



30 S. Valley Rd. Ste. 101C, Paoli, PA 19301
Phone: (267) 747-3669 Fax: (484) 383-0300

Consent for Cognoa Canvas Dx tool in Your Therapy Services at RiseNow Autism Innovations LLC.

The Parties agree that The Device (Canvas Dx) is intended for use by healthcare providers as an aid in the diagnosis of autism spectrum disorder (ASD) for patients ages 18 months through 72 months who are at risk for developmental delay based on concerns of a parent, caregiver, or healthcare provider. It is not intended for use as a stand-alone diagnostic device but as an adjunct to the diagnostic process. There are no contraindications to using Canvas Dx. The device is for prescription use only (Rx only). The Device is intended for use by healthcare professionals trained and qualified to interpret the results of a behavioral assessment examination and to diagnose ASD. The Device is intended for use in conjunction with patient history, clinical observations, and other clinical evidence the HCP determines are necessary before making clinical decisions. For instance, additional standardized testing may be sought to confirm the Device output, especially when the Device result is not Positive or Negative for ASD. Canvas Dx is intended for patients with caregivers who have functional English capability (8th grade reading level or above) and have access to a compatible smartphone with an internet connection in the home environment. The Device may give unreliable results if used in patients with other conditions that would have excluded them from the clinical study. The Device evaluation should be completed within 60 days of the time it is prescribed because neurodevelopmental milestones change rapidly in the indicated age group. It is recommended that Canvas Dx should not be used in patients with the following conditions or diseases, without limitation: (a) children with suspected auditory or visual hallucinations or with prior diagnosis of childhood onset schizophrenia, (b) children with known deafness or blindness, (c) children with known physical impairment affecting their ability to use their hands, (d) children with major dysmorphic features or prenatal exposure to teratogens such as fetal alcohol syndrome, (e) children with history or diagnosis of genetic conditions (such as Rett's Syndrome or Fragile X), (f) children with microcephaly, (g) children with history or prior diagnosis of epilepsy or seizures, (h) children with a history of or suspected neglect, or (i) children with history of brain defect injury or insult requiring interventions such as surgery or chronic medication.

Your Rights and Confidentiality Confidentiality: All information, including any data processed by an Cognoa is treated as part of your confidential health record and is



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protected by the same privacy and security standards as all other aspects of your care, including HIPAA.

Right to Revoke Consent: Your consent is voluntary. You have the right to withdraw this consent at any time by notifying your provider in writing. Revoking your consent may affect your ability to receive diagnostic services.

Client Acknowledgment and Consent

By signing below, I confirm that:

1. I have read and understood this form.
2. I have had the opportunity to ask questions about the use of Cognoa Canvas Dx in my child's treatment.
3. I voluntarily agree to the use of the Cognoa Canvas Dx tool for the purposes described above.

Name_____

Signed_____

Date_____