



**DEPARTMENT OF HEALTH AND HUMAN SERVICES
Health Resources and Services Administration
Health Systems Bureau
Rockville, MD 20857-5600**

**HRSA ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK
BOARD OF DIRECTORS ENTITY DESIGNATION AGREEMENT**

THIS HRSA OPTN BOARD OF DIRECTORS DESIGNATION AGREEMENT (the "Agreement") is entered into by and between the Health Resources and Services Administration ("HRSA"), an agency of the U.S. Department of Health and Human Services ("HHS"), and Independent Network of Volunteers for Equitable and Safe Transplants, Inc. ("INVEST").

WHEREAS, HRSA's Health Systems Bureau administers and oversees the Organ Procurement and Transplant Network ("OPTN") established by the National Organ Transplant Act of 1984, as amended, 42 U.S.C. § 273 *et seq.* ("NOTA").

WHEREAS, HRSA is the HHS operating division authorized to establish and operate the OPTN through multiple federal awards (e.g., contracts, grants, or cooperative agreements) including this OPTN Board of Directors Designation Agreement, as required by NOTA.

WHEREAS, the OPTN Board of Directors is responsible for ensuring an equitable organ allocation system for patients by developing organ allocation policies and establishing and maintaining OPTN membership criteria and standards consistent with the requirements of NOTA and its implementing regulations, and any other applicable federal laws, regulations, and guidance.

WHEREAS, HRSA via its authority to oversee and implement NOTA, hereby exercises its authority to designate the entity that is responsible for serving as the OPTN Board of Directors via this Agreement.

NOW THEREFORE, in consideration of the mutual promises contained in this Agreement, HRSA and INVEST agree as follows:

Section 1. OPTN Board of Directors' Status and Responsibilities. INVEST will perform such actions set forth in Section 1 and adhere to the other provisions set forth in this Agreement, NOTA and its implementing regulations, and any other applicable federal statutes, regulations, and guidance in exchange for being designated by HRSA as the OPTN Board of Directors for the duration of this Agreement. INVEST shall perform the following actions:

1.1 Develop, review, and enforce policies for organ allocation, procurement, and transplantation. INVEST, while acting as the OPTN Board of Directors, shall be responsible for developing, reviewing, and enforcing policies related to the equitable allocation of organs

consistent with the requirements of NOTA and its implementing regulations, directives of the Secretary, and any other applicable federal laws, regulations, and guidance.

1.2 Establish and enforce OPTN membership criteria and transplant and organ procurement organization program requirements. INVEST, while acting as the OPTN Board of Directors, will establish OPTN membership criteria, conduct reviews and evaluations of OPTN matters, and take actions consistent with NOTA and its implementing regulations, directives of the Secretary, and any other applicable federal laws, regulations, and guidance.

1.3 Establish committees as necessary to perform functions of the OPTN and to provide input and support for the OPTN Board of Directors' policy development responsibilities. INVEST, while acting as the OPTN Board of Directors, will establish such committees consistent with NOTA and its implementing regulations, directives of the Secretary, and any other applicable federal laws, regulations, and guidance.

1.4 INVEST, while acting as the OPTN Board of Directors, will under the oversight of HRSA work with OPTN contractors and other stakeholders to develop an OPTN budget and strategies for setting and achieving OPTN programmatic priorities. INVEST will further take all reasonable measures to respond to and comply with budget and programmatic priority requests from HRSA or the Secretary.

1.5 Take all other actions as necessary to comply with all laws, regulations, and directives of the Secretary as the Board of Directors of the OPTN. INVEST, while acting as the OPTN Board of Directors, will ensure ongoing compliance with NOTA and its implementing regulations, and all other applicable laws and regulations, and directives of the Secretary to the OPTN Board of Directors. INVEST will further take all reasonable measures to respond to and comply with any requests from HRSA or the Secretary as the OPTN Board of Directors.

1.6 INVEST will not act in any capacity outside its role as the designated OPTN Board of Directors. Notwithstanding the foregoing, INVEST may do such functions related to the continuation of its corporate existence in good standing.

Section 2. Agreement Representative. HRSA will perform oversight and provide guidance to INVEST via a designated HRSA Agreement Representative. HRSA shall notify INVEST in writing when the Agreement Representative has been designated. HRSA may change the Agreement Representative at any time and will notify INVEST in writing if such a change occurs.

Section 3. Operational Support for the OPTN Board of Directors. HRSA will provide INVEST support through an OPTN Board Support Contractor. INVEST shall collaborate with the OPTN Board Support Contractor to help it execute the OPTN Board of Directors' oversight and management responsibilities. Such support shall be consistent with the scope, terms and conditions, and available funding to the OPTN Board Support Contractor and in accordance with NOTA and its implementing regulations. HRSA will meet with INVEST on a quarterly basis to receive feedback on OPTN governance activities supported by contractors. When disputes arise between INVEST and the OPTN Board Support Contractor, INVEST will work with HRSA to

understand and resolve the dispute.

Section 4. Collaboration with HRSA and Other Federal Contractors/Awardees. INVEST will work collaboratively with HRSA and other federal contractors/awardees to implement the requirements of NOTA and its implementing regulations, directives of the Secretary, and any other applicable federal laws, regulations, and policies. HRSA will meet with INVEST on a quarterly basis to receive feedback on OPTN operations supported by contractors. When disputes arise between INVEST and any other contractor/awardee, INVEST will work with HRSA to understand and resolve the dispute.

Section 5. Special Election. In the event that the Secretary of HHS determines that it is in the best interest of the OPTN, the Secretary of HHS may hold a special election of all OPTN Board of Directors. The OPTN Board of Directors will be elected by OPTN members. INVEST shall abide by the terms and results of such special election and ensure an orderly and efficient transition to any new OPTN Board of Directors.

Section 6. No Expectation of Payment. INVEST agrees that any actions performed pursuant to this Agreement are provided without any expectation of payment from either HHS, HRSA, or any third party acting on HHS or HRSA's behalf, and the OPTN Board of Directors agree that it will not seek reimbursement from HHS or HRSA for performing such actions. Any reimbursement support will be provided by the appropriate OPTN Contractor, in accordance with the terms and conditions of that contract, for ancillary costs required for the Board of Directors to fulfill its functions. Neither HHS nor HRSA will have any financial liability to the OPTN Board of Directors. Nothing in this Agreement shall be deemed to be a commitment or obligation of Federal funds.

Section 7. Term and Termination. This Agreement is effective June 30, 2024 and shall have an initial term of one (1) year. This agreement will automatically renew for additional one (1) year terms, unless terminated as set forth in this paragraph. HRSA may terminate this Agreement for any reason at any time. INVEST may terminate this Agreement with 180 calendar days' written notice to HRSA. Any termination of this Agreement will be at no cost to HRSA or HHS. If the designation agreement is terminated, HRSA will assist INVEST in fulfilling its corporate compliance obligations associated with dissolution or termination of the designation. Such assistance will be provided by the appropriate OPTN Contractor in accordance with the terms and conditions of that contract.

Section 8. Retention of Records. All records relating to compliance with this Agreement should be provided to and maintained by the OPTN Board Support Contractor. If INVEST loses its designation as the OPTN Board of Directors or dissolves, all records in its possession, custody, and control must be transferred to the OPTN Board Support contractor or whoever HRSA so designates to maintain such records. INVEST may keep such records as are necessary for its ongoing corporate compliance and dissolution procedures, to be sent to the OPTN Board Support Contractor following dissolution.

Section 9. Compliance with Laws and Regulations. INVEST represents and warrants that as of the date and for the duration of this Agreement that it has obtained, and shall maintain, all

necessary Federal, State, and local licenses and permits required to conduct business in all applicable jurisdictions, and shall comply with all applicable Federal and State laws and regulations. INVEST, Inc. shall provide timely written notice to HRSA of actions brought against INVEST, Inc. by any governmental agency, professional licensing or regulatory agency, or private party.

Section 10. Compliance with Corporate Bylaws, Policies and Procedures. INVEST will comply with all applicable corporate bylaws, policies, and procedures. INVEST shall further provide HRSA with 90 days advance notice of any updates to any corporate policies or procedures, and make the same publicly available. INVEST shall not complete any changes to its Certificate of Incorporation, bylaws, the Whistleblower Policy and the Conflicts of Interest Policy without prior approval by HRSA.

Section 11. Rights in Data. HRSA shall have unlimited rights in any data created or produced by INVEST related to the OPTN and such data will be considered federal data.

Section 12. Indemnification and Hold Harmless. INVEST shall indemnify and hold HHS/HRSA harmless from any and all claims, losses, liabilities, costs and expenses (including, without limitation, attorneys' fees) arising out of the negligence or intentional acts or omissions of INVEST, Inc., its employees, officers and directors, and its agents and subcontractors, in performance of this Agreement. This obligation will apply during the term of this Agreement and thereafter.

HRSA shall provide indemnification insurance, including Directors & Officers (D&O) Insurance, for Board members and volunteers via the appropriate OPTN contractor, subject to the scope, terms and conditions, and available funding of that contract. This is not an open-ended commitment to indemnify INVEST or hold it harmless. Nothing in this Agreement, or INVEST's Articles of Incorporation or Bylaws, shall be viewed as an obligation for HRSA to provide indemnification to INVEST or any other party.

Section 13. Disputes.

The Parties shall communicate with one another in good faith and in a timely and cooperative manner when raising issues under this Article. Whenever disputes, disagreements, or misunderstandings arise, the Parties shall attempt to resolve the issue(s) involved by discussion and mutual agreement as soon as practicable.

Failing resolution by mutual agreement, the aggrieved Party may seek further joint review by Senior Officials of the Parties. The aggrieved Party shall document the dispute, disagreement, or misunderstanding by notifying the other Party in writing of the relevant facts, identifying unresolved issues, and specifying the clarification or remedy sought. In such case, the Senior Officials shall provide the other Party an opportunity to explain their position in writing, and shall conduct a review of the matter(s) in dispute to include conferring with each other and with the Parties if needed. The senior Government official shall render a decision in writing within thirty (30) calendar days of receipt of both Parties' written positions.

In the absence of a decision, or after appropriate exhaustion of the administrative and other remedies identified in this Agreement, either Party may pursue any right or remedy provided by law in a court of competent jurisdiction.

Section 14. Confidentiality.

- (a) **Confidentiality:** INVEST, Inc. shall guarantee strict confidentiality of all information identified by HRSA as Confidential.
- (b) Disclosure of information or data covered by this Confidentiality provision may only be made: after INVEST, Inc. receives prior written approval from HRSA. If INVEST is uncertain with regard to the proper handling of information or data under this Agreement, it must obtain a written determination from HRSA.
- (c) The obligations in this Confidentiality provision shall apply during the term of this Agreement and thereafter.

Section 15. Miscellaneous.

- (a) **Authority to Legally Bind.** HRSA represents that the party or parties signing below on its behalf is or are authorized to legally bind HRSA to this Agreement. INVEST represents and warrants that the party signing below on its behalf is authorized to legally bind INVEST to this Agreement.
- (b) **Governing Law.** This Agreement shall be governed by Federal law. To the extent any term of this Agreement is inconsistent with Federal law or regulation, the applicable Federal law or regulation shall govern.
- (c) **Assignment.** INVEST shall not assign this Agreement, or any of its rights and responsibilities under this Agreement, without the prior, written consent of HRSA, which may be withheld for any reason or for no reason at all.
- (d) **Amendment.** Changes to substantive terms and conditions of this Agreement may be effected only by a written bilateral modification to this Agreement signed by both parties.
- (e) **Relationship between Parties.** Nothing in this Agreement is intended to create an employment or agency relationship between the parties. Neither party shall be deemed to be an employee or agent of the other. HRSA is responsible for carrying out the requirements of NOTA, and in this capacity has designated INVEST as comprising the OPTN Board of Directors.
- (f) **Communications.** Any notice or communication pursuant to or regarding this Agreement shall be in writing. All notices and communications should be emailed to the HRSA Agreement Representative.

- (g) **Waiver.** The waiver or failure of either party to enforce the terms of this Agreement shall not constitute a waiver of that party's rights under this Agreement with respect to any other violation.
- (h) **Force Majeure.** Neither party shall be considered to have failed in the performance of this Agreement if such failure arises out of causes beyond the control and without the fault or negligence of the party failing to perform.
- (i) **Dissolution of Entity.** In the event that INVEST dissolves, it must pay any and all money or transfer its assets to HRSA or upon HRSA's direction exercise its best efforts and cooperation to ensure an orderly and efficient transition to any HRSA designated successor.
- (j) **Integration and Severability.** This Agreement constitutes the entire agreement and understanding between the parties with respect to the subject matter hereof and supersedes all prior agreements and understandings with respect to such subject matter. If any provision in this Agreement is waived or deemed illegal, invalid, or unenforceable, the legality, validity, and enforceability of the remaining provisions shall not be affected.
- (k) **Counterparts.** This Agreement may be executed in any number of counterparts, of which, when executed, shall be deemed to be an original and all of which together shall constitute one agreement.
- (l) **No outside income or assets.** As a party to this agreement INVEST will not undertake any other commercial or revenue generating tasks. Should INVEST acquire assets via unexpected or non-traditional means, it will notify HHS within 30 calendar days and abide by guidance provided by HRSA on how to divest itself of such assets.

Section 16. Breach of Agreement. In the event that INVEST fails to perform this Agreement or performance of this Agreement does not comply with the provisions, HRSA reserves its right to remove the designation as the OPTN Board of Directors, remove access to OPTN data and technology; and/or hold a special election of the OPTN Board of Directors, and appoint an interim executive committee to perform necessary governance services for the OPTN until the next election. INVEST shall exercise its best efforts and cooperation to ensure an orderly and efficient transition to any HRSA designated successor.

Subject to the terms of this Agreement, HRSA hereby designates the board of directors of INVEST to serve as the OPTN Board of Directors.

IN WITNESS WHEREOF, the duly appointed representatives of the parties have executed this Agreement as of the date(s) provided below.

INVEST, Inc.:

HRSA:

By: **/Richard Formica/**_____ By: **/Suma Nair/**_____

Printed: Richard Formica, MD

Printed: Suma Nair PhD, MS, RD

Title: President, OPTN

Title: Associate Administrator, Health Systems Bureau

Date: 7/24/2024

Date: 7/24/2024