Guide to Submission

VistaGen Therapeutics, Inc.
Submission #2011-ACD-001

(1)

hESC Registry Application Database

Detailed Listing for Request #: 2011-ACD-001
April 22, 2011

hESC Registry Application Search Results

Request #: 2011-ACD-001
Status: Pending

Review: ACD

Assurance: Yes (Section II(B))
Certification: Yes
Authority: Yes

Cell Lines: 3
Available: 3

Previous #:
2010-DRAFT-019

Email
Edit
Delete
Switch to ADM

Organization: VistaGen Therapeutics, Inc.
Org Address: 384 Oyster Point Blvd, #8 South San Francisco, CA 94080
DUNS: 032333986 **Grant Number(s):**
Signing Official (SO): Ralph Snodgrass / 650-244-9990 x222 / rsnodgrass@vistagen.com
Submitter of Request: / /
Submitter Comments: (None)

Line #1: K117
NIH Approval #:
Available: Yes - Yes under MTA for research uses only.
Embryo from U.S.: Yes
Embryo Donated in Year(s): 1999
Provider Name: VistaGen Therapeutics, Inc.
Provider Phone: 650-244-9990
Provider Email: bd@vistagen.com
Provider URL:
Provider Restrictions: This cell line will be made available to academic institutions, under a Material Transfer Agreement, for non-commercial NIH-funded research uses only. Cost reimbursement for providing the cell will be requested.

NIH Restrictions:

Additional Information:

Line #2: J618
NIH Approval #:
Available: Yes
Embryo from U.S.: Yes
Embryo Donated in Year(s): 1999
Provider Name: VistaGen Therapeutics, Inc.
Provider Phone: 650-244-9990
Provider Email: bd@vistagen.com
Provider URL:
Provider Restrictions: This cell line will be made available to academic institutions, under a Material Transfer Agreement, for non-commercial NIH-funded research uses only. Cost reimbursement for providing the cell will be requested.

NIH Restrictions:

Additional Information:

Line #3: J713
NIH Approval #:
Available: Yes
Embryo from U.S.: Yes

(2)

Embryo Donated in Year(s): 1999
Provider Name: VistaGen Therapeutics, Inc.
Provider Phone: 650-244-9990
Provider Email: bd@vistagen.com
Provider URL:
Provider Restrictions: This cell line will be made available to academic institutions, under a Material Transfer Agreement, for non-commercial NIH-funded research uses only. Cost reimbursement for providing the cell will be requested.

NIH Restrictions:

Additional Information:

Supporting Documents:
Document 1: (PDF - 02/02/2011) Summary of Supporting Documents
Document 2: (PDF - 02/02/2011) Informed consent
Document 3: (PDF - 02/02/2011) Letter from IVF clinic
Document 4: (PDF - 02/02/2011) Stem Cell Research Oversight (SCRO) committee approval
Document 5: (PDF - 02/02/2011) Stem Cell Research Oversight (SCRO) committee renewal
Document 6: (PDF - 02/02/2011) Assurance letter from VistaGen's signing official

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Administrative Comments: 18 Mar Submitter Response - uploaded by D.Hannemann 18 Mar 2011

8 Apr Submitter Response - uploaded by D.Hannemann 12 Apr 2011

Administrative Attachments:
Document 1: (PDF - 03/18/2011) 18 Mar Submitter Response to NIH Questions
Document 2: (PDF - 04/12/2011) 8 Apr Submitter Response Email

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Status History:
Draft: 08/16/2010
Pending: 02/03/2011

Emails Sent: 01/27/2011-Six_Month_Reminder_1_Email -- 02/03/2011-New_Applicaton_Email

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Added By: Commons\snodgrassso **On:** 08/16/2010 | **Last Updated By:** NIH\hannemannd **On:** 04/12/2011 | **Record ID:** 65

Total Record Count = 1

Administration Page

Logout of NIH Form 2890 Admin Site

(3)

VistaGen

VistaGen Therapeutics, Inc.
384 Oyster Point Blvd, #8
South San Francisco, CA 94080
650.244.9990 x222 (o) 650.244.9979 (f)
www.vistagen.com

H. Ralph Snodgrass, Ph.D.
President, CSO and Director

January 31, 2011

NIH Stem Cell Registry:

I hereby certify that the statements in the Request for Human Embryonic Stem Cell Line to be Approved for Use in NIH Funded Research (NIH Form 2890), submitted by Dr. Kristie Bonham, and below, are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties (U.S. Code, Title 18, Section1001).

I further confirm that that I have the authority and/or rights pertaining to the human embryonic stem cell line(s) identified in item 6 of the form to make this request for NIH review and determination of eligibility for use in NIH funded research (e.g., I am the owner, deriver or licensee or have written permission of the same to submit). Any and all restrictions on the use of the stem cell line are clearly and completely identified in item 8 of the form.

Assurance Statements (mark the appropriate statement with an "X"; you may only check **one** Assurance statement.):

_____ **Assurance in accord with Section II(A) of the NIH Guidelines:**

I hereby assure that the donation of the embryo from which the cell line(s) identified in item 6 was derived was in accordance with the elements of Section II(A) of the NIH Guidelines on Human Stem Cell Research.

OR

VistaGen

_XX___ Assurance in accord with Section II(B) of the NIH Guidelines:

I hereby assure that the embryo from which the cell line(s) identified in item 6 of the form was derived was donated prior to July 7, 2009, and the embryo: 1) was created using in vitro fertilization for reproductive purposes and was no longer needed for this purpose; and 2) was donated by individuals who sought reproductive treatment ("donor(s)") who gave voluntary written consent for the human embryo to be used for research purposes[1].

OR

_____ Assurance in accord with Section II(C) of the NIH Guidelines:

I hereby assure that the embryo from which the cell line(s) identified in item 6 of the form was derived was donated outside the United States on or after July 7, 2009, and the alternative procedural standards of the foreign country where the embryo was donated provide protections at least equivalent to those provided by Section II(A) of the NIH Guidelines on Human Stem Cell Research.

[1] The applicant is advised that the Working Group of the Advisory Committee to the NIH Director will consider submitted materials taking into account the principles articulated in Section II(A) of the NIH Guidelines for Human for Human Stem Cell Research, 45 CFR 46 Subpart A, and the following points to consider: during the informed consent process, including written and oral communications, whether the donor(s) were: (1) informed of other available options pertaining to the use of the embryo ; (2) offered any inducements for the donation of the embryo ; and (3) informed about what would happen to the embryo after the donation for research.

(5)

VistaGen

I acknowledge that I have read, understood, and agreed to the information provided on the form, including the Instructions for completing the form, and the Certification, Authority and Assurance provided above.

H. Ralph Snodgrass
President and CSO
VistaGen Therapeutics, Inc.

cc. S. Singh

(6)

VistaGen

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February 2, 2011

Summary of Supporting Documents for hESC Registry Request for human embryonic stem cell lines K117, J618, and J713

Produced by VistaGen Therapeutics, Inc.

Document 1: **Summary of Supporting Documents** (this page)

Document 2: **Redacted consent form used by the Colorado Reproductive Endocrinology infertility clinic for donation of IVF embryos for research.** This document demonstrates that human embryos created by in vitro fertilization for reproductive purposes were no longer needed for this purpose and that voluntary written consent was given for the embryos to be used for research purposes. This document also states that after donation, the embryos will be destroyed and will not be transferred to another person. This consent form was in use through 2004, the year the K117, J618, and J713 hES cell lines were derived from embryos donated in 1999. The last number of the date of donation has been left intact to verify that these particular embryos associated with the attached consent form were donated in 1999. VistaGen has been blinded to all patient identifier information and exact dates of donation so that patient confidentiality has been protected.

Document 3: Letter from the Colorado Reproductive Endocrinology infertility clinic. This letter was sent to VistaGen from the embryologist who was responsible for the embryo donation. It describes how patients no longer wanted their embryos at the time of donation. It also states that the Human Research Committee (IRB equivalent at the U of Colorado) did not consider embryos human subjects at that time and, therefore, did not require their approval. This document also indicates that there was no compensation paid for embryo donation, and that other options were presented to the patients who no longer wanted their embryos.

Document 4: Redacted Stem Cell Research Oversight (SCRO) committee original approval letter. This document demonstrates that the K117, J618, and J713 hES lines have already been reviewed and approved as acceptably derived by an independent, third party SCRO committee as required for human ES grant work funded through the California Institute of Regenerative Medicine (CIRM). This approval was originally granted on June 19, 2009 and was effective through June 18, 2010.

Document 5: Redacted Stem Cell Research Oversight (SCRO) committee renewal approval letter. Renewal of approval of K117, J618, and J713 hES lines by the independent third party SCRO committee. This document is effective May 27, 2010, through May 26, 2011.

Document 6: Certification and assurance letter from VistaGen's signing official.

COLORADO
REPRODUCTIVE ENDOCRINOLOGY

Rose Medical Center
4600 East Hale Parkway • Suite 350
Denver, Colorado 80220
Phone (303) 321-7115 • Fax (303) 321-9519
Toll Free 888-817-0124
www.coloradofertility.com

(7)

Lab#

117 hee

AGREEMENT FOR DISPOSAL OF EMBYROS
(allowing research on embryos prior to disposal)

I, _____ (wife) and
(please print names)

I, _____ (spouse/partner)

SSN: _____ SSN: _____

DOB: _____ DOB: _____

do hereby request and agree to have all of our cryopreserved embryos destroyed. We understand that the embryos will be transferred to another laboratory where research will be performed on these embryos but they will not be transferred to another person. We will have no embryos cryopreserved embryos remaining for later use.

_____ _____
(wife's signature) (date)

_____ _____
(spouse/partner's signature) (date)

_____ _____
(witness signature) (date)

IVF Clinic Assurance

(8)

Department of Molecular, Cellular, and Developmental Biology
Porter Biosciences Building
Campus Box 347
Boulder, Colorado 80309-0347
(303) 492-7743

Ralph Snodgrass, PhD.
Chief Scientific Officer
VistaGen Therapeutics, Inc.
384 Oyster Point Blvd, #8
South San Francisco, CA 94080

February 2, 2011

Dear Dr. Snodgrass:

The following is an update of my response given in May 27, 2009, which mistakenly was incorrectly date of May 27, 2006, addressing the questions relevant to applying for approval of the K117, J713, and J618 cell lines for the NIH registry of human embryonic stem cell lines.

1. All embryos were donated for research to Jonathan Van Blerkom at the University of Colorado, Boulder, from patients who no longer wanted to maintain them in a cryopreserved state. At the time of donation (between 1998 and 2004), there were no stipulations on the type of research, only that the research would involve their destruction as viable preimplantation stage embryos.
2. Each donation was accompanied by a signed and witnessed informed consent document from a private infertility clinic, Colorado Reproductive Endocrinology, Rose Medical Center, Denver, Colorado, which is unaffiliated with the University of Colorado, Boulder. As stated in the informed consent document, donated embryos would be removed from the clinic and used in a separate and unrelated laboratory facility.
3. The Human Research Committee at the University of Colorado, Boulder reviewed the research and informed consent documentation but did not consider their approval was required as human subjects were not involved. This was indicated by the acceptance of the sponsored research agreement by the Office of Contracts and Grants at the University of Colorado, Boulder.
4. There was no compensation paid to any of the donors, and no patient-specific information was given to the research laboratories that received the embryos or the cell lines derived therefrom.
5. Each of the owners was given the option to have their excess embryos destroyed or donated for research or to other, infertile couples.

Sincerely,

Jonathan Van Blerkom

(9)

THE STEM CELL ADVISORS, INC.
A California public benefit non-profit company

Stem Cell Research Oversight Approval
Protocol N-7954_A1
Development of an hES Cell-Based Assay System for Hepatocyte Differentiation Studies and Predictive Toxicology Drug Screening.
VistaGen Therapeutics, Inc.

Date: June 19, 2009

To: Kristina Bonham, PhD
Protocol Director, Senior Scientist I, Cell Biology
VistaGen Therapeutics, Inc., 384 Oyster Point Blvd., Suite 8
South San Francisco, CA 94080-1967

From: Theo Palmer, PhD, Chair
Stem Cell Research Oversight Committee
The Stem Cell Advisors, Inc., PO Box 20513, Palo Alto, CA 93409

Pursuant to California Health and Safety Code Section 125119 and Title 17 California Code of Regulations Sections 100070(b) and 1000070(c), research may not commence without SCRO committee review and approval. This letter certifies that on June 19, 2009, The Stem Cell Advisors (SCA) SCRO committee reviewed and approved the above referenced protocol.

SCA SCRO approval N-7954_A1 involves the use of human embryonic stem cell lines H9, H1, Hes-2, K117, J618, and J713.

The committee acknowledges receipt of provenance documents and other supporting materials for this review. It finds that Hes-2, H1 and H9 are approved by authorized authorities and are acceptably derived. It further finds K117, J618, and J713 are acceptable research materials for the in vitro uses described in the CIRM Tools and Technologies Award Research Proposal RT1-01012. A determination for other uses of K117, J618 and J713 was not considered at this time. The Committee notes the absence of a materials transfer agreement (MTA) for the Hes-2 Line.

This approval is effective June 19, 2009 and expires June 18, 2010.

Sincerely,

Theo Palmer, PhD, Chair

(10)

THE STEM CELL ADVISORS, INC.
A California public benefit non-profit company

Stem Cell Research Oversight Approval
SCA Protocol # N-7954_A1, Vistagen Therapeutics, Inc.

Date:	May 27, 2010
Contact Information:	Kristie Bonham, PhD, Protocol Director, Senior Scientist Vistagen Therapeutics, Inc., 384 Oyster Point Blvd., #8 South San Francisco, CA 94080
Project Title:	Development of an hES Cell-Based Assay System for Hepatocyte Differentiation Studies and Predictive Toxicology Drug Screening
Principal Investigator:	Kristie Bonham, PhD Senior Scientist

Research Category
Protocol N-7954_A1 involves the use of human embryonics stem cell lines H1, H9, Hes-2, K117, J618 and J713.

Level of SCRO Review and Outcome
Pursuant to Title 17 California Code of Regulations Sections 100070(b) and 100070(c), research may not commence without SCRO committee review and approval. This letter certifies that on May 27, 2010 the SCRO committee reviewed and approved the renewal of the protocol referenced above.

The SCRO Committee finds that H1, H9 and Hes-2 are approved by authorized authorities and are acceptably derived. It further finds K117, J618, and J713 are acceptable research materials for the in vitro uses described in the CIRM Tools and Technologies Award Research Proposal RT1-01012. A determination for other uses of K117, J618 and J713 was not considered at this time. The Committee notes the absence of a materials transfer agreement (MTA) for the Hes-2 Line.

Additional Reviews and Documentation
The committee reviewed provenance documents and other supporting materials during the first Full Review of this protocol in June 2009.

Approval, Expiration Date, Approval Signature
The SCRO committee approved renewal of Protocol #N-7954_A1 and approved as "acceptably derived" the use of the HESC lines H1, H9, Hes-2, K117, J618 and J713.

This approval is effective May 27, 2010 and expires May 26, 2011.

Theo Palmer, PhD,
Chair Stem Cell Research Oversight Committee, The Stem Cell Advisors, Inc.

(11)

Ralph Snodgrass

To: HESCREGISTRY (NIH/OD)
Subject: RE: New hESC Registry Application Request #2011-ACD-001

Hi Ellen,
Please find the answers to your questions below. I have also attached a printout of this e-mail and our answers.
Thanks for your time and effort on this.

--Ralph

H. Ralph Snodgrass, Ph.D.
President & CSO
VistaGen Therapeutics, Inc.
384 Oyster Point Blvd, #8
South San Francisco, CA 94080

(650) 244-9990 x222 (v)
(650) 244-9979 (f)
rsnodgrass@vistagen.com
www.vistagen.com

From: HESCREGISTRY (NIH/OD) [mailto:hescregistry@mail.nih.gov]
Sent: Monday, February 28, 2011 11:22 AM
To: rsnodgrass@vistagen.com
Cc: HESCREGISTRY (NIH/OD)
Subject: RE: New hESC Registry Application Request #2011-ACD-001

Hello Mr. Snodgrass,

Thank you again for your submission to NIH. The ACD Working Group has begun its review of this submission and has the following questions:

- Please explain where the hESC lines were derived

[Ralph Snodgrass]

No fresh embryos were used in any of the hES cell studies, only those in cryo-storage that were no longer wanted by patients and with written informed consent, were donated for research, especially for projects in which Dr. Van Blerkom was involved. The only stipulation was that as embryos, they would no longer be viable after experimental studies were complete. The embryos were frozen and the 1-8 cell stage. Dr. Van Blerkom was the laboratory director of Reproductive Genetics In Vitro, Denver, Colorado, from 1982-1998, and of Colorado Reproductive Endocrinology, Denver, Colorado, from 1998-present. The research that was performed during culture to the blastocyst stage in studies that related specific proteins secreted into culture medium with the normality of development in vitro, and for those that failed to progress to the blastocyst, with the ploidy of trophoblast and ICM cells. For these studies, trophectodermal

outgrowth of hatched blastocysts was the endpoint, and at the blastocyst stage, and in outgrowths, levels of certain proteins (e.g., VEGF and leptin) in culture medium were measured. During these studies, the ICM in outgrowths were continued in culture until evidence of colonies with the appearance of ES cells was obtained. At that point, cultures were shipped to Dr. Bonham at VistaGen Therapeutics, where the ES clones were further developed, stabilized, validated for pluripotent functionality, karyotype, free from microbial contamination, and then frozen stocks were prepared.

- Please describe the nature of the relationships (including any overlap in personnel) between Colorado Reproductive Endocrinology, the University of Colorado, Boulder, and VistaGen.

[Ralph Snodgrass]

Except for interactions with Dr. Van Blerkom, VistaGen had no direct interaction or affiliation with Reproductive Genetics In Vitro (RGIC) or Colorado Reproductive Endocrinology (CRE) or the University of Colorado. Dr. Van Blerkom is an advisor to VistaGen, and in the past VistaGen has financially supported, in part, some of his research directly involved with the early culture of human blastocysts for the purpose of producing hESCs.

- Please explain Mr. Jonathan Van Blerkom's position(s) at the time of embryo donation and his relationships with Colorado Reproductive Endocrinology, the University of Colorado, Boulder, and VistaGen.

[Ralph Snodgrass]

Dr. Van Blerkom was at the time, and remains, a professor in the department of Molecular, Cellular, and Developmental Biology at University of Colorado, Boulder, and as stated above, is an advisor to VistaGen. He is a co-founder of RGIV and CRE, the latter located at the Rose Medical Center in Denver. Both RGIV and CRE are private infertility practices that are not affiliated with the University of Colorado. RGIV closed for infertility treatment in 1999, and as of 2008, closed as a center for prenatal diagnosis.

- Please describe the role(s), if any, of Mr. Jonathan Van Blerkom in the fertility treatment of the embryo donors and derivation of these hESC lines or research using these hESCs.

[Ralph Snodgrass]

For the embryos used in hES generation, Dr. Sam Alexander, was the clinician responsible for interacting with the patients undergoing IVF, first at RGIV from 1987-1998 and later at CRE from 1998-2008. Dr. Van Blerkom was responsible for the laboratory phase of in vitro fertilization treatment, including fertilization, embryo culture, transfer and cryopreservation. As stated in #1 above, Dr. Van Blerkom was involved in basic research to improve the development of human embryos in vitro and to understand the causes of spontaneous developmental arrest during the preimplantation stage.

- Please explain what safeguards were in place to protect against influencing the patients regarding their decision to donate embryos to research.

[Ralph Snodgrass]

Neither Dr. Van Blerkom nor VistaGen had any contact with the patients, and at no instance was D. Van Blerkom part of any discussion of how embryos, no longer wanted by the patients to be maintained in cryo-storage, were to be treated (discarded, research, donated to other patients). Therefore, Dr. Van Blerkom was not in a position to influence patients in their decision making process, which solely involved Dr. Alexander, who was not involved in this research, which was conducted at Dr. Van Blerkom's research laboratory at the University of Colorado in Boulder. The embryos used to isolate the ES cells under discussion were excess, frozen and stored from IVF procedures performed significantly before the decision to produce ES cells.

- Please provide any other documentation provided to the embryo donors, or description of information provided orally to the donors, regarding the nature of the research.

[Ralph Snodgrass]

Due to the time frame of these IVF treatments, there was no requirement to document the information provided orally to the embryo donors prior to the IVF treatment. For those patients who some years later no longer wanted their excess embryos, maintained in cryopreservation, they were simply given three equal choices (first discussed orally at the time they were evaluated as candidates for IVF under the protocols for cryopreservation and maintenance): 1) destruction of the embryos; 2) donation to research; or 3) anonymous donation to another infertile couple.

In the late 1990s, "stem cell" research was not considered by this group when the informed consent was obtained and the embryos were produced and ultimately frozen. Therefore, the consent for "research" was unspecified, except that they would be used for research studies and that in the process, the embryos would be destroyed and studied by Dr. Van Blerkom in another laboratory. It wasn't until around 2000 or so, that the informed consent specified "research and/or stem cell research". The copy of the consent supplied is an anonymized copy of the exact form of consent used for the embryos used to prepare the ES cells in this application.

- Was the intent when the embryos were donated in 1999 to derive hESCs from the donated embryos?

[Ralph Snodgrass]

As indicated in #5 and #6 above, the embryos used for these cell lines were excess cryopreserved embryos produced during IVF procedures that predated the intent and the actual research undertaken to isolate the ES cell lines.

- Please provide any other documentation provided to the embryo donors, or description of information provided orally to the donors, regarding options for the use of their cryopreserved embryos.

[Ralph Snodgrass]

No other documents other than what has been supplied and discussed herein are available.

- If possible, please provide copies of the fertility treatment consents signed by the embryos donors.

[Ralph Snodgrass]

Other than the consents for research, the standard consents used in the IVF field were signed by patients at RGIV and CRE that indicated what treatments would be involved, such as gonadotropin therapy/controlled ovarian hyperstimulation, ultrasound, blood levels of gonadotropins (LH, FSH) and steroids (estrogen, progesterone), ultrasound guided ovum retrieval, IVF, and embryo transfer and cryopreservation, and possible adverse consequences and complications that could result, including hyperstimulation syndrome, the need for ICSI (intracytoplasmic sperm injection), higher order gestations (prior to 2004, when more than 2 embryos were transferred), failed fertilization, arrested or abnormal development during the preimplantation stages, no embryos suitable for cryopreservation, chromosomally abnormalities in newborns, and cryo-damage after thawing in subsequent transfer cycles. Patient-specific data cannot be supplied due to confidentiality.

Please let us know if you have any questions regarding this inquiry. Please submit any additional documentation to this email address, with any financial, commercial, confidential or proprietary information redacted, especially consent documents that may have personally indentifying information/names of donor(s) of the embryos.

Sincerely,
Ellen Gadbois

Ellen L. Gadbois, Ph.D.

(14)

From: Ralph Snodgrass
To: HESCREGISTRY (NIH/OD)
Cc: Jonathan Van Blerkom
Subject: RE: New hESC Registry Application Request #2011-ACD-001
Date: Friday, April 08, 2011 5:00:56 PM

Ellen,
Yes, all cell lines in this application were isolated from ICM outgrowths from blastocysts.] *

--Ralph

H. Ralph Snodgrass, Ph.D.
President & CSO
VistaGen Therapeutics, Inc.
384 Oyster Point Blvd, #8
South San Francisco, CA 94080

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rsnodgrass@vistagen.com
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From: HESCREGISTRY (NIH/OD) [mailto:hescregistry@mail.nih.gov]
Sent: Friday, April 08, 2011 1:05 PM
To: 'Ralph Snodgrass'
Cc: HESCREGISTRY (NIH/OD)
Subject: RE: New hESC Registry Application Request #2011-ACD-001

Dr. Snodgrass,

Thank you for this further information. Can you please confirm one item: were all of the hESC lines in this submission derived from blastocyst-stage embryos? The NIH Guidelines define "human embryonic stem cells" as "...cells that are derived from the inner cell mass of blastocyst stage human embryos...."

Thank you again.

Sincerely,
Ellen Gadbois

Ellen L. Gadbois, Ph.D.
Office of Science Policy Analysis
Bldg 1 Room 218D
National Institutes of Health
voice: 301-594-2567
fax: 301-402-0280

From: Ralph Snodgrass [mailto:rsnodgrass@vistagen.com]
Sent: Friday, March 18, 2011 3:31 PM
To: HESCREGISTRY (NIH/OD)
Subject: RE: New hESC Registry Application Request #2011-ACD-001

Hi Ellen,
Please find the answers to your questions below. I have also attached a printout of this e-mail and our answers.
Thanks for your time and effort on this.