

**Consent and Authorization Document**  
**iNEST: International Natural Procreative Technology Evaluation**  
**and Surveillance of Treatment for Infertility and Miscarriage**  
**International Institute for Restorative Reproductive Medicine (IIRRM)**  
**University of Utah, Department of Family and Preventive Medicine**

**Center ID#** \_\_\_\_\_

**Physician** \_\_\_\_\_

**Couple ID#** \_\_\_\_\_

**BACKGROUND**

Infertility is a common problem. Natural procreative technology (NPT) is an approach to the treatment of infertility that seeks to identify abnormalities of the woman's reproductive cycle (menstrual cycle), and where possible, correct them by medical intervention. An integral part of the approach is teaching couples to monitor the signs and symptoms of the fertility cycle with the Creighton Model FertilityCare System. NPT has helped many infertile couples get pregnant, but formal evaluation of the outcomes of NPT in medical practice has been limited to studies based in individual medical practices.

The purpose of this study is to evaluate live birth rates among couples who are treated by NPT for infertility and miscarriage. Comparisons will be made to those declining NPT treatment, waiting for NPT treatment, receiving other treatment, or stopping treatment. We seek to document specific pregnancy rates for different factors such as age and type of infertility diagnosis. We will also assess characteristics of environmental exposures that may be associated with infertility. Couples will be followed for up to three years, regardless of when they begin NPT treatment, or whether they continue treatment. This study is being conducted in multiple practices in different countries. We are seeking the broadest possible participation from couples who are considering NPT treatment. Data from all couples will be useful for this study, regardless of their individual circumstances or actual treatment.

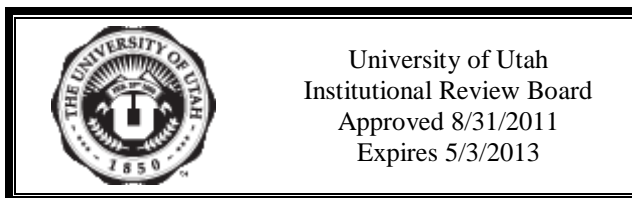
**STUDY PROCEDURES**

The clinical care given by your physician will be performed as usual, and will not be altered by this study.

If you agree to participate, we will collect information from you in three ways:

- 1) Questionnaires. These will be done at entry to the study, on an annual basis for the next three years, for any pregnancy, or whenever you exit the study. Questionnaires may be done by mail, email, web, or telephone. Each questionnaire has a woman's and a man's version, except the pregnancy questionnaire, which only has a woman's version. Each questionnaire will take approximately 30-45 minutes to complete.
- 2) Your own Creighton Model fertility charts.
- 3) Information about NPT treatment from the medical records of your NPT physician(s).

This data collection will continue for three years after your enrollment into the study.



We will keep track of all information, including information needed to contact you at the Study Center at the University of Utah Department of Family and Preventive Medicine, Division of Public Health . All information will be kept confidential. No personal information will be released to anyone outside the study. Results from all centers will be combined to be used for the analysis in this study. The summary analysis and reporting of data will make it impossible to identify any individual from the data.

### **RISKS**

Whether or not you enroll in this study will not change the NPT treatment that you receive. There are no special risks for this study beyond the inherent risks of any NPT treatments you undergo, which will be discussed with you by your physician as appropriate. Risks for participation in this study include the loss of time in responding to the questionnaires and potential discomfort in answering specific questions. You may choose not to answer any question that you wish.

### **BENEFITS**

If you wish, you may be able to access summary data about your own NPT treatment online through the secure study website. Your participation will help generate information about specific pregnancy rates and outcomes that will benefit future couples considering NPT treatment.

### **ALTERNATIVE PROCEDURES**

Your alternative to participating in this study is simply not to participate. Whether or not you enroll in this study will not change the NPT treatment that you receive, or your choice to pursue any other treatment.

### **CONFIDENTIALITY**

To ensure the confidentiality of study participants, all applicable laws pertaining to confidentiality will be observed. We will keep all research records that identify you private to the full extent allowed by law. Each participant will be assigned a unique study identification number that will be used for identification within the study database. Your identifying and contact information will be kept separately in a password-protected computer that is accessible only to authorized study personnel.

Information from your questionnaires may be shared with your NPT physician who is participating in this study, except for specific items that are identified in the questionnaires

Results of the study may be published; however, your name or other identifying information will not be contained in published materials. Only group data, not individual data will be reported in publications.

### **PERSON TO CONTACT**

The principal investigator (person in charge) of this study is Dr. Joseph B. Stanford, at the University of Utah, Department of Family and Preventive Medicine, in Salt Lake City, Utah. If you have questions, concerns, or complaints about this study, or if you feel you have been harmed by participating, you may call Dr. Stanford. Dr. Stanford can be reached at (1) 801-587-

3331. If you call during non-business hours, you can leave a message on Dr. Stanford's voicemail at any time (24 hours a day). Dr. Stanford can also be reached by email at [joseph.stanford@utah.edu](mailto:joseph.stanford@utah.edu). You should generally receive a response back within 2 business days.

### **INSTITUTIONAL REVIEW BOARD**

Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (1) 801-581-3655 or by e-mail at [irb@hsc.utah.edu](mailto:irb@hsc.utah.edu).

### **RESEARCH PARTICIPANT ADVOCATE**

You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at [participant.advocate@hsc.utah.edu](mailto:participant.advocate@hsc.utah.edu).

### **VOLUNTARY PARTICIPATION**

Your participation in this research is completely voluntary. If you refuse to participate, you will still receive exactly the same quality of medical care that you currently receive from the University of Utah Medical Center and any of its affiliated outpatient facilities. If you do decide to participate you still have the right to withdraw from the study at a future date. This will not affect the relationship that you have with the investigator or staff, nor the standard of care you receive. Refusal to participate or the decision to withdraw will involve no penalty or loss of benefits to which you are otherwise entitled.

### **COSTS AND COMPENSATION TO PARTICIPANTS**

1. You will each need to spend up to 30-45 minutes to complete each questionnaire associated with this study. You will receive questionnaires when entering the study, on an annual basis, for any pregnancy, and whenever you exit the study.
2. You will need to make copies of your Creighton Model charting available to your NPT physician to be sent to the Study Center.
3. You will each receive \$20 for completing the annual questionnaire, \$20 for the pregnancy questionnaire (woman only), and \$10 for the exit questionnaire.

### **NEW INFORMATION**

Sometimes during the course of a study, new information becomes available about the treatment that is being studied. If any findings develop during the course of the study which may reasonably relate to your willingness to participate in this study, these findings will be communicated to you.

### **NUMBER OF PARTICIPANTS**

This study is a multi-national study anticipated to enroll up to 1000 participants (500 couples) total each year for up to 20 years. The number enrolled at each individual practice site will vary according to the size of the local practice.

## **AUTHORIZATION FOR USE OF YOUR PROTECTED HEALTH INFORMATION**

Signing this document means you allow us, the researchers in this study, and others working with us to use information about your health for this research study. You can choose whether or not you will participate in this research study. However, in order to participate you have to sign this consent and authorization form.

This is the information we will collect and use to contact you for the questionnaires in the study:

- Name
- Address
- Telephone number(s)
- Email
- Other contact information
- Government identification number (such as Social Security Number in USA), if you choose to provide it
- Name and contact information of a close friend or relative

You may choose to provide as little or as much of the above information as you wish. We will keep it completely confidential and use it to contact you for questionnaires and link to information from your NPT physicians' medical records.

This is the health information we will collect from you by questionnaires and use for the study:

- Personal medical history, including fertility and reproductive history
- Current and past medications or therapies that may impact fertility
- Height and weight
- Information from your Creighton Model fertility charting
- Your own attitudes and opinions about your NPT treatment
- All treatments or interventions you receive or do yourself to try to get pregnant or maintain pregnancy
- Health information about the course and outcomes of pregnancy (including, but not limited to, type of delivery, sex of baby, birth weight), as provided by you directly, or as obtained from medical records of your NPT physician(s).

Others who will have access to your information for this research project are the University of Utah's Institutional Review Board (the committee that oversees research studying people) and authorized members of the University's workforce who need the information to perform their duties to ensure integrity of the research.

If we share your information with anyone outside the University of Utah Health Sciences Center, you will **not** be identified by name, social security number, address, telephone number, or any other information that would directly identify you, unless required by law. An identification number will be used as a reference number for anything that leaves the office. We will keep the key to the identification numbers on a password protected computer within the research center.

You may revoke this authorization. **This must be done in writing.** You must either give your revocation in person to your NPT physician, or mail it to Joseph B. Stanford, MD, MSPH, 375



Chipeta Way, Suite A, Salt Lake City, UT 84108, USA. If you revoke this authorization, we will not be able to collect new information about you, and you will be withdrawn from the research study. However, we can continue to use information we have already started to use in our research, as needed to maintain the integrity of the research.

This authorization does not have an expiration date. After you sign this, you will be given a copy with your signature.



**CONSENT**

I confirm that I have read and understand this consent and authorization document and have had the opportunity to ask questions. I will be given a signed copy of the consent and authorization form to keep. My participation in this study will continue for up to three years after the date I sign this form, *regardless of when I start actual NPT treatment or how long I continue with it*, unless I withdraw from the study.

**I agree to participate in this research study and authorize you to use and disclose health information about me for this study, as you have explained in this document.**

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Participant's Signature (female)	Participant's Name (female)	Date Signed
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Participant's Signature (male)	Participant's Name (male)	Date Signed
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Signature of Person Obtaining Authorization and Consent	Name	Date Signed
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**SEPARATE CONSENT FOR FUTURE STUDIES**

This study is for a three-year period. In the future, we may wish to conduct long-term outcome studies, for example of the children born under NPT treatment, or of the long-term health outcomes of women who received NPT treatment. May we contact you beyond the three-year period of this study to tell you about opportunities to participate in future studies?

Yes, you may contact me after 3 years to offer the opportunity for additional participation in studies

No, but you can ask my physician to contact me

No, please do not contact me after 3 years

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Woman's Signature	Date
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Man's Signature	Date
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**CONTACT INFORMATION:**

Please provide the following contact information. We will keep this information completely confidential and use it to find you for follow-up questionnaires in this study, or (if you have indicated on the previous page) to notify you about future studies. This information is voluntary.

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Woman's Full Name Man's Full Name

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Current Mailing Address City State/Province Postal Code Country

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Permanent Address (if different from above) City State/Province Postal Code Country

**Woman's Contact Information:**

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Home Phone Cell Phone Work Phone Other Phone

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Primary Email Address Secondary Email Address (if applicable)

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Date of Birth Country/Government Identification Number

**Man's Contact Information:**

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Home Phone Cell Phone Work Phone Other Phone

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Primary Email Address Secondary Email Address (if applicable)

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Date of Birth Country/Government Identification Number

In the event that you move and we are unable to locate you, please provide the name and contact information of a relative or friend we would be able to call and who could give us your contact information. Upon calling this person, we would only divulge that you participated in a University of Utah Study and that we need to contact you for follow-up.

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CONTACT PERSON PHONE NUMBER

