DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
11155 Dolfield Boulevard, Suite 117 Owings Mills, MD 21117 (410)779-5455 Fax:(410)779-5707	8/12/2025-8/14/2025
	FEI NUMBER 3003610950

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Katherine E. Cameron, M.D., Assistant Professor/Director of Third Party Reproduction

FIRM NAME	STREET ADDRESS
Johns Hopkins Fertility Center	10755 Falls Road Suite 400
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Lutherville, MD 21093-4506	Reproductive Human Tissue Establishment

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Donors were not screened by a review of relevant medical records for risk factors and clinical evidence of communicable disease agents and diseases.

Specifically,

All (b) (4) anonymous and directed oocyte donor records reviewed from approximately May 2023 through June 2025, revealed that the donor medical history interview questionnaire, DE-03.F1, "Risk Factor Assessment," Revision: B, Effectivity Date: 9/12/2019, was deficient.

For example, the donor medical history interview questionnaire did not screen for the following:

A. Donors who received any transfusion of blood or blood components in France between 1980 and the present. This same risk factor was also deficient in SOP DE-03, "Reproductive Donor Risk Factors," Revision: B, Effectivity Date: 09/12/2019.

B. Donors who have been treated for Chlamydia within the preceding 12 months.

C. Donors who have had Syphilis within the preceding 12 months.

D. Donors who have had Gonorrhea within the preceding 12 months.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	La-Tasha M Gunter, Investigator X La-Tasha M Gunter Investigator Signed By: LATASHA GUNTER - S Date Signed: 08-14-2025 08:16:36	8/14/2025

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E. Donors who are dependents of a civilian employee who resided at U.S. military bases in Northern Europe (Germany, Belgium, and the Netherlands) for 6 months or more cumulatively from 1980 through 1990, or elsewhere in Europe (Greece, Turkey, Spain, Portugal, and Italy) for 6 months or more cumulatively from 1980 through 1996.

F. Donors who spent three months or more cumulatively in the United Kingdom from the beginning of 1980 through the end of 1996. This same risk factor was also deficient in SOP DE-03, "Reproductive Donor Risk Factors," Revision: B, Effectivity Date: 09/12/2019.

Examples of anonymous and directed oocyte donors screened using the aforementioned deficient donor medical history interview questionnaire include but are not limited to the following:

1. Donor medical history interview questionnaire administered to directed oocyte donor (b) (4), (b) (6), (b) (7)(C) on (b) (6), (b) (7)(C). The donor was determined eligible on (b) (6), (b) (7)(C) and oocytes were recovered on (b) (6), (b) (7)(C).

2. Donor medical history interview questionnaire administered to directed oocyte donor (b) (4), (b) (6), (b) (7)(C) on (b) (6), (b) (7)(C). The donor was determined eligible on 11/14/24 and oocytes were recovered on (b) (6), (b) (7)(C). Tissue recovered from this donor was transferred to a recipient on (b) (6), (b) (7)(C).

3. Donor medical history interview questionnaire administered to anonymous oocyte donor (b) (4), (b) (6), (b) (7)(C) on (b) (6), (b) (7)(C). The donor was determined eligible on 11/22/24 and oocytes were recovered on (b) (6), (b) (7)(C). Tissue recovered from this donor was transferred to a recipient on (b) (6), (b) (7)(C).

4. Donor medical history interview questionnaire administered to anonymous oocyte donor (b) (4), (b) (6), (b) (7)(C) on (b) (6), (b) (7)(C). The donor was determined eligible on (b) (6), (b) (7)(C) and oocytes were recovered on (b) (6), (b) (7)(C). Tissue recovered from this donor was transferred to a recipient on (b) (6), (b) (7)(C) and (b) (6), (b) (7)(C).

OBSERVATION 2

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
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The summary of records for HCT/Ps did not contain the address of the establishment that made the donor-eligibility determination.

Specifically,

All (b) (4) directed and anonymous oocyte donor records reviewed from approximately May 2023 through June 2025, revealed that the summary of records did not include the address of the establishment that made the donor eligibility determination.

Examples include but are not limited to the summary of records for the following donors:

1. Directed oocyte donor (b) (4), (b) (6), (b) (7)(C) who was determined eligible on (b) (6), (b) (7)(C).

2. Anonymous oocyte donor (b) (4), (b) (6), (b) (7)(C) who was determined eligible on 11/22/24.

3. Directed oocyte donor (b) (4), (b) (6), (b) (7)(C) who was determined eligible on 11/14/24.

4. Anonymous oocyte donor (b) (4), (b) (6), (b) (7)(C) who was determined eligible on (b) (6), (b) (7)(C).

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

La-Tasha M Gunter, Investigator

X La-Tasha M Gunter
Investigator
Signed By: LATASHA GUNTER - S
Date Signed: 08-14-2025 08:16:36

DATE ISSUED
8/14/2025

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."