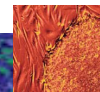


**Item #8:**  
**Consideration of Initiating Regulatory Rule  
Making Medical & Ethical Standards Regulation**

**Wednesday, December 11, 2013**

# 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**

