



HARVARD

Human Research Protection Program

Harvard University-Area
Committee on the Use of Human Subjects
44-R Brattle, Suite 200 (2nd floor)
Cambridge, MA 02138
IRB Registration - IRB00000109
Federal Wide Assurance - FWA00004837

Notification of Initial Study Exemption Determination

May 22, 2019

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Protocol Title: Evolution of Pregnancies in Cases of Fetal Abnormalities Incompatible with Life
Principal Investigator: Jocelyn Viterna
Protocol #: IRB19-0442
Funding Source: None
IRB Review Date: 5/22/2019
IRB Effective Date: 5/22/2019
IRB Review Action: Exempt

This Initial Study submission meets the criteria for exemption per the regulations found at 45 CFR 46.104(d) (4). As such, additional IRB review is not required.

The Principal Investigator is responsible for ensuring compliance with any applicable local government or institutional laws, legislation, regulations, and/or policies, whether conducting research internationally or nationally. Additionally, if local IRB/ethics review is required, it must be obtained before any human subjects research activities are conducted in the field. If assistance with applicable local requirements is needed, please contact the Harvard University-Area IRB office.

The documents that were finalized for this submission may be accessed through the IRB electronic submission management system at the following link: [IRB19-0442](#).

The determination that your research is exempt does not expire, and you will not file annual renewals. If changes to the research are proposed that would alter the IRB's original exemption determination, they should be submitted in ESTR by using the Modify Study button. If unsure, contact the Harvard University-Area IRB office.

The IRB made the following determinations:

- Research Information Security Level: The research is classified, using Harvard's Data Security Policy, as Level 1 Data.



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Please contact me at (617) 496-1261 or tonya_ferraro@harvard.edu with any questions.

Sincerely,

Tonya Ferraro
Senior IRB Administrator