Case Series Investigating Primary Ovarian Insufficiency (POI) as an Adverse Event after the HPV Vaccine

Admin	
Protocol ID	2023-164
Panel	No Panel Assigned
Student Investigator	XXXXXXX Signed 08/01/2023 6:44 PM MDT
PI Type	Student
Faculty/Preceptor	Signed 08/01/2023 9:42 PM MDT Benjamin Brooks 08/01/2023 **No COI Reported**
Campus	UT
Faculty/Preceptor Acceptance Status	Accepted 08/01/2023 9:42 PM MDT
Department	MSBS
PI Institution	
External co-PIs	
Review Type	Case Report/Not Human Subjects Research
Review Sub-Type	Case Report
Approval Status	Case Report/NHSR Approved
Submitted By	XXXXXXXX
Date Received	08/01/2023
Date of Completion	08/03/2023
Date Approved	08/03/2023
Proposed Start Date	08/01/2023
Proposed End Date	05/01/2024
Date Closed	
Type of Research	Student Research
Funding Source	
Sponsor	
Sponsor Contact	
Sponsor Address	
Sponsor Email	
Sponsor Phone	
Consent Waived	Yes - Request Full Waiver
Waiver of Documentation of Informed Consent	Requested
Regulatory Agency	None
Subjects	• Minors (under age 18)
Other Subjects Type	Women affected by the HPV vaccine between ages 14-45
Total Number of Subjects	5
Searchable Keywords	

Pre-Protocol Questionnaire	08/01/2023 Pre-Protocol Questionnaire.pdf
Notifications	08/03/2023 Case Report (NHSR) Approved.pdf
Approved Application Sections	08/03/2023 Approved Application Sections Start Here.pdf

Personnel

PI

XXXXXX (08/01/2023)

Responsibilities

1. What is the Campus Location for the Principal Investigator?

Answer:

Colorado

Faculty/Preceptor

Benjamin Brooks

Responsibilities

1. What is the Campus Location for the Principal Investigator?

Answer:

Utah

Case Reports

How many case reports will be included?

(If more than 5 case reports will be included, it is considered a case series and will require an Exempt category review by the IRB. Please proceed to an Exempt Category Applcation.)

Answer: ✔Less than 5
5 or More

Please briefly describe your case report(s):

Answer:

Case report on patients who have been diagnosed with primary ovarian insufficiency after receiving the HPV vaccine.

If a case report includes any personally identifying health information (PHI), a HIPAA Authorization must be obtained from the patient. Please obtain the hospital/medical clinic HIPAA Authorization template or the RVU template, fill it out and upload the final , signed Authorization form on your protocol page at the bottom under "Files".

(It is important that your HIPAA Authorization form include a statement that the release of PHI is for the purpose of developing a case report. Any changes you make to an institutional HIPAA Authorization form should be approved by the the HIPAA Privacy Officer at that institution.)

Either a HIPAA Authorization or a HIPAA Waiver Request must be uploaded on your protocol page under "Files".

Answer:

Waiver/Alteration of Informed Consent

Is this research regulated by the US Food and Drug Administration?

Answer: Yes
✔No

Is this research regulated by the US Department of Defense?

Answer: Yes
✔No

Explain why and how the research involves no more than minimal risk to the subjects:

Answer:

There is minimal to no risk for the patient. The case report involves the patient interviewing with the research team about any adverse events they have experienced after receiving the HPV vaccine.

Explain why the waiver will not adversely affect the rights and welfare of the subjects:

Answer:

There is no need for a waiver of informed consent.

Is the research team collecting identifiable private information and/or identifiable biospecimens?

Answer: Yes
✔No

Explain why the research could not be practicably be carried out without the waiver of informed consent:

Answer:

There is no need for a waiver of informed consent.

Correspondences

Publicationss

Project Reports

Modifications

Adverse Events

Event / Date	Status / Comments / Files	Submitted By
No Adverse Events Found.		

Deviations

Status	Deviations File/Comments	Submitted By
No Deviations Found		