



**Feedback on Implementation of
2005 NAS hES Cell Research Guidelines**

National Academy of Sciences

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Stem Cell Research at *Johnson & Johnson*

- ◆ **Recognized potential several years ago**
 - May offer important patient benefits in new ways to prevent, treat and cure disease
- ◆ **Also recognized ethical, moral, religious concerns about hES cell research**
 - Committed to appropriate balance of scientific pursuit and ethical/moral sensitivities
- ◆ **In 2002, established process to:**
 - Understand issues and perspectives
 - Implement guidelines for human pluripotent stem cell research
 - Ensure robust oversight of such research



Guidelines on Human Pluripotent Stem Cell Research

- ◆ **Insure that the highest ethical and scientific standards are maintained in any research program involving human stem cells**
- ◆ **Apply to research by Johnson & Johnson Operating Companies, external grant recipients, research collaborators and investments in external companies**
- ◆ **Require that any research involving hES cells complies with NAS Guidelines for Human Embryonic Stem Cell Research**



Committee on Human Pluripotent Stem Cell Research

- ◆ **Reviews and approves proposals for all investments and activities in hES cell research**
- ◆ **Oversees Guideline implementation**
- ◆ **ESCRO equivalent**
- ◆ **Composed of senior R&D leaders and executives from COSAT, Legal, and Public Affairs, and external experts in bioethics and health care**
 - **Senior Scientific Committee provides additional level of review by Corporate VP of COSAT and two R&D leaders at the rank of President or above**



Implementation of NAS hES Cell Research Guidelines

- ◆ **Process implementation has been smooth**
- ◆ **Adapted composition of “ESCRO” Committee**
 - **Selected appropriate lay person**
 - § **Requires an individual with broad perspective on public views and sensitivities**
 - § **Appointed a Johnson & Johnson senior public affairs professional who represents the general public**
 - **Specialized expertise**
 - § **Will engage external experts, as needed**

Potential ESCRO Issues: Human-NonHuman Animal Chimeras

- ◆ **NAS hES Cell Research Guidelines:**

“It is a subject of deep moral concern to many thoughtful people for whom the creation of animals with certain kinds or qualities of human tissues, such as neural or germline cells, would be offensive”

- ◆ **Testing of hES cells in animals generally will be required for hES cell therapies prior to introduction into humans and for regulatory approvals**

- ◆ **Need to balance clinical, regulatory, ethical and moral issues related to human-nonhuman animal chimeras**

- § **Support establishment of a national body to provide ongoing guidance**

Potential ESCRO Issues: Proliferation of hES Cell Rules

- ◆ Many countries, states and societies are promulgating rules, regulations, guidelines, opinions, etc. , regarding hES cell research
- ◆ Multi-center studies in hES cell research will necessitate ESCROs to be aware of and evaluate inconsistencies among various rules and guidelines
- ◆ Will NAS monitor developments and maintain up-to-date information and assessments to assist ESCROs?

Human Embryonic Stem Cell Research

Transformational, innovative technology



Unique, new challenges



NAS Guidelines for hES Cell Research

Thank you!