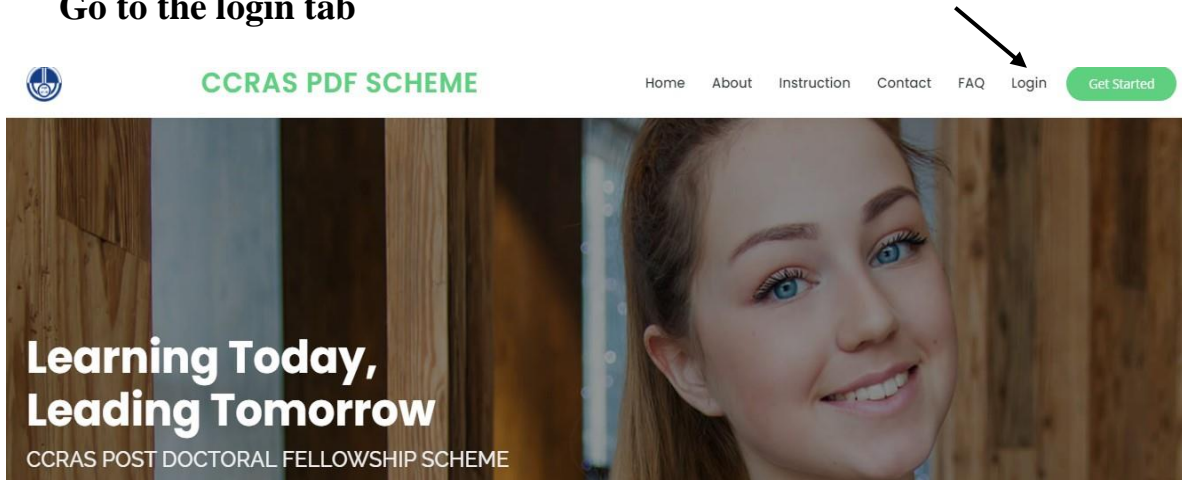# Reviewer Guidelines

Kindly follow the steps mentioned below to review the Project Proposal

1. **Kindly visit the website at PDF (pdf.ccras.org.in)**

   Go to the login tab
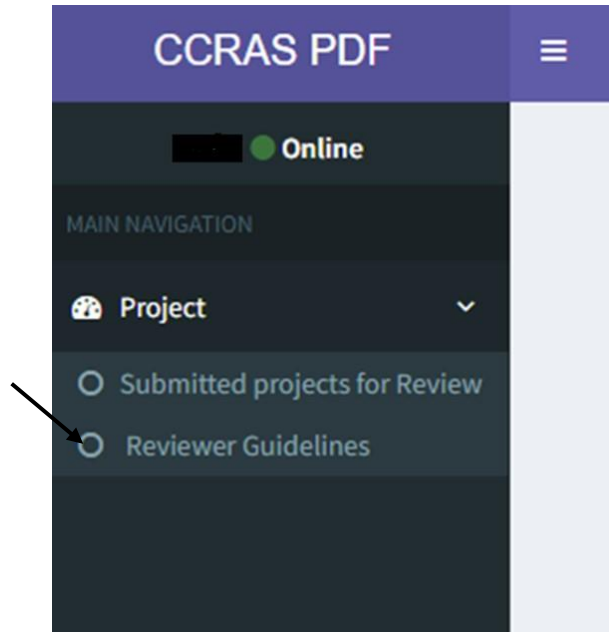

2. **Kindly login with the given credentials.**

3. Reviewer Dashboard will be seen.

4. Kindly click on reviewer Guidelines before reviewing the proposal.

Guidelines for Evaluation of Proposal

A. RESEARCH PLAN:

- ✓ Objectives – Accurate, Feasible, Specific, measurable ✓ Procedures/Method of data collection are elaborative.
- ✓ Appropriateness of Study Design.
- ✓ Assessment tools are relevant and scientific.
- ✓ Appropriateness of methods of data analysis/ statistical analysis.
- ✓ Reviewers need to correlate the title with methodology and gap analysis.

B. NOVELTY:

- ✓ Novelty of idea.
- ✓ New approach in the existing concepts/ knowledge. ✓ Formulation of the problem and hypotheses.

C. RELEVANCE & FEASIBILITY

- ✓ Significance of research question.
- ✓ Relevance in terms of Translational value.
- ✓ Appropriateness of timeline.
- ✓ Achievability of the Objectives.

❖ **The research proposal should have relevance to the discipline of Ayurveda, ensuring that the research outcomes contribute positively to the advancement of Ayurvedic Science.**

5. **Following this kindly click on View Submitted Project**
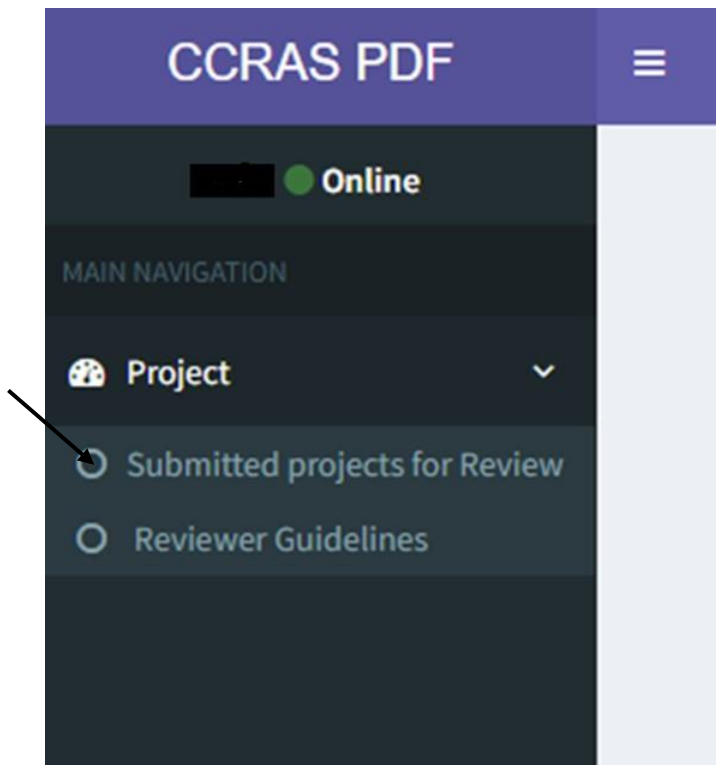
6. Kindly click on the view button to view the Project Proposal.

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7. Further, click on the View button to see the entire Project Proposal

Project

■ **PDF Reference ID** PDF/195/20

■ **Research Area** Ayurveda Biology / System Biology

■ **Name Of Department**

■ **Project Title** Effect of Ayurvedic intervention on Cognition in Type-2 diabetes mellitus patients – A two-arm observational study

■ **Project Introduction** Diabetes mellitus (DM) is a chronic metabolic disorder characterized by hyperglycemia and caused by impairments in insulin secretion (Kaveeshwar and Cornwall 2014). Even if disturbed sugar homeostasis is one of hallmark of DM, there are many health issues which are connected to it. Research studies following large groups over many years suggest that adults with Type 2 diabetes have a higher risk of developing Alzheimer's, they found that even people who had diabetes for less than 10 years had deficits in memory function typically associated hippocampus. They found that people with diabetes had smaller hippocampal sizes than people without diabetes. They also discovered that the decreases in hippocampal size were correlated to HbA1C blood levels, suggesting that HbA1C could be used to indicate hippocampal function and/or the onset of memory loss (Larger 2018). Deleterious effect on cognition, particularly on verbal memory or complex information processing, is very commonly seen in Type 2 DM patients (Sharma et al. 2016). However, there are limited studies in the Indian population reporting brain changes associated with these cognitive deficits in Type 2 DM. Also, there is no fMRI study which has shown the effect of Ayurvedic intervention in Type 2 DM. The Ayurvedic concept and practice of Prameha Chikitsa correlates with diagnosis and treatment of Type 2 DM. It includes multiple approaches including external, internal treatments and lifestyle alterations thus, it is called as whole-system approach. Considering complex systemic nature of the disease, multi-factorial Ayurvedic treatment is likely to sustainably alleviate many symptoms of Type 2 DM, than single target molecular drugs. In this proposed study, we would like to evaluate possible effect of Whole-System Ayurveda treatment for Type 2 DM on the cognitive changes. Internationally accepted cognitive test battery, psychological questionnaires, fMRI, blood parameters and standardized questionnaires for assessing Ayurvedic parameters will be used.

■ **Project Objective** To evaluate the effect of Whole System Ayurvedic treatment in Type 2 DM patients with a focus on nervous system structure and function. Primary Objective: To study the effect of Whole System Ayurveda treatment for Type 2 DM on cognitive performance (Attention, Learning, Memory, Spatial memory, and Visuospatial tasks) and related structural changes. Secondary Objective: Comparative analysis of cognitive performance, brain structure and function in healthy and Type 2 DM patients.

■ **Methodology** 85 participants (50 Type 2 DM subjects and 35 age-, gender-matched healthy controls) of both genders aged 40 to 65 years from urban population will be recruited for the study. (Upper limit to minimize differences in brain structural changes related to normal aging). If individuals match the required inclusion/exclusion criteria, they will be informed about the study and after informed consent they will be assessed further. • Cognitive assessment includes internationally accepted questionnaires & cognitive tests for (Attention, Learning, Memory, Spatial memory, and Visuospatial tasks). • Blood parameters- CBC, Blood sugar profile, Liver function test (LFT), Renal function test (RFT), Lipid profile, TSH, Vit-B12, Vit D and ESR. (HbA1c > 7 & < 9 will be selected to maintain homogeneity and reduce variation in the Type 2 DM characteristics of the participants, especially with respect to glucose metabolism and cognitive performance. This would be helpful to generate meaningful data through statistical analysis). • Bodily constitution (Prakriti) and digestive health (Agni) of the participant would be assessed using standard questionnaires developed based on Ayurvedic concepts and practice. Prakriti questionnaire will be collected only once during the baseline through AYUSOFT software. As Prakriti of a person is indication of physiological strengths and weaknesses which includes metabolic & cognitive health. Thus, we would like to explore correlation of Prakriti with health parameters and cognitive performance in the study participants. Agni plays an important role in overall health of an individual. As Ayurveda believes it is route cause of all diseases., This is very relevant to Type 2 DM, so to understand the status of Agni before and after the course of treatment Agni Questionnaire is collected. • Brain fMRI Studies- fMRI is performed to screen for health status of the brain and to know about effect of diabetes on different areas of brain and compare it with post treatment effect, it will be carried out twice during the study period. (At baseline & endline). • After the initial assessment (Cognitive assessment, Ayurveda assessment, blood profiling & fMRI) participants will be divided as: Healthy individuals (Group 1) and Type 2 DM patients (Group 2). The second group will be further divided as patients on Allopathic intervention alone (Group 2a) patients taking Allopathy as well as Whole System Ayurveda (Group 2b). Only baseline data will be collected for healthy participants (Group 1), to compare the effect of diabetes on cognition. • Data will be collected thrice during the study period for Group 2. ☒ Baseline ☒ Midline (6 months) ☒ Endline (1 year) Initially after the baseline recruitment, participants of Group 2a will continue their treatment protocol as suggested by their endocrinologists and they will be assessed again at midline & endline, results will be compared with Group 2b. The participants from Group 2b will be treated following the concept of Whole System Ayurveda by clinical investigators from I-AIM. Broadly the treatment involves detailed investigation based on Ayurvedic parameters like Prakriti, Vikriti, Hetu etc which help in differential understanding etiology and prognosis of the problem for each participant and designing of personalized treatment. The treatment would largely involve Shodhana (Cleansing/Correcting), Shamana (Healing treatment) and Rasayana (Rejuvenation) along with their allopathy protocol. We are looking for an integrative approach using ayurveda principles, hence we have taken the study using Ayurveda principles for Group 2b. Altering the dosage/Change of their regular allopathic medication will not be done by treating physician from I-AIM, however any changes (reduction/stoppage or change of medication) by their endocrinologist will be noted during the study period.

■ **Project Implication**

■ **Project Reference** 1. Kaveeshwar, Seema Abhijeet, and Jon Cornwall. 2014. "The Current State of Diabetes Mellitus in India." Australasian Medical Journal 7 (1): 45–48. https://doi.org/10.4066/AMJ.2014.1979. 2. Larger, Étienne. 2018. "Diabetes and Cognitive Decline." Correspondances En MHND 22 (7): 165–68. 3. Sharma, Manuj, Irene Petersen, Irwin Nazareth, and Sonia J Coton. 2016. "An Algorithm for Identification and Classification of Individuals with Type 1 and Type 2 Diabetes Mellitus in a Large Primary Care Database." Clinical Epidemiology 8: 373–80. https://doi.org/10.2147/CLEP.S113415. 4. Tripathy, Jaya Prasad, J S Thakur, Gursimer Jeet, Sohan Chawla, Sanjay Jain, Arnab Pal, Rajendra Prasad, and Rajiv Saran. 2017. "Prevalence and Risk Factors of Diabetes in a Large Community-Based Study in North India: Results from a STEPS Survey in Punjab, India." Diabetology & Metabolic Syndrome 9: 8. https://doi.org/10.1186/s13098-017-0207-3 5. Biessels, Geert Jan, and Florin Despa. 2018. "Cognitive Decline and Dementia in Diabetes Mellitus: Mechanisms and Clinical Implications." Nature Reviews Endocrinology 14 (10): 591–604. https://doi.org/10.1038/s41574-018-0048-7

■ Project_Synopsis   VIEW

8. After reviewing the proposal, kindly click on the Comments button.

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9. Kindly read the declaration of conflict of interest and click on the Yes/No button.

■REVIEWER GUIDELINES

NO ∨

Declaration of conflict of interest if any:

I have gone through the PDF Proposal assigned to me and hereby declare that I am no where related to the student.

Still, if it is revealed during the process, I shall notify the Council immediately and declare my competing interests therein.

Non-disclosure

By accepting to review the proposal, I hereby agree that I am obliged to destroy any copies of this proposal and cannot share its content in any form with anyone without prior intimation to the Council.

Reviewer's Consent:

After reading the declaration and non-disclosure clause, I am willingly giving my consent to become the Reviewer for PDF Scheme.

I accept

No ∨

When clicked on No, then only fields for suggestions & recommendations will be visible.

10. Kindly provide your comments/suggestions in the space provided and give your recommendation by clicking on Yes/No button.

Suggestions and Comments

Suggestions and Comments for the candidate

Recommendation for further Presentation/Interview of candidate:

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Review Date

mm/dd/yyyy

Submit

11. Kindly record your response by clicking on submit button.

Suggestions and Comments

Suggestions and Comments for the candidate

Recommendation for further Presentation/Interview of candidate:

No

Review Date

mm/dd/yyyy

Submit