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Complete COI & Expertise

If you have been approved to be a Reviewer and invited to potentially serve on a Merit Review panel for a PCORI Funding Announcement (PFA), you will receive an email notification from a PCORI Merit Review Officer (MRO). In this email, you will be asked to navigate to PCORI Online to first confirm that you do not have any PFA-level Conflicts of Interest (COIs), and then to self-report your expertise and potential COIs for specific applications on the panel. Our aims are to match applications to the expertise or experience of our reviewers and to develop a balanced panel that is representative of our diverse patient and stakeholder communities.

In both the preliminary Online Review and the In-Person Review phases, Reviewers access their assigned Applications through the Reviewer Dashboard in PCORI Online. In this online portal, Reviewers provide critiques and score Applications based on PCORI’s Merit Review criteria. They also evaluate Human Subjects Protections and adherence to the PCORI Methodology Standards.

This section provides guidance on how to:

1.1 Complete PFA-level COI
1.2 Complete COI & Expertise Forms
1.1 Complete PFA-Level Conflict of Interest (COI)
Prior to being assigned Applications to review, you must first complete all COI & Expertise Forms. Upon logging in to PCORI Online, you will be asked to first confirm that you do not have any PFA-level Conflicts of Interest (COIs), and then asked to self-report your expertise and potential COIs for specific applications on the panel. There will be a COI & Expertise Form for each Application on the panel you have been invited to potentially serve.

If you have been asked to indicate Conflicts of Interest and Expertise for applications on a Merit Review panel, first navigate to the Reviewer Portal through PCORI Online to get started.

2. Enter your User Name and Password, and click ‘Log in.’

![Login Screen]

**Note:** If you have forgotten your password, navigate to the Appendix for further instructions.
3. Once logged in, you will be directed to the PCORI Online home page. All Merit Review tasks will be completed in this system. To access the Merit Review Dashboard click the **Merit Review** tile. The text of the Merit Review button will reflect the current outstanding task for the Merit Reviewer. At this step, the button text is ‘**Indicate COI and Expertise**.’ However, if you have been invited to serve as a reviewer for another cycle, the button will display ‘**Access the Merit Reviewer Dashboard**.’ If so, click the **COI & Expertise** tab on the next page to access your outstanding COI & Expertise forms.

**Note:** To return to this page at any point, click the **Home** tab in the top left corner.
4. Complete the PFA-level COI & Expertise form by clicking the link(s) under the **PCORI Funding Announcement** header (e.g. 'Implementation of PCORI-Funded Patient-Centered Outcomes Research Results,' as shown in example below).

![PCORI Funding Announcement](image)

**Note:** If you are assigned to multiple panels, you will return to this page once you’ve completed all COI & Expertise forms applicable to the first PFA.

5. Provide a response to the **PFA-level COI** question and click ‘**Submit**.’

![Submit Button](image)

**Note:** If you mark ‘Yes’ or ‘Unclear’, you will be prompted to provide additional details and your Panel MRO will reach out to you for more information. If you mark ‘No,’ you will then indicate Application-level COI and Expertise (see next page for detailed instructions).
1.2 Complete Conflict of Interest (COI) & Expertise Forms
If you do not have a PFA-level Conflict of Interest, you will be directed to complete Application-level COIs.

1. Click the COI & Expertise Number to open the record and respond to the questions.

2. Review the COI Information, COI Policy, and Non-Disclosure Agreement located at the top of the page.
3. Scroll down to **Conflict of Interest Disclosure** section to review the Application information, including **Project Title**, **Program Organization**, **Principal Investigator**, and **Application Key Personnel**.

4. In the **Conflict of Interest Disclosure** section, indicate any COI with the Application information above.
   a. If you do not have a COI, select ‘**No – The reviewer has no COI with this application.**’
   b. If you have a COI, select the COI statement that best applies.
   c. If you are unsure whether your situation qualifies as a COI, please select ‘**Unclear if COI Exists**’ and explain the potential conflict. Your MRO will review the potential conflict and let you know if a COI exists.
5. Scroll down to the **Expertise Rating** section and review the **Instructions**, **Technical Abstract**, and **Public Abstract**.

6. Select the applicable **Expertise Level**.

7. Click ‘Submit.’

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**Expertise Rating**

Below are descriptions for each level of expertise. Scientist reviewers are expected to rate their level of expertise. Patients and stakeholders are encouraged to rate their level of expertise or may choose not to designate a level of expertise by selecting ‘None or Not Applicable.’

- **High**
  - The Reviewer is able to evaluate the application with little or no need to make use of background material or the relevant literature. The Reviewer has likely published in areas closely related to the science presented in the application.

- **Medium**
  - The Reviewer has most of the knowledge to evaluate the application but will require some review of relevant literature to fill in details or increase familiarity with the system employed. The Reviewer may employ similar methodologies in his or her own work but may need to review the literature for recent data relevant to the application.

- **Low**
  - The Reviewer understands the broad concepts but is unfamiliar with the specific methodology or other details, and reviewing the application would require considerable preparation.

- **None or Not Applicable**
  - The Reviewer has only superficial or no familiarity with the concepts and methodology described in the application, or the Reviewer chooses not to answer the question about his/her expertise.

**Technical Abstract**

Background: Those with secondary progressive or primary progressive MS find symptom management a priority. Symptomatic fatigue and emotional changes are identified as common and important to function and quality of life. Many with progressive MS, no longer eligible for disease modifying therapies, are interested in alternatives to medications to manage symptoms. Complementary therapies (CAM) are often sought. Some of the most widely used are mind-body therapies such as yoga or mindfulness. Mindfulness meditation is an acceptable and easily adaptable method for managing progressive symptoms. Those with SPMS and PFRM have built trusting relationships with MS specialty nurses over the time of living with MS. MS specialty nurses are highly trusted. Embrace a holistic care model and have a significant impact on MS quality of life. Objective: This study will compare relaxation therapy to medications for the management of fatigue and emotional changes in MS patients with progressive MS. The intervention is monitored by MS certified nurses to progressive patients in their homes through a secure computer, phone or tablet application. Methods: Following an initial focus group of stakeholders to include patients finalizing the design and implementation of the study, we will use a multi-centered, single-blinded, randomized controlled trial to recruit 50 secondary and primary progressive MS patients with report of fatigue and or emotional changes. Patients will be recruited through integrated care practices, and community neurology practices throughout the United States. Participants will be randomly assigned to integrative restoration, a meditation or medication maintenance with a computer generated random number sequence to assure stratification by symptom, gender, race and ethnicity. Research assessors will be masked to treatment allocation. The primary outcome is a decrease of two or more points on the Fatigue Severity Scale (FSS). Secondary outcomes anticipate a decrease in depression scores on the Beck Depression Inventory II (BDI II) and greater than one point increase in quality of life, self-efficacy and self-management behaviors. The study will finalize with an additional focus group to include patients and other stakeholders, that gather qualitative data on the applicability of study findings to the general population. The primary analysis is based on parametric statistics.

**Public Abstract**

Background: Those with secondary progressive or primary progressive MS find symptom management a priority. Symptoms of fatigue and emotional changes are identified as common and important to function and quality of life. Many with progressive MS, no longer eligible for disease modifying therapies, are interested in alternatives to medications to manage symptoms. Complementary therapies (CAM) are often sought. Some of the most widely used are mind-body therapies such as yoga or mindfulness. Mindfulness meditation is an acceptable and easily adaptable method for managing progressive symptoms. Those with SPMS and PFRM have built trusting relationships with MS specialty nurses over the time of living with MS. MS specialty nurses are highly trusted. Embrace a holistic care model and have a significant impact on MS quality of life. Objective: This study will compare relaxation therapy to medications for the management of fatigue and emotional changes in those with progressive MS. The intervention is monitored by MS certified nurses to progressive patients in their homes through a secure computer, phone or tablet application. Methods: Following an initial focus group of stakeholders to include patients finalizing the design and implementation of the study, we will use a multi-centered, single-blinded, randomized controlled trial to recruit 50 secondary and primary progressive MS patients with report of fatigue and or emotional changes. Patients will be recruited through integrated care practices, and community neurology practices throughout the United States. Participants will be randomly assigned to integrative restoration, a meditation or medication maintenance with a computer generated random number sequence to assure stratification by symptom, gender, race and ethnicity. Research assessors will be masked to treatment allocation. The primary outcome is a decrease of two or more points on the Fatigue Severity Scale (FSS). Secondary outcomes anticipate a decrease in depression scores on the Beck Depression Inventory II (BDI II) and greater than one point increase in quality of life, self-efficacy and self-management behaviors. The study will finalize with an additional focus group to include patients and other stakeholders, that gather qualitative data on the applicability of study findings to the general population. The primary analysis is based on parametric statistics.
8. After the page refreshes, repeat steps 1-7 for all remaining COI & Expertise Forms in the list.
9. Once you complete a COI & Expertise form, it will be removed from your list. When no COI & Expertise Forms remain in the list, you have completed all COI & Expertise Forms for this PFA.
10. If you are assigned to another panel, click the Indicate COI & Expertise tab to return to the list of panels and repeat Section 1.1 and Section 1.2 for all assigned panels.
Appendix

A.1 Retrieve a Forgotten Password

2. If you do not know or have forgotten your PCORI Online password, click ‘Forgot your password?’ to retrieve it.
3. On the following screen, enter your username (i.e. your email address), and click ‘Reset Password.’
4. After submission, you will receive a system-generated email with instructions on how to reset your password.
A.2 Register as a New User

2. Click the ‘New User?’ link.
3. On the following page, enter information in the required fields (designated with a red asterisk*), and create a password.
4. Click ‘Join PCORI Portal.’
5. From here, the **Contact Information** page will appear asking you to submit additional information.
6. After entering in all required information, click **Submit**.