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**DIPARTIMENTO DI SCIENZE STATISTICHE**

via C. Battisti, 241  
35121 Padova  
tel +39 049 8274168  
fax +39 049 8274170  
dipstat@stat.unipd.it  
dipartimento.stat@pec.unipd.it  
CF 80006480281  
P.IVA 00742430283

**DATA BANK: FERTILI, BILLINGS, BARRETT-MARSHALL, LONDON and VICENZA**

The data bank may be accessed by **researchers working within Universities, Institutions and Research institutions, members of Scientific Associations and staff of Centres for the Natural Regulation of Fertility.**

To access any file in the bank, the Applicant shall:

- 1) send the Director of the Department of Statistical Sciences the Application Form (facsimile A), which shall be signed by the Licensee or (for Institutions with legal personality) by a legal representative, specifically describing the statistical and scientific purposes for using the data, and enclose a detailed research project, drawn up according to the guidelines of Art. 2 of the Agreement for use of the databases.
- 2) the Director of the Department of Statistical Sciences, supported by a Commission of experts appointed to this specific aim, shall examine the project. Upon acceptance of the Licensee's Application, the Director will send the Licensee the Agreement for access to the Data Bank.\*
- 3) the Applicant shall accept the provisions of the Contract for the use of the Data Bank by signing and sending to the Director of the Department the Acceptance Form (facsimile B) and the Research Protocol (facsimile C). Acceptance form and Research Protocol shall be signed by all persons involved in the relevant research.

**\*Art. 2 Research requirements**

1. Research **must comply with the objectives stated in Enclosure 1**, and must be carried out on the basis of the project to be drawn up according to the relevant sector-related methodological standards also in order to prove that the processing is performed for suitable, actual statistical or scientific purposes.
2. The project, referred to in paragraph 1, shall contain the following: Title of the Research Project, Name of the Scientific Coordinator of the Research Project, Names of the Members of the Research Group, Description of the Research Project, Objective of the Research Project, Methods of Analysis and Duration of the Research Project. The project shall additionally:
  - a) specify the measures to be adopted in processing personal data with a view to ensure respect for the Italian Code of conduct as well as for personal data protection according to Italian legislation;
  - b) designate the data processors, if any;
  - c) contain a statement whereby the entities concerned undertake to abide by the provisions of the Code. A similar statement shall also be rendered by the entities –researchers, data processors and persons in charge of the processing-- involved in the relevant research (facsimile C).

### Objectives of the Study

The objective of the study is to estimate the probability of conception following intercourse on each day of the cycle as a function of the distance from the first day of temperature shift, its peak or other symptoms of the mucus (ovulation method). Presence or absence of mucus, its characteristics, the woman's age, use of contraceptives over the previous 6 months, etc., will be taken into account.

In family planning and infertility management, accurate estimation of fecundability on different days of the cycle through usual home indicators like basal body temperature and mucus would prove important from various points of view, particularly in natural fertility regulation.

The knowledge of the duration and occurrence of the "fertile" phase, the probability of conception on each day, and the fecundability pattern within the cycle enable:

1. to compare the reliability of different methods commonly used to determine the "unsafe" period according to objective evidence devoid of the confounding factor of differential behavioural components;
2. to compare the acceptability of these methods in terms of duration of the abstinence period at the same rate as possible failures;
3. to find methods with shorter periodical abstinence linked to a given control of uncertainty deriving from biological variability;
4. to provide indirect estimates of the reliability of physical or biological devices and all other fertility detection methods;
5. to propose and test new algorithms associated with the more usual clinical indicators either separately or jointly: basal body temperature and mucus;
6. to verify the probability of conception associated with different types of mucus;
7. to evaluate the sensitivity of the calculated parameters of fecundability by comparing the results drawn from evidence collected in different centres;
8. to provide a differential estimate of the said parameters for distinct categories of subjects;
9. in fertility management. to choose the optimal days of treatment.

(from Fecundability Study / October, 1993)