

Materials Submitted to NIH
from the University of Texas Health Science Center at Houston
Submissions #2010-ACD-003 & 2010-ACD-004

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NOTE: Duplicative information in the submission is not included.

hESC Registry Application Database

Detailed Listing for Request #: 2010-ACD-003

November 24, 2010

①

hESC Registry Application Search Results**Request #:** 2010-ACD-003**Status:** Pending**Review:** ACD**Assurance:** Yes (Section II(B))**Certification:** Yes**Authority:** Yes**Cell Lines:** 1**Available:** 1**Previous #:**

2010-DRAFT-007

[Email](#)[Edit](#)[Delete](#)[Switch to ADM](#)**Organization:** The University of Texas Health Science Center at Houston**Org Address:** Post Office Box 20036 Houston, Texas 77225-0036**DUNS:** 800771594 **Grant Number(s):****Signing Official (SO):** Johnna Kincaid / 713-500-3999 / osp@uth.tmc.edu**Submitter of Request:** Rick A. Wetsel, PhD / 713-500-2412 / Rick.A.Wetsel@uth.tmc.edu**Submitter Comments:** (None)**Line #1:** CR1**NIH Approval #:****Available:** Yes**Embryo from U.S.:** Yes**Embryo Donated in Year(s):** 2006**Provider Name:** Rick Wetsel, PhD**Provider Phone:** 713-500-2412**Provider Email:** Rick.A.Wetsel@uth.tmc.edu**Provider URL:****Provider Restrictions:** Restrictions will include cost recovery for academic and research use. No commercial use permitted, without prior approval/authorization.**NIH Restrictions:****Additional Information:****Supporting Documents:**Document 1: (PDF - 02/26/2010) Investigator and SO LetterDocument 2: (PDF - 02/26/2010) Institutional Approval - hESC Research Oversight CommitteeDocument 3: (PDF - 02/26/2010) IVF Laboratory - Confirmation LetterDocument 4: (PDF - 02/26/2010) Biological Parents' Consent FormDocument 5: (PDF - 02/26/2010) Institute Confirmation of Receipt Letter**Administrative Comments:** Uploaded 9 Jun 2010 email Correspondence - by D. Hannemann on 10 Jun 2010

Uploaded 9 Jun 2010 Corrected email Correspondence - by D. Hannemann 10 Jun 2010

Uploaded 9 Jun 2010 email Attachments (4 documents)-by D. Hanneman on 10 Jun 2010

Uploaded NIH Staff IIB Analysis - by DHannemann on 16 Jun 2010

SO certifications corrected by E. Gadbois July 8 2010

emails uploaded E. Gadbois 13 August 2010

email uploaded E. Gadbois 20 Sept 2010

Replaced Research Consent (Admin Doc 5) with add'l redactions - by DHannemann on 12 Nov 2010

Replaced Donation Consent (Admin Doc 6) with add'l redactions - by DHannemann on 12 Nov 2010

Uploaded submission document compilation pdf - by DHannemann 17 Nov 2010

②

Administrative Attachments:

Document 1: (PDF - 06/10/2010) Email Correspondence 9 Jun 2010
Document 2: (PDF - 06/10/2010) Correction to email Correspondence 9 Jun 2010
Document 3: (PDF - 06/10/2010) Original Cover Letter for Submission
Document 4: (PDF - 06/10/2010) S.O. Assurance
Document 5: (PDF - 11/12/2010) Research Consent
Document 6: (PDF - 11/12/2010) Donation Consent
Document 7: (DOC - 06/16/2010) NIH Staff IIB Analysis (cell line CR1)
Document 8: (PDF - 08/13/2010) 12 Aug 2010 email from Wetsel
Document 9: (DOC - 08/13/2010) 12 Aug 201 email attachment
Document 10: (PDF - 09/20/2010) 23 August questions to UTX
Document 11: (PDF - 10/18/2010) UTX response re. liability
Document 12: (PDF - 10/28/2010) Wetsel email October 26 2010
Document 13: (PDF - 10/28/2010) Wetsel attachment October 26 2010
Document 14: (PDF - 11/18/2010) Submission Document Compilation (as of 17 Nov 2010)

Status History:**Draft:** 02/26/2010**Pending:** 02/26/2010**Emails Sent:** 02/26/2010-New_Applicaton_Email**Added By:** CommonsRWETSE **On:** 02/26/2010 | **Last Updated**
By: NIHhannemannd **On:** 11/18/2010 | **Record ID:** 53**Total Record Count = 1 ***[Administration Page](#)[Logout of NIH Form 2890 Admin Site](#)

hESC Registry Application Database

Detailed Listing for Request #: 2010-ACD-004

November 24, 2010

③

hESC Registry Application Search Results**Request #:** 2010-ACD-004**Status:** Pending**Review:** ACD**Assurance:** Yes (Section II(B))**Certification:** Yes**Authority:** Yes**Cell Lines:** 1**Available:** 1**Previous #:**

2010-DRAFT-008

[Email](#)[Edit](#)[Delete](#)[Switch to ADM](#)**Organization:** The University of Texas Health Science Center at Houston**Org Address:** Post Office Box 20036 Houston, Texas 77225-0036**DUNS:** 800771594 **Grant Number(s):****Signing Official (SO):** Johnna Kincaid / 713-500-3999 / osp@uth.tmc.edu**Submitter of Request:** Rick A. Wetsel, PhD / 713-500-2412 / Rick.A.Wetsel@uth.tmc.edu**Submitter Comments:** (None)**Line #1:** CR2**NIH Approval #:****Available:** Yes**Embryo from U.S.:** Yes**Embryo Donated in Year(s):** 2006**Provider Name:** Rick Wetsel, PhD**Provider Phone:** 713-500-2412**Provider Email:** Rick.A.Wetsel@uth.tmc.edu**Provider URL:****Provider Restrictions:** Restrictions will include cost recovery for academic and research use. No commercial use permitted, without prior approval/authorization.**NIH Restrictions:****Additional Information:****Supporting Documents:****Document 1:** (PDF - 02/26/2010) Investigator and SO Letter**Document 2:** (PDF - 02/26/2010) Institutional Approval - hESC Research Oversight Committee**Document 3:** (PDF - 02/26/2010) IVF Laboratory - Confirmation Letter**Document 4:** (PDF - 02/26/2010) Biological Parents' Consent Form**Document 5:** (PDF - 02/26/2010) Institute Confirmation of Receipt Letter**Administrative Comments:** Uploaded 9 Jun 2010 email Correspondence - by D. Hannemann 10 Jun 2010

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(4)

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Document 7: (DOC - 06/16/2010) NIH Staff IIB Analysis (cell line CR2)
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Document 9: (DOC - 08/13/2010) 12 Aug 2010 email attachment
Document 10: (PDF - 09/20/2010) 23 August questions to UTX
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By: NIH\hannemannd **On:** 11/18/2010 | **Record ID:** 54**Total Record Count = 1 ***[Administration Page](#)[Logout of NIH Form 2890 Admin Site](#)



THE UNIVERSITY of TEXAS
HEALTH SCIENCE CENTER AT HOUSTON
THE BROWN FOUNDATION INSTITUTE OF MOLECULAR MEDICINE
FOR THE PREVENTION OF HUMAN DISEASES

1825 Pressler Street
Houston, Texas 77030

713 500 2400
713 500 2420 fax

June 9, 2010

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 Rick Wetsel, Ph.D., 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, Section 1001).

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

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 donated prior to July 7, 2009, and the embryo: 1) was created using in vitro fertilization for reproduction and was no longer needed for this purpose: and 2) was donated by individuals who sought reproduction ("donor(s)") who gave voluntary written consent for the human embryo to be used for research purposes. 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)

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of the NIH Guide for Human Stem Cell Research, 45 CFR 46 Subpart A, and the following points concerning the informed consent process, including written and oral communications, whether the donor(s) were 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.

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 donated outside the United States on or after July 7, 2009, and the alternative procedural standards country where the embryo was donated provide protections at least equivalent to those provided by of the NIH Guidelines on Human Stem Cell Research.

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.



Peter J. Davies, M.D., Ph.D.

Provost & Executive Vice President

Office of Research

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON
Notification Form of Outcome of Review
Human Embryonic Stem Cell Research Oversight Committee

This Form notifies the investigator and the Office of Sponsored Projects of the outcome of the internal review of research involving the collection, derivation, or use of human embryonic stem cells that the investigator disclosed on the research project indicated below.

Investigator's Name:	Dr. Rick Wetsel
Project Title/Sponsor:	Derivation of Human Embryonic Stem Cells

Outcome of Review of Research Conflicts of Interest

- Project approved by Executive Vice President for Research or designee
- Project approved by Executive Vice President for Research or designee with existing Human Embryonic Stem Cell Research Management Plan.
- Project approval currently pending. A subcommittee will meet on _____ to discuss further.
- Project not approved by Executive Vice President for Research.

Executive Vice President for Research

06/04/08 or
Date

Chair, Human Embryonic Stem Cell Oversight Committee Date

Distribution:

- Investigator
- Office of Sponsored Projects

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April 23, 2006

Irma Gigli, M.D.
Deputy Director,
Brown Foundation Institute of Molecular Medicine
University of Texas Health Science Center-Houston

Dear Dr. Gigli,

The _____ has recently donated fertilized human eggs to your research program. This letter is to confirm that all the donated fertilized eggs had the informed written consent of the biological parents. The biological parents did not receive a financial incentive for their donation. Furthermore, all the donated fertilized eggs were an IVF surplus, were less than 14 days in development and were not marked for re-implantation.

Sincerely,

Laboratory Director

IVF Laboratory

Consents are available upon request.

4282006



THE UNIVERSITY of TEXAS
HEALTH SCIENCE CENTER AT HOUSTON

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Irma Gigli, MD

The Walter & Mary Mischer Professor in Molecular Medicine

Director, Research Center for Immunology & Autoimmune Diseases

Deputy Director, Institute of Molecular Medicine

2121 W. Holcombe Blvd., Suite 900

713 500 2401

Houston, Texas 77030

713 500 2420 fax

October 4, 2005

On behalf of the Brown Foundation Institute of Molecular Medicine for the Prevention of Human Diseases, I would like to thank you and acknowledge the receipt of fertilized human eggs from your clinic. In accordance with our institutional consent following Federal and State guidelines, the donated fertilized eggs transferred to us will be exclusively used for future research purposes.

Sincerely,

Irma Gigli, M.D.

Deputy Director, Brown Foundation Institute of Molecular Medicine

for the Prevention of Human Diseases

The Hans J. Müller-Eberhard Chair in Immunology

The Walter & Mary Mischer Distinguished Professor of Molecular Medicine

* Cell Line "CRL" (NIH notation)

Rec'd 8/19/04

U of Texas
stem cell
#48, 49

11

CONSENT TO DISCARD CRYOPRESERVED EMBRYOS

NOTE: THIS WRITTEN CONSENT IS AN IMPORTANT DOCUMENT AND THE COPY PROVIDED TO YOU SHOULD BE RETAINED WITH OTHER VITAL RECORDS FOR FUTURE REFERENCE

[Redacted] (Print Patient's full name) [Redacted] DOB [Redacted] SS#
[Redacted] (Print Partner's full name) [Redacted] DOB [Redacted] SS#

I/We, being the rightful and legal owners of the embryos specified herein and hereafter referred to as the "Embryos", no longer wish to retain these Embryos for my/our own use in attempting to establish a pregnancy.

I/We have considered the alternative of releasing my/our embryos to an outside embryo donation agency (Consent # 4), donating my/our embryos to research (Consent # 32) or releasing the my/our embryos to a long-term storage facility (Consent #4) and find each to be unacceptable.

The Embryos currently in cryogenic storage at the [Redacted] are identified as follows:

Date of Cryopreservation (Printed on Vessel Housing Specimen) (Month, Date, Year)	Embryo ID Number (Printed on Vessel Housing Specimen)	Name (Printed on Vessel Housing Specimen)
3-18-01	1258	[Redacted]
3-21-01	1260	[Redacted]

Straws Cryopreserved: 4 Straws Thawed: 0 Straws remaining cryopreserved at the 4

The specimen(s) has been identified unequivocally by: *error 3/18/04*

Representative Signature & Title:
[Redacted]
Patient Partner

Rel to Univ of Texas stem cell 10/18/05

I/We wish to release my/our cryopreserved embryos to the [Redacted] IVF Laboratory to utilize in staff training and/or development. They will not be used to establish a pregnancy.

I/We have had the opportunity to discuss our decision to discard the Embryos specified herein and understand that removal of these Embryos from cryogenic storage will render them non-viable and therefore no longer available for the purpose of attempting to establish a pregnancy. My/Our decision is to remove these Embryos from cryogenic storage by the process specified herein.

I/We hereby authorize a [Redacted] staff member to remove the Embryos specified above from cryogenic storage. I/We understand that a 60 day waiting period is required from receipt of this consent by the [Redacted] until the time these Embryos are actually discarded.

OR
Either or both of us will confirm the identity of these Embryos specified above and remove them from cryogenic storage.

I/We wish to receive written confirmation that the Embryos specified above have been discarded.

OR
I/We do not wish to receive confirmation following the discard procedure.

Patient Signature: [Redacted] Date: 8-19-04
Partner Signature (if applicable): [Redacted] Date: 8-19-04
Witness (Printed name and title): _____ Date: 19 Aug 2004
Witness Signature: _____ Picture ID confirmed by: [Signature]

Consents signed outside the practice must be notarized and dated. BOTH partners (as applicable) MUST sign this consent.

Please donate for stem cell research at [Redacted]

* Cell Line "CRI" (NIH notation)

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CONSENT TO RELEASE OF CRYOPRESERVED EMBRYOS®

NOTE: THIS WRITTEN CONSENT IS AN IMPORTANT DOCUMENT AND THE COPY PROVIDED TO YOU SHOULD BE RETAINED WITH OTHER VITAL RECORDS FOR FUTURE REFERENCE

I/We hereby request and authorize UCSF/UTX (name of other Program or Transporter) to release the embryo(s) identified below to either me or

IDENTITY OF EMBRYO(S)

Patient Name: [Redacted] Date of Birth: [Redacted]

Partner Name: [Redacted] Date of Birth: [Redacted]

Date of Cryopreservation (Printed on Vessel Housing Specimen) (Month, Date, Year)	Embryo ID Number (Printed on Vessel Housing Specimen)	Name (Printed on Vessel Housing Specimen)
3/18/2001	1258	[Redacted]
3/21/2001	1260	[Redacted]

(Month, Date, Year) Date released: 2/10/18/2005 Time released: 1420

Representative: _____ Signature: _____

RELEASE AND COVENANT NOT TO SUE

I/We have identified each specimen unequivocally and cryopreserved each specimen using procedures known to preserve, as far as is technically possible, the original biological properties of each specimen with an understanding that the specimen(s) would be used by the patient in attempting to establish a pregnancy. I/We understand that in order to preserve the original biological properties of each specimen as far as is technically possible, each specimen must remain cryopreserved in liquid nitrogen until such time as it is removed from liquid nitrogen and thawed according to the method specified by the I/We have been afforded adequate opportunity to have my/our questions regarding the identity, biological status and transport of each specimen answered by a representative of the

I/We understand that I/we have full and sole responsibility for the transport and disposition of each specimen and hereby release from any and all responsibility relating to my/our transporting the specimen(s) identified above and covenant not to sue its physicians, employees, and agents, for any and all claims, damages or causes of action arising out of or related to the specimens following transfer of these specimens to us.

Date: 8-19-04

Partner (if applicable) Date: 8-19-04

Witness Date: 19 Aug 2004

Consents signed outside the practice must be notarized and dated.

RECEIPT OF EMBRYO(S)

I/We acknowledge that each specimen was received by us in good condition and cryopreserved in liquid nitrogen. A copy of the laboratory worksheet pertaining to this specimen(s), together with a summary of the procedure specified by for thawing the specimen(s) was/was not (circle one) provided to me/us.

Date received: _____ Time received: _____

Patient or Representative _____ Signature: _____

Relationship to Patient: _____ Picture ID confirmed by: _____

* Cell Line "CR2" (with notation)

Univ of Texas
Stem cell

Rec'd
2/11/04

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CONSENT TO RELEASE OF CRYOPRESERVED EMBRYOS®

#43

NOTE: THIS WRITTEN CONSENT IS AN IMPORTANT DOCUMENT AND THE COPY PROVIDED TO YOU SHOULD BE RETAINED WITH OTHER VITAL RECORDS FOR FUTURE REFERENCE

I/We hereby request and authorize _____ to release the embryo(s) identified below to either me or _____ (name of other Program or Transporter).

IDENTITY OF EMBRYO(S) UTX ESC program TEVA Zsigmond

Patient Name: _____ Date of Birth: _____

Partner Name: _____ Date of Birth: _____

Date of Cryopreservation (Printed on Vessel Housing Specimen) (Month, Date, Year)	Embryo ID Number (Printed on Vessel Housing Specimen)	Name (Printed on Vessel Housing Specimen)
12-19-1996	548	
_____	_____	_____
_____	_____	_____

(Month, Date, Year) Date released: 10-18-05 Time released: 14:00

Representative: _____ Signature: _____

RELEASE AND COVENANT NOT TO SUE

I/We have identified each specimen unequivocally and cryopreserved each specimen using procedures known to preserve, as far as is technically possible, the original biological properties of each specimen with an understanding that the specimen(s) would be used by the patient in attempting to establish a pregnancy. I/We understand that in order to preserve the original biological properties of each specimen as far as is technically possible, each specimen must remain cryopreserved in liquid nitrogen until such time as it is removed from liquid nitrogen and thawed according to the method specified by _____. I/We have been afforded adequate opportunity to have my/our questions regarding the identity, biological status and transport of each specimen answered by a representative of _____

I/We understand that I/we have full and sole responsibility for the transport and disposition of each specimen and hereby release _____ from any and all responsibility relating to my/our transporting the specimen(s) identified above and covenant not to sue the _____ its physicians, employees, and agents, for any and all claims, damages or causes of action arising out of or relating to these specimens following transfer of these specimens to us.

Female Partner _____ Date 2/11/04

Partner (if applicable) _____ Date 2/11/04

Witness _____ Date 2/11/04 CDL's verified

Consents signed outside the practice must be notarized and dated.

RECEIPT OF EMBRYO(S)

I/We acknowledge that each specimen was received by us in good condition and cryopreserved in liquid nitrogen. A copy of the laboratory worksheet pertaining to this specimen(s), together with a summary of the procedure specified by _____ for thawing the specimen(s) was/was not (circle one) provided to me/us.

Date received: _____ Time received: _____
Patient or Representative _____ Signature: _____
Relationship to Patient: _____ Picture ID confirmed by: _____

* Cell Line "CR2" (NIH notation)

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CONSENT TO DONATE OOCYTES (EGGS)©

(Print Female's full name)

N/A

(Print Partner's full name)

Special Considerations

Donating oocytes (eggs), whether to an unknown woman or to a relative or close friend, entails risks which are fairly well known from a medical perspective because components of the treatment cycle are medically identical to those infertile women undergo. Some of the effects on a fertile woman of donating oocytes may not be identical, though, and the emotional and psychological risks to a woman and/or her partner and family of giving up her eggs to another woman are currently unknown.

I/we certify that the genetic and medical history forms I/we filled out are complete and accurate to the best of my/our knowledge.

I/we understand that to reasonably assure that I/we will not transmit an infection to the recipient, I will have a physical examination. In addition, I/we will have a blood test for HIV (the virus that causes AIDS). Because I/we understand there is no absolute test for detecting infection, I/we also hereby verify that I/we have not, to my/our knowledge, contracted HIV or used intravenous drugs. I/we also verify that I/we are involved in a monogamous relationship and have not had sexual contact with someone with HIV/AIDS, or someone who used intravenous drugs. Furthermore, I agree not to have unprotected sexual intercourse from the time of the cycle start until the onset of my next menses.

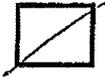
I/we hereby acknowledge that I/we have received the *Assisted Reproductive Technologies Booklet* (# _____) and have had ample opportunity to review it. I/we have been directed, not only to such portions of the Booklet as deal with specific procedures, but to the sections entitled "Donor Services." I/we have read and understand the general information provided in such Booklet, and after consultation with my/our physician, during which our individual medical circumstances were discussed and any of our questions were answered, I/we hereby consent to the following:

■ **Oocyte (Egg) Development and Monitoring**

Initial

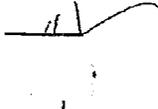
Female

Partner



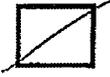
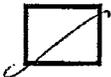
Natural cycle oocyte (egg) development and monitoring

or



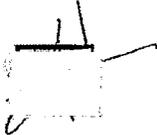
Stimulated Cycle oocyte (egg) development and monitoring

■ **Transvaginal Oocyte (Egg) Retrieval**



Laparoscopy to be performed in the event that ovaries are inaccessible with transvaginal approach (laparoscopy requires general anesthesia)

or



No laparoscopy to be performed in the event that ovaries inaccessible with transvaginal approach.

■ **RISKS OF PROCEDURE**

I/we have been fully advised of the risks and benefits of each of the procedures initialed above, as well as ART generally, and have been informed of the available alternatives and the risks and benefits of such alternatives. This information, which is generally contained in the *Assisted Reproductive Technologies Booklet*, has been supplemented by my/our consultation with our physician. I/we understand that the long term emotional and psychological consequences of this form of family building are not known, especially when sisters or other close relatives have an on-going involvement in the life of the child/children.

■ Donation of Oocytes (Eggs)

I [redacted] do hereby donate all retrieved
(name of donor) (number)
oocytes (eggs) to _____ (name of clinic or other recipient) for transfer
(specific purpose).

I [redacted] do hereby provide for the following
(name of donor)
disposition of any unused oocytes (eggs): N/A

In the case of anonymous oocyte donation, I will receive a stipend of \$ 3000.00 upon completion of the cycle for the inconvenience, time, travel expenses and possible loss of income because of my medical services. If the cycle is canceled by _____ for medical reasons, through no fault of mine, prior to retrieval and after beginning medications, I will receive \$ 1000.00. If I withdraw from the program at any time, for non-medical, personal reasons, I will receive no reimbursement and I understand that, in such circumstances, the cost of the medication and treatment related to the donation process will be borne by the network site. I have medical insurance which will cover the cost of complications arising from the process. ~~I understand that I am solely responsible for paying for any medical treatment required in connection with complications arising from the process.~~

I certify that I have such medical insurance of the following type:

Name of Carrier

Certificate # Group Name (if applicable)

I understand that the legal status of oocyte donation is as yet uncertain and that there may be changes in the law, especially regarding anonymity, in the future. I have had the opportunity to seek legal counsel; I understand the policies of the _____ regarding disclosure of information, communications with other physicians and audit data release.

It is understood that, even after signing this consent to donate oocytes, I may withdraw from the program without it affecting my future therapy or clinical care and there will be no penalty (except as herein outlined) or loss of benefits to which I am otherwise entitled.

■ Relinquishment of all rights to the oocytes and any resulting embryos or offspring

It has been explained to me/us that the legal rights and obligations of the parties involved, including the rights of the embryo(s) and infant(s) born as the result of the donor oocyte service, and the ramification of any resulting embryo transfer procedure are not free from doubt. I/we have been advised, and have had the opportunity to, consult our own legal counsel. I/we have also had the opportunity to consult with a physician and psychologist/counselor. I/we have considered all of the information provided to us, from various sources, and knowingly relinquish all rights of any kind, to the oocytes and any resulting embryo(s) or child(ren).

THIS CONSENT IS AN IMPORTANT DOCUMENT THAT SHOULD BE RETAINED BY THE PATIENT WITH OTHER VITAL RECORDS.

I/We agree to the above treatment and the options indicated:

[Redacted Signature] 6/19/98
Female Signature Date

Partner (if applicable) Date

Witness 6/19/98
Date

The above named woman/couple has been informed and counseled by me and others regarding the risks and benefits of the relevant treatment options and the potential impact of donation. The woman/couple appeared capable of understanding the information presented as demonstrated by our discussion and the responsive nature of the participation of the woman/couple. The physician/surgeon shall retain this original consent in the patient's medical record and provide a copy to the patient (and to the hospital, if applicable).

Physician/Surgeon Date

Psychologist/Counselor Date

To be signed in the case of repeat cycles, if previous cycle more than one year ago:

I/We wish to participate in another cycle of essentially the same type:

Female Date

Partner (if applicable) Date

Witness Date

From: [Wetsel, Rick A](#)
To: [HESCREGISTRY \(NIH/NIDCD\)](#)
Cc: [Zsigmond, Eva M](#); [Davies, Peter J](#); [Kincaid, Johnna K](#); [Staller, Arlene D](#)
Subject: RE: New hESC Registry Application Request #2010-ACD-003
Date: Wednesday, June 09, 2010 3:36:20 PM
Attachments: [Cover Letter NIH hESCs CR1 CR2 Wetsel0001.pdf](#)
[Signing official with assurances in requested format.pdf](#)
[Consent Forms RC1\(1260\) and RC2\(548\) for Research.pdf](#)
[Release of Egg donation for 548 \(RC2\).pdf](#)

Dear Dr. Gadbois: Please find attached four PDF files. The first is the original cover letter describing the submission for approval (cover letter dated Feb 17); the second is the signing official assurance letter done in the format requested; the third is the parents' consent forms that the discarded embryos could be used for research purposes; the fourth is the consent and release form for donation of eggs. This fourth document pertains to RC2 which was generated from a donated embryo in which a third party donated egg was fertilized by the father but for reproductive purposes for an infertile female (mother). The generation of RC1 is more straightforward in that the egg came from the female (mother) requesting fertility treatment. RC1 was generated from donated embryo 1260, and RC2 was generated from embryo 548. Our laboratory was contacted by the fertility clinic when the discarded embryos could no longer be used by a UCSF faculty member had left the university. Rather than discarding them, they contacted us to see if we would like to use them. We accepted the donations and used private funds to derive RC1 and RC2. When we received the embryos, the only identification provided were the numbers 1260 and 548. We were sent the general consent forms by the clinic (enclosed with Feb 17th NIH submission), but these forms contained no signatures or names. When requested by the NIH registry committee, we obtained copies of the signed patient consent forms. All name identifiers were removed from these copies. If this email needs clarification, please feel free to call me at 713-500-2412. I will be out of the country from June 10th until June 22nd, but Dr. Zsigmond will be available during that time.



Thank you for all your assistance.

Best wishes,

Rick

Rick A. Wetsel, Ph.D.
 William S. Kilroy, Sr., Chair in Pulmonary Disease
 Professor of Molecular Medicine
 Director-Research Center for Immunology and Autoimmune Diseases
 Director-Laboratory for Developmental Biology
 The Brown Foundation Institute of Molecular Medicine for the Prevention of Human Diseases
 University of Texas Health Science Center at Houston
 1825 Pressler Street
 Houston, Texas
 Phone: 713-500-2412
 FAX: 713-500-2420
 Email: Rick.A.Wetsel@uth.tmc.edu

From: HESCREGISTRY (NIH/NIDCD) [<mailto:hescregistry@mail.nih.gov>]
Sent: Friday, June 04, 2010 3:49 PM
To: Wetsel, Rick A; Kincaid, Johnna K
Cc: Davies, Peter J; Staller, Arlene D; Zsigmond, Eva M; HESCREGISTRY (NIH/NIDCD)
Subject: RE: New hESC Registry Application Request #2010-ACD-003

Hi Dr. Wetsel,

At this point I have to upload additional documents to your submission myself, so please do send the documents to this email. If I have any initial questions I'll get back to you before alerting the reviewers.

Thanks much,
 Ellen Gadbois

Ellen L. Gadbois, Ph.D.

From: [Wetsel, Rick A](#)
To: [HESCREGISTRY \(NIH/NIDCD\)](#)
Subject: FW: New hESC Registry Application Request #2010-ACD-003
Date: Wednesday, June 09, 2010 3:32:26 PM
Attachments: [Cover Letter NIH hESCs CR1 CR2 Wetsel0001.pdf](#)
[Signing official with assurances in requested format.pdf](#)
[Consent Forms RC1\(1260\) and RC2\(548\) for Research.pdf](#)
[Release of Egg donation for 548 \(RC2\).pdf](#)

Dear Dr. Gadbois: I just noticed that in my email, the CR is written backwards. They should be CR1 and CR2 not RC1 and RC2. I was lucky enough to receive a RC1 grant recently, so I guess I was still fixated on that while composing the email. Thanks again, Rick



From: Wetsel, Rick A
Sent: Wednesday, June 09, 2010 2:24 PM
To: 'HESCREGISTRY (NIH/NIDCD)'
Cc: Zsigmond, Eva M; Davies, Peter J; Kincaid, Johnna K; Staller, Arlene D
Subject: RE: New hESC Registry Application Request #2010-ACD-003

Dear Dr. Gadbois: Please find attached four PDF files. The first is the original cover letter describing the submission for approval (cover letter dated Feb 17); the second is the signing official assurance letter done in the format requested; the third is the parents' consent forms that the discarded embryos could be used for research purposes; the fourth is the consent and release form for donation of eggs. This fourth document pertains to RC2 which was generated from a donated embryo in which a third party donated egg was fertilized by the father but for reproductive purposes for an infertile female (mother). The generation of RC1 is more straightforward in that the egg came from the female (mother) requesting fertility treatment. RC1 was generated from donated embryo 1260, and RC2 was generated from embryo 548. Our laboratory was contacted by the clinic when the discarded embryos could no longer be used by a UCSF faculty member had left the university. Rather than discarding them, they contacted us to see if we would like to use them. We accepted the donations and used private funds to derive RC1 and RC2. When we received the embryos, the only identification provided were the numbers 1260 and 548. We were sent the general consent forms by the clinic (enclosed with Feb 17th NIH submission), but these forms contained no signatures or names. When requested by the NIH registry committee, we obtained copies of the signed patient consent forms. All name identifiers were removed from these copies. If this email needs clarification, please feel free to call me at 713-500-2412. I will be out of the country from June 10th until June 22nd, but Dr. Zsigmond will be available during that time.

Thank you for all your assistance.

Best wishes,

Rick

Rick A. Wetsel, Ph.D.
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Phone: 713-500-2412
FAX: 713-500-2420
Email: Rick.A.Wetsel@uth.tmc.edu

From: HESCREGISTRY (NIH/NIDCD) [<mailto:hescregistry@mail.nih.gov>]
Sent: Friday, June 04, 2010 3:49 PM
To: Wetsel, Rick A; Kincaid, Johnna K
Cc: Davies, Peter J; Staller, Arlene D; Zsigmond, Eva M; HESCREGISTRY (NIH/NIDCD)
Subject: RE: New hESC Registry Application Request #2010-ACD-003

Hi Dr. Wetsel,

12 August 2010 Email from Submitter

20

Hello Ms. Kincaid and Dr. Wetsel,

The NIH Working Group for Human Embryonic Stem Cell Eligibility Review is continuing its consideration of submissions #2010-ACD-003 and #2010-ACD-004 (for cell lines CR1 and CR2) under Section IIB of the NIH Guidelines for Human Stem Cell Research. The Working Group has asked if you can respond to the following questions:

1. Please provide the IVF clinical treatment consents signed by the embryo donors, if available (with patient identifiers redacted).

Response: [redacted] / stated that the clinical treatment consents signed by the embryo donors are stored off site. She stated that if it is absolutely necessary for approval of the hES cell lines she will try and retrieve them.

*

2. Please explain why a *Consent to Discard Cryopreserved Embryos* form was used rather than a consent form specific for research.

Response: [redacted] stated that the reason there were two forms for #1260 (consent to discard and consent to release) was that the donors wanted the embryos to be either discarded (destroyed) or used for research. The donors of #1260 indicated verbally that they preferred the release for research over being discarded, but they were in agreement with either outcome. In contrast, the donors of #548 strongly wanted their donation to be used for research purposes—hence only the consent to release form was signed.

*

3. Please provide any documents for donation of embryos to research signed by the embryo donors of embryos #548 and #1260, if such consent documents exist. In particular, we note that the *Consent to Release of Cryopreserved Embryos* for embryo # 1260 refers to a Consent #32 for donation of embryos to research. If Consent #32 was not used, please explain why not.

Response: [redacted] stated that the "consent to release form" is the release form for research purposes. The consent #32 form was for IRB approved in house fertility clinical research, which the donors of #1260 declined.

*

4. Please verify that embryos #548 and #1260 were released directly to the embryo donors, as stated in the *Consent to Release of Cryopreserved Embryos* forms. We note that the form for embryo #548 refers to release "to either me or UTX esc program/Eva Zsigmond," so it is unclear who actually received the embryo and how it was delivered to the University of Texas.

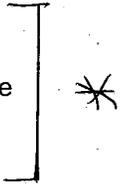
Response: The embryos were released by the donors for research purposes in general with no requirement that they be sent to any particular university. The IVF clinic subsequently sent them to the University of Texas-Houston, Institute of Molecular Medicine, Embryonic Stem Cell Program, c/o Dr. Eva Zsigmond. The cryopreserved embryos were shipped in a dry-shipper, containing liquid Nitrogen. The empty dry-shipper was sent from the University of Texas and was returned with the frozen embryos by the IVF clinic.

*

5. Please confirm that the members of the couples who sought reproductive treatment all signed written consents for the donation of embryos #548 and #1260 for research. (Please note that

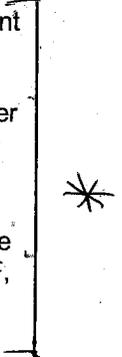
consent of gamete donors for donation of embryos to research is not required under the NIH Guidelines for Human Stem Cell Research, but consent is required by the actual individuals who sought treatment, even if they were not the gamete donors.)

Response: For both embryos #548 and #1260 the "Consent to Release of Cryopreserved Embryos" forms have been signed by both partners who sought reproductive assistance from the IVF clinic. Their names have been blacked-out in order to comply with patient de-identification policies.



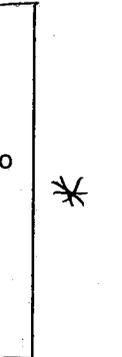
- 6. For embryo #1260, please explain where it is documented that the donor couple signed a consent for donation of the embryo to the University of Texas. (It is not clear who made the handwritten notation "Please donate for stem cell research at UCSF" since that is neither signed nor dated, and it is not clear who crossed off "USCF" and wrote "Rel to Univ of Texas stem cell" and whether the donors approved that change.)

Response: As discussed in response #4, the embryos were released by the donors for research in general and not to a particular University. The IVF clinic initially had an arrangement to donate embryos to UCSF for research purposes. After the investigator receiving the embryos left UCSF, the IVF clinic arranged for further donations to be sent to the University of Texas-Houston.



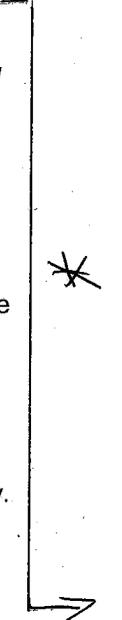
- 7. Please explain the relevance of the following language and whether the University of Texas believes the language applies to the University of Texas. From the *Consent to Release of Cryopreserved Embryos*: "I/We understand that I/we have full and sole responsibility for the transport and disposition of each specimen and hereby release _____ from any and all responsibility relating to my/our transporting the specimen(s) identified above and covenant not to sue _____ its physicians, employees, and agents, for any and all claims, damages or causes of action arising out of or relating to these specimens following transfer of these specimens to us."

Response: Yes we are in agreement with the language. If you feel that this needs to be added as part of the letter from Dr. Peter Davies, please let us know.



- 8. The *Consent to Discard Cryopreserved Embryo* form for embryo #1260 states that a "60 day waiting period is required from receipt of this consent by the _____ until the time these Embryos are actually discarded." For embryos #548 and #1260, the *Consent to Release of Cryopreserved Embryos* forms were signed more than a year before the embryos were released from the _____. Please explain the timing.

Response: We have added timelines at the end of the document, which hopefully will make the history of the donations clearer. The embryos did remain cryopreserved for about a year after the "Consent to Release" form was signed by the donors. As discussed in response #6, UCSF no longer was interested in accepting these embryos and the arrangement between the IVF clinic and the University of Texas-Houston was not yet in place.



The 60 day waiting period only applied for embryos that were destined to be discarded. Neither embryos #548 or #1260 were to be discarded. Therefore, the 60 day waiting period did not apply. It may appear confusing for #1260 since the donors signed both "Consent to Discard and

"Consent to Release" forms. However, as stated by [redacted] above the donors indicated verbally that they preferred that the embryos be released for research rather than be discarded.

*

- 9. Please explain why the letter from Dr. Gigli to [redacted] acknowledging receipt of fertilized human eggs is dated October 4, 2005, when embryos #548 and #1260 were released from the [redacted] on October 18, 2005 and October 10 or 18 (writing is unclear), 2005, respectively.

*

Response: As arrangements were being made between the IVF clinic and our Institute, Dr. Irma Gigli the Deputy Director of the IMM-UT-Houston prepared the letter in anticipation of the release and shipment of the embryos. In short, she was writing the letter to indicate that the IMM-UT Houston was in agreement with receiving the donated embryos for research purposes. Therefore, the date of her letter was somewhat earlier than the date documented on the "IVF release forms".

- 10. Please explain why the *Consent to Donate Oocytes (Eggs)* is dated 6/19/1998 while embryo #548 was cryopreserved on 12/19/1996.

*

Response: The donors and the IVF clinic discuss options of what to do with their cryopreserved embryos once it is decided that they will not longer need them for fertility purposes. This is often a few years past the date of cryopreservation.

- 11. Please provide any documentation explaining how the donors of embryo #548 were informed of other available options pertaining to the use of the embryos remaining after reproductive treatment.

*

Response: [redacted] stated the following: They received all forms and were presented with all the different options available to them. They then decided to release them for research purposes.

- 12. Please confirm that embryos #548 and #1260 were blastocyst-stage embryos.

*

Response: #548 was a 2 day old fertilized egg. #1260 was a 6 day old blastocyst

Please let me know if you have any questions about this request.

Sincerely,
Ellen Gadbois

hESC Registry Application Request #2010-ACD-003 and #2010-ACD-004

Timeline of Embryo Release for Research

1260 (6 day old blastocyst, not from oocyte donor)

Retrieval date:	3/15/2001
Date of cryopreservation:	3/21/2001
Date of consent to discard cryopreserved embryos;	8/19/2004
Date of consent to release cryopreserved embryos- signed by donors	8/19/2004

(Note: for this blastocyst, on 8/19/2004, the donor parents signed a consent form to discard the embryos, as well as another form to release the embryos)

Date of consent to release cryopreserved embryos- signed by IVF clinic	10/18/2005
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548 (2 day old fertilized egg, from oocyte donor)

Retrieval date:	12/17/1996
Date of cryopreservation:	12/19/1996
Date of consent to release cryopreserved embryos- signed by donors	2/11/2004

Questions from NIH (23 August 2010 email)

(24)

From: HESCREGISTRY (NIH/OD)
To: "Wetsel, Rick A"
Cc: Davies, Peter J; Zsigmond, Eva M; HESCREGISTRY (NIH/OD)
Subject: RE: hESC Registry Application Request #2010-ACD-003 and #2010-ACD-004
Date: Monday, August 23, 2010 10:51:30 AM
Attachments: NIH hES Review additional questions with responses plus timeline.doc

Hello Dr. Wetsel,

Thank you for your response (attached for reference). The working group has several follow-up questions:

Regarding Question 1 ("Please provide the IVF clinical treatment consents signed by the embryo donors, if available (with patient identifiers redacted)"): Yes, please do provide the clinical IVF consents.

Regarding Question 7 ("Please explain the relevance of the following language..."): I think I was not clear in the initial question. Do you understand this language to mean that the embryo donors waive legal rights with respect to stem cell research conducted by the University of Texas? Similarly, do you think this language means that the embryo donors waive legal rights with respect to the involvement of _____ in the stem cell research? Or is the language only a waiver of liability for the transport of the embryos and not related to the conduct of the research?

Regarding Question 11 ("Please provide any documentation explaining how the donors of embryo #548 were informed of other available options pertaining to the use of the embryos remaining after reproductive treatment."): Can you provide further information or documentation on what options were explained to the embryo donors?

Regarding Question 12 ("Please confirm that embryos #548 and #1260 were blastocyst-stage embryos."): NIH needs confirmation that the hESCs were derived from the inner cell mass of blastocyst-stage embryos in order for the lines to be considered under the NIH Guidelines (as currently written). Was embryo #548 grown in culture to the blastocyst stage before the hESC line was derived? It would also be helpful if you could provide the protocol describing the research.

Please let me know if you have any questions regarding this request.

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: Wetsel, Rick A [mailto:Rick.A.Wetsel@uth.tmc.edu]
Sent: Thursday, August 12, 2010 7:06 PM
To: HESCREGISTRY (NIH/OD)
Cc: Davies, Peter J; Zsigmond, Eva M
Subject: RE: hESC Registry Application Request #2010-ACD-003 and #2010-ACD-004

Dear Dr. Gadbois: Please find attached to this email a word document containing our responses to the questions from the Working Group. Our responses are indicated in blue beneath each question. I apologize for our delayed reply. _____ was out of the country for several weeks and we were unable to reach her by phone or email. Since most of the questions required her input, we had to wait for her return. If you need any further clarification or information, please just let me know. Thank you for all your help.

Best wishes,

Rick Wetsel

Rick A. Wetsel, Ph.D.
William S. Kilroy, Sr., Chair in Pulmonary Disease
Professor of Molecular Medicine
Director-Research Center for Immunology and Autoimmune Diseases
Director-Laboratory for Developmental Biology
The Brown Foundation Institute of Molecular Medicine for the Prevention of Human Diseases
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Phone: 713-500-2412



Office of the Provost and Executive Vice President for Research

Peter J.A. Davies, MD, PhD
Provost and Executive Vice President of Research
Roger J. Bulger, MD Distinguished Professor

October 8, 2010

Ellen L. Gadbois, PhD
Office of Science Policy Analysis
National Institutes of Health
Building 1 - Shannon Building, 218
1 Center Drive
Bethesda, MD 20892

RE: hESC Registry Application Request #2010-ACD-003 and #2010-ACD-004

Dear Dr. Gadbois,

Dr. Wetsel has indicated that you have asked for the interpretation by the University of a clause in a document signed by a donor of embryonic stem cells. The clause is part of a document entitled "Consent to Release of Cryopreserved Embryo" and states:

"I/We understand that I/we have full and sole responsibility for the transport and disposition of each specimen and hereby release the [redacted] from any and all responsibility relating to my/our transporting the specimen(s) identified above and covenant not to sue the [redacted], its physicians, employees, and agents, for any and all claims, damages or causes of action arising out of or relating to these specimens following transfer of these specimens to us."

The University has understood this clause to be a waiver of liability against the [redacted] should there be a problem with the embryos due to transport. We do not interpret this clause to be related to the conduct of the research. Claims made against the University were not contemplated in this clause, as the University was not a party to the document.

The ESCRO committee evaluated all of the consent documentation together as a whole and determined that the risk to the University was acceptable, even though this particular waiver language does not contemplate the research activities of the University.

Sincerely,

Peter Davies, M.D.
Provost and Executive Vice President of Research
The University of Texas Health Science Center at Houston

Cc: Dr. Rick Wetsel
Ms. Christina Solis
Ms. Arlene Staller

713.500.3082 phone 713.500.3069 fax
Peter.J.Davies@uth.tmc.edu
7000 Fannin, Suite 1715
Houston, Texas 77030
www.uthouston.edu/provost/

From: [Wetsel, Rick A](#)
To: [HESCREGISTRY \(NIH/OD\); Davies, Peter J](#)
Cc: [Zsigmond, Eva M](#)
Subject: RE: Oct 8 correspondence received; several questions remaining
Date: Tuesday, October 26, 2010 8:25:47 PM
Attachments: [Reproductive Science.pdf](#)

Dear Dr. Gadbois: I am writing regarding question 12. I have attached a copy of the "Embryo Release Log" that was sent from the IVF clinic at the time that we received the embryos. This document verifies that #548 was a two day oldembryo and #1260 was a 6 day old blastocyst. Embryo #548 was grown in culture to the blastocyst stage prior to the isolation of the inner cell mass. The CR1 and CR2 hESC lines were derived from the inner cell mass of the blastocyst-stage embryos following the published protocol of J.A. Thomson et al (Science Vol. 282, 1998).

*

There are still two remaining questions: (1). IVF clinical treatment clinical consents and (11). Documentation that the donors of embryo #548 were informed of other available options.

Before the injunction was filed, [redacted] had said that she would retrieve the clinical treatment consents, but that they were offsite and it would take her a couple of weeks. She also stated that other options were provided to the donors verbally.

However, once the injunction was filed, [redacted] will no longer answer my emails or phone calls. I am assuming that she is afraid that the fertility clinics involved in the approved NIH hESC lines may be sued if the federal judges agree in the end with injunction. She was always very responsive to our questions prior to the injunction, so I am assuming she afraid to respond in writing until the case is settled. Of course this has really upset our financial donor, who donated a considerable amount of money in the hope that someday UT would have their own early passage hESCs for federally funded research.

*

At the moment, I am not certain that we can get written documents for questions 1 and 11. If you have any suggestions on how to proceed, please let me know.

Thank you.

Best wishes,

Rick Wetsel

From: HESCREGISTRY (NIH/OD) [mailto:hescregistry@mail.nih.gov]
Sent: Monday, October 18, 2010 8:58 AM
To: Davies, Peter J; Wetsel, Rick A
Cc: Zsigmond, Eva M; HESCREGISTRY (NIH/OD)
Subject: Oct 8 correspondence received; several questions remaining

Hello Dr. Davies,

I am writing to notify you that I just received your letter of October 8 regarding the liability language. Thank you very much for your response.

There are several other questions (listed below) below that are still outstanding. Please send your replies to this email address—it is much faster and (more reliable) than sending paper responses.

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: HESCREGISTRY (NIH/OD)