



**U.S. Food and Drug Administration (FDA)
Center for Devices and Radiological Health (CDRH)
Patient Engagement Advisory Committee (PEAC) Meeting
Virtual**

Guiding Principles for Virtual Breakout Sessions to Discuss Hypothetical Scenario

July 12, 2022

1. Participation in the breakout session is completely voluntary.
2. Participants in the breakout session cannot ask questions of one another but can comment on the questions or prompts included in the scenario and on the comments provided by other participants. FDA moderators and notetakers will interrupt you if you question one another. This restriction is a requirement of the Federal Advisory Committee Act.
3. FDA moderators will guide the discussion but will not be providing comments or feedback. They will also not be acting in their role as FDA staff members but solely as moderators to ensure that your voice is captured.
4. Participants in the breakout session should mute their phone if they are not speaking.

PEAC MEDICAL DEVICE AR/VR SCENARIO

Please note that this is a hypothetical scenario and is not describing a real device or patient situation. We are asking that you imagine yourself in the scenarios below as you answer the questions.

You are a single parent with a 7-year-old daughter diagnosed with Autism. You had seen your child struggle in kindergarten, as the teachers observed your daughter with sensory, attention, and social issues. You too had noticed some of these characteristics. Your child takes medications to help manage her disorder. However, challenges arose with adherence to medications – at times your daughter resisted taking the pills and at other times simply had difficulty swallowing the pills. You want your daughter to receive the treatment she needs and at the same time feel comfortable with the treatment, so you begin to look into other options.

On an online parent support group forum you come across a device, an AR/VR device that helps individuals with autistic symptoms develop coping strategies they can use to be more comfortable in unfamiliar, stressful, or uncomfortable environments. You make an appointment with a child psychiatrist to discuss the device.

- 1) What would you expect your health care provider to communicate to you about the device?**
- 2) Do you think your health care provider should be the main point of contact to educate you about the device?**
- 3) Would you expect/want to receive training and information about the device from anyone else besides your health care provider?**

At the appointment, you discuss the concerns with medication adherence with your daughter's child psychiatrist and ask about the option to try a new AR/VR device/technology for Autism symptoms, to potentially help your daughter develop coping strategies. AR/VR devices are typically designed and fitted for adults, but the psychiatrist indicates that she has had some success using the device with children as well. The child psychiatrist discusses the potential side effects/risks of this device which could include, but are not limited to, headaches, worsened vision, eye strain, facial redness, increased night terrors, dizziness, seizure, nausea, or double vision. The child psychiatrist suggests you consider the device as a treatment option for your daughter.

- 4) How would you weigh the benefits/risk tradeoff in deciding whether your daughter will use this device?**
- 5) What additional information could help you make a decision about the need to use the device to supplement medication use?**



You decide to try the AR/VR technology. At the training session the child psychiatrist discusses recommended guidelines for using the device, such as 15 minutes per day, and an adult/caregiver be present to while child uses the device, and help with device set-up etc. While you are still inclined to try the device, you are concerned about whether the design (fit and form-factor etc.) of the device will work for your daughter. Furthermore, as a single parent, with a stressful job and limited support system you are concerned about your availability to supervise your daughter while she uses the device. Finally, as someone who is not technology savvy and does not have a healthcare background, you are not sure how to check if your child is using the device properly and safely, or if the device is functioning well.

- 6) Since you can't see what your child is watching, what would you like to see to feel confident that the device is doing what it's supposed to do?**
- 7) Is being informed of the 15 minutes per day duration sufficient to achieve the prescribed time and give you the confidence your daughter is using the device as prescribed, or would a software control, such as an automatic shutoff, be better? Please explain.**
- 8) What concerns do you have about your child's perception of reality as a result of routine use of the device? What concerns if any, do you have about overuse or underuse?**