

OPTN

ORGAN PROCUREMENT AND
TRANSPLANTATION NETWORK

*Bylaws of
Independent
Network of
Volunteers for
Equitable and
Safe Transplants
Inc.*

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Article I: Purpose and Definitions

1.1 Purpose

The specific and only purpose for which the Independent Network of Volunteers for Equitable and Safe Transplants Inc. (“INVEST”) is organized is to serve, upon designation by the Health Resources and Services Administration (“HRSA”), as the Board of Directors of the Organ Procurement and Transplantation Network (“OPTN”) consistent with the requirements of the National Organ Transplant Act of 1984, as amended, 42 U.S.C. § 273 et seq. (“NOTA”) and its implementing regulations, and any other applicable federal laws and regulations. In furtherance of such purpose, INVEST, operating under the designation of and oversight by the U.S. Department of Health and Human Services (“HHS”), will fulfill the functions required of the Board of Directors to ensure an equitable organ allocation system for patients as provided in NOTA, implementing regulations, and in HHS awards (e.g., grants, contracts, cooperative agreements) for the operation of the OPTN.

For so long as the Board of Directors of INVEST serves as the Board of Directors of the OPTN, these Bylaws shall also function as the Bylaws of the OPTN, and relevant provisions relating to the function and operation of the OPTN shall govern that organization.

1.2 Definitions

A. Participants in the OPTN

According to the OPTN Final Rule, which implements certain provisions of NOTA, the OPTN “shall admit and retain as members the following:

- All organ procurement organizations;
- Transplant hospitals participating in the Medicare or Medicaid programs; and
- Other organizations, institutions, and individuals that have an interest in the fields of organ donation or transplantation.”

As “members” is used in various guiding documents, from NOTA to INVEST and OPTN bylaws, below are general explanations of key uses of the term:

B. INVEST

INVEST is a not-for-profit corporation whose sole purpose is to serve as the Board of Directors of the OPTN.

C. INVEST Board of Directors / Directors / Board Members

INVEST Board of Directors, upon designation as the OPTN Board of Directors by HHS, will fulfill the role of the OPTN Board of Directors. The INVEST Board of Directors is elected by the OPTN members and ratified by the INVEST Board of Directors. The voting Directors of INVEST are the legal members of INVEST.

The OPTN Board of Directors creates organ allocation policies after consideration of advice and guidance from volunteer committee members as well as public comments. The OPTN Board of Directors also creates OPTN membership criteria, and OPTN membership policies. The OPTN Board oversees policy compliance,

responds to HRSA oversight, and works across the OPTN and with HRSA to improve the organ transplant system for the benefit of patients.

D. OPTN Members

Members of the OPTN consist of all organ procurement organizations, transplant hospitals that participate in the Medicare and Medicaid programs, and other organizations, institutions, and individuals that have an interest in the fields of organ donation or transplantation. See 42 CFR § 121.3(b)(1). A complete list of institutional members can be found at optn.transplant.hrsa.gov. These members agree to adhere to the organ allocation policies, to adhere to membership policies, to provide input on and insights into the transplant system to the OPTN, and to work across the OPTN for the benefit of patients. OPTN members are not legal members of the INVEST corporation, but may be conferred certain rights under the INVEST and OPTN's Bylaws and/or OPTN Policies and/or OPTN Management and Membership Policies (e.g., voting for INVEST Directors).

E. OPTN Volunteers / Committee Members

The OPTN Board can appoint volunteers to serve on OPTN committees. Volunteers do not need to be members of OPTN. They provide their expertise and assistance on OPTN Board-sanctioned activities.

Article II: Members of INVEST

The voting Directors of INVEST shall be the members of INVEST for all purposes under the Delaware General Corporation Law (the “DGCL”). All actions, consents, and approvals taken by the voting Directors of INVEST shall be and shall be deemed to be taken by them as the members and as the voting Directors of INVEST for all purposes, whether or not the specific action, consent, or approval specifically references them as acting as members at the time. All meetings of the INVEST Board of Directors shall be and shall be deemed to be meetings of the INVEST Board of Directors acting both as the voting Directors and as the members of INVEST.

Article III: Board of Directors

3.1 Composition

The INVEST Board of Directors must have at least 34 but not more than 42 voting Directors, excluding the ex-officio Directors.

Three non-voting Directors are:

- The OPTN Executive Director
- Two designees from HHS

These three Directors serve *ex-officio*, do not have a vote on the INVEST Board of Directors on any matter, and do not count towards any quorum or other requirements for any action of the Board.

All voting Directors serve on the INVEST Board without compensation.

A. Officers

The INVEST Board of Directors includes the following officers:

1. President
2. Vice president
3. Vice president of patient and donor affairs
4. Treasurer
5. Secretary

Additional officers may include one or more assistant treasurers and assistant secretaries, who are periodically nominated by the president and elected by the INVEST Board of Directors.

Officers may hold only one position on the INVEST Board at a time, except when an officer is appointed by the INVEST Board in an additional officer role to fill a vacancy for the unexpired term of another officer.

Each officer of the INVEST Board of Directors will serve as the same officer of the OPTN. Officers must perform their duties in accordance with these Bylaws and the OPTN policy on Officers.

B. Regional Councillors

The INVEST Board must include regional councillors who are representatives chosen by the voting members of the OPTN of each of the 11 geographic regions in the United States and ratified by the INVEST Board of Directors. The regional councillor serves as the region's representative on the INVEST Board of Directors. If the regional councillor is absent from a INVEST Board of Directors meeting, the associate councillor may represent the region in place of the councillor, but the associate councillor does not have a vote. The councillor from each

region is responsible, along with the president and the OPTN Executive Director, for coordinating regional activities to transact the business of the OPTN.

C. At-Large Directors

The INVEST Board must ensure that At-Large Directors represent the following categories:

- Transplant physicians and surgeons. Approximately 50 percent of the voting Directors will be surgeons or physicians directly involved in organ transplantation or donation.
- Non-physician transplant professionals, including transplant coordinators and individuals representing organ procurement organizations (OPOs) and transplant hospitals.
- Histocompatibility professionals.
- Individuals served by the OPTN, including transplant candidates, recipients, organ donors and their family members. At least 25 percent of the Directors will come from this category. These directors should represent the minority and gender diversity of this population.
- Voluntary health organization representatives.
- At least one pediatric specialist.
- Non-transplant professionals, including professionals from law, theology, ethics, health care financing, public health, social and behavioral sciences, and labor or management unrelated to health care.

Directors representing transplant candidates, recipients, donors, and family members are required to certify that they are not employees of, or do not act on behalf of, OPOs, transplant hospitals, voluntary health organizations, transplant coordinators, histocompatibility professionals, or other non-physician transplant professionals. The INVEST Board of Directors may, however, waive this requirement for as many as 50 percent of these Directors.

The immediate past president of the INVEST Board of Directors is a director of the INVEST Board for a one-year term following the term as president.

3.2 Election of Voting Directors

The voting Directors must approve by majority vote of those present a slate of nominees to be included on the national ballot for the annual meeting of the OPTN members. All voting Directors are elected by vote of OPTN members with voting privileges and OPTN member electors and ratified by the INVEST Board of Directors. The OPTN members and OPTN member electors vote, either in person or by proxy, at the annual meeting of the OPTN members when a quorum is present. Voting Directors may also be elected by the OPTN members with voting privileges and OPTN member electors at any special meeting of the OPTN members and ratified by the INVEST Board of Directors. Therefore, to qualify as a voting Director on the INVEST Board, a voting Director must be approved by both the OPTN members and the INVEST Board of Directors, except that the INVEST Board of Directors may fill vacancies on the INVEST Board as provided in *Article 3.4: Vacancies*.

Each OPTN member and OPTN member elector has only one vote for each Director position.

For more information about OPTN members and voting privileges, please refer to the OPTN policies.

A. Election of Officers

For so long as the INVEST Board of Directors serves as the Board of Directors of the OPTN, the president and vice president are elected by vote of OPTN members and ratified by the INVEST Board of Directors each year. The treasurer is elected by vote of OPTN members and ratified by the INVEST Board of Directors in odd-numbered years. The secretary and the Vice President of Patient and Donor Affairs are elected by vote of OPTN members and ratified by the INVEST Board of Directors in even-numbered years.

B. Election of Regional Councillors

Each OPTN region must elect an associate councillor, according to the OPTN policy on Regions. Unless otherwise determined by the nominating region, the associate councillor will subsequently become the region's nominee for regional councillor. The regional councillor nominee will be included on the national ballot of candidates for the Board of Directors.

C. Election of At-Large Directors

For so long as the Board of Directors of INVEST serves as the Board of Directors of the OPTN, At-Large Directors will be elected by vote of OPTN members with voting privileges and OPTN member electors and ratified by the Board of Directors.

3.3 Terms

All Director terms begin on July 1 following the annual meeting of the OPTN members to elect the INVEST Board of Directors and following ratification of that election by the INVEST Board of Directors.

A. Officer Terms

The president and vice-president serve one-year terms. The president and vice-president may not serve consecutive terms, except in the case of a vacancy in the office of president. If the vice president becomes president due to a vacancy, the vice president will be eligible for one succeeding one-year term as president.

The treasurer, secretary, and the vice president of patient and donor affairs serve two-year terms. These officers may serve consecutive terms.

The INVEST Board of Directors may extend the term of an officer up to one year by majority vote of all voting Directors present at the meeting when in the best interest of the OPTN and on an exceptions basis only. An officer's term may not be extended more than two consecutive times. Such extensions of the term of an officer should be rare exceptions, and supported by documented evidence as to why the extension is in the OPTN's best interest. The INVEST Board of Directors shall consider this evidence in determining whether to extend the term of an officer.

B. Regional Councillor Terms

Regional councillors serve for a term of two years. Regional councillors must reside or be employed in the region they represent at all times during their term.

Regional councillors cannot serve consecutive terms in the regional councillor role, except when appointed by a majority of voting Directors to serve for up to one year before or after their term as regional councillor to fill a vacancy in their respective region.

C. At-Large Director Terms

At-Large Directors will serve for a term of two years, with exceptions as noted below.

These At-Large Directors serve three-year terms:

- Transplant candidates.
- Transplant recipients.
- Organ donors.
- Family members of transplant candidates, recipients or organ donors.
- Representatives of voluntary health organizations.
- Representatives of the general public.

The INVEST Board of Directors may extend the term of an At-Large Director for one year, by majority vote of all voting Directors present at the meeting. An At-Large Director's term may not be extended more than two consecutive times.

3.4 Vacancies

Except in the case of a vacancy in the office of president, the INVEST Board of Directors may fill a vacancy on the INVEST Board of Directors by appointing a Director by majority of all voting Directors for the unexpired portion of the Director's term.

If there is a vacancy in the office of president, the vice president will become president and will serve in that role for the unexpired portion of the term.

3.5 Removals

The INVEST Board of Directors may remove a Director for any reason with at least two-thirds vote of all voting Directors at any regular or special meeting of the Board of Directors.

3.6 Meetings

The INVEST Board of Directors will hold regular meetings at least twice each year at a time and location selected by the OPTN Executive Director. The INVEST Board of Directors will hold one of these meetings

in the Washington, D.C. metropolitan area. The OPTN Executive Director or the president may call other regular or special meetings as it considers necessary. The INVEST Board may also call a special meeting with at least 25 percent of voting Directors submitting a written request to the OPTN Executive Director.

The INVEST Board of Directors must ensure that meetings are open to the public. However, the INVEST Board of Directors may hold closed sessions for discussions involving confidential medical peer review matters including OPTN membership approval, credentials, monitoring, or disciplinary matters as defined in the OPTN contract. The INVEST Board may also hold closed sessions for discussing matters involving individuals where an open meeting would compromise their privacy.

Representatives from the Federal Government serving on the INVEST Board of Directors, or their chosen representatives, will be included in closed sessions of INVEST Board meetings.

A. Notice of Meetings

Approximately two weeks prior to a regular meeting of the INVEST Board, the OPTN Executive Director must provide the Directors written notice, including information on the date, time, place, and agenda for the meeting. The OPTN Executive Director must distribute the INVEST Board of Directors meeting agenda to Directors at least 10 days before the date of the meeting.

A Director who signs a waiver of notice at any time will be exempt from the requirement of written notice. A Director who attends a meeting is assumed to have had adequate notice of the meeting unless the Director attends only to object that the meeting is not lawfully convened.

B. Quorum

Fifty percent of the voting Directors constitute a quorum for transacting business at any meeting of the INVEST Board.

The following Directors do not count toward the quorum requirements specified in these Bylaws:

- Individuals serving on the INVEST Board of Directors as representatives of the U.S. Department of Health and Human Service (HHS)
- The OPTN Executive Director

C. Board Actions

When a quorum is achieved, a majority vote of the voting Directors present is required to act at the meeting. There are two exceptions to the majority requirement:

1. When different voting requirements are defined in the Bylaws.
2. When an amendment to the Bylaws requires approval by a majority of *all* of the voting Directors, not just those present at the meeting.

D. Actions without a Meeting

The INVEST Board may take action without a convened meeting if there is unanimous written consent of all voting Directors. In order for actions to be taken without a meeting, all voting Directors must vote on the action, and the vote must be unanimous.

3.7 Compliance with Applicable Laws, Governing Documents, and Policies

All Directors must follow all applicable laws, regulations, governing documents, and policies of INVEST and the OPTN as a whole. These include the OPTN Charter, Bylaws, regulations and policies such as the Conflict of Interest Policy, Whistleblower Policy, and Record Retention Policy. Additionally, all Directors must follow the requirements of HHS awards (e.g. grants, contracts, cooperative agreements) to INVEST relating to the OPTN.

3.8 Relationship of the INVEST Board and the OPTN Contractors

With the exception of the OPTN Executive Director, no director on the INVEST Board of Directors can be an employee of, or serve on the board of directors of, any organization awarded grants, contracts, or cooperative agreements to support the OPTN.

Article IV: Nominating Committee

The Nominating Committee will recommend candidates for election as officers and Directors.

4.1 Composition

The president will appoint up to 15 voting individuals from current Directors to the Nominating Committee.

The Nominating Committee must include:

- The president
- The immediate past president
- The vice president
- The vice president of patient and donor affairs
- The minority transplant professional representative
- One histocompatibility laboratory representative
- One OPO representative
- One transplant coordinator representative
- Three patient and donor affairs representatives, including at least one representative who is not an employee of, or does not have a similar relationship with OPOs, transplant centers, voluntary health organizations, transplant coordinators, histocompatibility experts, or other non-physician transplant professionals.

The president may appoint up to 4 additional individuals from any voting Directors.

The following serve *ex-officio* and do not have a vote on the Nominating Committee:

- The OPTN Executive Director
- Two designees from the U.S. Department of Health and Human Services (HHS)
- The past president directly preceding the immediate past president

4.2 Vacancies

With the exception of vacancies in officer positions, the president will appoint Directors to fill vacancies on the Nominating Committee. If the vacancy is an officer position, the newly elected officer will be automatically designated as a Nominating Committee member.

Article V: Executive and other Committees

The Executive Committee, as directed by the president who serves as its Chair, performs the following tasks:

- Continues the work of the INVEST Board of Directors without the necessity of convening the entire INVEST Board.
- Considers any issues that require expedited action between meetings of the INVEST Board of Directors.
- Provides advice to the INVEST Board.

5.1 Authority

The Executive Committee can approve two types of actions:

1. Interim actions, which are immediately in effect unless otherwise stated in the resolution and remain in effect until the next INVEST Board meeting. The entire INVEST Board must approve the interim action at the next board meeting to make it permanent.
2. Final actions, which are as binding and enforceable as those approved by the entire INVEST Board of Directors, unless the INVEST Board specifically limits the Executive Committee from taking the action.

The president has discretion to defer matters for any reason until they can be considered by the entire INVEST Board.

5.2 Composition

The Executive Committee is composed of no more than 12 individuals selected from the INVEST Board of Directors so that the Executive Committee is made up of:

- Approximately 50 percent transplant surgeons and transplant physicians directly involved in transplantation.
- At least 25 percent transplant candidates, recipients, donors and their family members.
- At least one member of the general public.
- One OPO representative.

The Executive Committee includes the following Directors:

1. The president, who serves as the Chair of the Executive Committee
2. The Immediate Past president
3. The Vice-president
4. The Vice-president of Patient and Donor Affairs
5. The Secretary
6. The treasurer

7. A minority transplant professional representative

Four other members of the Executive Committee are selected so that there is at least one member from each of the following four categories:

1. Transplant Coordinator Representatives
2. Histocompatibility laboratory Representatives
3. Public Representatives (including organ donors and recipients, family members or voluntary health organizations)

The following serve *ex-officio* and do not have a vote on the Executive Committee:

- The OPTN Executive Director
- Two designees from The U.S. Department of Health and Human Services (HHS) One of the U.S. Department of Health and Human Services (HHS) Project Officers for the OPTN and the Director of the Division of Transplantation, or a representative they designate

5.3 Other Committees

The INVEST Board of Directors shall establish such other committees are necessary to perform the duties of the OPTN.

5.4 Selection

The officers of the INVEST Board of Directors are automatically designated as Executive Committee members. The remaining five Executive Committee members will be elected by a vote of the voting Directors.

5.5 Term

Executive Committee members serve terms of one year, except for those designated Executive Committee members who are officers of the INVEST Board of Directors. Officers who are members of the Executive Committee serve for the duration of their term in office.

5.6 Removals and Vacancies

With the exception of officers, the INVEST Board of Directors may remove a Director from the Executive Committee for any reason with a majority vote of the voting Directors present at a meeting. The INVEST Board may only remove an officer from the Executive Committee by removing the officer from the INVEST Board as outlined in *Article 3.5: Removals*.

If a vacancy occurs, the voting Directors may fill a vacancy on the Executive Committee for the unexpired portion of a term. If the vacancy is an officer position, the newly elected officer will be automatically designated as an Executive Committee member for the unexpired portion of the term. If the vacancy is within the remaining five Executive Committee members, the replacement will be determined by the

process outlined in *Article 5.4: Selection*.

Article VI: Executive Director

HRSA, via an OPTN Contractor, will direct the employment of a full time Executive Director who is appointed by the INVEST Board of Directors and reports to the president.

6.1 Responsibilities

The Executive Director has the following responsibilities:

1. Coordinates the activities of the Permanent Standing Committees.
2. Maintains the current list of names and addresses of the Directors and OPTN members.
3. Compiles key information from OPTN Contractors, including the revenues and expenses of the OPTN, and provides such information to the Board of Directors and individual Directors upon their request.

6.2 Term

The INVEST Board of Directors determines the term of the Executive Director. The Executive Director may be reappointed upon the INVEST Board's determination that the responsibilities of this position have been accomplished successfully.

Article VII: Officers

The officers of the INVEST Board of Directors and the OPTN are the:

1. President
2. Vice president
3. Vice president of patient and donor affairs
4. Treasurer
5. Secretary

7.1 President

The president will preside at all meetings of the OPTN members and INVEST Board of Directors.

7.2 Vice President

The vice president is the president-elect of the INVEST Board of Directors and the OPTN and serves as an *ex-officio*, non-voting member of the Membership and Professional Standards Committee (MPSC). If the president is absent, the vice president performs all duties required of the president, as well as any other duties required by the INVEST Board of Directors or these Bylaws.

7.3 Vice President of Patient and Donor Affairs

The vice president of patient and donor affairs represents the interests of patients, donors and their family members on the INVEST Board of Directors.

7.4 Treasurer

The treasurer will regularly review the revenues and expenses of the OPTN, serve as Chair of the Finance Committee and report to the INVEST Board of Directors regarding the financial condition of the OPTN as a whole at the INVEST Board's request. The treasurer must ensure that an annual audit and report of OPTN finances as reported by each of the OPTN contractors are completed, and provide copies of both to the Directors and OPTN Executive Director. The treasurer is also an assistant secretary and has the authority to sign in place of the secretary when the signature of the secretary of the OPTN is required on any document.

7.5 Secretary

The secretary attends all meetings of the OPTN members and INVEST Board of Directors, and keeps the minutes of the business transacted at these meetings. Whenever the signature of the secretary of the OPTN is required, the treasurer or OPTN Executive Director has the authority to sign for the secretary.

7.6 Assistant Secretaries

One or more assistant secretaries may perform all duties required of the secretary if the secretary is absent for any reason.

7.7 Other Duties

The officers of the INVEST Board of Directors and the OPTN will have other powers and duties that are designated to them by the INVEST Board of Directors, or as required by law.

7.8 Resignation

An officer may resign at any time by giving written notice to the OPTN Executive Director. If an officer vacancy occurs, the voting Directors may appoint a new officer according to *Article 3.4 Vacancies*.

Article VIII: Indemnification

INVEST shall indemnify, advance expenses, and hold harmless, to the fullest extent permitted by applicable law as it presently exists or may hereafter be amended, any person (a "Covered Person") who was or is made or is threatened to be made a party or is otherwise involved in any action, suit, or proceeding, whether civil, criminal, administrative, or investigative (a "Proceeding"), by reason of the fact that the Covered Person is or was a director, officer, volunteer committee member, or other volunteer of ~~or officer of~~ INVEST, or, while a director, officer, volunteer committee member, or other volunteer of ~~or officer of~~ INVEST, is or was serving at the request of INVEST as a director, officer, committee member, volunteer, employee, or agent of another corporation or of a partnership, joint venture, trust, enterprise, or nonprofit entity, including service with respect to employee benefit plans, against all liability and loss suffered and expenses (including attorneys' fees) reasonably incurred by such Covered Person. Notwithstanding the preceding sentence, except for claims for indemnification (following the final disposition of such Proceeding) or advancement of expenses not paid in full, INVEST shall be required to indemnify a Covered Person in connection with a Proceeding (or part thereof) commenced by such Covered Person only if the commencement of such Proceeding (or part thereof) by the Covered Person was authorized in the specific case by the INVEST Board of Directors. Any amendment, repeal, or modification of this Article VIII shall not adversely affect any right or protection hereunder of any person in respect of any act or omission occurring prior to the time of such repeal or modification.

Article IX: Amendment of Bylaws

9.1 Voting Requirements

The INVEST Board of Directors may amend the Bylaws with a majority vote of all voting Directors. Any amendment passed by the INVEST Board of Directors is in effect until the next annual meeting of the OPTN members. Every amendment to the Bylaws approved by the INVEST Board of Directors must be confirmed by a majority vote of a quorum of the OPTN members present, in person or by proxy, at the annual meeting of the OPTN members. If the amendment is not confirmed at the annual meeting of the OPTN members, the amendment is repealed, effective from the date of the annual meeting.

The Bylaws must comply with NOTA and its implementing regulations, requirements of HHS awards (e.g. grants, contracts, cooperative agreements) to INVEST relating to the OPTN, and any other applicable federal laws, regulations, and guidance.

9.2 Notice

Each Director must receive notice of any meeting where there will be a proposal to amend the Bylaws. The notice will be sent to the address on file with the OPTN Executive Director, or by any method that, in the opinion of the OPTN Executive Director, gives adequate notice to the Directors. Notices for meetings must be sent no more than 60 days or no fewer than 10 days before the date of the meeting. The proposed amendment must be provided with the meeting notice.

9.3 Non-substantive Changes to Bylaws

The OPTN Executive Director may correct *any* of the following:

- Capitalization or punctuation, as needed to maintain consistency with the current bylaws and policies
- Typographical, spelling, or grammatical errors
- Lettering and numbering of a rule or the subparts of a rule, according to style conventions in current policy
- Cross-references to rules or sections that are cited incorrectly because of subsequent repeal, amendment, or reorganization of the sections cited

The Executive Committee will retrospectively review any of these changes made to the bylaws by the OPTN Executive Director. The OPTN Executive Director may not make any substantive changes to the bylaws without approval of the INVEST Board of Directors.