SV-ONE Quick Consent Guide

This document provides guidance on acquiring consent from participants at care centers previously in NPC-QIC and/or FON that have now joined the Single Ventricle Outcomes NEtwork (SV-ONE). SV-ONE received a waiver of consent for the use of data already collected in both the NPC-QIC and FON Registries. The waiver of consent allows sites to finish NPC-QIC data collection for patients through first year of life under the original NPC-QIC consent. The waiver does not permit all new data collection under SV-ONE.

When to use the SV-ONE consent form

You should begin using the SV-ONE consent form only after your site has received IRB approval for SV-ONE.

What this means for patients enrolled in NPC-QIC

- You may complete data collection through first year of life under the original NPC-QIC consent; SV-ONE consent is not required for the first year of life data collection.
- If you plan to continue follow-up beyond the first year of life, you may choose to obtain SV-ONE consent. Obtain assent if required by local policy.

What this means for patients enrolled in FON

- Since FON is a lifetime registry, you can continue to follow up under the existing FON consent.
- You **do not** need to reconsent participants due to the transition to SV-ONE.
- Use the SV-ONE consent only if:
    - The participant reaches an age milestone requiring a new consent or assent.
    - The participant had never consented previously.

When SV-ONE consent or assent is required

- Age of assent: Child reaches the local age where assent is required. Obtain assent and keep parental permission.
- Age of consent: Participant reaches the local age of majority. Obtain SV-ONE consent from the participant.
- New enrollment: Participant was not previously consented under FON or NPC-QIC.
- NPC-QIC beyond first year of life: To continue follow-up under SV-ONE, obtain SV-ONE consent.
- Return after withdrawal: New SV-ONE consent is required.

When SV-ONE consent or assent is *not* required

- Continuing FON participation under an existing FON consent (before SV-ONE transition).
- Using previously collected data from FON or NPC-QIC data (covered by the waiver).
- Completing NPC-QIC data collection through first year of life under the original NPC-QIC consent.

For questions, contact the SV-ONE regulatory team: ereg-SVONE@cchmc.org.

SV-ONE Consent Process Map

