

## **GUIDELINES FOR ESTABLISHMENT AND OPERATION OF PACEMAKER BANKS**

**Mission: *Making “Poor” Hearts Beat Better***

### **PREAMBLE**

Over one million people die or live a foreshortened, compromised life because they need but cannot afford a pacemaker, implantable defibrillator or cardiac resynchronization device. HEARTBEAT INTERNATIONAL, a United States based 501c3 charitable organization, desires to provide the needed devices and related medical care to as many needy patients as possible. HEARTBEAT INTERNATIONAL obtains implantable devices from the pacemaker industry and distributes them worldwide through a network of approved distribution sites herein referred to as Pacemaker Banks.

### **WHAT IS HEARTBEAT INTERNATIONAL?**

HEARTBEAT INTERNATIONAL is a United States based 501c3 charitable organization, so designated by the Internal Revenue Service of the United States. HEARTBEAT INTERNATIONAL'S governance arises from the Board of Directors who represent the diversity of the organizations and individuals that include:

1. Doctors and hospitals from both the United States and International community.
2. Members of Rotary Clubs worldwide, and other Civic organizations.
3. Representatives of the manufacturers of cardiac pacemakers in the United States and abroad.
4. Representatives of the healthcare community, government officials, and healthcare policy makers both domestically and internationally.
5. Members of the United States and International business communities.
6. Concerned individuals from the private sector.

### **WHAT IS THE MISSION OF HEARTBEAT INTERNATIONAL?**

The Mission of HEARTBEAT INTERNATIONAL is *“Making ‘Poor’ Hearts Beat Better”* through the distribution and implantation of new, usually life saving, cardiac pacemakers, implantable defibrillators and cardiac resynchronization devices (hereafter referred to as “implantable devices”) in the impoverished population of the world through approved Pacemaker Banks. Participating pacemaker manufacturers donate implantable devices to

HEARTBEAT INTERNATIONAL and are implanted by carefully selected and approved physicians at approved hospital facilities. The impoverished recipients of the implantable devices receive the device, physician and hospital services, follow-up evaluations at no charge to the patient for the life cycle of the implantable device.

Secondary purposes include:

1. Continuing education for all participating physicians and ancillary personnel in the ever expanding field of cardiac rhythm management disorders.
2. Continuing education in the broader field of cardiovascular medicine.
3. Continuing education and programs directed at preventative strategies for cardiovascular disease

Future goals include the provision of other cardiac devices such as heart valves and stents, and educational programming and training prerequisite to the clinical need and application of these devices.

Since HEARTBEAT INTERNATIONAL'S founding in 1984, HEARTBEAT INTERNATIONAL has valued the importance of its humanitarian mission on the lives of patients, their families and loved ones; including the enormous economic impact on life saving and life changing intervention when the patients health is resorted and he or she is returned to a productive and meaningful life. We believe and bear witness that the relationships born out of HEARTBEAT INTERNATIONAL'S mission fosters goodwill and lasting friendships, and are testimony to the use of *Pacemakers as Peacemakers*. PEACE and UNDERSTANDING are important and necessary offspring to the mission.

## **ORGANIZATION OF A HEARTBEAT INTERNATIONAL PACEMAKER BANK**

### **History**

The structure of HEARTBEAT INTERNATIONAL'S distribution arm, the Pacemaker Bank (PMB) was historically predicated on a single Rotary Club petitioning HEARTBEAT INTERNATIONAL to initiate a PMB. The Rotary Club recruited implanting physicians and one or more hospitals, and the bank was the project of that Club, with a Board of Directors forged to govern and meet the requirements of HEARTBEAT INTERNATIONAL. The most critical operational role of the Rotary Club was to insure the integrity of the program, i.e. that an indigent patient was the recipient of the implanted device and that no monetary demand was made by any party (patient, doctor, hospital, or Rotarian). This indispensable role is preserved today in virtually every location where HEARTBEAT INTERNATIONAL operates.

### **Pacemaker Bank Structure**

The Board of Directors of HEARTBEAT INTERNATIONAL has ruled that a PMB will no longer be the exclusive project of an individual club, but rather will encompass multiple Rotary Clubs and members of the community. The desire of the Board of Directors of HEARTBEAT INTERNATIONAL is that "National" PMBs be established with the goal to extend its life saving services to the impoverished population throughout the entire country.

Alternate to a National PMB and Board of Directors, a Board constituted by multiple Rotary Clubs (minimum of three) or a Rotary District and other parties from the community from a large geographic area is acceptable.

In those rare areas of the world where there are no Rotary Clubs, a PBM may be established by other interested parties and or organizations (civic or other) subject to the approval of the Board of Directors of HEARTBEAT INTERNATIONAL and operational compliance of the PMB.

**Board of Directors:** A HEARTBEAT INTERNATIONAL PMB is organized and operated by a Board of Directors consisting of at least five (5), but no more than eleven (11) members, one of whom is the Medical Director (see below). With the possible exception of the Medical Director, the members of the Board of Directors are leaders of the sponsoring District and participating Rotary Clubs (or other organization in the absence of Rotary sponsorship). Additional members shall be selected from the community at large and reflect time available, talent or resources that would be valuable to the mission and expansion of the PMB.

The founding members of the PMB Board of Directors will identify a Chairman, Vice Chairman, and other officers as deemed necessary; and define the term of each member of the Board. It is desirable that a rotation over a two- to three-year period be established for members and officers. Members and officers of the Board of Directors may serve successive terms if the sponsoring organization believes it is desirable.

The Medical Director, even if a Rotarian or member of other sponsoring organization, serves on the PMB Board of Directors, but **may not be** Chairman of the Board. Rotarians or members of the other sponsoring organization who are physicians may be on the Board of Directors; however, the majority of the membership of the Board of Directors must not have direct involvement in the professional use of pacemakers.

Bylaws and operating policies must be written and adopted by the Board of Directors. Other legal certifications as appropriate should be pursued to facilitate formation of a national PMB and or to assure smooth importation of inventory to the PMB. The Board of Directors is responsible for drafting marketing and fund raising plans.

**Implanting Physicians:** The Board of Directors, guided by the Medical Director, will identify a panel of qualified physicians who agree to implant HEARTBEAT INTERNATIONAL donated implantable devices in impoverished patients without charging professional fees. The qualifications of the physicians selected by the local Bank will be reviewed by HEARTBEAT INTERNATIONAL's Board of Directors to be certain that the identified physicians meet the requirements established by the Board of Directors of HEARTBEAT INTERNATIONAL and the Pacemaker Committee of the ACC. These organizations strive to ensure that the implantable devices that have been donated will be implanted safely by experienced physicians. It is not intended that a HEARTBEAT INTERNATIONAL PMB become a "private domain" of a single cardiologist, or pair of cardiologists, or even a professional group of cardiologists and/or cardiovascular surgeons. Physician representation from more than one hospital is encouraged.

**Social Workers:** The Board of Directors of the local Bank will also identify one or more Social Workers who will review the socioeconomic aspects of potential recipients and supply the information to the Medical Director and the Board of Directors for review. The

Board of Directors, or its designee, must be assured that a potential recipient of an implantable device is indeed impoverished, not just medically needy, before releasing the implantable device.

**Hospital(s) Used for Implantation:** The Medical Director will identify one or more hospitals (ideally all hospitals caring or willing to care for the poor) in which the donated implantable devices will be implanted, and will supply the Board of Directors of HEARTBEAT INTERNATIONAL with information necessary to establish that the hospitals meet established criteria for ensuring the safe and effective implantation of the donated implantable devices. **NOTE:** It is desired that the patients deemed impoverished and thereby qualified for HEARTBEAT INTERNATIONAL implantable devices to not be subjected to a fee for hospital services directly related to the device implantation.

**Implantable Device Repository:** The local PMB Board of Directors or a Committee of the Board maintains the custody of the donated implantable devices until needed for implantation. Furthermore, the Board of Directors is responsible to see that the follow-up requirements, described below, are met and reported to the Secretariat of HEARTBEAT INTERNATIONAL. The Board may delegate this responsibility to the Medical Director, but the Board is ultimately held responsible for these functions.

It is expected that the Board of Directors of the PMB will support the use of implantable devices to improve the quality of life and, in some cases, preserve the life of the recipient of a HEARTBEAT INTERNATIONAL pacemaker. They may arrange transportation for a patient to the hospital and/or follow-up site. They may secure funds for purchasing special monitoring equipment, endocardial leads, etc., for implantable devices. Furthermore, it is expected that they will help support attendees from their Bank to the Annual HEARTBEAT INTERNATIONAL Workshops.

It is **not intended** that HEARTBEAT INTERNATIONAL implantable devices be implanted:

1. In patients who are not impoverished and do not normally reside in the area served medically by the municipality in which the Rotary Club operates,
2. In hospitals which have not been approved by the Board of Directors of HEARTBEAT INTERNATIONAL, or
3. By physicians who have not previously been approved by HEARTBEAT INTERNATIONAL.

**Follow-up of Pacemaker Recipients:** The Board of Directors of the local PMB will ensure that the function of the pacemaker and the general health of each device recipient are evaluated every three months for the first year, and every year thereafter, increasing the frequency as battery strength begins significant decline. This evaluation will be conducted by a competent physician, approved by the Medical Director. The status of the patient will be reported to the Secretariat of HEARTBEAT INTERNATIONAL in the format directed by HEARTBEAT INTERNATIONAL. Such follow-up is essential in order to satisfy the concerns of the device manufacturers regarding the function of the products that they have donated.

## **DISTRIBUTION AND REPORTING OF HEARTBEAT INTERNATIONAL PACEMAKERS:**

**Designating Recipients:** Any physician may refer for consideration, as a recipient of a HEARTBEAT INTERNATIONAL donated implantable device, an impoverished patient needing an implantable device and residing in the area served medically by the municipality in which the PMB is located. The clinical record of the patient will be reviewed by the Medical Director to determine if an implantable device is indeed needed. The Social Worker will review the socioeconomic status of the potential recipient to determine that the patient is impoverished.

The Board of Directors or a committee of the Board will assess medical records and the economic assessment of the Social Worker. Only when the Board or Board appointed committee determine medical need (for an implantable device) is met and economic criteria proves the patient candidate to be impoverished shall the device be released to the Medical Director or physician previously approved by the Board of Directors of HEARTBEAT INTERNATIONAL to implant the donated pacemaker. Only physicians approved by the HEARTBEAT INTERNATIONAL Board of Directors can implant HEARTBEAT INTERNATIONAL donated devices.

The PMB Board of Directors is to maintain written documentation of all implantable devices both in inventory or released to approved physicians.

Forms for recording the patient data, and a release form must be completed and sent promptly to HEARTBEAT INTERNATIONAL within 72 hours of implantation. Implantation reports must be properly completed and submitted to HEARTBEAT INTERNATIONAL for at least 70% of devices received before a replenishment order will be approved by HEARTBEAT INTERNATIONAL.

The Board of Directors of the local PMB must establish policies for operating the PMB repository 24 hours per day, 7 days per week. No single person can assume responsibility for releasing devices if the regulations have not been met.

**Follow-up:** A mechanism for following up the function of each implantable device every three months for the first year and yearly thereafter must be established. Follow-up forms must be returned to HEARTBEAT INTERNATIONAL after each follow-up visit. The purpose of such close follow-up is to assure the HEARTBEAT INTERNATIONAL Board of Directors that only high quality patient care is given.

The location and function of all pacemakers, defibrillators and cardiac resynchronization devices are carefully stored in the HEARTBEAT INTERNATIONAL computerized databank. The Board of Directors of HEARTBEAT INTERNATIONAL **will not approve** distribution of additional devices to Banks that do not comply with the carefully established guidelines for operation of HEARTBEAT INTERNATIONAL PMBs.

**Removal of an Implanted Pacemaker, Defibrillator or Cardiac Resynchronization Device:** Should an implantable device be removed for any reason, including death, HEARTBEAT INTERNATIONAL should be informed as to the manner of disposal. An effort should be made to recover all pacemakers after death.

**Supplying Devices to Pacemaker Banks:** A variety of influences affect the supply of devices that a PMB receives including:

1. Supply of devices and leads donated from industry,
2. Availability of avenues of transportation,
3. Reporting status, and
4. Need.

Different methods have been used for distributing implantable devices to individual PMBs. The obstacles are different for each Bank. Therefore, it is the responsibility of the PMB Board of Directors (or their designee) to investigate all options and notify HEARTBEAT INTERNATIONAL as to the available means of distribution. It is preferable to have a shipping option available so that distribution can be made to the individual Bank as supply increases. When we have to depend on friendly couriers, we may not have devices on hand when the courier is traveling and vice versa. The first option listed has proven to be the easiest, most reliable avenue yet. We mention these options so that you may realize that ability to receive shipments from HEARTBEAT INTERNATIONAL is vital to the continuance of your PMB.

1. Prior arrangements made with an import/export company who will accept shipments from HEARTBEAT INTERNATIONAL on behalf of the PMB and forward the devices to Bank, even on short notice.
2. Ship via air freight to the nearest airport. Prior arrangement made with a specific customs broker who will clear the devices through customs and will contact the PMB when a shipment arrives.
3. Ship directly to the PMB Board of Directors or its designee using a courier service. Prior arrangements made so that there will be no delays or denial for entry by the customs service.
4. Equipment may be hand-carried by a member of the PMB Board of Directors or designee traveling to and from the United States. Inform HEARTBEAT INTERNATIONAL of the travel arrangements of any such person so that if HEARTBEAT INTERNATIONAL has any devices they may be forwarded to the traveler.
5. Devices may be forwarded to physicians who attend seminars/conferences in the U.S. and the physicians will then carry the devices back to the PMBs.

## **REVIEW OF ACTIVITIES OF LOCAL HEARTBEAT INTERNATIONAL PACEMAKER BANK**

The model and serial numbers of all equipment donated to approved PMBs will be recorded by HEARTBEAT INTERNATIONAL in a computerized databank. Each PMB will send to HEARTBEAT INTERNATIONAL the completed forms regarding patient selection, pacemaker implantation and follow-up.

The status of reporting will be reviewed annually by the leadership of HEARTBEAT INTERNATIONAL. Failure to supply the requested information in a timely manner will result in HEARTBEAT INTERNATIONAL withholding supply of additional implantable devices until such time as reports are made current.

Repeated deficiencies in supplying the required information over a one-year period may result in the HEARTBEAT INTERNATIONAL Board of Directors placing a Bank on probation. Failure to correct selection and/or reporting deficiencies during a one-year period will result in the HEARTBEAT INTERNATIONAL Board of Directors terminating the relationship with the Bank.

From time to time HEARTBEAT INTERNATIONAL will request an inventory report from any or all PMBs. This report will require detailed information on:

- Devices by type, model and serial number in inventory
- A list of implanted devices by type, model and serial number matched with the name of patient recipients
- Other information as required

## **HEARTBEAT INTERNATIONAL PACEMAKER BANK**

### **PRINCIPLES FOR OPERATION**

1. The Board of Directors of the Pacemaker Bank must consist of at least five members, but no more than eleven members, one of whom is the Medical Director. With the possible exception of the Medical Director, the members of the Board of Directors are leaders of the sponsoring Rotary Clubs or other approved sponsoring organization. Experience has shown that Board member(s) who are not medically experienced/oriented, should be receptive to guidance/advice regarding medical matters; i.e., hospital procedures, etc. from colleagues who are.
2. The Board of Directors is the governing organization for the Pacemaker Bank. All decisions must be approved by the Board of Directors; therefore, the Board must meet on a regular basis.
3. The Medical Director must have specific training and expertise in pacemaker implantation and follow-up. The Medical Director is responsible for determining a patient's medical need for a pacemaker and for providing patient follow-up after initial implantation all at no charge to approved patients.
4. The participating Rotary Clubs or other approved sponsoring organization, through local social workers or other process deemed appropriate by the Board is responsible for proving that the proposed pacemaker recipient is impoverished.
5. Once indigency has been determined, the patient is not to be charged for hospital and/or medical services directly associated with the pacemaker implantation and/or follow-up.
6. The Pacemaker Bank Board of Directors or their approved designee is responsible for submitting pacemaker implant reports to Heartbeat International
7. Pacemakers and leads can be housed in either the hospital or other location deemed appropriate by the Board of Directors. The Board is responsible for maintaining accurate inventory records and providing pacemaker implant and follow-up forms to HBI on a timely basis.
8. The Board of Directors is responsible for identifying a reliable mechanism / process for pacemaker inventory receipt, which results in successful clearance of Customs.
9. The Board of Directors and sponsoring Rotary Clubs are responsible for an annual membership fee of \$5,000 per year.
10. Within six months of Pacemaker Bank approval The Board of Directors will devise and submit to the HEARTBEAT INTERNATIONAL Board of Directors a marketing plan detailing the manner and mechanisms employed by the Pacemaker Bank to inform the medical community and general population of the availability and programs of the pacemaker bank.

11. The Board of Directors will devise and submit a plan to raise funds to the HEARTBEAT INTERNATIONAL Board of Directors within six months of Pacemaker Bank approval. Funds raised will be shared between the pacemaker bank and HEARTBEAT INTERNATIONAL on prescribed and agreed upon basis.

Failure to abide with these Principles of Operation will result in progressive disciplinary actions against the pacemaker bank by the HEARTBEAT INTERNATIONAL Board of Directors, and may lead to cessation of services after sufficient time to cure has elapsed.

I have read and agree with the Principles of Operations herein, and by my signature I acknowledge that I am a legal representative of the Pacemaker Bank Board of Directors, and the Pacemaker Bank Board of Directors agrees to said Principles of Operations.

**Pacemaker Bank**

Print name and position: \_\_\_\_\_

Sign: \_\_\_\_\_

**HEARTBEAT INTERNATIONAL**

Print name and position: \_\_\_\_\_

Sign: \_\_\_\_\_