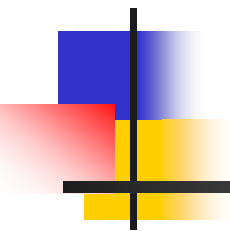


National Survey of Embryonic Stem Cell Research Oversight (ESCRO) Committees



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Philosophy

University of Connecticut

Presented at Stem Conn07
March 27-28, Hartford Connecticut



Aim of the Study

- To obtain a national snap shot of the current state of stem cell research oversight.
- To share information that may be of use to research institutions in this emerging area.



Research Methods

- A questionnaire was created and conducted through Zoomerang, an on-line commercial survey service.
- This survey was conducted between January 9 – February 16, 2007.
- 140 individuals were sent an e-mail request to complete the survey, which consisted of 118 universities, institutes, or companies.
- An original list was compiled of ESCRO departments and institutions that conduct stem cell research in the U.S. since there is no pre-existing list with this information.
- A web search was done to identify universities or other institutions that were conducting stem cell research (adult or embryonic). Then either the institutional chair of the ESCRO or IRB, or a top research administrator was contacted by phone to verify their role and contact information.
- We asked that only one person per institution respond to the email.



Research Methods Continued

- All replies were anonymous, and thus follow-up questions were not possible
- 40 people responded to the survey:
 - 29 completed
 - 11 partially completed
- Excel was used to organize and analyze the survey results.
- The survey is for informational purposes only, and is NOT scientifically reliable or valid.
- N varies throughout the survey because not all questions were mandatory. Thus, respondents could skip questions.
- Participants were asked to answer questions about their ESCRO's policies and guidelines, internal structure, and collaborations with other ESCROs.

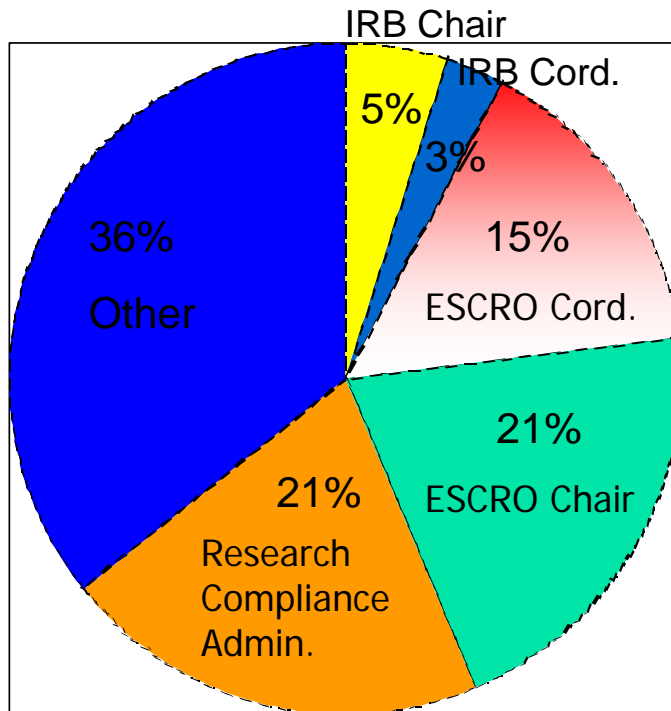


Survey Outline

- I. Institutional Character of Respondents (Slides #6 – 12)
- II. ESCRO Membership (Slides #13 – 15)
- III. ESCRO Responsibility and Activity (Slides #16 -20)
- IV. Acceptance of Cell Lines (Slides #21 - 23)
- V. Payment to Gamete Donors (Slides #24 - 29)
- VI. Adoption of NAS Guidelines (Slides #30 – 33)
- VII. Conflict of Interest Policies (Slides #34 - 35)
- VIII. ESCRO Educational Activities (Slides #36 - 37)
- IX. Collaborations between Other Institutions (Slides #38 - 39)
- X. Questions for Further Discussion and Conclusions
(Slides #40 -41)

Section I.

Professional Titles of Respondents



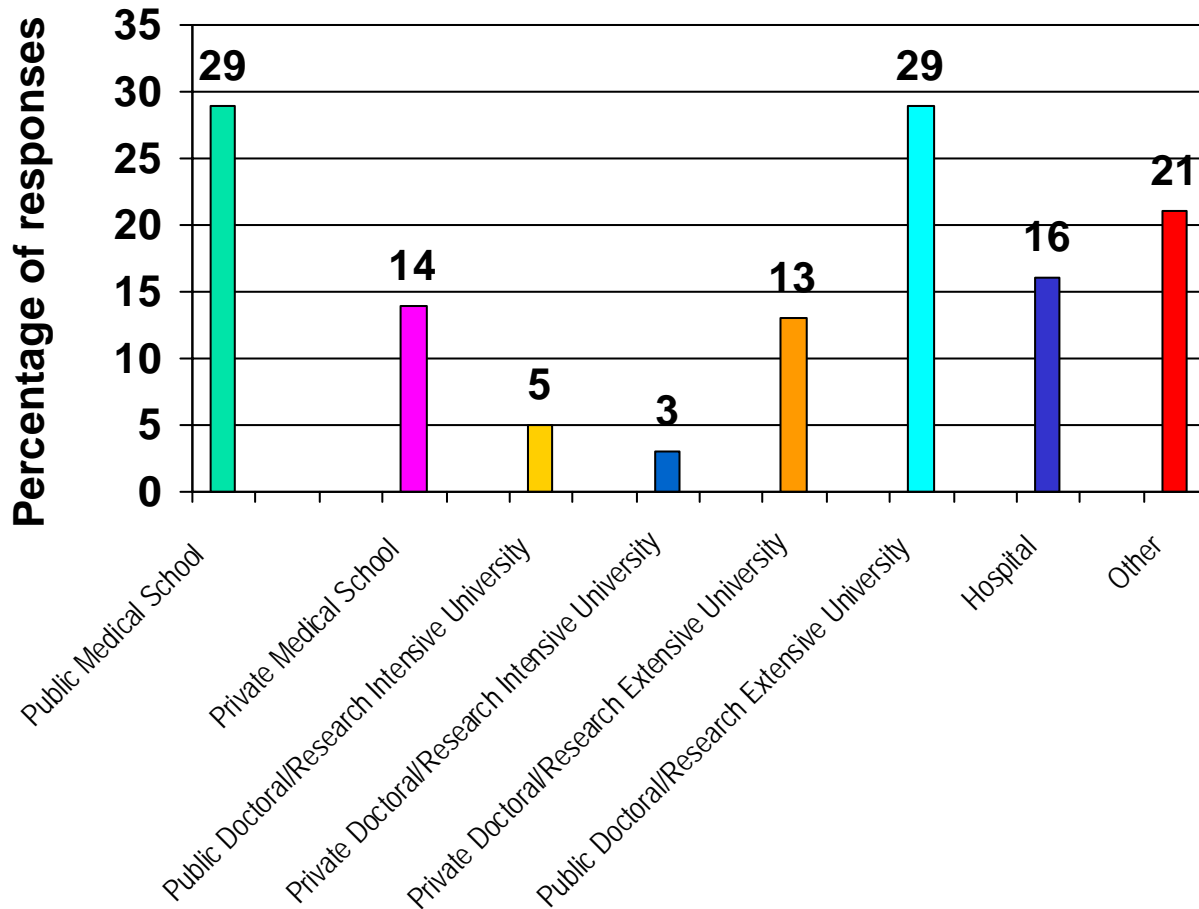
N= 39

Other answers:

- Interested citizen
- Legal officer
- IRB Manager
- Professor of Pathology
- Associate Vice Chancellor
- Faculty Member

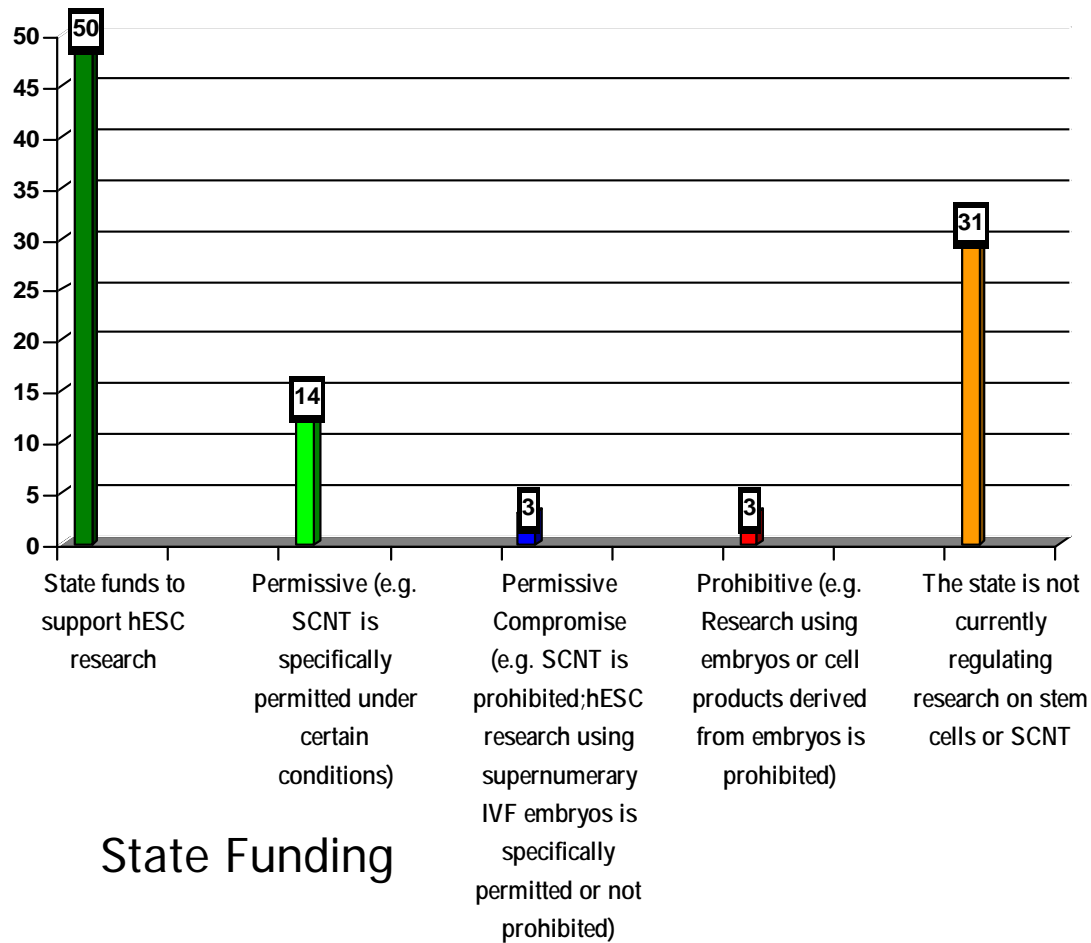
Institutional Category of Participants

(check all that apply)



N = 34

State Funding and Regulatory Environment of the Respondents



N= 36

State Funding



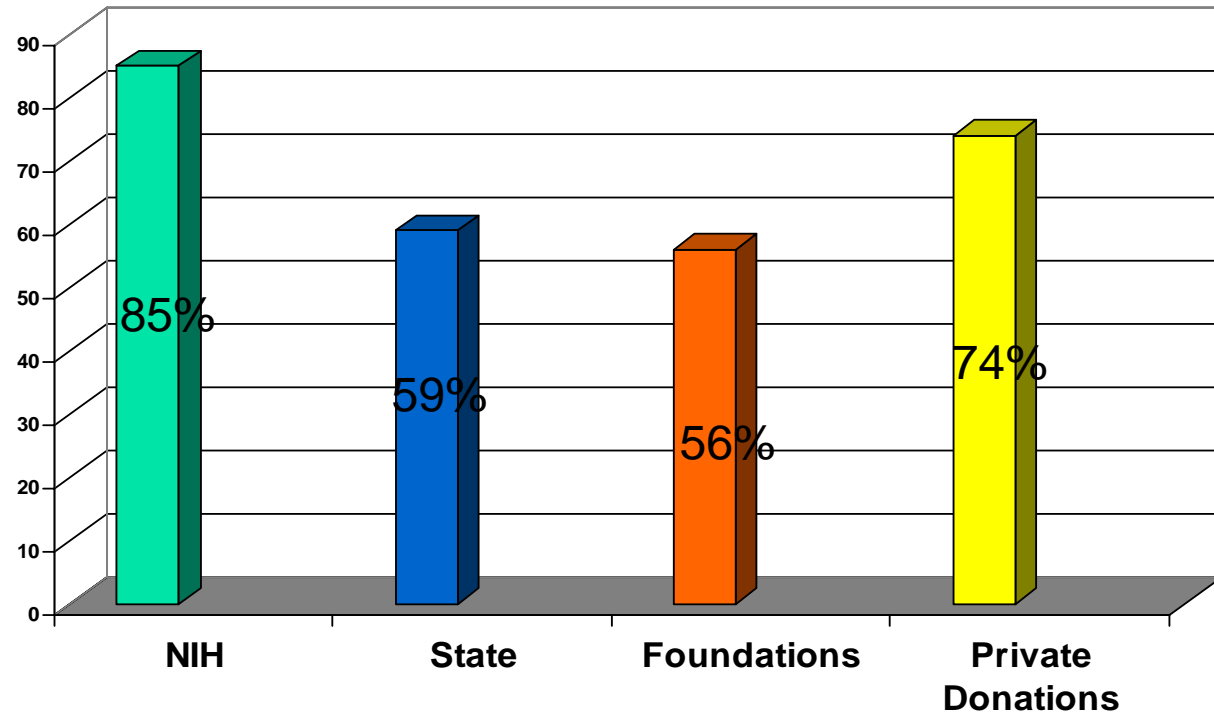
Are There Any Researchers at Your Institution Who are Currently Conducting or Planning to Conduct Human Embryonic Stem Cell Research?"

- 88% answered "Yes".
- Participants who responded "No" were asked for their final thoughts and exited the survey.

N = 40

Institutional Sources of Funding for hESC Research

(Check all that apply)



Sources of Funding

N= 35

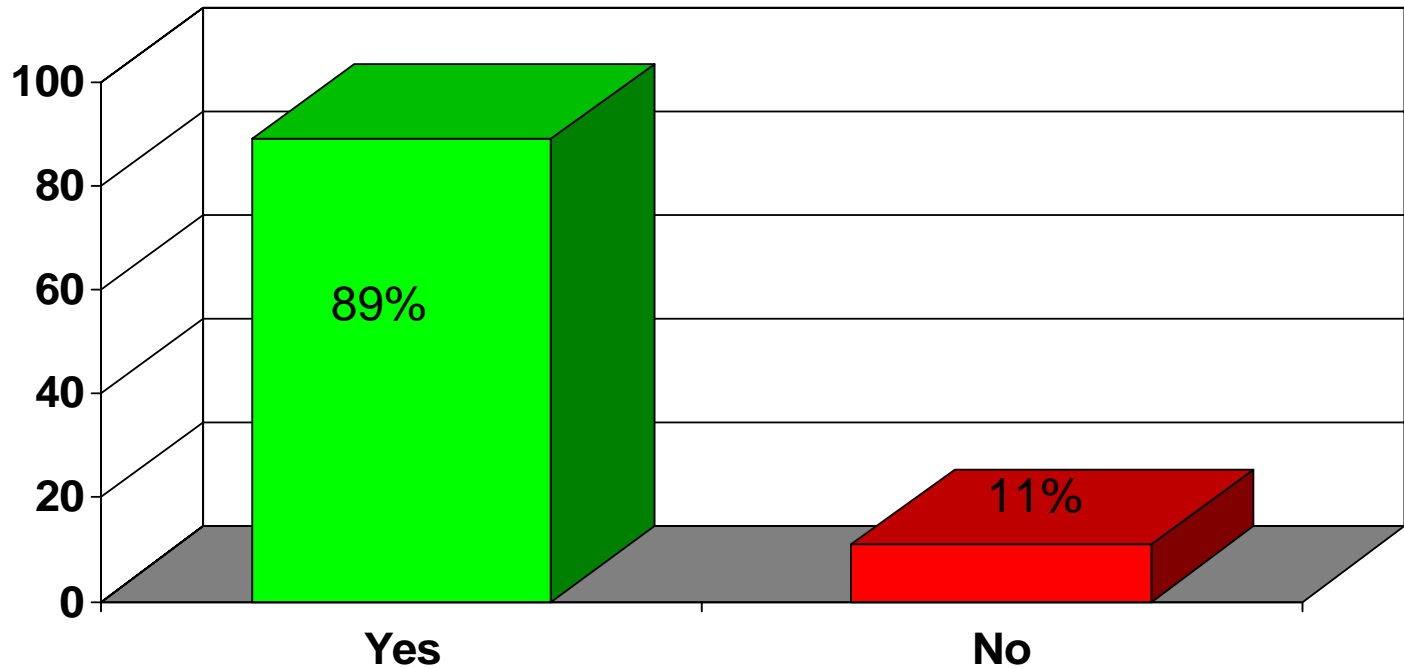


Does Your Institution Currently Have an ESCRO?

- 25 institutions, or 75%, responded “Yes”, and of those almost 80% of the ESCROs were formed in 2006.
- Of those 9 institutions responding “No,” 75% said they plan on establishing an ESCRO in the near future.

N = 34

Are Your ESCRO and IRB Committees Separate?



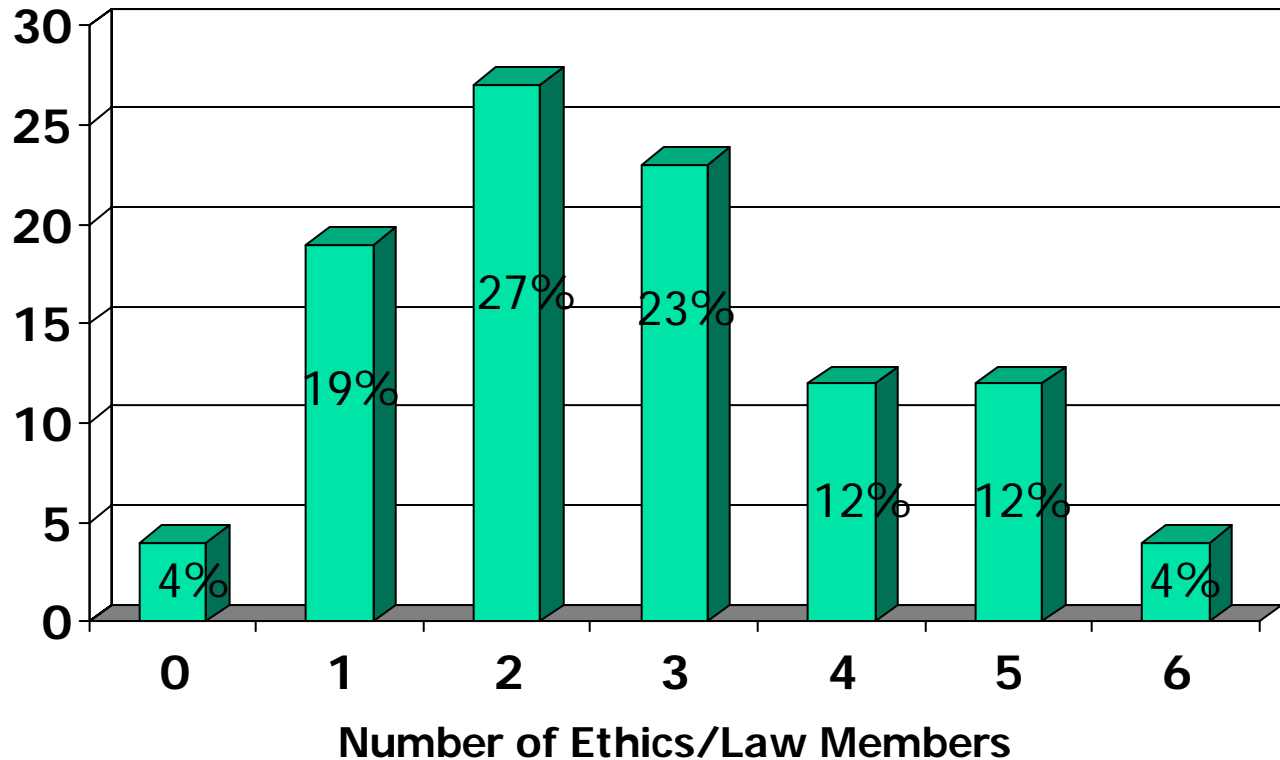
N=27



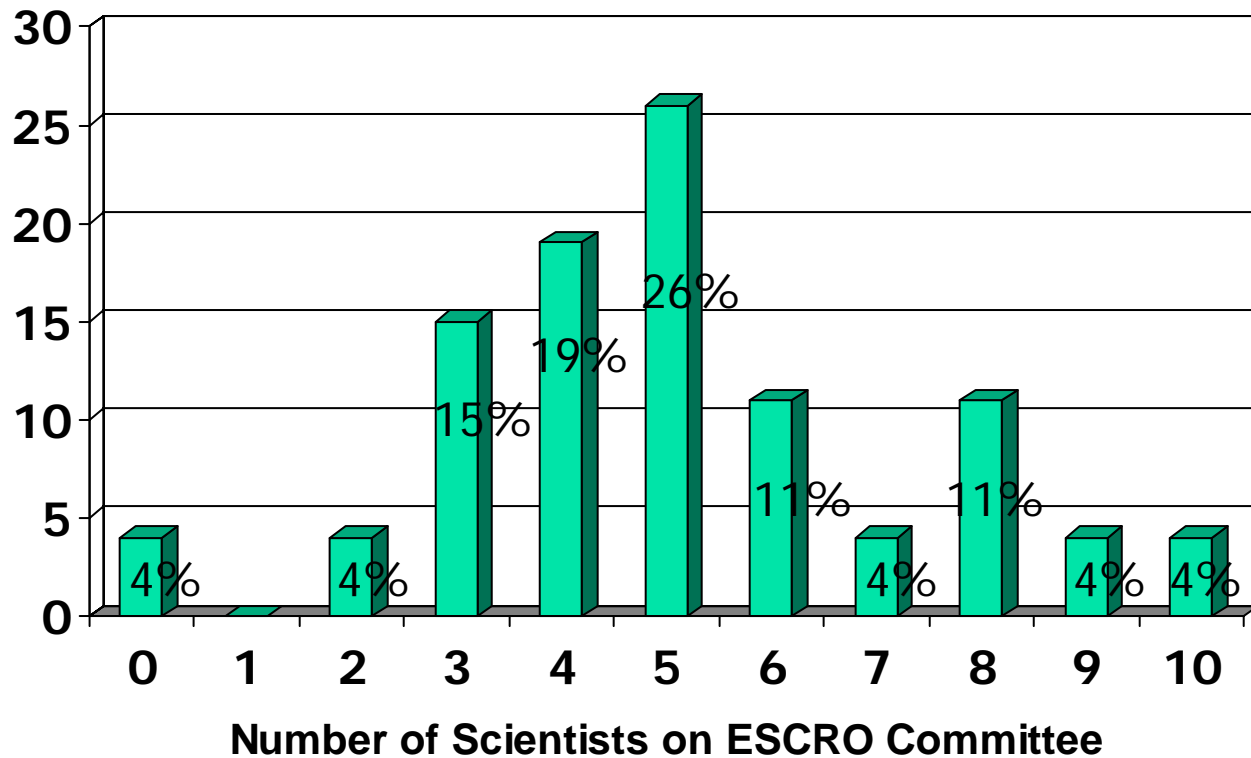
Section II: ESCRO Membership

- “Does your ESCRO membership include an external ethical/legal expert?”
All respondents stated “No.” N = 3
- “Does your ESCRO membership include an external scientific expert?”
All respondents said “No.” N = 3
- “Does your ESCRO have a community representative?”
50% said Yes, and 50% said No. N = 4

Number of Ethics/Law Experts on ESCRO Committee



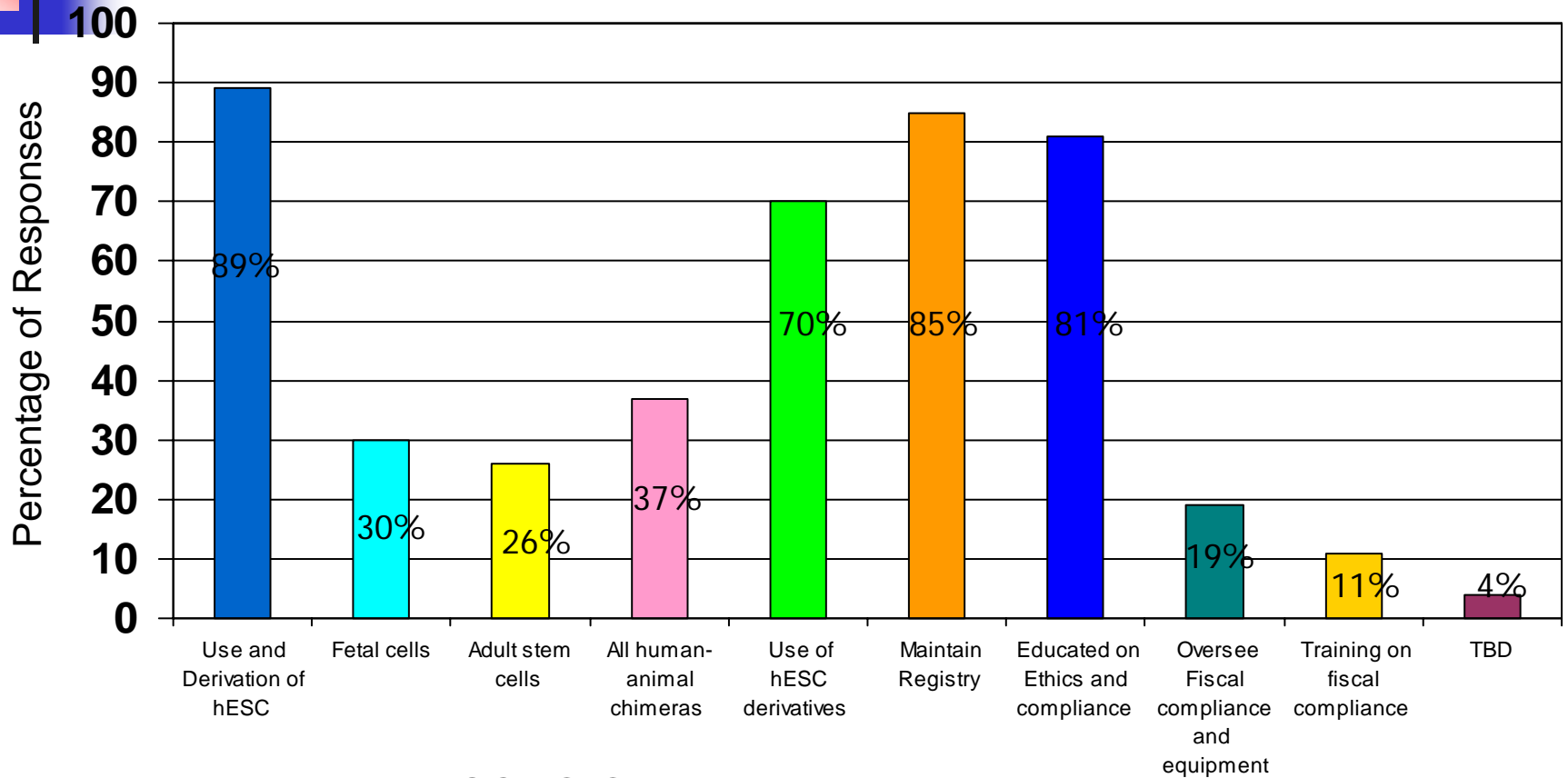
Number of Scientists on ESCRO Committee



Section III.

ESCRO Oversight Responsibilities

(Check all that apply)

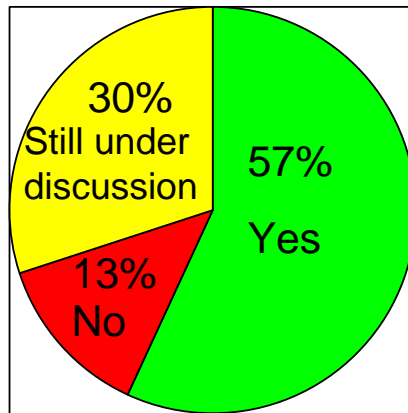


N = 25

ESCRO Oversight Responsibilities

Does Your ESCRO Have Final Approval on Research Projects?

ESCRO Gives Final Approval

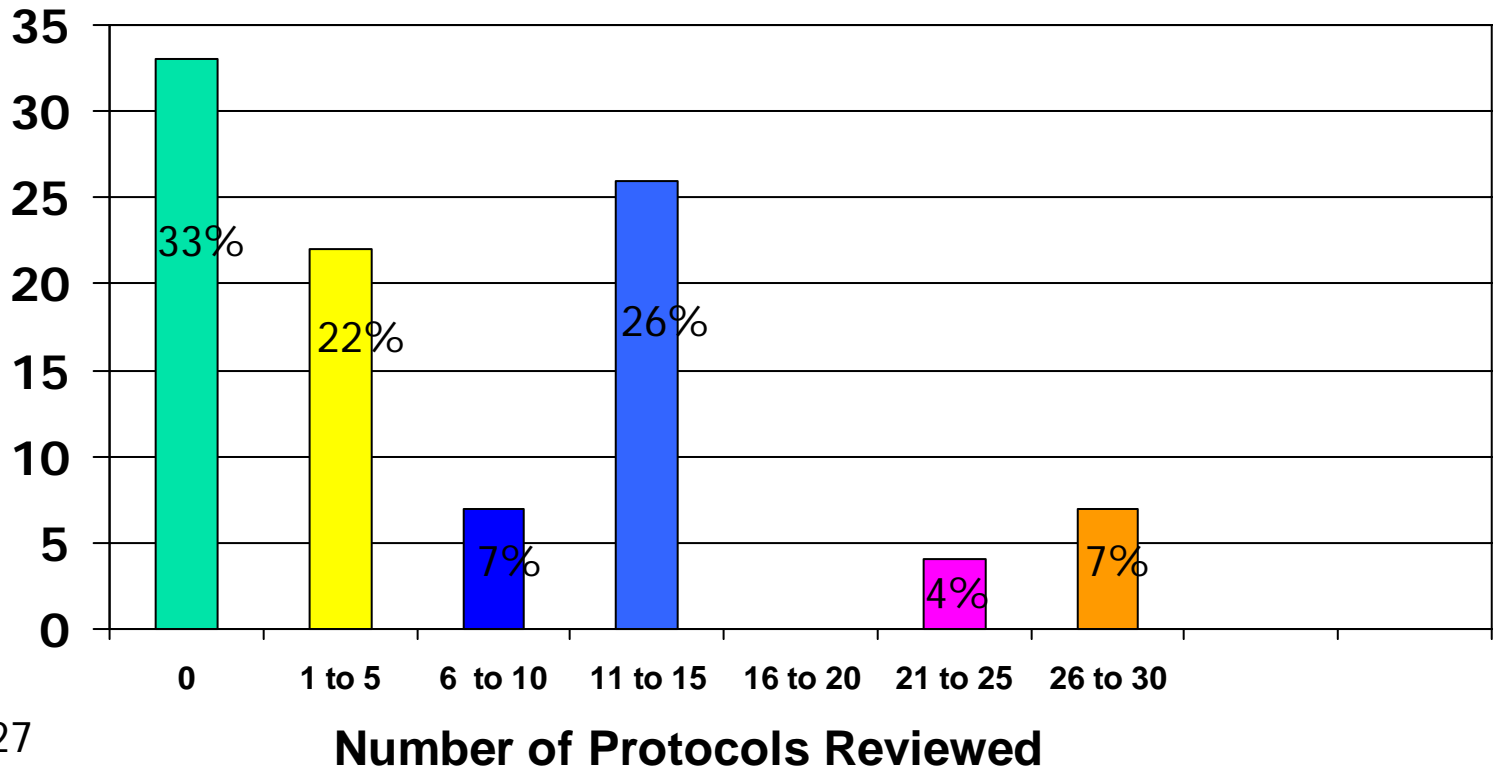


N = 30

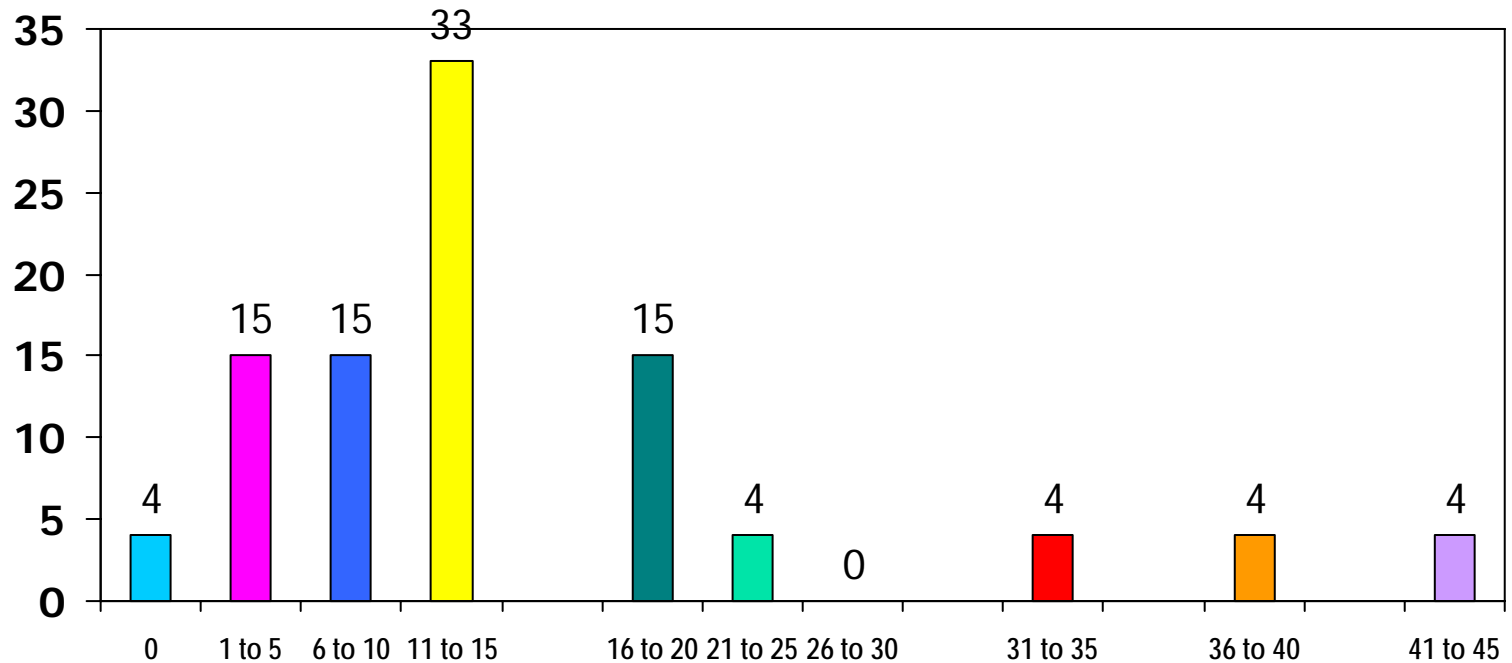
If not ESCRO, who?

- Vice Chancellor of Research.
- Financial compliance committee.
- If the project required IRB approval IRB has final say in approving the project.

Number of Protocols Reviewed by ESCRO Since September 2005



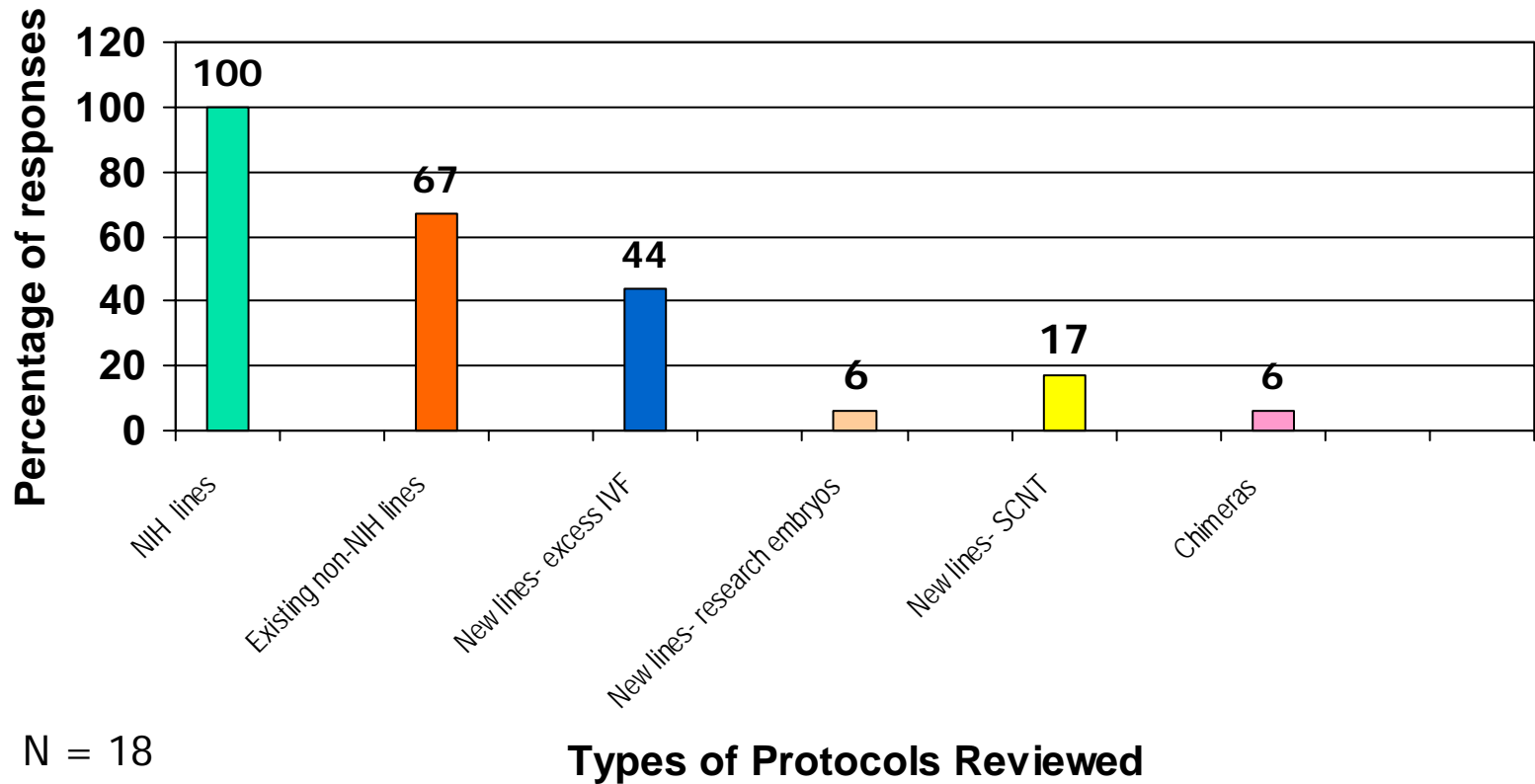
Estimated Number of Protocols to be Reviewed in the Next 12 Months



N = 26

Estimated Number of Protocols to be Reviewed

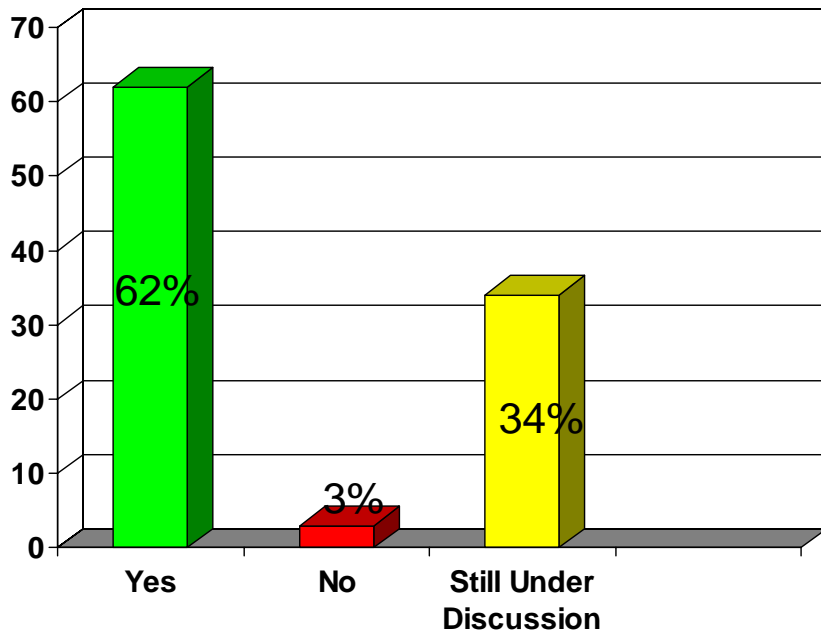
Types of Protocols Already Reviewed by ESCRO



Section IV.

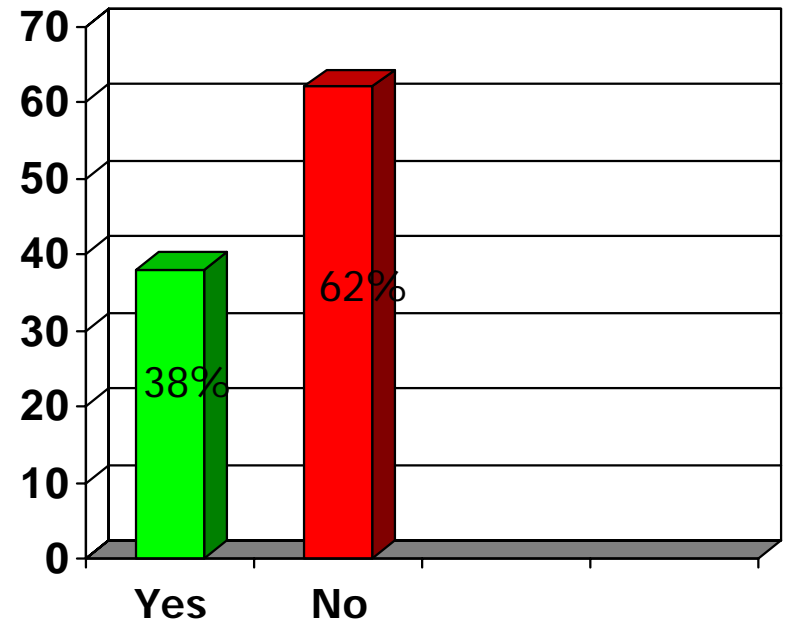
Has Your ESCRO Accepted Some NIH-Registered Lines?

ESCRO Acceptance of Some NIH-Registered Lines



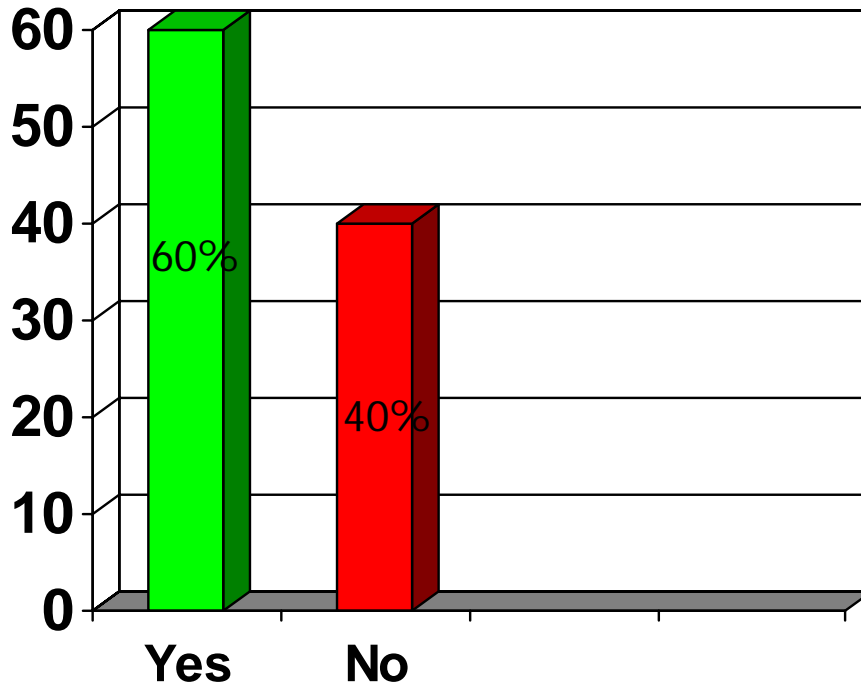
N=29

If accepted, did ESCRO investigate provenance of the lines?



N=13

Has Your ESCRO Accepted All NIH-Registered Lines?

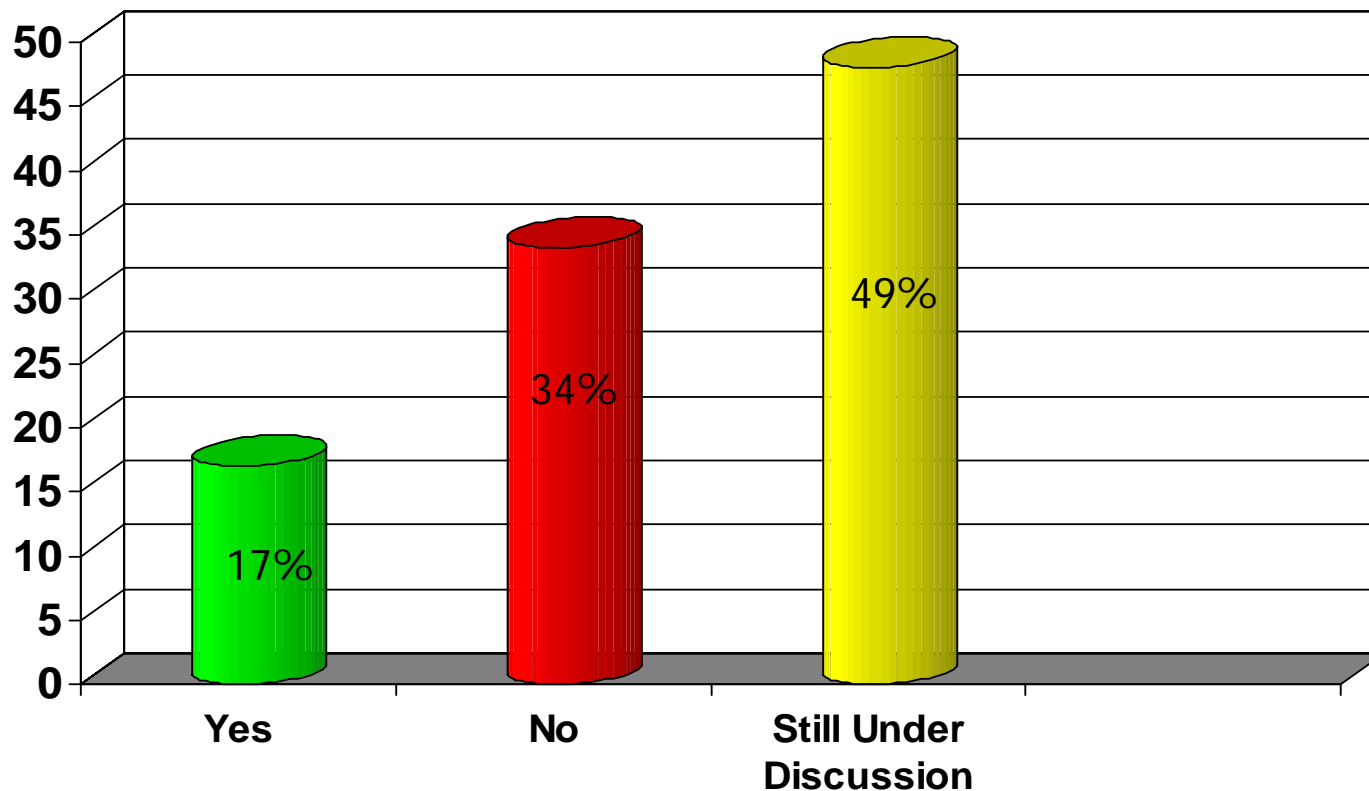


N = 20

If No, reasons for not accepting all NIH-Registered Lines:

- Still under discussion.
- ESCRO will review each protocol individually.
- We have only received requests for 4 lines thus far.
- Only reviewing those in use at our institution.

Does Your ESCRO Have Different Criteria for Informed Consent of hESC Lines Derived Prior to and After the NAS 2005 Guidelines?



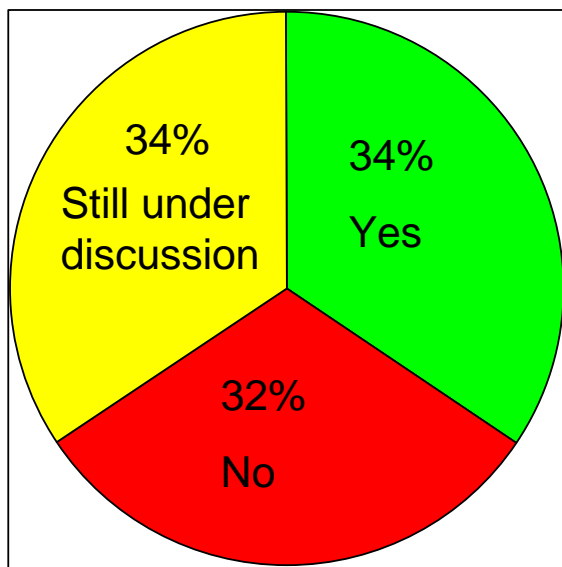
N=29

Difference in criteria for IC's of hESC derived before and after NAS 2005 guidelines.

Section V.

Does Your State or Institution Permit Reimbursement of Direct or Indirect Expenses to Oocyte Donors for Stem Cell Research?

Reimbursement of Expenses to Oocyte Donors



N = 29

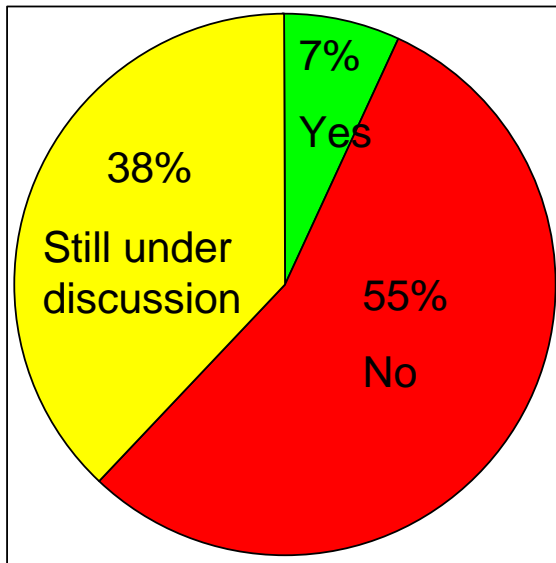
If Yes, Permitted

Reimbursements:

- Transportation
- Childcare
- Housing
- Medical care
- Health insurance
- Determined on case by case basis

Does Your State or Institution Permit Compensation of Direct or Indirect Expenses to Oocyte Donors for Stem Cell Research?

Compensation of Expenses to Oocyte Donors



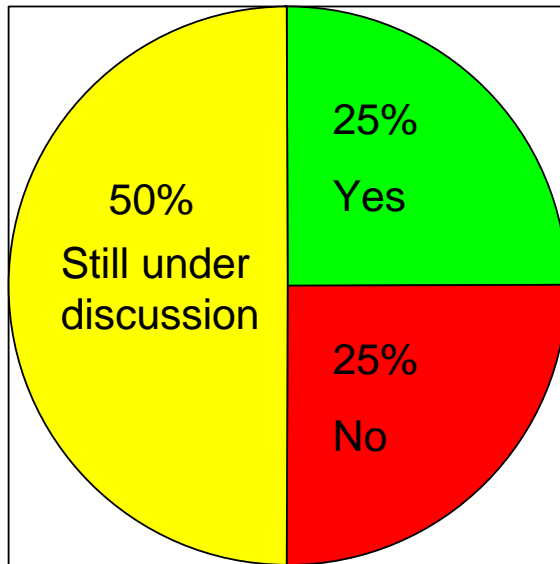
N = 29

If Yes, Permitted Compensations:

- To Be Determined
- Transportation
- Medical costs

Does Your State or Institution Permit Reimbursement of Direct or Indirect Expenses to Sperm Donors for Stem Cell Research?

Reimbursement of Expenses to Sperm Donors



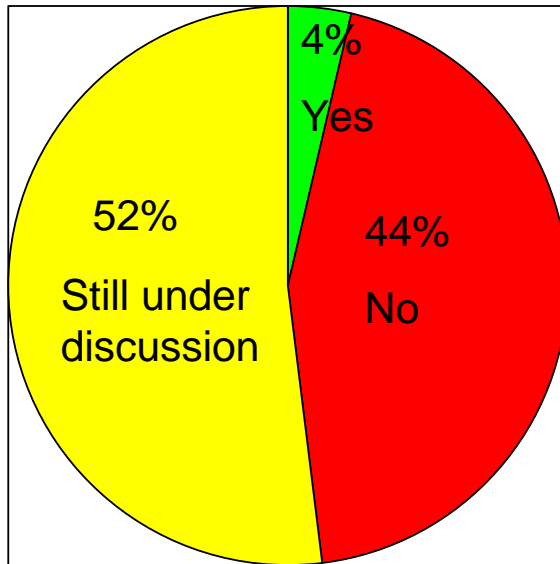
N = 28

If Yes, Permissible Reimbursements:

- Transportation
- Expenses IRB has determined reimbursable. e.g. medical care, housing, child care and lost wages

Does Your State or Institution Permit Compensation of Direct or Indirect Expenses to Sperm Donors for Stem Cell Research?

Compensation of Expenses to Sperm Donors



N = 27

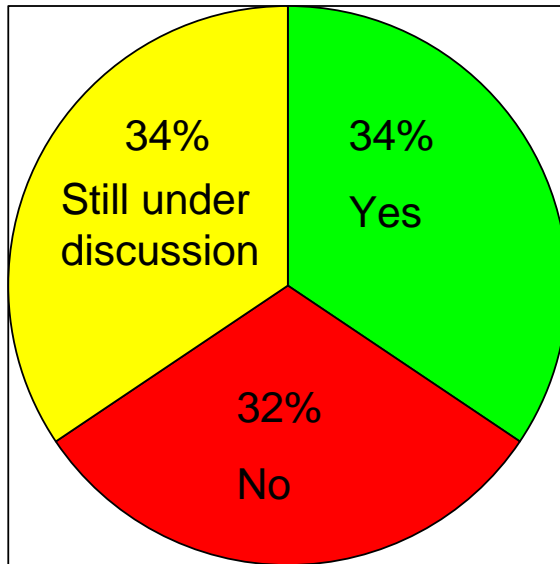
If Yes, Permissible

Reimbursements:

- Out of pocket costs e.g. transportation

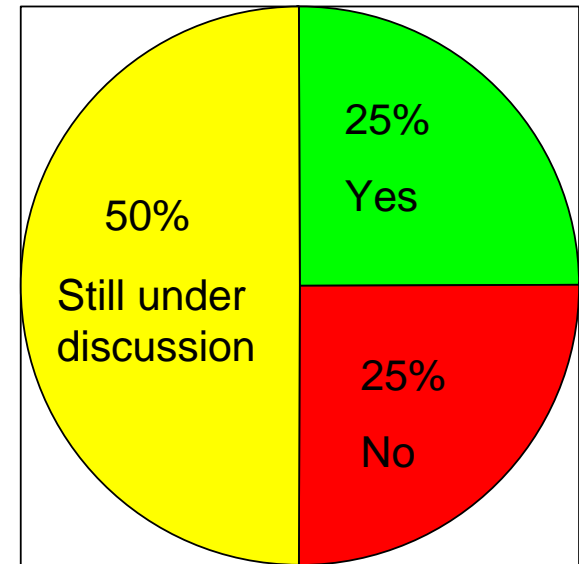
Contrast of State or Institutional Policies of Reimbursement for Oocyte and Sperm Donors

Reimbursement of Expenses to Oocyte Donors



N = 29

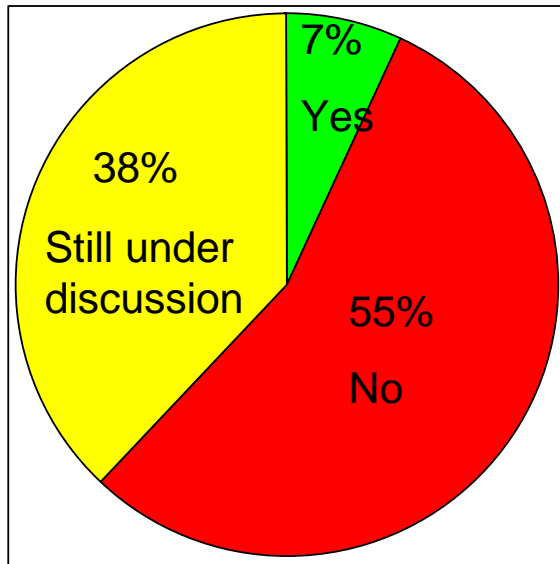
Reimbursement of Expenses to Sperm Donors



N = 28

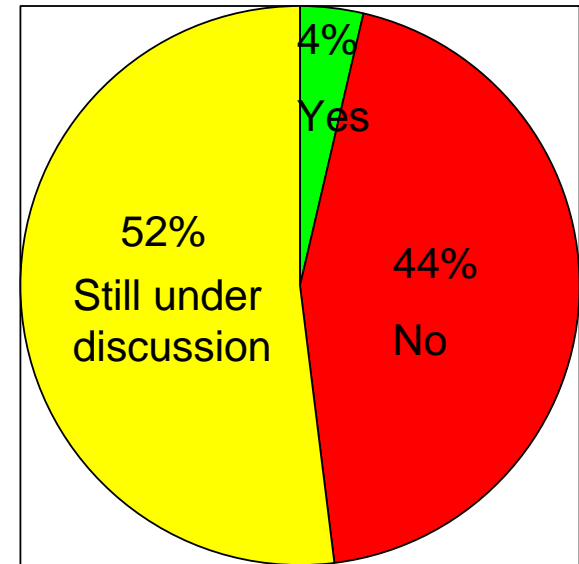
Contrast of State or Institutional Policies of Compensation for Oocyte and Sperm Donors

Compensation of Expenses to Oocyte Donors



N = 29

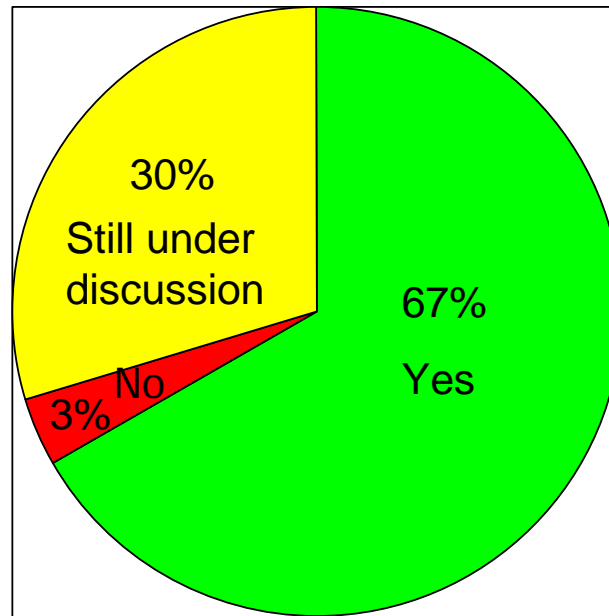
Compensation of Expenses to Sperm Donors



N = 27

Section VI.

Has Your ESCRO Implemented the 2005 NAS Guidelines?



N=27



What Policies That Supplement the NAS Guidelines has Your ESCRO Developed for Overseeing the Derivation of New Lines from Excess IVF Embryos?

- California Institute for Regenerative Medicine (CIRM) Regulations are used.
- California State Law SB1260.
- Clear statements of biomedical rationale for new lines are required. The number of requested embryos are required as well.
- Our state does not permit derivation of new stem cell lines.
- Still under discussion (50%).



What Policies That Supplement the NAS Guidelines has Your ESCRO Developed for Creating New Embryos Solely for Research Purposes, including using SCNT?

- California Institute for Regenerative Medicine (CIRM) Regulations are used.
- This is not allowed at our institution.
- Our state does not permit the creation of new embryos for the purpose of research.
- Still under discussion (more than half stated this).

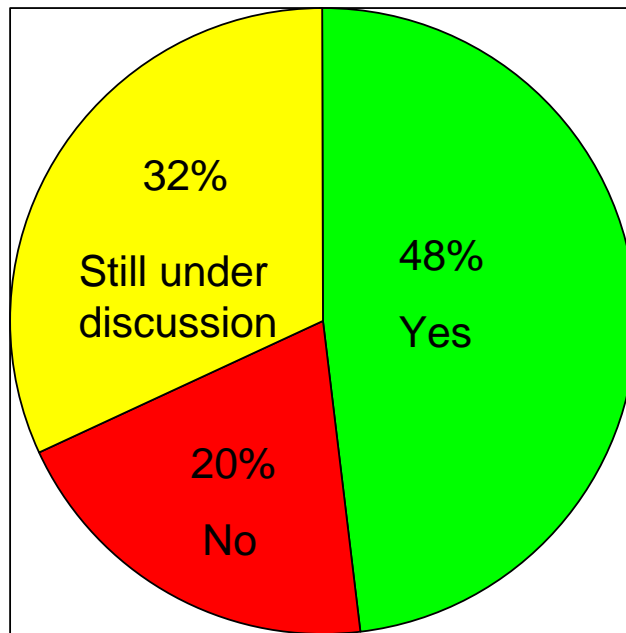


What Policies That Supplement the NAS Guidelines has Your ESCRO Developed for Overseeing the Creation of Chimeras?

- Questions regarding number of cells to be injected, location of injection, stage of development of the animal are asked. Additionally a description of how breeding will be prevented is needed.
- Follow NAS guidelines and focus primarily on likelihood of contribution to brain and gamete function.
- Protocols involving chimeras require extra ethical scrutiny and are reviewed by ESCRO committee.
- Still Under Discussion (more than half stated this).
- None yet.

Section VII.

Does Your ESCRO Have a Policy for Managing Financial Conflicts of Interest (COI)?

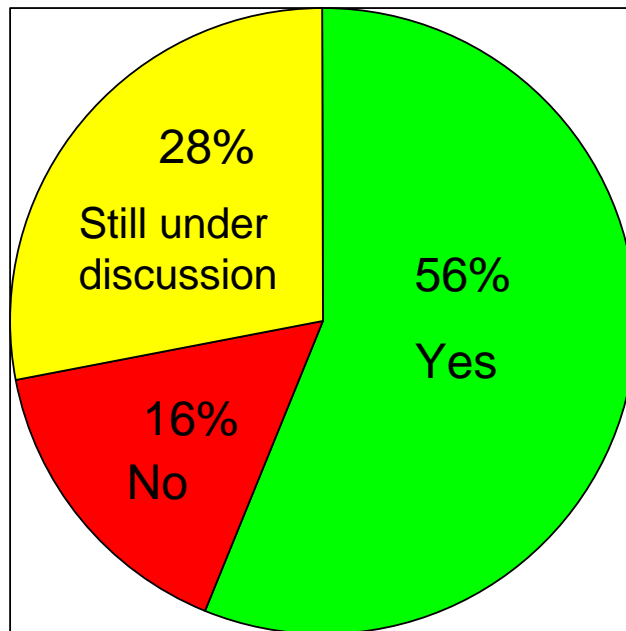


N=25

If Yes, Policies Implemented:

- Member may not vote or review proposal.
- Member not considered as part of quorum for that meeting.
- University must review COI cases.
- Disclosure of COI is given at beginning of each ESCRO meeting.

Does Your ESCRO Have a Policy on Managing Personal/Professional Conflicts of Interest (COI)?



N=25

If Yes, Policies Implemented:

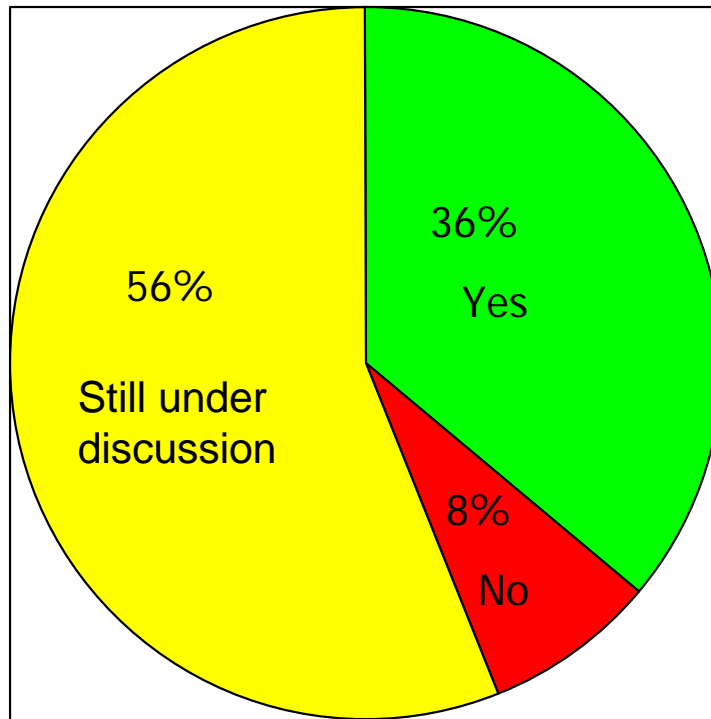
- Recusal.
- COI member must leave room for discussion and vote.
- COI person cannot be P.I. on project, but can be Co-P.I.
- ESCRO members are polled at each meeting about COI.
- Standard COI policies.

Section VIII.

Has Your ESCRO Developed a Program for Educating Investigators About Ethical Issues and Guidelines for hESC Research?

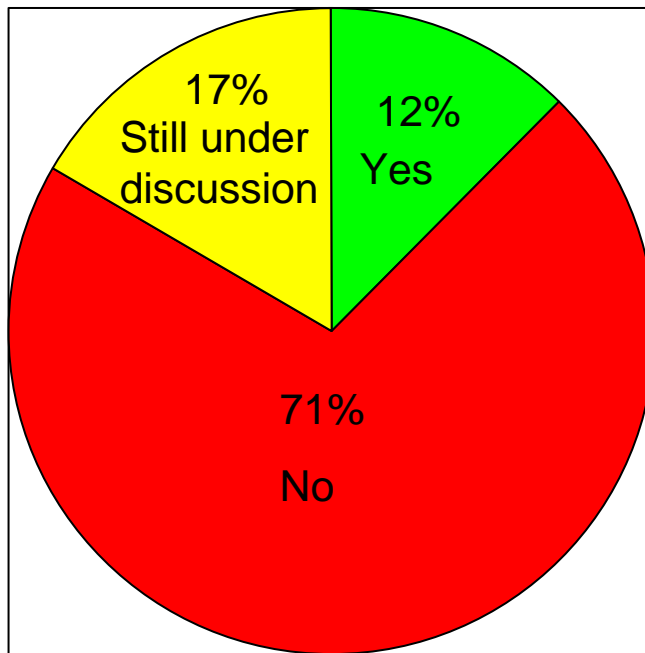
If Yes, Describe Program:

- Campus wide workshops and discussions on ethical issues with use of hESCs.
- Annual lecture.
- Website, newsletter, talks to various faculty groups.
- Web-based training is planned.
- Online course for researchers is currently being developed.



N = 25

Has Your ESCRO Engaged the Public in a Discussion on hESC Research Issues and Policies?



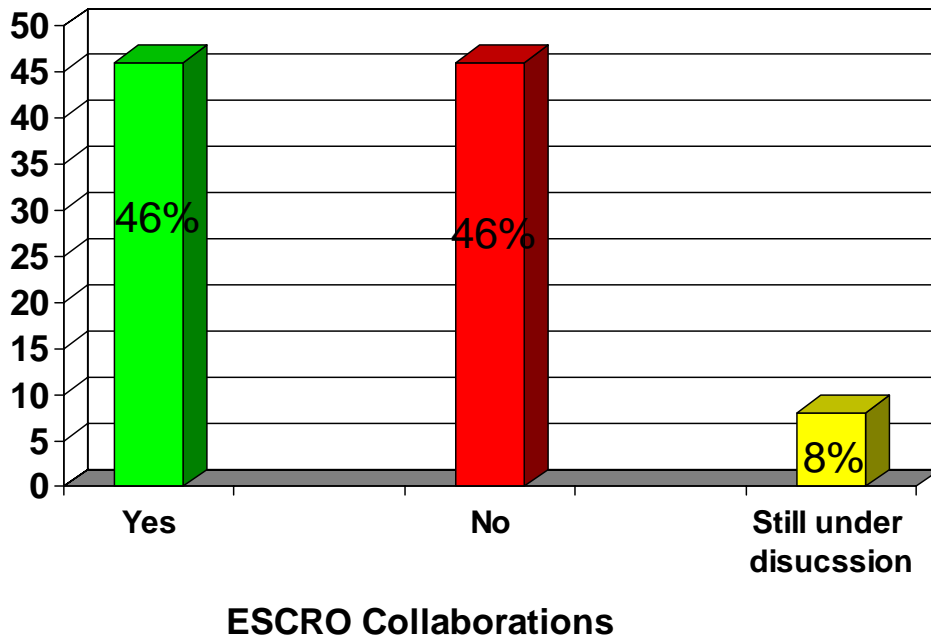
N = 24

If Yes, Describe Venue or Process:

- ESCRO members have participated in five public programs about hESC research.
- A public conference was held in Spring 2006.
- Various campus sponsored public forums with ESCRO members.

Section IX.

Have There Been Collaborations Between Your ESCRO and Other ESCROs in Developing Guidelines and Policies?

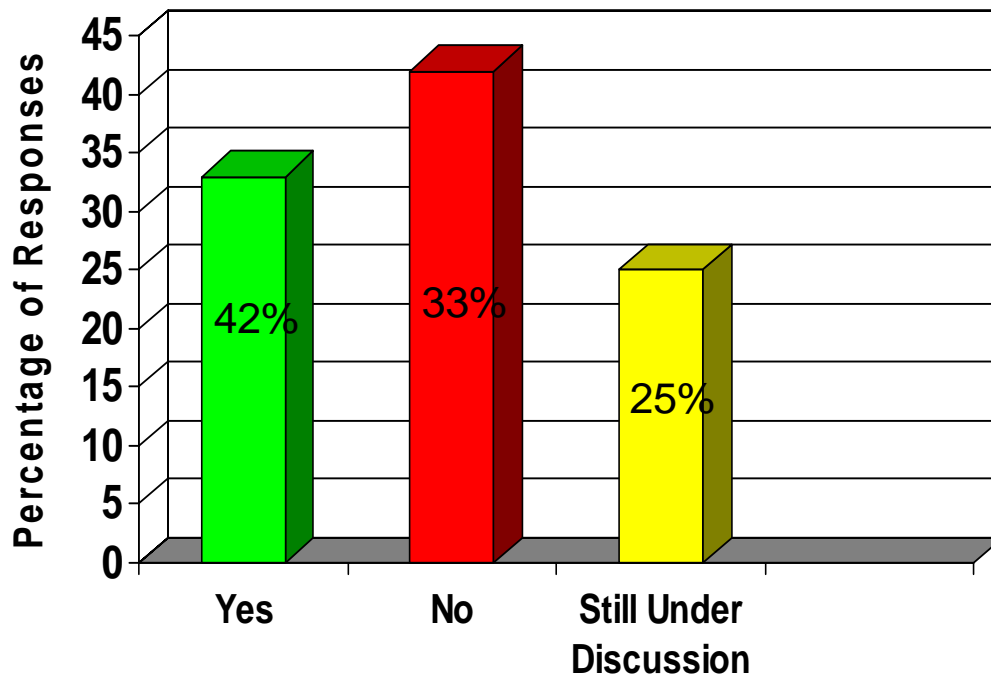


N=24

If Yes, Nature of Collaborations:

- State wide meetings and sharing of documents and provenance information.
- Chairs of ESCROs in the state correspond by e-mail and meet to develop policies.
- Joint presentations at a major conference and ongoing discussions about documents and policies.

Are There Formalized Collaborations Between Your Institutions and Others for Sharing Stem Cell Lines and Embryos?



Collaborations Between Institutions to Share Stem Cell Lines or Embryos

N = 24

If Yes, Nature of Collaborations:

- Partnered with another institution in a stem cell bank and core.
- hESC lines are both shared with and obtained from other institutions.
- MTA process.
- Transplantation of ES-derived differentiated cell populations.



Section X.

Suggested Topics for Further Discussion

- Discussion of ethical issues associated with hESC research. How do people view ethical issues? How to insure researchers understand the issues and conduct ethical research?
- Discussion of provenance of established lines being placed in an easily accessible location for all to see, such as the internet.
- NAS provenance criteria and level of ESCRO review.
- Should ESCROs include non-scientific members in order to democratize the process and provide a voice for the lay community?
- When is research with a hESC derivative no longer subject to ESCRO oversight?
- Should ESCROs review proposals using adult stem cells or only those that involve pluripotency?
- Sharing of ideas from ESCRO committees with established or more developed guidelines
- To what extent should derivatives be monitored?
- Under what conditions would/should a research proposal be rejected? Are there any cell lines out there that have been obtained under questionable circumstances? How can/should an institution prepare for creating and maintaining clinical quality cells?
- Many schools will not create a committee until there are bonafide regulations.
- Do other committees feel that hESCs on the NIH registry have sufficient evidence of provenance?
- Are other committees reviewing protocols that involve chimeras or simply those that involve the germ-line or brain? Do other committees review protocols utilizing adult stem cell protocols?



Conclusion

- Most ESCRO's throughout the U.S. are still in their beginning phases.
- Acceptance of NIH-registered lines is an area of continued discussion.
- There is a gender divide in regards to reimbursement and compensation for oocyte and sperm donors.
- This survey has allowed us to better understand the areas in which ESCRO policies and guidelines need to be developed such as:
 - ESCRO Oversight Committee Responsibilities
 - Implementation of NAS Guidelines
 - State or Institutional policies on reimbursement and compensation for oocyte and sperm donors
 - Educational training for investigators
 - Policies and guidelines for overseeing the creation of chimeras
 - Policies and guidelines for creating new embryos solely for research purposes
 - Policies and guidelines for overseeing the derivation of new lines from excess IVF embryos