



## **Roles, rights, and responsibilities of PROMIS® National Centers**

Approved by the PHO Board of Directors

March 17, 2017

### **Aim**

This document describes the rights and responsibilities of PROMIS® National Centers (PNC) in their role in facilitating the translation, validation, and distribution of PROMIS items, short forms, item banks, and item parameters (hereafter called “PROMIS materials”) outside the US and to make PROMIS tools readily available for use. For academic, scientific, and clinical communities availability should be made at low or no cost.

### **Role of the PNC**

Each PNC is part of the PROMIS Health Organization (PHO) and will work with the PHO board to promote application of PROMIS Methods and Scientific Standards for the use and development of all PROMIS materials and to promote international harmonization and standardization of PRO measurement. The PNC will facilitate access to PROMIS instruments worldwide in the form of short forms and Computer Adaptive Testing (CAT).

### **Eligibility**

Eligible researchers and institutions wanting to establish a PNC in their countries must have measurement expertise, including knowledge of IRT and CAT, and a track record of translating, validating and using Patient-Reported Outcome Measures (PROMs) in research and clinical practice in adults and children. They must be knowledgeable about the PROMIS initiative to answer questions and offer support to (potential) PROMIS users. All applicants will be required to submit a [letter of commitment to the principles outlined in this document](#), including a plan for outreach to potential users. Given that the role of the PNC is to promote application of PROMIS Methods and Scientific Standards for the use and development of all PROMIS tools, eligible researchers and institutions should disclose any conflicting business interest that would appear to discourage promotion of the application of PROMIS. The PHO board will review any potential conflicts of interest and determine whether they make the applicant ineligible for serving as a PNC.

### **Translations**

One goal of the PROMIS initiative is to facilitate rigorous translations of PROMIS items into multiple languages. All translations need to adhere to the translation section of the most updated version of the *PROMIS® Instrument Development and Psychometric Evaluation Scientific Standards* document.

Translated PROMIS items are considered derivative products of existing intellectual property. However, national regulations may attribute independent intellectual property rights to the translation. To facilitate the accessibility of PROMIS materials worldwide, those participating in the translation of PROMIS items will need to agree to transfer their IP ownership rights to the PHO; in exchange the PHO will provide non-commercial scientific collaborators developing PROMIS item translations the right to use their translated PROMIS items under the conditions listed below. Only the PNC and the PNC of the US (hereafter called “PHO central office”), will have the right to distribute the PROMIS materials in that particular country.

The PHO language coordinator will be responsible for coordinating all translation efforts performed to ensure one unique translation per language. PNCs are encouraged to work actively with the PHO language coordinator. The PHO language coordinator will be responsible to provide translations for all PROMIS items within a reasonable time frame. Third parties can also translate items subject to PHO approval.

Final translations are approved by the PHO and, where relevant, the participating PNC. In case of disagreement that cannot be resolved through discussion, the PHO Board will make the final decision. In all cases, prior to release and use, translations must undergo a quality review to verify harmonization across languages by the PHO board or its designee, currently performed at the Medical Social Sciences Department at Northwestern University. This review will be subject to a fee.

The most current and accurate versions of the PROMIS materials will be included in the PROMIS central library, housed and managed by the PHO central office, currently at Northwestern University in Chicago, IL. All PNCs will have access to this library. It is a shared responsibility of the PNCs and PHO central office to make sure that these materials are accurate.

## **Distribution**

The PHO holds the distribution rights of all PROMIS materials in all language versions and in all countries with certain restrictions resulting from the origin of some of the PROMIS items. These rights are not relinquished with the issuance of a license to a given PNC. The PHO board grants to the PNC an exclusive, revocable (see Termination), non-transferable, non-sub licensable, and non-assignable license to use, reproduce, distribute, publish and display the PROMIS materials in the local country. This includes the right to offer PROMIS materials through computerized scoring or CAT software solutions.

PNCs serve as the primary distributor for use of the native language PROMIS materials in a specific country (e.g. national studies), while PHO central office serves as the primary distributor for non-native language versions of the PROMIS materials within one country or all languages across multiple countries (e.g. multi-national studies and international Electronic Health Record companies, such as EPIC).

PNCs and PHO central office will notify users of PROMIS tools about the user agreement in which they are accepting the general “PROMIS Terms and Conditions” stating that it is not allowed to change the formulation or lay-out of PROMIS items and that it is not allowed to distribute PROMIS items to others or translate PROMIS items into other languages.

## **Cost Recovery**

Although the goal is to make PROMIS tools available at no or low cost, PHO central office and PNCs will incur operating costs. Thus, the PHO board and each PNC will mutually agree on how PROMIS materials will be implemented and used by national and international organizations and about charging fees within individual contracts based on the principles of this framework. As the PHO does not have resources to support PNCs, each PNC is expected to adhere to the principles of the PHO model to support sustainability. PNCs will inform the PHO board about any changes in their approach that could potentially affect the use and availability of PROMIS materials, and approval of such changes is within the purview of the PHO Board.

While the PHO central office and PNCs will endeavor to impose similar fee structures, individual PNCs may vary in the strategies used to cover administrative/distribution (A&D) costs, as well as their research/development (R&D) efforts. Within the following paragraphs potential revenue sources are listed, which may be part of the specific sustainability model. PNCs are not required to charge any of these fees. Different fees may be assessed from different types of users.

### *Distribution fee*

A distribution fee may be charged by PNC to cover personnel and material costs for distributing translated PROMIS materials in its own country. This distribution fee should be set on a cost recovery basis and not include license or royalty charges.

### *Usage fee*

US English and US Spanish PROMIS items translated with US government funds are available at no charge. Individual PNCs may ask users of PROMIS instruments (e.g. EPIC) in its own country for a usage fee to cover costs for translations.

### *Service fee*

A service fee may be charged by the PNC for use of an electronic assessment platform or scoring services. Each PNC will determine fees for this services. PNCs do not need to provide an electronic data capturing solution.

The usage and service fee revenues shall be used to further develop, translate and validate PROMIS materials, after A&D costs are extracted.

### *Quality assurance*

If PNCs offer PROMIS materials through computerized scoring or CAT software solutions, the adequacy of the CAT software and scoring algorithms, i.e. the correctness of the score estimation, needs to be demonstrated. The use of PROMIS measures in a CAT platform requires a PHO endorsed certification process of that platform. The PNC needs to establish a mechanism to evaluate and document the adequacy of the software and scoring algorithms. Standard test protocols will be made available by the PHO.

### *Educational efforts and materials*

To maintain the scientific standards education of potential users is essential. To promote use of PROMIS methodology and maintenance of PROMIS standards when developing or using PROMIS materials, the PNC may organize workshops, develop other educational materials, and encourage users to recognize those educational efforts. PNCs may charge workshops fees and fees for other educational materials to recover educational costs.

To encourage the attendance of training opportunities, a PROMIS Certification status may be introduced. Certification as a “PROMIS User” is intended as a voluntary status, not required for one to be able to use PROMIS. Certification would be encouraged, to indicate that one has properly mastered assessment, scoring and interpretation of PROMIS tools. International requirements for a certification status (e.g. attendance of workshops) will be defined by the PHO board after consulting with the PNCs. If the PHO board introduces a Certification Status, PNCs will have the exclusive rights to provide a PROMIS certification within their country.

### **Termination**

The PHO license to the PNC can be terminated if the PNC is no longer able to fulfill its role despite appropriate support from the PHO board and PHO central office. Indicators that the PNC is not able to function in the way it is intended include that the PNC does not address inquiries or distribute PROMIS materials in a timely manner or PNC leaders are unable to provide reasonable support to any researcher in accordance to the role of the PNC as defined above.

The PNC can also terminate its commitment if no sustainable model can be established, or if the PHO board or PHO central office are not fulfilling their role in supporting the PNC, as described above.

If the agreement is terminated, PNC researchers having provided PROMIS translations will retain the right to use their translated PROMIS items for their own studies.