IRB MOTHER PREMATURE INTERACTION DURING FEEDING: OBSERVATIONAL STUDY

BY. HARYATININGSIH PURWANDARI



INFORMED CONSENT FOR RESPONDENT

Name of principles investigator Advisor		Haryatiningsih P. Prof. Huang, Mei-Chih
Name of organization	:	Jurusan Keperawatan, FIKES, Unsoed, Purwokerto
Name of sponsor	:	_
Name of proposal and version	:	Mother premature interaction during feeding: Observational study

PART I. INFORMATIONAL SHEET

- INTRODUCTION
 - WE ARE STUDENTS FROM AHS, NCKU, TAINAN, TAIWAN.
 - WE ARE DOING RESEARCH ON BEHAVIOR OF MOTHER AND PRETERM DURING FEEDING.
 - PREMATURE BABIES ARE BORN BEFORE 37 WEEKS OF GESTATION.
 - THE MAIN PROBLEM PRETERM TREATED IN HOSPITAL IS FEEDING PROBLEM.
- PURPOSE
 - WE WILL INVESTIGATE BEHAVIOR OF MOTHER AND PREMATURE DURING FEEDING IN HOSPITAL SETTING.

TYPE OF RESEARCH

- OBSERVATIONAL STUDY.
- WE WILL CAPTURE YOUR INTERACTION WITH YOUR BABIES DURING FEEDING SITUATION USING CAMCORDER.

PARTICIPATION SELECTION

- WE WILL SELECTED MOTHER AND PRETERM BABIES WITH AGE START FROM 34 WEEK OF GESTATION, THE BABY WHO HOSPITALIZED, ALREADY INITIATE WITH ORAL FEEDING.
- WE WILL SELECT ALL SUBJECT THAT ELIGIBLE IN THIS STUDY, DURING COLLECTION DATA.
- WE ARE INVITING YOU TO TAKE PART IN THIS RESEARCH BECAUSE IT IS
 IMPORTANT TO KNOW BEHAVIOR FROM MOTHER AND PRETERM DURING
 FEEDING. USING THIS STUDY, WE WILL KNOW YOUR QUALITY OF
 INTERACTION BETWEEN YOU AND YOUR BABY.
- BECAUSE YOUR BABY IS PRETERM AND HOSPITALIZED, WE AREA ASKING IF YOU WOULD ALLOW YOUR BABY AND YOU TO PARTICIPATE.



- YOUR CHOICE TO HAVE YOUR BABY AND YOU PARTICIPATING IN THIS STUDY IS ENTIRELY VOLUNTARY. IT IS YOUR DECISION WHETHER YOU AND YOUR BABY WILL JOIN OR NOT IN THIS STUDY.
- IF YOU CHOOSE TO NOT CONSENT IN THIS STUDY, ALL SERVICES YOU
 AND YOUR BABY IN HOSPITAL NOT CHANGING AND WILL CONTINUE.
- YOU MAY ALSO CHOOSE TO CHANGE YOUR DECISION AND STOP PARTICIPATING, EVEN IF YOU AGREE EARLIER, AND THE SERVICE FOR BOTH OF YOU IN HOSPITAL WILL CONTINUE.

PROCEDURE

- OBSERVATIONAL STUDY
- RESEARCHER WILL SELECT TIME BASED ON YOUR PREFERENCES (CONSIDER WITH FEEDING TIME IN THIS INSTITUTION).
- LOCATION TO TAKE VIDEO IN FEEDING ROOM, PERINATOLOGY WARD, RSMS.
- YOU WILL ASK TO GIVE YOUR BABY MILK (BOTTLE FEEDING OR BREAST FEEDING), AN EXPERT CLINICAL PRACTICE WILL ACCOMPANY YOU DURING THIS PROCESS.
- THE INTERACTION PROCESS DURING FEEDING WILL BE CAPTURE USE CAMCORDER.
- THE VIDEO WILL BE STORE IN PC AND ONLY RESEARCHER WILL ACCESS THE FILM.

DURATION

• THIS RESEARCH TAKES 1 MONTH IN TOTAL. FOR EACH SUBJECTS, WE JUST CAPTURE YOUR INTERACTION DURING FEEDING IN ONE EVENT OR ONE TIME (NOT MORE 1 OUR).

SIDE EFFECT

NO SIDE EFFECT

RISK

- FOR PRETERM IN 34 WEEKS, THEY ALREADY HAVE CAPABILITY TO ORAL FEEDING.
- BUT WE OUGHT TO PREPARE WITH <u>RISK FOR ASPIRATION</u> → PRESENCE EXPERT CLINICAL PRACTICE TO ACCOMPANY THIS FEEDING PROCESS.
- CLINICAL PRACTICE WILL IDENTIFY THE BEHAVIOR DURING FEEDING PROCESS→ TO PREVENT RISK.
- IF BABY HAVE A CHOKE→ A EXPERT CLINICAL PRACTICE WILL IMPLEMENTED PROTOCOL TO SOLVE THE PROBLEM (HELP TO BURP, POSITIONING, GIVE O2, ETC.)

DISCOMFORT

- BY PARTICIPATING IN THIS STUDY IT IS POSSIBLE THAT YOU AND YOUR BABY MAY EXPERIENCE DISCOMFORT SUCH AS YOU AND YOUR BABY NOT COMFORTABLE IN FEEDING SITUATION BECAUSE PRESENCE SOMEONE WHO CAPTURE YOUR INTERACTION OR CLINICAL PRACTICE.
- ANTICIPATING THIS SITUATION, WE ASSURE THAT PERSONAL WHO CAPTURE YOUR INTERACTION OR CLINICAL PRACTICE IS WOMEN. THE PRESENCE OF OTHER WOMEN IN FEEDING ROOM WILL BE MADE COMFORTABLE.

BENEFITS

- IF YOU AND YOUR BABY PARTICIPATING IN THIS RESEARCH, BOTH OF YOU WILL GIVE BENEFIT.
 - 1. YOUR QUALITY OF INTERACTION DURING FEEDING WILL BE IDENTIFIED.
 - 2. YOU WILL KNOW HOW TO IDENTIFY THE PRETERM INFANT FEEDING CUES.
 - 3. YOU WILL KNOW YOUR BEHAVIOR WHEN DEALING WITH PRETERM SIGNAL AND EVALUATE IT.
 - 4. YOUR SENSITIVITY TO INFANT CUE WILL BE IMPROVE→ YOU KNOW HOW TO DEAL WITH INFANT'S CUE.
 - 5. BABY WILL GET APPROPRIATE RESPONSE FROM MOTHER (DURING FEEDING)-→EFFECTIVE FEEDING→ SMOOTH FEEDING PROCESS → REGULATORY

REIMBURSEMENTS

BECAUSE YOU AND YOUR BABIES TAKE APART IN THIS RESEARCH, YOU
WILL BE REIMBURSED WITH MONEY IDR 40.000 (EQUAL NTD 100) AND
YOU WILL PROVIDE WITH SNACKS DURING TAKE VIDEO.

CONFIDENTIALITY

THE INFORMATION THAT WE COLLECT FROM THIS STUDY WILL KEEP
CONFIDENTIAL. INFORMATION ABOUT BOTH OF YOU WILL PUT AWAY
AND NO ONE BUT RESEARCHER WILL BE ABLE TO SEE IT. THE NAME WILL
BE CODE USING NUMBER AND ONLY THE RESEARCHER KNOW THIS
CODE. ALL INFORMATION WILL BE KEEP IN THE LOCKER USING KEY.

SHARING OF THE RESULTS.

 THE INFORMATION THAT WE GET FROM THIS RESEARCH WILL BE SHARE WITH YOU BEFORE IT IS MADE WIDELY AVAILABLE TO PUBLIC.
 CONFIDENTIALITY INFORMATION NOT BE SHARED. AFTER THIS, WE WILL PUBLISH THE RESULTS.

RIGHT TO REFUSE OR WITHDRAW

- IF YOU CHOOSE TO NOT CONSENT IN THIS STUDY, ALL SERVICES YOU AND YOUR BABY IN HOSPITAL NOT CHANGING AND WILL CONTINUE.
- YOU MAY ALSO CHOOSE TO CHANGE YOUR DECISION AND STOP PARTICIPATING, EVEN IF YOU AGREE EARLIER, AND THE SERVICE FOR BOTH OF YOU IN HOSPITAL WILL CONTINUE.

WHO CONTACT

- IF YOU HAVE QUESTION, PLEASE CONTACT US (HARYATININGSIH PURWANDARI, JURUSAN KEPERAWATAN FIKES UNSOED, +62-81227935441, ADDRESS: GEDUNG KEPERAWATAN, JL. DR. SOEPARNO, KARANGWANGKAL, PURWOKERTO, EMAIL:HARYOETI.UNSOED@GMAIL.COM.)
- IF YOU WANT TO KNOW ABOUT IRB, PLEASE CONTACT BIOETHICS UNIT, MEDICINE FACULTY, UNSOED (JL. DR. GUMBREG NO. 1, MERSI, PURWOKERTO 53112 | DEPTBIOETIK.FKUNSOED@GMAIL.COM | +62-281-622022 EXT.101).

PART II. CERTIFICATE OF CONSENT

 I HAVE READ THE FOREGOING INFORMATION, OR IT HAS BEEN READ TO ME. I HAVE HAD THE OPPORTUNITY TO ASK QUESTION ABOUT IT AND ANY QUESTIONS THAT I HAVE ASKED HAVE BEEN ANSWERED TO MY SATISFACTION. I CONSENT VOLUNTARY FOR ME AND MY BABY TO PARTICIPATE AS SUBJECT IN THIS STUDY.

PRINT NAME OF PRETERM

PRINT NAME OF MOTHER

SIGNATURE OF MOTHER

DATE: DAY/MONTH/YEAR

Thank for your attention