

Establishing an ESCRO Committee

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Step Number 1

**Define what is involved in
the institutional oversight
of hESC research and
clarify the delegation of
responsibility**

Step Number 1

Potential Scope of Responsibility:

1. Finance review:
 - a. Space
 - b. Time commitment
 - c. Equipment and supplies
2. IP issues – agreements, licenses and MTAs etc.
3. Focused review of protocols
 - a. ESCRO
 - b. Other committees: IRB, IACUC, IBC
4. Education program
5. Compliance Program
6. Bank for hESCs

Step Number 1

Question:

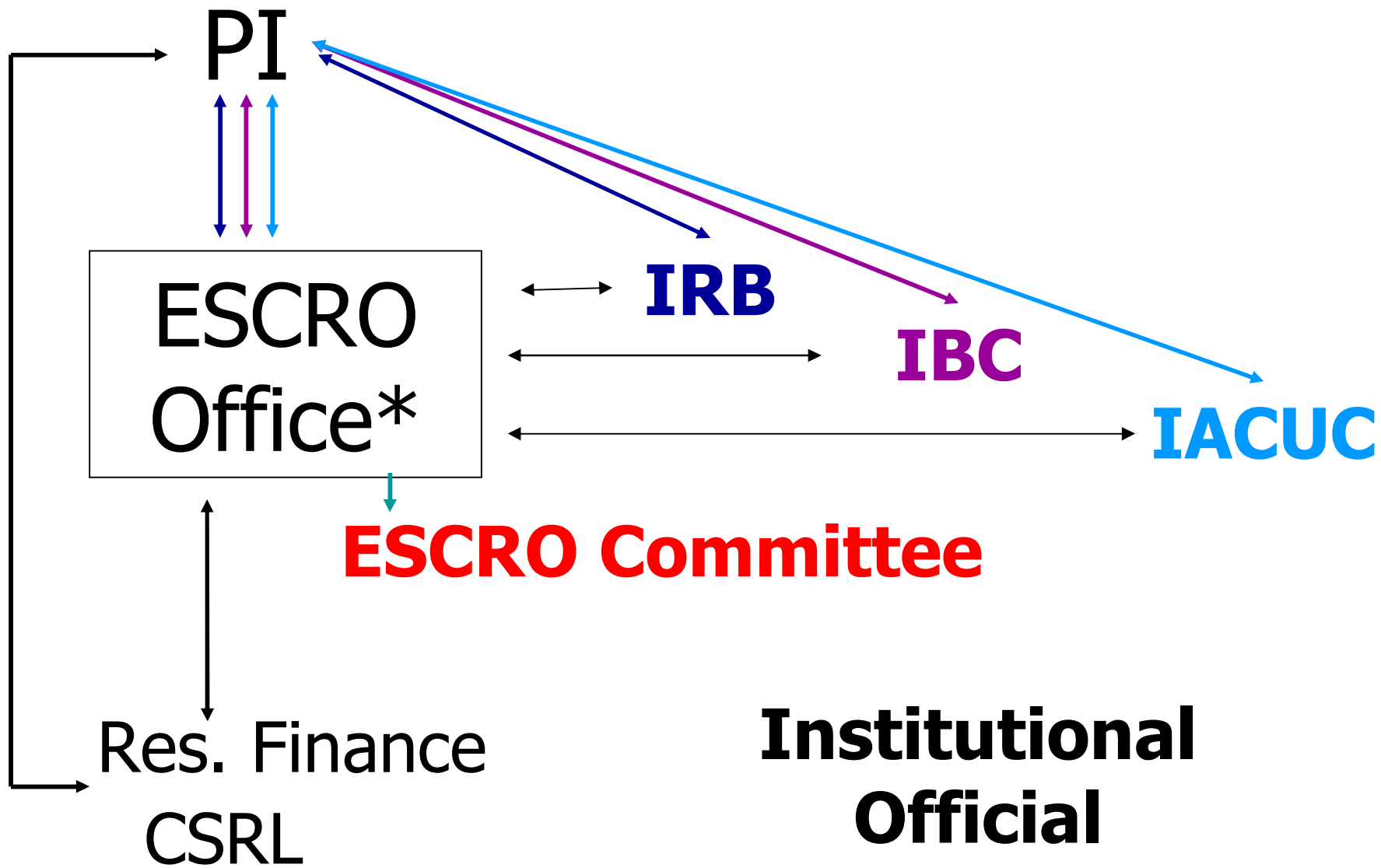
What scope of responsibility would you prefer?

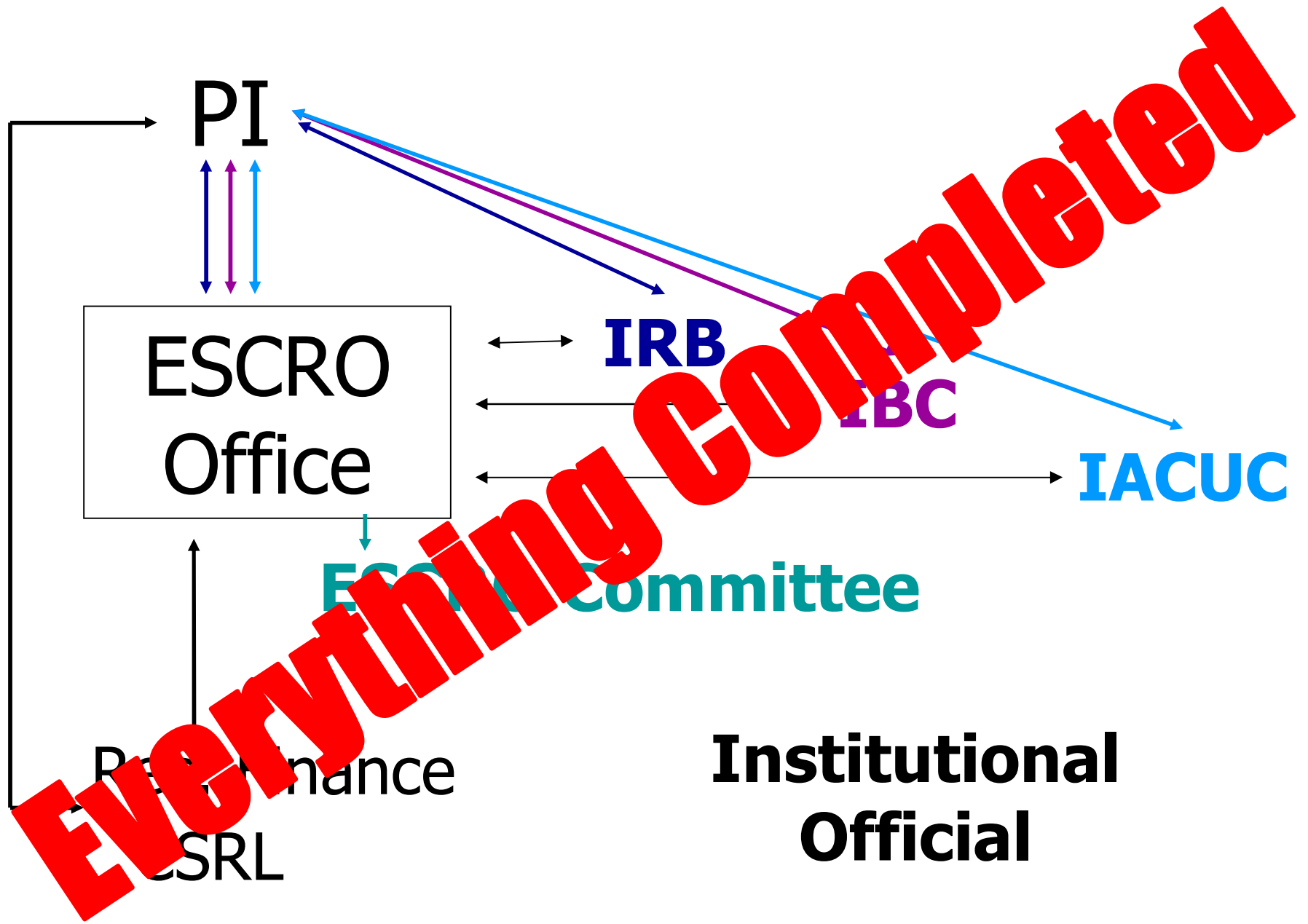
- Consider how your institution currently oversees all aspects of clinical research
- Consider how well the various components of oversight work together now

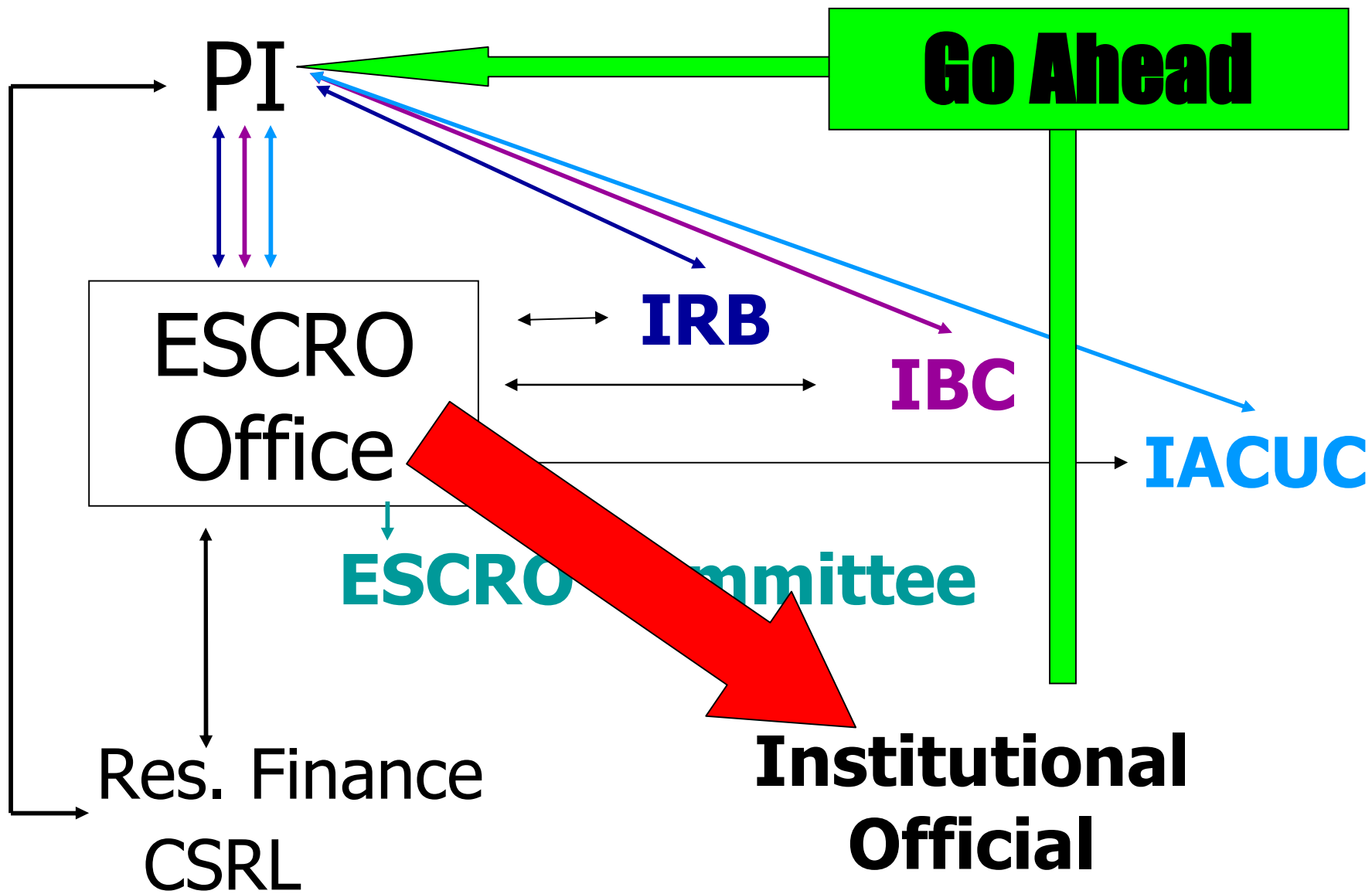
Step Number 1

For your consideration:

- If you are responsible for all aspects of oversight, consider an ESCRO Office as well as an ESCRO Committee.
- If you are only responsible for the ESCRO Committee review of protocols – be certain you know who is responsible for the rest and develop lines of communication.







Step Number 2

**Accept that you need
access to an ESCRO
Committee**

Step Number 2

Questions:

1. Do you have to have your own?
2. Can you use someone else's?
3. Should you try to create a single ESCRO that would be responsible for you as well as some/all affiliates?

Step Number 2

For your consideration:

- How much hESC research is planned at your hospital? At affiliates?
- Will 'your' PIs work in collaboration with investigators from the affiliates?
- Do the IRBs/IACUCs/IBCs from all affiliates have working relationships?

Step Number 2

For your consideration:

- Reliance on another ESCRO has some difficulty
 - No 'track records'
 - Guidance only
 - No (C)ommon Rule
 - Complex interaction with other oversight bodies (IRB, IACUC, IBC)

Step Number 3

**If you are the one who
must create the ESCRO
Committee.**

Step Number 3

“Your” ESCRO Committee.

Questions:

1. Organizationally – where does it sit?
2. To whom does it answer?
3. Who is going to pay for it? Who is going to staff it?
4. Will it be ‘free-standing’ or will it be a subcommittee of the IRB or other committee?

Step Number 3

For your consideration:

- Whether free-standing or a sub-committee – delineate who is responsible for what? And clearly identify those areas of overlap – and who has final authority. For example:
 - Informed consent process and form: IRB and ESCRO
 - Final protocol approval: Is an ESCRO approval enough to start the research?
 - Creation of chimeras: IACUC and ESCRO

Step Number 3

For your consideration:

- The ESCRO could report to the same institutional official responsible for the IRB/IACUC/IBC.
- Define the needs of the committee and calculate the resources needed to maintain the committee.
 - It is NOT an add-on to any pre-existing committee or function.

Step Number 4

Molding the ESCRO Committee.

**What should your
committee look like?**

Step Number 4

Molding the ESCRO Committee.

Questions:

1. How many members?
 - a. What categories of members?
 - b. Who is considered conflicted?
2. Meeting how often?
3. Rules of operation:
 - a. Borrow from the IRB/IACUC models?
 - b. Wing it?

Step Number 4

For your consideration:

- Valuable expertise for the committee
 - Scientists with expertise in stem cell biology and developmental biology
 - Clinicians
 - IVF professionals
 - Ethicists
 - Regulatory experts
 - Community members
 - Legal

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Define a quorum by both size and 'type' of member present.

Step Number 4

For your consideration:

- Valuable expertise for the committee
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 - Clinicians
 - Life professionals
 - Ethicists
 - Regulatory experts
 - Community members
 - Legal

**DOES EVERYONE
WOTES?**

Step Number 4

For your consideration:

- The committee members as well as you are all on a steep curve.
- Even if the number of protocols is small – routine meetings may be helpful.
- Do NOT 'wing it.' Develop concrete rules of operation. The IRB model provides a good template. And if IRB rules do not work – be willing to course correct.

Step Number 5

Figuring out policies.

Gotta have 'em!

Step Number 5

Figuring out policies.

1. Will the ESCRO Committee write the policies?
 - a. If not, who will?
2. Who can sign-off on policies?
3. Will the policies be consistent with the NAS and/or ISSCR Guidelines?
 - a. If not, how will differences be justified?

Step Number 5

For your consideration:

- If you are not consistent with NAS (or other) Guidelines
 - Suggest ESCRO Committee develop justification document
 - Institutional Official should be notified and possibly be asked to approve

Step Number 6

**What will the ESCRO
Committee review?**

And how?

Step Number 6

What will the ESCRO Committee Review? And how?

Questions:

1. human Embryonic Stem Cells (hESC) only?
2. All 'pluripotent' stem cells
 - Amniotic Fluid Cells
 - Reprogrammed cells
3. Non-pluripotent stem cells (Adult and other)

Step Number 6

What will the ESCRO Committee Review? And how?

Questions:

1. Derivation of targeted stem cells
2. Use of stem cells
 - Identifiable versus unidentifiable
 - All uses or just chimeras?
3. Use of stem cell derivatives?

Step Number 6

What will the ESCRO Committee Review? And how?

Questions:

1. Will all protocols require full committee review?
2. Will there be any administrative review?

If yes, how will this be conducted?

Step Number 6

For your consideration:

- Use IRB and IACUC as possible templates for policies of protocol review
- Beware of duplicating existing review – i.e. consent form review and the IRB
- Be aware and beware of state laws

Step Number 7

So, the IRB and the IACUC and the IBC want to know what the impact of the ESCRO Committee is on the status quo.

Step Number 7

IRB and ESCRO and IACUC and IBC – who has the final say?

1. Will the reviews be parallel? Or linear?
2. Does one committee have the final say on the consent form?
3. Does one committee have the final say on the experimental design?
4. Who tells the investigator that s/he can begin the research? (Who has final say?)

Step Number 7

For your consideration:

- First figure out who has the final say and will give the 'go-ahead'
- Discuss with existing oversight committees re: roles

Activity	ESCRO full review	ESCRO adm. review	IRB	IACUC	IBC (COMS)	Other
1. hESC Derivation						
a. from embryos						
b. via SCNT						
2. Pluripotent Deriv'n						
a. Amniotic fluid						
b. Other						

Activity	ESCRO full review	ESCRO adm review	IRB	IACUC	IBC	Other
3. Non-chimera use						
a. ID hESCs						
b. non-ID hESCs						
c. ID pluripotent						
d. non-ID pluripotent						
4. Chimera Research						
a. hESCs						
b. Pluripotent						
c. Other stem cells						
5. Derivatives						
a. of hESC						
b. Pluripotent						

Step Number 8

Going forward

Questions:

1. How do you know if you are on the 'right' track?
2. How to keep up with changing guidance and guidelines?

Step Number 8

For your consideration:

- Be willing to course-correct
- Seek out support
 - Other ESCROs at other institutions
- Guideline folks (NAS and ISSCR)