for this study, and is required in order for you to take part in the study.

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study

- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

9.3 What happens to information about me after the study is over or if I leave the study before it is finished?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have left the study.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

9.4 When does my permission expire?

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Dr. Katherine J. Gold
Mailing Address: Department of Family Medicine/Department of OB&GYN
1018 Fuller Street, Ann Arbor, MI 48104-1213

Telephone:	(734) 998-2249
Email:	ktgold@umich.edu
Study Coordinator:	Martha Boggs, BS, CCRC
Mailing Address:	1018 Fuller Street, Ann Arbor, MI 48104-1213
Telephone:	(734) 998-4412
Email:	haabme@umich.edu

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.
When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?
You are welcome to print this document so that you have a copy for your records.

12. SIGNATURES

Please Initial in this box to show that you are willing to have your final phone interview recorded as outlined in Section 4.1. This is only used to be sure we can accurately capture what you say.

By clicking on the 'I Accept' button below, you are giving an electronic signature of participation in the study. There is no actual paper that you will need to sign.