



## **GUIDELINE OF COMPLIANCE**

**&**

## **CODE OF CONDUCT**

**authorized on April 12<sup>th</sup>, 2019  
at the AGM of the ISMST  
in Auckland, New Zealand**



Dedicated to: Dr. Richard Thiele

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## Introduction

ISMST is a non-profit medical and scientific association whose purpose is to support the development and research of the medical extracorporeal shockwave treatments and to improve the education and training of shockwave medical users. This society cooperates with state health authorities and public health institutions compiling statements, reports and surveys dealing with medical shockwave treatments. The society also cooperates with other medical and scientific associations with similar interests, especially with the national societies for medical shockwave treatments.

ISMST supports communication between producers, suppliers and users of shockwave devices to establish guidelines and standards for refining the use of those devices to improve clinical outcomes.

Our Financial resources comprise Membership dues, Course and Conference registration fees (including industrial sponsoring and financial contributions for social events organized in conjunction with professional meetings), donations, bequests and grants made possible and permitted by law.

The objective and the purpose of our Society since its foundation in 1997 are to promote research and development of shockwave treatments exchanging experiences with the scientific and medical community of the world and spreading the knowledge. We have endeavored on that mission so that ESWT will eventually the benefit the patients.

In striving to achieve these aims, we should not compromise our ethics or principles because Integrity and ethical conduct is at the foundations of our organization.

The Guideline of Compliance and Code of Conduct sets out our legal and ethical principles for carrying out our activities as members of the ISMST and applies to officials, members, employees and to others who act for us. It is a summary of our acting principles, and gives the information an official, member or employee needs so he/she can manage his/her activities concerning to the society. Everyone must keep to this Guideline of Compliance and Code of Conduct and the related procedures.

Basically, nothing should ever affect our commitment to honesty and integrity, and we do believe that acting with honesty and integrity is more than just keeping to the law. Those who deal with us, like the patients we treat, should also expect that we will meet accepted ethical standards. We should always behave ethically even in situations where the law is unclear or is still developing. We all count on each other to uphold these standards to make sure that we keep our reputation for honesty.

We are committed to preventing, detecting and reporting any fraud, bribery or corruption.

We are committed to a culture of innovation and trust. We are going to regularly reassess this Guideline of Compliance and Code of Conduct to improve it, and it is

possible that we will make further adjustments aimed at improving the effectiveness, recognizing that is a dynamic concept and that no Guideline can completely prevent individual persons (officials, members or employees...) for improper conduct. This Guideline of Compliance and Conduct Code will be updated and revised as appropriate.

We are committed to promptly respond to any offence undertaking the appropriate disciplinary and corrective actions.

We are committed to monitoring our conduct and taking appropriate action to discipline anybody who violates our Code of Conduct.

Finally, we encourage other people who deal with us, companies, suppliers and service providers, to adopt and maintain similar conduct and ethics principles.

## 1. Definitions:

**ISMST Officials** are members of the ISMST and nominated at the following boards:

1.1 - **Managing Board**

1.2 - **Advisory Board**

1.3 - **Financial Advisors**

1.4 – **Board of Senators**

1.5 – **Board of Honorary Fellows**

It is an honor for a member to be appointed as Official of the ISMST, even though having this position involves to fulfil its duties and to take over its responsibilities.

The members of the boards are announced at the ISMST homepage with their curriculum vitae and their disclosure statements. Their accordance is assumed and there is no separate compliance statement requirement.

The **Compliance Official at the Managing Board (COMB)** is the Official who undertakes the responsibility and authority of operating and monitoring the compliance guideline program, and will serve as focal point for compliance activities.

The **Compliance Committee (CC)** is the committee established to advise the COMB and assist in the implementation of the Compliance Guideline Program.

## **2. ISMST's Compliance General Policies**

### **2.1- ISMST's Compliance General Policies for Members**

#### **2.1.1- Members should act in ISMST's best interests and value ISMST's reputation:**

They should:

- Undertake their responsibilities and pay their dues with appropriate care and diligence.

- Deal honestly with other members, Officials, employees, industrial sponsors and other third parties.

- Behave in a way that takes into account our impact on the broader medical and scientific community in both the short and long term.

- Use all of ISMST's educational and organizational means and materials appropriately and for proper purposes.

- Not improperly disclose any information about ISMST that is not already in the public domain.

- Attempt to prevent the continuation of any unethical or illegal activity carried out by other Official, member, employee, provider or company identifying that person or company to the COMB, if there is a reasonable basis to believe so. Speaking up is the right thing to do if there is a Compliance concern.

- Speak up when becoming aware that someone is subject to retaliation for raising a Compliance concern in good faith.

#### **2.1.2- Members should act with honesty and integrity:**

They should:

- Act honestly and with integrity in a way that their honesty is beyond question.

- Adhere to the truth, and not knowingly mislead directly or indirectly or make false statements, or mislead by omission.

- Not use the name of ISMST to further any personal or other business transaction.

- Use materials, means and services provided to them by ISMST, strictly in accordance with the terms on which they are provided.

### **2.1.3- Members should treat others with respect and value difference:**

They should:

- Treat all people with whom they deal with dignity and respect.
- Never unlawfully discriminate, harass or bully anyone. This includes being sensitive to behavior that might be acceptable to them but not to others.

### **2.1.4- Members should respect and maintain privacy and confidentiality:**

They should:

- Collect, process and use personal data only to the extent that such is necessary for defined, clear and lawful purposes.
- Be sure that data are used in a way that are transparent for those concerned and observe their right to information and correction as well as to protect their right to possible objection, blocking or deleting the data.
- Respect the privacy of others.

### **2.1.5- Members should identify Conflicts of Interests and manage them responsibly:**

They should:

- Fully disclose active private or other business interests promptly and any other matters which may lead to potential or actual conflicts of interest in accordance with such policies that the Members may adapt from time to time.
- Comply with the ISMST Members Disclosure of Interest Policy and Policy for handling Conflicts of Interest.

### **2.1.6- Members should not make or receive improper payments, benefits or gains:**

They should:

- Never try to influence improperly the outcome of an official decision, for example by offering a payment or benefit that is not legitimately due. Such payments or benefits are unacceptable.

### **2.1.7- Members abide by and comply with this Guideline of Compliance and Code of Conduct, the law and applicable ISMST policies and procedures:**

- Members should be familiar and comply with all relevant laws and regulations applicable to them.
- Accordingly, Members must not take any action, or fail to take any action, that may breach the law or applicable ISMST policies, procedures or practices.
- On the other hand, Members are obligated to seek help or advice upon suspicion or legal uncertainty about the existence of corruption or white-collar crime. This advice will be provided by the COMB and the CC, or an external legal advisor if necessary.
- Members must complete all induction and education programs required of them by the MB to build and maintain their awareness and understanding of relevant laws, policies, procedures and practices.
- Members, Officials and employees should be required to sign and date a statement that reflects their knowledge of, and commitment to the standards of conduct. This attestation should be retained by the General Secretary.

### **2.2- ISMST's Compliance General Policies for Officials**

ISMST Officials, as ISMST Members, must be committed to respect and **fulfil all the General Policies assigned to the Members** at the previous paragraphs. Furthermore, simply for being honored to this nomination, they are obliged more strongly to comply with each and every of these Compliance Policies.

In addition, they should:

- Exercise any authorities responsibly and within their limits. Officials are responsible for understanding their authorities, including any relevant limits, and are accountable for how they are used.
- Not make promises or commitments they know ISMST does not intend, or would be unable, to honor.
- Ensure that confidential information relating to ISMST's MB and ISMST's operations is not given by them either inadvertently or deliberately to third parties without the consent of ISMST.
- Not improperly use information obtained by them as Official of ISMST for personal financial gain, nor to obtain financial benefit for any other person or business.

- Never accept or offer any improper payment or benefit in connection with their role as an ISMST Official.
- Never accept any gift, reward or entertainment, including discounted products, free travel or accommodation, if it could create any obligation or expectation that could conflict with their role as ISMST Official. If in any doubt, Officials should discuss the matter with the President, the COMB and the MB.
- Never try to influence improperly the outcome of an official decision, for example by offering a payment or benefit that is not legitimately due. Such payments or benefits are unacceptable.
- Officials are subject to diverse legal responsibilities and should be familiar and comply with all relevant laws and regulations applicable to them.
- Accordingly, Officials must not take any action, or fail to take any action, that may breach the law or applicable ISMST policies, procedures or practices.
- On the other hand, Officials are obligated to seek help or advice upon suspicion or legal uncertainty about the existence of corruption or white-collar crime. This advice will be provided by the COMB and the CC, or an external legal advisor if necessary.
- Officials must complete all induction and education programs required of them by the MB to build and maintain their awareness and understanding of relevant laws, policies, procedures and practices.
- Officials and employees should be required to sign and date a statement that reflects their knowledge of, and commitment to the standards of conduct. This attestation should be retained by the General Secretary.

## **2.3- ISMST's Compliance General Policies for Promoting Members.**

**2.3.1- Promoting Members should comply with each and every ISMST's Compliance General Policies for Members mentioned at the section 2.1 of this Guideline.**

**2.3.2- Promoting Members should provide appropriate education and training support for Health Professionals on using its ESWT devices.**

Promoting Members should provide appropriate education and training support to potential users of ESWT devices, consistent with legal requirements and following the updated guides, recommendations and consensus published by the ISMST.

**2.3.3 – Promoting Members must comply with all the Public Health Administrations detailed requirements relating to marketing their plans.**

Promoting Members should have policies to assure the completeness and accuracy of all the marketing materials. Promoting Members should require their representatives to adhere the law and this Compliance Guideline: they will never authorize or allow a representative or other service provider to act improperly on their behalf. Promoting Members must take all appropriate steps to ensure that marketing personnel are presenting clear, complete and accurate information to potential clients.

#### **2.3.4- Promoting Members should not violate the anti-Kickback statutes and regulations.**

Promoting Members must not offer or make improper payments (whether directly or indirectly, in cash or in kind) to any ISMST Official, Government Official or any other person, or encourage others to do so.

The restrictions on improper payments do not cover legitimate and lawful payments to Health professionals for genuine business reasons, including Arrangements.

Contracts with marketing personnel should be reviewed by legal counsel to be sure they do not violate the anti-kickback statute and other applicable statutes and regulations.

#### **2.3.5- Promoting Members conduct on Hiring relatives and other dealings.**

Promoting Members should not hire as an employee or a Third Party Representative any Immediate Family Member or an ISMST Official to encourage the ISMST Official to use or buy their devices or services or to obtain or retain business.

Promoting Members may not allow any individual whom knows to have an intermediate family relationship with any ISMST Official to act as the sales or account representative for that ISMST Official unless they have written approval from the Compliance Officer (COMB) of the ISMST.

To request approval, the Promoting Member must provide all relevant information related to the qualifications and background of the candidate and the proposed position and duties.

Other than authorized transactions in connection with their business, Promoting Members may not have any commercial dealings with any ISMST Official, Entity or organization that is owned or controlled by an ISMST Official or an Immediate Family Member of an ISMST Official, unless they have the written approval of the COMB.

#### **2.3.6. Promoting Members conduct on Meetings and Conferences**

All meetings between Promoting Members, ISMST Officials and Health Professionals must be professional and for a proper purpose.

These meetings may be promotional or other business meetings to discuss, for example, product features, sales terms or contracts, or education and training meetings available to Health Professionals to help them use their products safely and effectively.

If events involve out-of-town travel for some Officials or Health Professionals, Promoting Members may pay for their reasonable travel and modest accommodation costs in line with all relevant laws an industry Compliance Codes.

Promoting Members will not invite or pay any expense for an ISMST Official personal guest or a Health Professional guest.

Meals may be provided as a courtesy while conducting these meetings and conferences, and these invitations will be addressed only to those Officials and Professionals who actually go to the meeting.

No other expenses will be paid.

### **2.3.7- Promoting Members and ISMST Arrangements**

Appropriate Arrangements may include Consulting, Professional Meetings and speaking engagements, Teaching, Clinical Studies and Publications, License agreements, and Research, Grants and Donations.

All Arrangements are based on a documented Needs Assessment and they will be addressed to the ISMST MB (Education Coordinator and COMB).

Consultants will be selected based on the Promoting Members' Needs, the Consultant skills and experience, and sometimes, on the geographic location of the event.

Payments for consulting services must not exceed the fair market value for the services, using information on compensation from an independent organization (if feasible). The CC must review and approve the method of determining the fair market value for each geographic region. Promoting Members and their Third Party representatives may never enter into improper financial Arrangements with an ISMST Official or Health Professional to reward them for buying or using a product.

### **2.3.8.- Promoting Members and Royalties**

Promoting Members may enter into a royalty Arrangement with an ISMST Official for a product or service only if a substantial and corresponding contribution to developing the product or service has been or is expected to be made for that ISMST Official or Health Professional or by a group in which the Official or HP is involved

### **2.3.9- Grants and Donations**

Promoting Members may make Grants or Donations for educational, charitable or humanitarian purposes in line with all applicable laws, Industry Codes and this Guideline of Compliance, especially to support genuine independent medical research to advance medical science or educations, as long as the Grant has well-defined aims and milestones that are not linked to buying their products or services.

### **2.3.10- Promoting Members will cooperate actively with ISMST and Governmental authorities.**

Promoting Members will cooperate with ISMST and Governmental Authorities on exchanging information and detecting unethical behaviors, infractions to the law or actions that may breach these Compliance policies.

### **3.- Official of Compliance at the MB (COMB) & Compliance Committee**

#### **3.1- Official of Compliance, Compliance Official (COMB)**

An Official of Compliance (COMB) will be elected and appointed to the MB.

The COMB will take charge with the responsibility and authority of operating and monitoring the compliance guideline program, and will serve as focal point for compliance activities.

The elected COMB will be in charge during three years, when other new election will be held at the MBM during the annual Congress. The COMB might retain the charge if he/she is elected again.

The COMB will report directly to the President and the MB.

The COMB will have the possibility to get appropriate legal counsel when necessary.

In case of any issue comes through interfering with an ongoing inquiry the COMB should have full authority to stop that inquiry and/or the submission of data that he/she believes is problematic until the issue in question has been resolved.

The COMB should be copied on the results of all internal audit reports and work closely with board members in the areas that require certification.

The COMB should have the authority to review all documents and other information that are relevant to compliance activities, including records concerning ISMST arrangements with other parties, including employees, professionals, relevant independent contractors, suppliers, agents and companies.

The COMB will be enabled to review contracts and obligations (seeking the advice of legal counsel, where appropriate) that may contain referral and payment provisions that could violate statutory or regulatory requirements.

Duties:

- Overseeing and monitoring the implementation of the Compliance Guideline program.
- Reporting on a regular basis to the MB, the President and the Compliance Committee on the progress of implementation Compliance Guideline program.
- Periodically revising the Guideline in light of changes in the ISMST's needs and in the law and procedures of Governmental plans.
- Developing, coordinating and participating in educational and training programs that seek to ensure that all Officials, members and employees know and understand this Guideline of Compliance.

- Assisting the MB in coordinating internal Compliance reviews.
- Independently investigating and acting on matters related to compliance, including the flexibility to design and coordinate internal investigations (e.g., responding to reports of problems or suspected violations) and any resulting corrective action with Officials, members, employees, providers, agents...
- Developing policies and programs that encourage Officials, members and employees to report suspected fraud and other improprieties without fear of retaliation.
- Continuing the momentum of the Compliance Guideline program and the accomplishment of its objectives.

### 3.2- Compliance Committee (CC)

A Compliance Committee (CC) of three members will be established to advise the COMB and assist in the implementation of the Compliance Guideline Program.

After a proposal of the COMB, these three members will be elected by the MB from the board of Officials of the ISMST.

The members of the CC will not have any active commercial, financial or contractual relationship with any company related with the use, fabrication or marketing of the ESWT devices.

The elected CC will be in charge during three years, when other new election will be held at the MBM during the annual Congress. The CC members might retain the charge if they are elected again.

The COMB will manage the CC.

The CC members will be trained on the policies and procedures of the Compliance Guideline Program.

The CC responsibilities should include:

- Analyzing the ISMST's regulatory environment, the legal requirements with which it must comply and specific risk areas.
- Assessing existing policies and procedures that address these areas for possible incorporation into the Compliance Guideline Program.
- Working with appropriate Officials and members, as well as providers, to develop standards of conduct and policies and procedures that promote allegiance to the ISMST's Compliance Guideline Program.

- Recommending and monitoring the development of internal systems and controls to carry out the ISMST's policies and procedures.
- Determining the appropriate strategy and approach to promote compliance with the Guideline program and detection of any potential violations, such as hotlines and other fraud reporting mechanisms.
- Developing a system to solicit, evaluate and respond to complaints and problems.
- Monitoring internal and external audits and investigations for the purpose of identifying troublesome issues and deficient areas experienced by the ISMST and implementing corrective and preventive action.
- The CC may also address other functions as the Compliance concept becomes part of the overall operating structure and routine.

#### **4.- Settings of effective Information & Communication**

An open line of communication between the COMB and ISMST Officials, members, employees and providers is critical to the successful implementation of a Compliance Guideline Program and the reduction of any potential for fraud, abuse and waste.

The ISMST will have in place both a mechanism for the reporting of improper conduct, as well as a mechanism for more routine types of communication among the COMB, CC and the MB.

**4.1- Hot line for Reports of Potential Misconduct:** in any event, several independent reporting paths will be created for an Official, a member or an employee to report fraud, waste or abuse so that those reports cannot be diverted by other Officials, members or other personnel.

**An e-Mail address will be published on a conspicuous point at the homepage of the ISMST's webpage** so that it will be readily available to everybody.

4.2- Matters reported should be **documented and investigated promptly** to determine their veracity and significance.

4.3- A **log** should be maintained by the COMB that records such reports, including the nature of any investigation and its results.

4.4- Such information should be included in reports to the President and the CC.

4.5- Employees, Members, Officers and Providers should be permitted to report matters on a **confidential** basis. To encourage such reporting written confidentiality and non-retaliation policies should be developed and published on that point of the webpage in order to everybody be aware of these policies to encourage communication and the reporting of incidents of potential fraud. No retribution or sanction against whistle-blowers will be tolerated.

4.6.- While the ISMST should always strive to maintain the confidentiality of the reporter's identity, the policies should explicitly communicate that there may be a point where the individual's identity may become known or may have to be revealed.

## **5.- Monitoring and Auditing**

### **5.1- Internal Monitoring and Auditing**

- An effective Guideline of Compliance and Conduct Code Program will incorporate thorough monitoring of its implementation and regular reporting.

- Compliance reports created by this ongoing monitoring, including reports of suspected non-compliance will be maintained by the COMB and reviewed with the ISMST President and CC.

- The extent and frequency of the audit function may vary but will be held at least once a year.

- In particular the audits will focus on the risk areas identified earlier in this document, specially the data and information that affect payments.

### **5.2- External Monitoring and Auditing**

Depending on the situation and the risk factors an external Monitoring and Auditing may be required to obtain an adequate audit function.

**5.3- Sampling protocols:** Monitoring techniques will include sampling protocols that permit the COMB to identify and review variations from an established baseline. Significant variations from the baseline should trigger a reasonable inquiry to determine the cause of the deviation.

- If the inquiry determines that the deviation occurred for legitimate, explainable reasons, the COMB may want to limit any corrective action or take no action.

- If it is determined that the deviation was caused by improper procedures, misunderstanding of rules, including fraud and systemic problems, the ISMST will take prompt steps to correct the problem.

- Periodic (at a minimum, annual) reviews of whether the Compliance Guideline elements have been satisfied will be carried out. Such reviews may support a determination that appropriate records have been created and maintained to document the implementation of an effective Compliance program.

- Anti-Kickback and other Inducements: ISMST will periodically review its contractual documents and discussions with providers and companies to ensure that “swapping” is not occurring.

## **6.- Responding promptly to detected offenses, developing corrective action and reporting to institutions**

Violations of the ISMST's Compliance Guideline and Code of Conduct, failures to comply with applicable law, rules, instructions and other types of misconduct may threaten the ISMST's status as reliable, honest and trustworthy scientific society.

Detected but uncorrected misconduct can seriously endanger the mission, reputation and legal status of the ISMST. Consequently, it is important that the COMB and other Officials promptly investigate and take appropriate action with respect to any reports or reasonable indications of suspected noncompliance.

6.1- The ISMST will conduct a timely, reasonable inquiry into the misconduct.

6.2- If the ISMST, after having confirmed the evidence of misconduct, determines disciplinary action is warranted, it should be prompted and imposed in accordance with the society's written standards of disciplinary action.

6.3- If after reasonable inquiry the ISMST has determined that the misconduct may also violate criminal, civil or administrative law, it will report the existence of the misconduct promptly to the appropriate Government authority within a reasonable period, but not more than 60 days after determination that a violation may have occurred.

6.4- When reporting potential violations to the Government will provide all evidence relevant to the potential violation, including the impact of the potential violation on beneficiaries and any potential cost impact.

6.5- Failure to notify a violation within a reasonable period of time could be interpreted as an intentional attempt to conceal the violation from the Government, thereby establishing an independent basis for a criminal violation with respect to the ISMST, as well as any individuals who may have been involved. For this reason, the ISMST's Compliance Guideline will ensure that violations are identified quickly and promptly corrected.

6.6- If an inquiry of an alleged violation is undertaken and the COMB believes the integrity of the inquiry may be at stake because of the presence of Officials or Members or Employees under investigation, those subjects will be removed from their current activities until the inquiry is completed (unless an internal or Government-led undercover operation known to the ISMST is in effect). In addition, the COMB will take appropriate steps to secure or prevent the destruction of documents or other evidence relevant to the inquiry.

6.7- Finally, the ISMST will initiate and implement appropriate corrective action, disciplinary actions and modifications of procedures to ensure the problem does not recur.

## **7.- Grants and Donations**

7.1- The ISMST may make Grants or Donations for educational, charitable or humanitarian purposes in line with all applicable laws and this Guideline of Compliance and Code of Conduct.

7.2- Grants and Donations may only be awarded when the AGM of the ISMST, at proposal of the MB, has approved them.

7.3- The MB may ask for approval of Grants or Donations for these purposes:

- Support genuine independent medical research to advance Shockwave Medical Treatments science or education, as long as the Grant has well-defined aims and milestones.
- Charitable organizations or accredited charitable purposes, such as to support care for those in most need, patient education, public education or to sponsor events where the proceeds are aimed at charitable purposes.

7.4- The awarding of the donations must be transparent: the purpose, the recipient of the donation and the receipt for the donation from the recipient will be documented and easily verifiable.

7.5- No-charitable organizations or companies in which a member of the MB has a specific participation should never receive an ISMST donation.

## APPENDIX I:

### **.- Fees, Travel Costs and Expenses for ISMST Officials and ISMST working groups.-**

**There is no right for ISMST officials to be exempted from any fee.**

All regulations are **recommendations**, which can be withdrawn by the Managing Board and/or the Organizing Committee in case of tense and tight financial situation.

This will be communicated to all the Officials three months before the Congress

#### **A1.1- Annual fees of the ISMST membership**

Members of the Managing Board and Senators are exempted from annual fees of the ISMST membership.

#### **A1.2- Congresses**

A1.2.1- Only **members of the Managing Board** are exempted from all the participation fees at the ISMST congresses (including social events). **Senators** are exempted from the participation fees and they will be invited to the MB Dinner, but they will have to pay for other social events. **Honorary Fellows** will get similar fees. **Other Officials** attending the MBM also will be invited the MB Dinner, but they will have to pay the participation fees and for other social functions

A1.2.2- In addition, all **members of the Organizing committee** are exempted from the fees as the members of the Managing Board.

#### **A1.2.3- Spouses and accompanying persons:**

A1.2.3.1- Only **one** spouse or accompanying person from the members of the Managing Board and the Organizing Committee are exempted from the social events participation fees.

A1.2.3.2- There is no free entrance for **children** at the congress (including coffee and lunch breaks).

A1.2.3.3- At the **social events** there will be the possibility to concede a discount for children. This will be decided by the organizing committee and has to be agreed by the majority of the committee.

#### A1.2.4- **Presidential guests**

A1.2.4.1- Presidential guests have to be announced at and accepted by the organizing committee.

A1.2.4.2- **Keynote speakers** can be proposed as presidential guests.

A1.2.4.3- Presidential guests are exempted from the participation fees at the ISMST congresses (including social events).

A1.2.4.4- Only one spouse or accompanying person from each presidential guest is exempted from the social events participation fees.

#### A1.3- **ISMST Certification Course**

A1.3.1- Members of the Managing Board and all members of the Organizing Committee are exempted from the **participation fees**.

A1.3.2- Reimbursement of the “ISMST Certification Course“(= “ICC” or “ISMST-CC”) lectures: 300 €uros for each lecture (depending on the budget situation).

#### A1.4.- **Travel Costs and Expenses for ISMST working groups**

ISMST working groups are engaged with different topics (e.g. workshop, website, etc...), and those meetings are organized on different locations outside the Managing Board Meetings.

Local costs (venue, food & beverage, dinner, etc...), accommodation and traveling costs of the participants will be supported by an amount, which has to be calculated and proposed by the organizer and confirmed by the Managing Board. If the meeting is organized without debriefing at the MB Meeting, the members of the MB have to be asked (e.g. by email) and an answer has to be given by all members. The event will be supported and may start, if there is no veto by one of the MB members and the majority supports the meeting.

## APPENDIX II:

### **.- Participation at Courses and Meetings, and Cooperation with Companies -.**

#### **A2.1- Participation at Certification Courses on ESWT:**

An Official of the ISMST will not participate at **Certification Courses** organized by societies and companies other than ISMST, or ISMST in collaboration with its national allied societies, on their own or in collaboration with national health authorities.

#### **A2.2- Participation at Meetings and Encounters organized by other companies:**

An Official of the ISMST can participate as special guest at Meetings and Encounters organized by other societies, entities, organisms and companies, provided his/her expert knowledge on the technics or/and acquaintance with the use of a specific device is required. A Company also may ask or invite the ISMST to send an expert or instructor for a Meeting or Encounter on ESWT. The Education Coordinator and the Scientific Secretary, after informing the MB, will recommend an instructor among the list of instructors of the ISMST, taking in consideration geographical aspects and personal availability of them. The ISMST reserves its right to ask for a fee in these situations, which shall be decided by the MB.

In any case the following conditions, **general conditions**, must be fulfilled:

A2.2.1- The **event will never be entitled as Course**.

A2.2.2- **No Certification nor Capacitation Diploma**, other than the Attendance Diploma **will be given** to the attendants.

A2.2.3- A **CC approval is required** to attend this kind of event. The Official should **communicate** this invitation as soon as possible to the COMB, at least with 20 days of advance before the date of the event. All the data and information must be conveyed and facilitated. After consulting the CC, an answer approving or refusing this participation at the event will be given within the term of ten days.

A2.2.4- The CC will watch out that all conditions are fulfilled at the event.

A2.2.5- The Official can receive a remuneration from the organizing company for his/her participation at the event. In this case this should be declared on his/her Disclosure statements.

A2.2.6- In case of voluntarily violation of these conditions the Official can be sanctioned. The COMB, after a decision of the CC, will notify the MB of the ISMST, who will decide the sanction.

**A2.2.7- Participation at meetings from a single company for user training, for demonstration of devices and SW technology, and participation at meetings, conventions and congresses which are supported by more than one company:**

The Official should:

- Comply with the general conditions above mentioned.
- Try that the event does not interfere with the events scheduled by the ISMST, neither in date nor in place.
- Never use the logo of ISMST nor utilize its representation without obtaining the correspondent permission from the MB, or at least, from the President, the Scientific Secretary and the Education Coordinator.
- Respect the policies approved by the ISMST.
- Prevent himself from using derogatory comparisons with other companies.
- Ensure that provided opinions are non-partisan, scientifically correct and clinically accurate.
- Try to emphasize his/her interventions on the medical, scientific and technological aspects of the Shockwave Treatments and its applications, mentioning the least possible the devices brands and companies.

**A2.3- Companies as partners, whose devices are used by the ISMST Official:**

The Official should:

- Communicate to the MB, or at least to the COMB, the existence of this relationship and should keep updated his/her public disclosures of interest. Royalties and fair market reimbursement for reasonable administrative costs in conducting or participating in a scientifically sound research clinical trial are acceptable.
- Respect the policies approved by the ISMST.
- In the event there is a risk of Conflict of Interest with the ISMST this cooperation must be terminated.