# Informed Consent Form

Group Interventions for Abused, Suicidal Black Women

IRB Approval Date: November 7, 2022

NCT00601939

IRB00045774
IRB Approved
11/7/2022



**Emory University School of Medicine – Grady Health System**
**Consent and Authorization to be a Research Subject**

**Title**: Group Interventions for Abused, Suicidal Black Women

**Principal Investigator**: Nadine Kaslow, Ph.D.

**Introduction/Purpose:**

We are asking you to volunteer to be in a research project. The research is for African American women who have been abused by a partner and who have made a suicide attempt. We have asked you to be in the study because you are between the ages of 18 and 64 and have been seen at Grady Health System for health or mental health reasons. The purpose of this study is to learn what would help other women. Each woman will be in the project for about 15 months. Over the course of three years, we will survey about 400 women.

**Procedures:** The project will include:

1) **Screening** - A research team member will meet with you for about 20-30 minutes and ask you questions to see if you can be in the project.

2) **Survey** - If you can be in the project, a research team member will give you a survey at Grady Health System. This person will ask you questions about your life events, concerns, feelings, and thoughts. The team member will read 28 questionnaires to you. This will take about 2 hours. After you complete the questionnaires, we will talk to you for about 30 minutes to an hour about the types of treatment for you. We will also talk to you about reasons you may not be able to be in treatment. After you finish this survey, we will ask you to come back in a week to complete a second one hour survey.

3) **Treatment -** After the survey, you will be put in one of two groups by chance. Like flipping a coin, you will have a 50-50 chance of being put in either group. In one group, you will get health care at Grady Health System. In the other group, you will get health care at Grady Health System, *and* we will ask you to attend 10 weekly group meetings with up to 12 other women at Grady Health System. Each meeting will last 90 minutes and will be led by research team members. These meetings will be videotaped and/or audio-taped. The purpose of the tapes is to monitor the therapists' treatment of you. These videotapes will not be used to diagnose you. We will not transcribe the tapes. We will destroy the tapes after viewing. We will call you on 4 occasions to see how you are feeling. We will also help you get resources that you may need. You will have access to our Resource Room.

4) **Post-treatment survey and three follow-up surveys.** Within one week of the first survey, we will contact you again to complete a survey about mental health concerns and your views on life and relationships. We will then survey you three more times, for a total of 5 surveys. These surveys will be completed as follows:

   (1) 10 weeks after the first survey or after you have completed the treatment group
   (2) 6 months after the second survey
   (3) 6 months after the third survey

Each of the follow-up surveys will take about 2 hours to complete. The purpose of the follow-up surveys

is to let us know how, if at all, you were helped. The survey allows us to compare the two groups to learn which is most helpful for women.

**Risks:**

It may be hard to talk about your life events, feelings, worries, or concerns. You do not have to answer any questions that make you feel uncomfortable. If you become upset by anything in the survey or the group sessions, have safety concerns, or if you feel suicidal, you will be able to talk with someone who can help you. There is some chance that the treatments you receive will not be helpful to you. Since the study takes time, your partner may find out about it. We will not tell your partner. If you are in the group that meets for 10 weeks, we will establish group rules to ask people not to talk about group outside of group. Since this study will test a new therapy, there may be risks or discomforts that are not yet known.

**Benefits:**

You may not benefit from this study. Our research team hopes to learn new things that may help others in a similar situation. We hope you will benefit from this research by having the chance to share your thoughts and feelings, and by learning about ways of coping and getting community resources.

**Alternatives:**

You may choose not to participate in this project and to receive counseling or medications at your local community mental health center or from a mental health professional in the community.

**Protected Health Information (PHI):**

*Protected health information (PHI) is any health information that identifies you. The researchers may need to look at your study record that contains PHI. Government agencies that make rules about how research is done have the right to review these records. Sponsors also have the right to review records. We may also have to share records if court ordered.*

*We will not use or share your records in any ways other than the ways we describe in this form. We will keep your records private to the extent allowed by law. We will do this even if outside review of your records occurs. We will use a study number or other code rather than your name on study records where we can. Your name and other facts will not appear when we present this study or publish its results. Information regarding a suspicion of child or elder abuse or neglect will be reported to the Department of Family and Children's Services.*

*Under the Health Insurance Portability and Accountability Act (HIPAA), we must provide you with information about what PHI will be used and how it will be used and shared. This section of this form provides you with this information regarding your PHI. If you decide to volunteer, then you will be agreeing to let the researchers and any other persons, companies or agencies use and share your PHI for the study. Please review this section very carefully.*

*What PHI will the Research Team Use:*

*The researchers will request your name, patient identification number, medical records number, and birth date. The Researchers will also ask about your medical and mental history. They will record your response in your research file. None of this information will go into your Grady medical/billing records.*

*Who will Collect the PHI:*

*The Researchers will collect the PHI described above. If any of the PHI is to be shared with other persons, then the Researchers will be responsible for sharing the PHI*

*Purpose, Use and Sharing of PHI*

*The PHI will be used by or shared with the following persons, agencies or companies for the purposes listed in the chart below:*

| *Person/Entity* | *Purpose* |
|---|---|
| *Researchers* | *Researchers will conduct the study to find out which treatments are most helpful to women who are abused and suicidal.* |
| *Governmental Agencies including the Office for Human Research Protections* | *To monitor safety and compliance with laws and regulations.* |
| *Emory University personnel, committees and departments including the Institutional Review Board and the Office of Research Compliance* | *To monitor safety and compliance with laws, regulations and University policies and procedures.* |
| *Grady Health Systems personnel, committees and departments including Grady Research Oversight Committee* | *To monitor safety and compliance with laws, regulations and Hospital policies and procedures.* |
| *National Institute of Mental Health, National Center for Injury Prevention and Control* | *To provide oversight for the study.* |
| *Statisticians hired by the study sponsor.* | *To perform data analysis.* |

*Expiration Date or Event:*

*The Researchers will add your PHI to a database. After data has been collected, your Consent will expire and your PHI will no longer be used.*

*Your Right to Ask Us Not to Use Your PHI Any More:*

*At any time, you have the right to ask the researchers not to use or share your PHI. If you make this decision, the researchers may no longer be able to provide you with treatment, but your decision will not affect your current or future health care. There will be not be a penalty or loss of any other benefits.*

*If you decide that you do not want your PHI shared or used, you may complete and sign the letter you receive with your copy of this Consent Form. If you need another copy of this form, you may ask the researchers to provide you with one. When we receive your signed letter, we will not make any other use of your PHI or share it with anyone else, except study sponsors and regulatory bodies. We will not ask the study sponsor, governmental agencies or other parties to return any data we provided before you signed the letter. After we receive your letter, we will still provide the study sponsor, regulatory bodies and any other parties with any data necessary for the research. We will provide any governmental or University personnel,*

*departments or committees with any data they may need to follow laws, regulations or policies. These agencies may also need the data to adverse events.*

*Signature and Date:*

*The Researchers will ask you to sign and date this form.*

*PHI May be Re-disclosed:*

*If we share your PHI to one of the other parties described above, that party might further share your PHI to another party. If your PHI is further shared, then the information is no longer covered by HIPAA.*

*Clinical Trials Statement:*

*A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. 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.*

**Payment:**

You will be paid for your time and inconvenience for completing each of the surveys and group meetings that you attend. You will be paid $25 for the first survey, $25 for the second survey, $35 for the third survey, $45 for the fourth survey and $55 for the fifth survey. If you are in the group that attends group meetings, you will be paid $15 for each meeting you attend. Childcare will be provided for your children during the group meetings. The money paid to you will thank you for your participation and assist you with transportation.

**Costs:**

There will not be any cost to you for being in this study.

**Emory University and Grady Health System Disclaimer:**

We will arrange for emergency care if you are injured by this research. Emory University and Grady Health System have not set aside funds to pay for this care if an accident occurs.

**Contact Persons:**

If you have any questions about this study or believe you have been injured by this research, contact Dr. Nadine Kaslow at [redacted], the Principal Investigator for the Project. Call or email the Emory University Institutional Review Board at (404) 712-0720 or (877) 503-9797 or irb@emory.edu if you have any questions about your rights as a research participant in this study. If you are patient receiving care from the Grady Health System and you have a question about your rights, you may contact the Office of Research Administration at research@gmh.edu.

**New Findings:**

We may learn new things during this study that you may need to know. We can also learn about things that might make you want to stop being in this study. If so, you will be notified about any new information.

**Voluntary Participation:**

Your participation is completely voluntary. You have the right to refuse to be in this study. You can stop at any time after giving your consent. This decision will not affect your current or future medical care or any other benefits. The study investigator may stop you from taking part in this study at any time if they decide it is in your best interest. You may also choose to participate in the study, but not want have any birthday cards or interview reminders mailed to you. If you do not want mail sent to you, you can ask us to check the "do not send mail line" on your contact page.

We will give you a copy of this consent form to keep.

If you are willing to volunteer for this research, please sign below:

| | | |
|---|---|---|
| **Subject's Printed Name** | | |
| **Subject's signature** | **Date** | **Time** |
| **Witness** | **Date** | **Time** |
| **Person Obtaining Consent** | **Date** | **Time** |