

# Mental Health Research: Participant Eligibility Criteria Form

v1.3 [23<sup>rd</sup> July 2019]

## Eligibility Criteria

Eligibility Assessor Name: .....

Client/Patient Full Name: .....

<p><b><u>Client/Patient Declaration</u></b></p> <p>I consent to answer questions in order to determine my eligibility for this research study. In so doing, I understand that my eligibility or otherwise for this study, has nothing whatsoever to do with my value as a person and whether I am eligible or not, my medical care will continue as usual.</p> <p>Client/Patient Signature: ..... Date:.....</p> <p><i>Witnessed by</i></p> <p>Witness Name: ..... Date:.....</p>	
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Question / Evaluation	Yes	No	In-Eligibility criteria	Eligibility Test for exclusion or inclusion
<p><b>Itinerant</b></p> <p>Does this person consider themselves of “no fixed address”?</p>			If YES, NOT eligible	
<p><b>Near Vision</b></p> <p>Does this person have <b>any difficulties with near vision</b> (even with corrective glasses or contact lenses) that will prevent them from reading the screen and using the study research website?</p>			If YES, NOT eligible	The participant must be able to comfortably read 12 point text (with screen set to standard A4 viewing size).

<b>Orientation in person, space and time</b> <b>Time:</b> (give day of week-mth-year) <b>Place:</b> (give current location) <b>Person:</b> (give full name)  Does this person answer accurately?			If NO, NOT eligible	
<b>Mental Health Act</b> Is the person <b>detained under the Mental Health Act?</b>			If YES, NOT eligible	
<b>EU Citizenship</b> Is the person a <b>citizen of the European Union (E.U.)?</b>			If YES, (GDPR criteria apply) NOT eligible	
<b>English Comprehension</b> Does the person <b>understand and fluently speak English?</b>			If NO, NOT eligible	
<b>English Typing</b> Is this person able to <b>TYPE some words on a computer?</b>			If NO, NOT eligible	
<b>Supplement Use</b> Does this person take <b>herbal supplements, regular vitamin supplements?</b>			If YES, NOT eligible unless willing to voluntarily omit these for purpose of the trial	Eligible if willing to voluntarily omit these for purpose of trial (as per their signed consent form)
<b>Acute Medical Conditions</b> Does this person have any <b>acute medical condition or upper respiratory tract infection?</b>			If yes, NOT eligible	
<b>Neurological Disorder</b> Does this person have any <b>Neurological Disorder</b> e.g. stroke history, chronic brain injury delirium, disorder of conscious state or other organic brain pathology, chronic pain?			If YES, NOT eligible	
<b>Vision Impairment</b> Does this person have <b>any vision disability?</b> e.g. full or partial blindness, visual field loss, macular degeneration, untreated glaucoma			If YES, NOT eligible	
<b>Hearing Impairment</b> Does this person have any current <b>severe hearing disabilities</b> e.g. deafness or current ear infection?			If YES, NOT eligible	

<p><b>Neuromuscular Disorder</b></p> <p>Does this person have any <b>Neuromuscular Disorder</b>, e.g. multiple sclerosis, muscular atrophy, chronic fatigue, motor neurone disease, amyotrophic lateral sclerosis, Parkinson’s disease?</p>			<p>Patient is eligible, if able to type words adequately and meets other above criteria.</p>	<p>Type ..... Duration .....</p> <p>Please advise participant they may enter trial under supervision and omit those measures that require fine motor control.</p>
<p><b>Substance Use</b></p> <p>Does this person <b>use illicit substances or consume excessive amounts of alcohol</b>?</p>				<p>If YES, is eligible but assessing clinician needs to ensure accurate completion of the <b>substance use assessment questions</b>.</p> <p><b>NOTE:</b> The practice Clinician must also complete the separate <b>Risk Assessment Form</b> to determine if the patient is safe to register for this research study.</p>
<p><b>Suicide and Aggression History</b></p> <p>Does this person have a past or recent <b>history of suicidality or aggression</b> either as thoughts or acts?</p>				<p>If YES, the participant may still be eligible for this study, <b>HOWEVER</b></p> <p>The participant’s current need for help may predominate over any research participation.</p> <p><b>NOTE:</b> The practice Clinician must complete the separate <b>Risk Assessment Form</b> to determine if the patient is safe to register for this research study.</p>
<p><b>Suicide and Aggression Current State</b></p> <p>Is this person currently <b>suicidal or aggressive</b>? Ask the following:</p> <p><i>“Are you currently experiencing thoughts of harming yourself or others in any way?”</i></p>				<p>If YES, the participant may still be eligible for this study, <b>HOWEVER</b></p> <p>The participant’s current need for help may predominate over any research participation.</p> <p>Therefore, you need to alert your practice clinician to this YES answer <b>BEFORE the participant leaves the practice, so that they can receive urgent clinical review</b>.</p> <p><b>NOTE:</b> The practice Clinician must complete the separate <b>Risk Assessment Form</b> to determine if the patient is safe to register for this research study.</p>

Eligibility Determination	Yes	No	Comments
Is the participant eligible to proceed in the study?			

**Whatever the participant's eligibility status, THANK them for answering the questions.**

Please gently and tactfully advise the participant of their eligibility or ineligibility status and if ineligible, reassure them that the criteria are purely scientific and have nothing to do with them as a person.

If there are matters relating to **substance abuse** or **self-harm risk (suicide)** or **aggression**, please inform your practice clinician of reasons which require attention before the participant leaves your clinic. The practice clinician must complete the separate **Risk Assessment Form** to determine if the patient is safe to register for this research study.

If the participant is eligible (and there is no indication of substance use, suicidality or aggression), they may be given a **Patient Information Sheet** and full study **Consent Form** to sign at this point, so they can proceed in the study. They will also need a study access **Code**. Please assist them to register and then login to the study website. (If the participant is under 18 years, please remember to get another co-consent from a guardian). All forms for this purpose are provided on the accompanying website.

**If there is a wait between ascertaining eligibility and seeing the doctor, the eligible, consented participant may, with your supervision continue to the research website to complete all or part of their personal assessment questions and/or sensory processing assessment in a quiet place.**