

## Study Group Working Notes #4: ESCRO Efficiency, Authority, Membership and Function & Operation

Study Group: Oversight Mechanisms

Reference: Section 100004

Background: Comments from the public and Working Group members have been received regarding the issues of ESCRO efficiency, authority, membership, and function and operation.

ESCRO Efficiency: Commentators have suggested that implementing the NA recommendation – namely, establishing an ESCRO committee having the expertise in stem cell research issues – would be difficult and very expensive; it also may be unrealistic to imagine that each institution would be able to find the necessary scientists, personnel, and members of the public with sufficient expertise.

ESCRO Authority: There may be research performed in collaboration with two or more institutions where each institution has established an ESCRO. In such cases, should there be a lead ESCRO that has primary responsibility for research oversight? This is both an efficiency issue and an accountability issue where it may be helpful for researchers to have a single point of contact for oversight.

ESCRO Membership: In the current draft of the guidelines, the ESCRO provides two primary functions (1) technical review of proposed research and (2) tracking (e.g. registry responsibility) of stem cell research. Ethical review is performed by the IRB. Since the ESCRO's primary role is scientific / technical review the rationale for including a member from the public is unclear. In addition, there was another comment indicating that a member of the "public" is difficult to define.

ESCRO Function and Operations: For regulatory clarity, the primary ESCRO committee functions (1) technical review of research and (2) tracking should be identified in specific sections.

Current Standards:

ESCRO Efficiency: draft standards allow *the establishment of a joint ESCRO committee that would assume oversight responsibilities for two or more research institutions, provided the ESCRO has oversight authority for each institution consistent with the requirements of the regulations.*

ESCRO Authority: Two or more institutions could authorize a single ESCRO to provide oversight for collaborative research based on joint ESCRO standard cited above.

ESCRO Membership: *An ESCRO shall have at least five members including representatives of the public, persons with expertise in developmental biology, stem cell research, molecular biology, assisted reproduction, and ethical and legal issues in stem cell research.*

ESCRO Function and Operation: Existing language is substantially similar to the proposed language below.

Options Recommendation & Proposed Language:

ESCRO Efficiency: No need to change language.

ESCRO Authority: Could provide clarifying language, but may not be essential, for example:

*If two or more institutions are involved in CIRM-funded collaborative research and each institution has an established ESCRO, a single lead ESCRO may be designated for the purpose of providing oversight for the CIRM-funded collaborative. The lead ESCRO shall have responsibility for maintaining all necessary documentation pursuant to this chapter.*

ESCRO Membership Option 1: Consistent with NA Guidelines

The committee shall, at a minimum, include a representative of the public, a member with expertise in ethical and legal issues surrounding hES cell research, and such persons as necessary with expertise in developmental biology, stem cell research, molecular biology, and assisted reproduction.

ESCRO Membership Option 2: Could focus on expertise required.

An ESCRO shall have at least five members including representatives with expertise in developmental biology, stem cell research, molecular biology, assisted reproduction, and ethical and legal issues in stem cell research.

ESCRO Function and Operation:

- (a) Function and operation: The designated ESCRO shall provide expertise to support the (1) evaluation of scientific merit and (2) documentation of compliance with all CIRM-funded research performed by the institution. The ESCRO shall facilitate education of investigators with applicable requirements of this chapter. An ESCRO may provide oversight for two or more funded research institutions, provided the ESCRO has oversight authority consistent with the requirements of this chapter.
- (1) Evaluation of scientific merit: The ESCRO shall provide the expertise necessary to support scientific review consistent with section 100005, and other applicable CIRM requirements.
- (2) Documentation of compliance: The ESCRO or its designee shall maintain a research registry that includes but is not limited to documentation of (1) *[stem cell]* research conducted by the institution, (2) *[stem cells]* lines derived or used by institutional investigators [as described in 100008?] and (3) any required review or notification requirement as described in Section 100005.