

# **CIRM's hESC Census Project: Evaluating the Value of ESCRO Review & Oversight**

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# Project Goals

## Primary:

- Goal is to document hESC line utilization by grant number
- Distinguish at least 3 categories: (1) NIH approved “Bush” lines, (2) NIH registry lines (3) CIRM-derived lines

## Secondary:

- Goal is to code hESC line utilization by area of research
- Code hESC utilization grant according to our established disease categories on the CRIM web page

## Tracking and assessing the rise of state-funded stem cell research

VOLUME 28 NUMBER 12 DECEMBER 2010 **NATURE BIOTECHNOLOGY**

## Access to human embryonic stem cell lines

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Cell Stem Cell  
**Brief Report**



### Distribution of Human Embryonic Stem Cell Lines: Who, When, and Where

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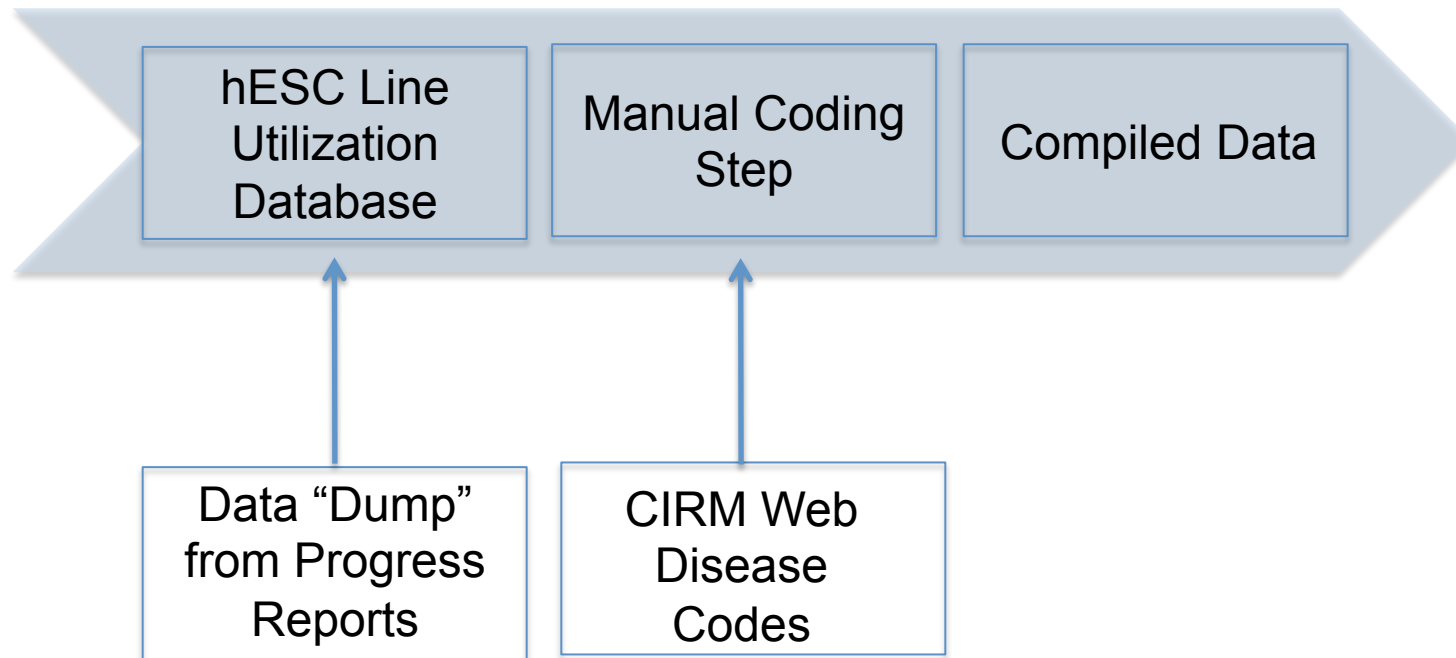
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This study reports data from a recent survey of stem cell scientists in the United States to assess the importance of access concerns in the development of hESC science (**Supplementary Methods**). The survey included scientists working with a range of cell types and had an overall response rate of ~31%. The analysis reported here focuses on the subset of respondents ( $n = 205$ )

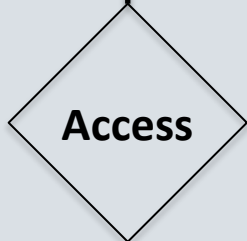
This analysis lends empirical support to previously anecdotal concerns over the ability of hESC scientists to acquire key research tools. The prevalence of delays and the inability of 28% of hESC scientist respondents to acquire a desired cell line suggest that ongoing efforts to simplify the process of acquiring hESC lines should be continued and, if possible, accelerated<sup>2,10</sup>.

# Census Draws on CIRM Progress Reports



# Protocol Documents hESC Utilization by Grant Award

**6.30.11 capture  
cell line utilization  
n = 339 events**



- Create unique record for each hESC line with grant ID
- Standardize hESC line names
- Regulator code table for each hESC line
- Relate tables and populate column for each hESC line / grant

**7.21.11 QC  
primary data with  
tables**

**97 grants with 1  
or more utilization  
events**

**138 unique hESC  
line utilized in the  
97 awards**

**8.11.11 Grant  
number and 1<sup>o</sup> and  
2<sup>o</sup> disease focus**

# hESC Lines Fall into Five Regulatory Categories

Table 1: CIRM Grantee hESC Utilization by Regulatory Status

Regulatory Status	Number of Lines	Percent
[1] Current NIH Registry lines	35	25
[2] CIRM derived Lines (not in current NIH Registry)	9	7
[3] ESCRO approved lines	70	51
[4] NIH Registry prior to 2009	10	7
[5] UKSCB lines	14	10
<b>Totals:</b>	<b>138</b>	<b>100</b>

# Three Out of Ten Most Frequently Used Lines Not NIH Approved

Table 2: hESC Lines Most Frequently Used by CIRM Grantees

Line Name	Number of Grants	NIH Approved
H9	77	Yes
H1	53	Yes
HuES-9	17	Yes
H7	15	Yes
HSF1	13	No
HSF6	11	No
HuES-6	11	Yes
HuES-7	10	Yes
HuES-1	8	Yes
HES 2	7	No



## Use of hESC Lines by CIRM Grantees: The Value of Embryonic Stem Cell Research Oversight (ESCRO) Committees

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### Introduction

Human embryonic stem cell (hESC) research occupies an exceptional place in science because governments and funding organizations have adopted unique policies to influence research conduct [1]. These policies often extend to the research tools themselves, hESC lines. For example, the U.S. NIH maintains a registry of hESC lines approved for use in research it funds. The U.K. Stem Cell Bank employs a vetting procedure to ensure deposited lines conform to specific requirements.

As a consequence the use of specific hESC lines is a topic of ongoing international interest because utilization patterns serve as a research and evaluation tool. For example, previous studies have examined utilization patterns to evaluate the impact of state-based research programs [2]. McCormic et. al. examined distribution rates and patterns of hESC line utilization as an indicator of state research capacity [3]. Karmali et al. [4] examined the use of hESC lines not eligible for NIH funding as an indicator of the efficacy of state-funded stem cell research programs [4]. These studies quantified transfers

To be acceptably derived any one of the following criteria must be met:<sup>1</sup>

1. Be approved for use in NIH-funded research after March 2009 ([NIH Registry Lines](http://stemcells.nih.gov/research/registry/)) [<http://stemcells.nih.gov/research/registry/>]
2. Be derived by a CIRM-funded grantee in accordance with CIRM requirements ([CIRM-derived lines](http://www.cirm.ca.gov/files/reg/pdf/Reg100080_SM_Acct_Standards.pdf)) [[http://www.cirm.ca.gov/files/reg/pdf/Reg100080\\_SM\\_Acct\\_Standards.pdf](http://www.cirm.ca.gov/files/reg/pdf/Reg100080_SM_Acct_Standards.pdf)]
3. Be determined to meet CIRM standards by anESCRO committee (ESCRO approved lines)
4. Be NIH-approved prior to 2009 but not currently listed in the NIH Registry ([NIH Registry prior to 2009](http://stemcells.nih.gov/staticresources/research/registry/PDFs/FormerRegistry.pdf)) [<http://stemcells.nih.gov/staticresources/research/registry/PDFs/FormerRegistry.pdf>]
5. Be deposited in the UK Stem Cell Bank ([UKSCB lines](http://www.ukstemcellbank.org.uk/stemcelllines.cfm)) [<http://www.ukstemcellbank.org.uk/stemcelllines.cfm>]



# CIRM Disseminates Findings for Broad Audiences



## CIRM Research Results

Summaries of publications based on funding by the California Institute for Regenerative Medicine

WEDNESDAY, DECEMBER 14, 2011

### ➔ Limited access to human embryonic stem cell lines? Survey says...

Geoff Lomax is CIRM's Senior Officer to the [Standards Working Group](#)

Is the ability to obtain embryonic stem cell lines hindering research, what factors influence access, and does availability vary by state? These questions have been the subject research and their answers are not entirely clear. [A recent publication in Nature](#) by Aaron Levine of the Georgia Institute of Technology suggests that access issues do impact research. In his paper, he writes:

“an inability to acquire certain hESC lines have likely hindered hESC science in the United States.”

This conclusion is based on a survey of stem cell scientists in the United States. Levine focused his discussion on the subset who reported using human embryonic stem cells. A sizable number of these scientists-- 38%--reported excessive delay in obtaining lines and 28% reported they were unable to acquire a stem cell line they wanted to study. Factors attributed to delays included problems with materials transfer agreements (MTAs) and an inability to obtain approval from an

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