

**ICOC SCIENTIFIC AND MEDICAL ACCOUNTABILITY STANDARDS
WORKING GROUP – RESPONSIBILITIES AND OPERATING PROCEDURES**

Role of the Scientific and Medical Accountability Standards Working Group (SMAS WG).

The SMAS WG advises the ICOC on the adoption of rules and guidelines. While the SMAS WG's charge is open ended, the Initiative identifies some of the areas of focus for the SMAS WG.

The SMAS WG provides the ICOC with advice and recommendations regarding [125290.55(b)]:

- (1) **scientific, medical and ethical standards** (and any need to revise previously adopted standards),
- (2) **medical, socioeconomic, and financial standards** for aspects of clinical trials and therapy delivery to patients, including, safe and ethical procedures for obtaining materials and cells for research and clinical efforts, treatment of human subjects, and compliance with patient privacy laws,
- (3) **oversight** of funded research to ensure compliance with the standards,
- (4) **relevant ethical and regulatory issues**, and
- (5) **rules and procedures for the SMAS WG's operations.**

The ICOC is required to adopt standards on certain matters, and the SMAS WG should include these matters among those it considers [125290.35(b)]:

- (1) **Informed Consent** – (initially based on the NIH 1/1/03 standards, modified to adapt to the mission and objectives of CIRM).
- (2) **Controls on Research Involving Humans** - (initially based on the NIH 1/1/03 IRB standards, modified to adapt to the mission and objectives of CIRM).
- (3) **Prohibition on Compensation** to research donors or participants
- (4) **Assuring compliance with patient privacy laws.**
- (5) **Limitations on Payments for Cells** to reasonable payment for costs.
- (6) **Time Limits for Obtaining Cells** (initially be 8 to 12 days after cell division begins).

The ICOC is also charged with (i) the creation of policies regarding **intellectual property rights** arising from research funded by the institute [125290.30(h) and 125290.40(h)] and (ii) adoption of **conflict of interest rules** (based on standards applicable to members of scientific review committees of the National Institutes of Health) for working group members who are not ICOC members [125290.50(e)(1)]. The ICOC has to decide whether it will request the SMAS WG (or a special body created by the ICOC) to make recommendations on IP and conflict of interest related matters.

WORKING GROUP ISSUES – STANDARDS WORKING GROUP

Working Group Operating Procedures

ICOC Establishes Working Group Operating Procedures and Other Guidelines. The ICOC establishes rules and guidelines for the operation of the working groups [125290.40(g)]. The ICOC's must follow Bagley-Keane in establishing these guidelines and its records relating to establishing the guidelines are subject to disclosure under the California Public Records Act (PRA). In addition, the ICOC must follow the California Administrative Procedure Act (APA) in adopting rules for the operation of the working groups, except that the ICOC may adopt interim guidelines that are effective for up to 270 days. [Note: APA definition of regulation includes rules but not guidelines.]

Working Groups Recommend Guidelines to the ICOC. Each working group shall recommend to the ICOC rules, procedures, and practices for that working group[125290.50(d)]. In making its final decision, however, the ICOC is not obligated to give any particular weight to the WG recommendations.

Working Group Meetings and Records are Not Subject to Bagley-Keene and Public Records Act. The operations and records of the working groups are explicitly outside the regulation of Bagley-Keene and the PRA [125290.50(f)]. The only exception is the requirement that the records of the working groups submitted as part of a working group's recommendations to the ICOC for approval shall be subject to the PRA [125290.50(f)]. While there is no statutory requirement that the working groups submit records, working groups will likely submit some materials in connection with their recommendations to the ICOC because (i) as a practical matter, a working group will want to submit some records in support of its proposals, and (ii) the ICOC will need documentary evidence to support its adoption, modification or rejection of working group proposals in order to comply with the APA, which requires the ICOC to rely on evidence in the record to support its decisions.

Conflict of Interest and IP Guidelines. If the ICOC sets up a advisory panel(s) other than the SMAS WG to recommend Conflict of Interest or IP guidelines, the panel(s) will not enjoy the statutory exemption from Bagley-Keene and the PRA. However, if the panel(s) function is solely advisory, the panel(s) might be outside of many or all of the Bagley-Keene and PRA restrictions.

Note on Expiration of Current Conflict of Interest Rules: The current Conflict of Interest standards for working group members will expire 270 days after their adoption (approximately 12/31/05 for standards adopted at the April 6 ICOC meeting).