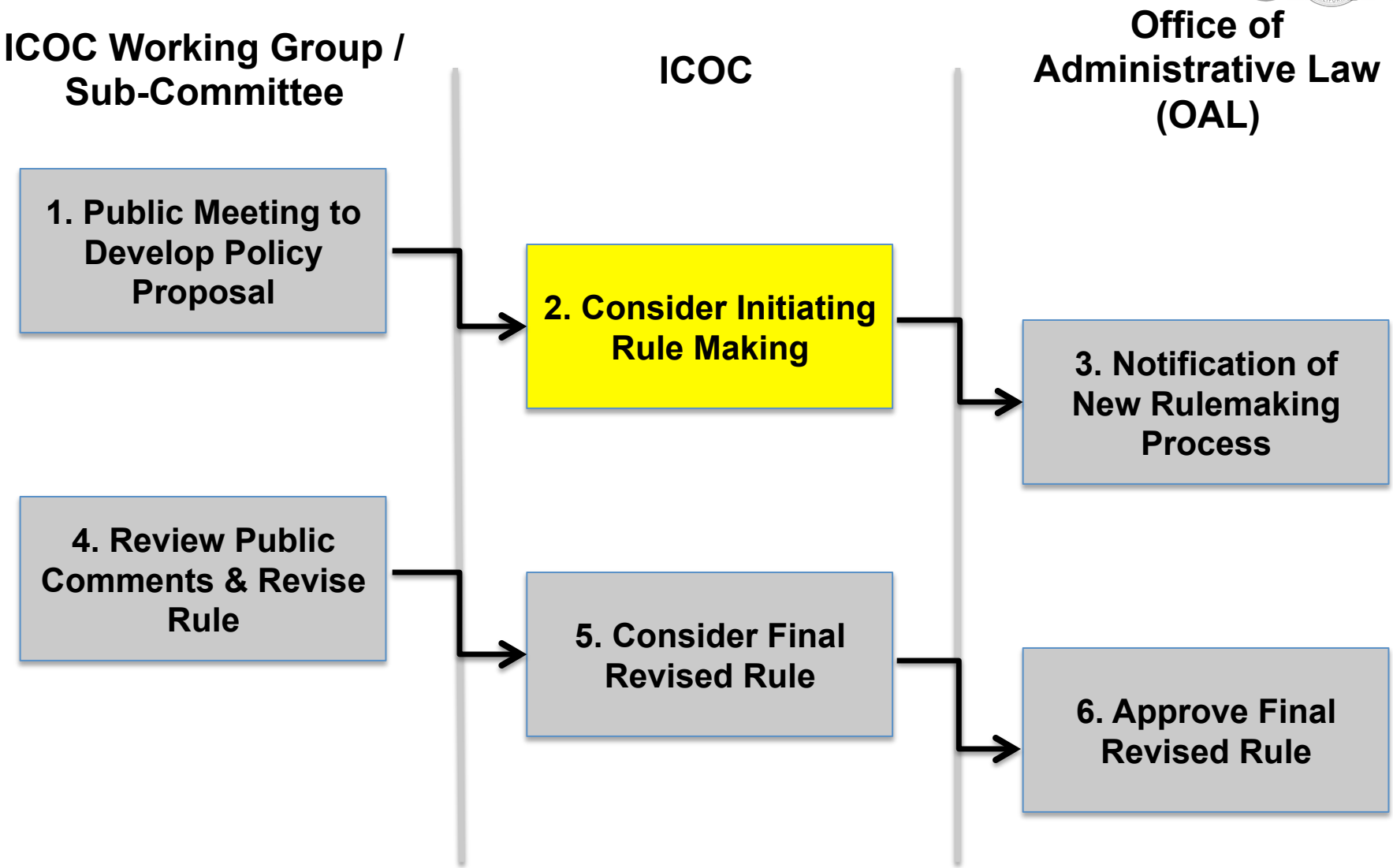
CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

The state stem cell agency

Item #10:
Consideration of Initiating Regulatory Rule Making Medical & Ethical Standards Regulation

January 29, 2014

CIRM Regulatory Rulemaking Process



Policy Background

- **Existing CIRM regulations require a Stem Cell Research Oversight (SCRO) Committee to review and approve clinical studies**
- **CIRM also requires grantees to comply with Federal regulations for the protection of human subjects – the *Common Rule***
- **The *Common Rule* requires an institutional review board (IRB) to review, approve and monitor clinical studies**
- **Therefore under existing CIRM regulations the SCRO and IRB are required to review and approve clinical studies**

SWG Recommendation

- Some grantees have concentrated clinical expertise within the IRB
- There was unanimous consensus among the SWG membership that IRBs, with appropriate expertise, can effectively review and monitor clinical research
- The SWG supported amending the regulations to provide flexibility where the IRB or SCRO may perform review and oversight of clinical research
- CIRM recommends initiating the Office of Administrative Law rule making process for this regulatory amendment