

**Memorial**  
**Hospital of South Bend**  
*Quality of Life*

Jamie Reinebold, MSW  
Prenatal Care Coordinator  
Memorial Hospital  
South Bend, IN

June 11, 2008

Dear Ms. Reinebold:

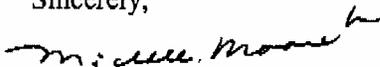
This letter acknowledges the completed review of protocol, "**Foundations for Alcohol Cessation; Education and Support (FACES)**". As you know, the full board review of this protocol was initiated on June 4, 2008.

As Chair, it is my pleasure to inform you that the revised protocol, (including Appendix A through F), and new consent form, have been approved for an initial one year period beginning June 11, 2008 and expiring June 10, 2009. Memorial Hospital operates in accordance with federal regulations; our assurance number is FWA 0005819.

Please be advised that a progress report will be required at the end of the approval period or the completion of the study, whichever occurs first. For your convenience, I have enclosed a copy of the Progress Report Form. Although unlikely, the IRB must be notified of significant adverse events that are felt to be protocol-related.

Thanks you for your interest in conducting research at Memorial Hospital. If you are in need of additional information, please feel free to contact me at 647-3468.

Sincerely,



Michelle Moore, RPh  
Chair, IRB



Program ID \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

**FACES Program**  
Demographics/Release/IRB Consent

Client Name \_\_\_\_\_ DOB \_\_\_\_\_

Address \_\_\_\_\_ Zip Code \_\_\_\_\_

Phone \_\_\_\_\_ Contact \_\_\_\_\_

EDC \_\_\_\_\_ Phone \_\_\_\_\_

**Consent for Release of Information**

- I give consent for the FACES Program, a part of Memorial Health System, to release and/or exchange information from physicians, agencies and other programs for which I may qualify.
- I also give consent for data collected during my program participation to be released to funding sources.
- Information that may be shared includes:  
 Past Medical Information    Current Medical Information    Social Support Information  
 Current Nutritional Information    Substance Use Information    Summary of current services
- I understand this information is confidential, and only the information for which I give consent will be shared. The data shared with the funding source will remain confidential, with no identifying information released. This information is to be used only to verify program effectiveness and outcomes.
- I understand this consent form is good for one (1) year from this date unless I revoke this permission in writing.

Client Signature \_\_\_\_\_ Date \_\_\_\_\_

Parent/Guardian If under 18 years \_\_\_\_\_

Witness \_\_\_\_\_ Date \_\_\_\_\_

**The IRB Consent form on the back of this document  
must be signed by all participants at intake.**

Program ID \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

**FACES Program**  
Demographics/Release/IRB Consent

**Program Participant:**

By signing this document I acknowledge that I have been given a copy of the FACES IRB Consent. The FACES program goals and procedures have been explained to me. No guarantees have been made regarding the results of my participating in this program. I will receive a signed copy of this consent form for my records.

I agree to participate in the FACES project. My participation is voluntary and I do not have to sign this form if I do not want to participate.

Signature of Participant: \_\_\_\_\_

Date: \_\_\_\_\_ Time: \_\_\_\_\_ AM/PM (circle)

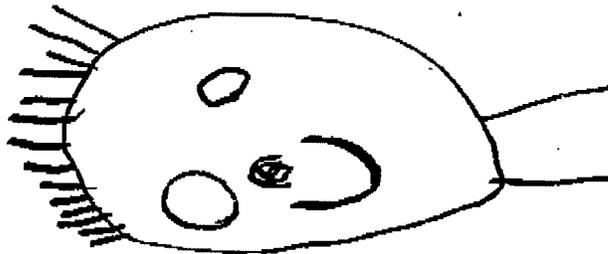
**Person Obtaining Consent**

I have explained to \_\_\_\_\_ the nature and purpose of the FACES project and the risk involved. I have answered and will answer all questions to the best of my ability. I will give a copy of this consent to the participant.

Signature of Person Obtaining Consent: \_\_\_\_\_

Date: \_\_\_\_\_ Time: \_\_\_\_\_ AM/PM (circle)

# FACES



IRB Consent  
Information

**Study Title:**  
Foundations for Alcohol Cessation;  
Education & Support (FACES)

**Primary Investigator:**  
Jamie Reinebold, MSW  
**Phone:** (574) 647-1354  
**Address:** Memorial Hospital WIC  
325 N. Lafayette Blvd  
South Bend, IN 46601

You are being asked to participate in a program designed to help pregnant women refrain from alcohol use during pregnancy. This consent form describes the project procedures, the risks and benefits of participation and how your confidentiality will be maintained. Your participation is voluntary. Please take the time to ask questions to become comfortable in making the decision whether or not to participate. This process is called informed consent. If you decide to participate in this project, you will be asked to sign a release form.

**Why is this project being done?**

The purpose of this study is to help pregnant women refrain from alcohol use during pregnancy. Alcohol use while you are pregnant can cause harm to your baby's brain and other organs. Many women are unaware that alcohol use during pregnancy may be harmful to their babies.

**How many people will take part in this project?**

All pregnant women initiating services in the St. Joseph County WIC program will be screened for alcohol use. Any woman who has a history of alcohol use during pregnancy is eligible to participate.

**What is involved in this project?**

All pregnant women will be screened for alcohol use by the nutritionists in the WIC offices. Any woman who reports any amount of alcohol use since conception will receive a second screen. A short educational workbook will be reviewed. Women who are at risk for alcohol abuse or addiction will be referred to the Perinatal Exposure Prevention Program (PEPP) for further referral to treatment. Women at low risk will be contacted by a FACES educator on a monthly basis and asked about recent alcohol use. A brief survey will be sent to your home after your baby is born asking about the baby's weight and length.

**How long will I be in the study?**

You will be contacted by a FACES educator once a month until you are 36 weeks pregnant. A brief survey will be sent to you after you have delivered your baby.

**What are the risks of this study?**

The risks are minimal. The funding source has asked that reports be sent to them twice a year. This information is used to determine the effectiveness of the program. All information about your history of alcohol use will be kept confidential. Your chart will be locked in a file cabinet. Your name will not be used to transfer any data.

**What are the benefits to taking part in this program?**

You may earn up to four BABE coupons for participating. The educators and staff of the FACES program will offer you support and referrals to community resources if you need them.

**What options are there?**

You may choose not to participate. The decision whether or not to participate will not affect your care at Memorial Hospital or your eligibility in the WIC program.

**What are the costs to participate?**

There is no cost to you or your insurance company.

**Will I be paid to participate?**

You will not be paid to participate. You may earn up to four BABE coupons for participating.

**What about confidentiality?**

The FACES program will not include your name or any other identifying information in the data sent to the funding source. Your chart will be kept in a locked file cabinet and will be accessible only to the FACES staff. By signing the release form, you are allowing the project team access to the information they gather during your participation in the project. The project team includes the investigator and FACES educators.

If you should qualify for a referral to the PEPP program, you will be informed before the referral takes place and you will have the option to refuse contact with any referral source.

**What are my rights as a participant?**

Taking part in the FACES project is voluntary. If you choose not to participate neither your care at Memorial Hospital will be affected nor will it change your eligibility to receive WIC benefits. You may choose not to participate at any time during the project. Leaving the project will not affect your care at Memorial Hospital or change your eligibility in the WIC program.

If you choose to leave the program, you must inform the investigator in writing at the address on the first page. The investigator may still use your information that was collected prior to your written notice.

**Who do I call if I have questions?**

You have been given an outline of the project through your conversation with the FACES educator. If you have further questions you can ask them directly or you can call Janie Reinhold, MSW at 674-1354.

If you have any questions regarding your rights in this project you may contact the Institutional Review Board, which is concerned with the rights of individuals in research programs and projects concerning vulnerable populations. You may contact the IRB chair, Michelle Moore, R.Ph. anytime Monday through Friday by calling (574) 647-3468 or by writing: Institutional Review Board, Memorial Hospital and Health System, 615 N. Michigan, South Bend, IN 46601.

**A copy of the signed consent is attached.**