

# FIVNAT

Commission of the Swiss Society for Reproductive Medicine (SSRM)

## Regulation

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### I. Name and seat

FIVNAT is a commission of the Swiss Society for Reproductive Medicine (SSRM) and has the same legal seat.

### II. Objectives

Its objectives are:

- 1 Collect data to establish annual statistics about the ART techniques of affiliated Swiss IVF centers
- 2 Develop and promote the quality of the data register
- 3 Organize and overview the audits defined by FIVNAT – on a voluntary basis. Support the cantonal doctors in the inspections of the Swiss IVF centers required by Swiss Law
- 4 Cultivate a close contact with other national registers in the world
- 5 Transmit the Swiss statistical data after validation to interested parties (the world registry, Swiss Academy for medical sciences, European and international registries, patient-organisations, and other)
- 6 Transmit the Swiss statistical data after validation to the Swiss Federal Bureau of statistics.
- 7 Publish the global statistical data and its interpretation via the European IVF Monitoring (EIM/ESHRE) in Human Reproduction and via the International Committee Monitoring Assisted Reproductive Technologies (ICMART) in Fertility and Sterility
- 8 Create a platform for members to reach higher standards and better quality by encouraging medical and biological quality control
- 9 Manage the list of the centers, which as members of FIVNAT are carrying out medically assisted procreation (IVF and related procedures) in Switzerland
- 10 Secure the registration of data via computerized methods

### III. Membership

- 1 Membership is open on a free basis to all centers which are in the possession of the cantonal authorization to practice IVF and related procedures in Switzerland and fulfill the following conditions:
  - a) A physician, which fulfills the requirements according to Art. 2 of the FMedV must be the head of the center
  - b) Each center needs to have a head of the laboratory that fulfills Art. 2 of the FMedV.
  - c) The head of the center as well as the head of the laboratory must be SSRM member
- 2 Centers are defined as organizational entities which have received from the official cantonal authorities the authorization to practice reproductive medicine according to Art. 2 of the FMedV.
- 3 Private practices who work together with one laboratory are considered as one center
- 4 In case of cooperation between different clinicians with one laboratory, the laboratory is regarded as the center and will thus receive a FIVNAT number. Each physician who is involved with this specific laboratory will be attributed a FIVNAT sub-number
- 5 Application  
The application form - together with the signed FIVNAT regulations - must be sent to the Office. The FIVNAT Board decides about the application and their decision is forwarded to the applicant. FIVNAT does not have individual members, only IVF centers can become members.

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#### Member exclusion (center)

A member can be excluded from FIVNAT by the following:

- Serious violation against the FIVNAT regulation upon decision of the FIVNAT Board  
The reason for exclusion is explained in a written report by the FIVNAT Board to the member concerned.  
The authority for appeal is the SSRM Board of the SSRM
- A center having lost its official authorization to practice reproductive medicine is excluded automatically.
- Nonpayment of the annual cycle fee despite two reminders

#### **IV. Organisation**

FIVNAT is organized as follows:

a: Members (centers)

b: FIVNAT Board

c: Statistician

d: Administrative Manager

e: Ombudsman

f: Auditors

#### **a. Members**

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##### Annual meeting

- Each year an annual meeting will be held, to which all active collaborators of the centers are invited.
- Each center has one vote, regardless of the number of sub centers or cycles. Each center will receive one voting card at the beginning of the annual meeting.
- The invitation to the annual meeting must be sent 4 weeks prior to the meeting

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##### Voting procedure

- Voting in writing is acceptable when an annual meeting cannot take place
- Election and voting are agreed upon simple majority vote of the members present. In case of equality of votes the president has the deciding vote.
- Voting by proxy is not acceptable

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##### The annual member meeting has the following task and competences

- approve minutes of the annual meetings
- approve annual report by the FIVNAT president
- propose FIVNAT Board member candidates for election by the SGRM Board
- propose changes on the FIVNAT regulations
- propose a candidate for the ombudsman position
- propose candidates for the position of FIVNAT auditor
- discuss extraordinary expenses above CHF 50.000

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##### Duties of the members

The member centers of FIVNAT commit themselves to the following:

- accept these regulations
- submit to FIVNAT all data requested by FIVNAT for the preparation of the statistical analyses
- accept the principal of internal and external audits
- keep a log book with consecutive numbers of all cycles of patients, which undergo an IVF, ICSI or cryo cycle (starting at stimulation)
- pay the yearly cycle fee upon receipt of an invoice
- submit to FIVNAT Office a list of all active collaborators
- submit all data via the FIVNAT owned online software tool in order to transmit them to the Swiss Federal Office of Statistics. The data can be entered manually online or imported from already existing local programs of the centers.
- participate on a regular basis at the annual meeting of FIVNAT

5 Rights of the members

- Receive a certificate of membership to FIVNAT and additionally receive a certificate of the performed external audit
- Receive a confidential report once a year. This report includes the results of the center and of the national data, including a summary of the data as well as a list of the cycles submitted to FIVNAT. For subcenters, the individual results are put into relation to their respective center and to the national data.
- Receive the yearly report with the global statistical data via the SGRM Website
- Participate in all FIVNAT meetings.
- Receive all official documents of FIVNAT such as minutes of the meetings, regulations etc.

6 Documents

6.1 Documents in relation to FIVNAT

All documents will be sent to the head of the center and to the head of the laboratory.

The distribution among the collaborators in each center is the responsibility of the center itself

6.2 Documents in relation to the FIVNAT registry (online software) are sent to all registered users of the software.

b. **FIVNAT Board**

The Board consists of

- the President (member of the SSRM Board)
- the President elect
- and a maximum of 7 additional members

1 The President of FIVNAT is member of the SSRM Board and is elected by the SSRM General Assembly  
2 The other members of the Board are proposed by the FIVNAT member meeting and approved by the SGRM Board

3 The FIVNAT Board members are elected for 3 years; re-election twice is possible

4 The position of president can only be held for 3 years

5 The FIVNAT Board is composed by members coming from private practice, representatives from public hospitals and University clinics. An equal distribution among the language region must be taken into account.

6 All FIVNAT Board members must be active in a FIVNAT center

The duties of the Board are

1 Mandate the independent statistician to perform statistical analysis of the data

2 Mandate the independent statistician to send a (confidential) report to each center once a year including summary of the data as well as a list of the cycles submitted to FIVNAT

3 Mandate the independent statistician to write a yearly report, which is being presented at the annual meeting of FIVNAT. This report includes the following:

- List of FIVNAT centers
- Global statistical results of all member centers

4 To organize one or more FIVNAT meetings, of which one must be the annual meeting

6 Transmit the global statistical, anonymized statistical data to the following:

- Board SSRM
- European and International registries
- Swiss Federal Office of statistics

7 Organize and supervise the FIVNAT audits

8 Propose an administrative manager for the daily business of FIVNAT. It is acceptable to propose the administrator of the SSRM.

9 Appoint Auditors and sign contracts after approval by the SGRM Board

10 Appoint the Ombudsman

11 Edit the annual report by the FIVNAT President for publication in the SGRM organs (Website, etc.)

12 Proposition of third parties (statistician, etc.)

13 Discuss the SGRM – FIVNAT budget

14 Propose to the SGRM Board all necessary improvements in the field of IT.

## Board meetings

Several Board meetings can take place every year

The Board meetings are headed by the President in his absence by the President elect

The FIVNAT Board has a quorum if at least 5 Board members are present

Voting is done by majority vote of the Board members present

Voting can also be done in writing on any topic, provided that no Board member requests oral discussion

### Executive Board – Statistician, Administrative Manager and Ombudsman

The statistician and the administrative manager carry out their respective duties and in addition they attend the Board meetings with no right for voting

They are the only persons together with the Ombudsman to have access to the identification of the centers and are therefore entitled to contact the individual centers on behalf of the FIVNAT Board or under other circumstances

They have no access to patient's identifications such as First name and Last name

They are all three bound to medical secrecy

## V. **FIVNAT Audits & Auditors**

1 An audit every second year with or without the cantonal doctor will be organized

2 The FIVNAT Board will receive a summarized - anonymized report

3 The FIVNAT Board may ask for further information about an audit if circumstances require such steps

4 Auditors should not be active in any Swiss IVF center

5 The Auditors are financed by FIVNAT

## VI. **Ombudsman**

The ombudsman duty is to contact a center in confidentiality in which the statistician has found an irregularity in the data submission

At the annual meeting an anonymous report is presented by the Ombudsman if a given center does not follow the propositions made by the ombudsman, the annual member meeting will decide on the measures to be taken.

The position of the ombudsman is without compensation, only travel expenses are reimbursed

The ombudsman must be physician and not be involved or active in any Swiss IVF center

The ombudsman is elected for 3 years and can be re-elected twice

## VII. **Financing of FIVNAT**

1 An entrance fee of CHF 3.000.-- is required for each new center. If a new subcenter is founded within an existing center an entrance fee of CHF 500.—is required.

2 The participating centers must pay an annual fee to the SGRM which is determined according to the cost coverage principle.

The amount is paid pro rata of the numbers of the cycles performed in the preceding year per cycle initiated. Charged are fresh and cryo cycles.

3 The minimal amount is CHF 10.00 and the maximum amount is CHF 25.00 per cycle. Within this frame the FIVNAT Board shall determine the fee on an annual basis.

4 The fee will be automatically raised according to the cost of living every second year; starting in 2015 for the cycles 2014.

5 The minimal participation per center is CHF 1.500.-- per year.

6 The finances of FIVNAT are managed by the SSRM; a separate account is provided and individual accounting is secured

VIII. **Additional regulations**

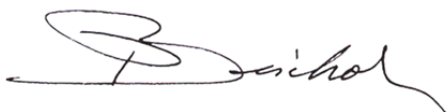
Non-Disclosure

- 1 The FIVNAT Board members, the administrative manager, the statistician, Auditors and Ombudsman are bound to medical secrecy for all aspects regarding FIVNAT. The data of the individual center are only available to the statistician, the administrative manager and to the Ombudsman.
- 2 These regulations are written in English.
- 3 Written form includes letters, fax and e-mail

These regulations have been approved by the SGRM Board and accepted at the FIVNAT meeting of November 27, 2014 in Bern and come into force immediately thereafter.

Bern, November 27, 2014

On behalf of the FIVNAT Board



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Professor Paul Bischof, President FIVNAT