

HAC Policies and Procedures

Pregnant Women

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Can pregnant women participate in research?

Federal regulations [45 CFR 46.207] stipulate that any research involving pregnant women in any manner must have specific approval for their participation. There are specific requirements and exceptions to the consent requirements in these situations and the research should contact the HAC Administrative Office for specific directions.

NOTE: The Augusta VAMC has additional requirements and please see the Augusta VAMC web page for additional information.

What's the Definition of Pregnancy?

Pregnancy is the period of time from confirmation of implantation (through any of the presumptive signs of pregnancy, such as missed menses, or by a medically acceptable pregnancy test), until expulsion or extraction of the fetus.

Can Subjects Be Excluded From The Study If They Are Pregnant?

Yes, if appropriate for their safety.

Will The HAC Require Any Additional Safeguards For Pregnant Women?

Additional safeguards may be requested by the HAC to avoid undue influence and coercion. There are specific requirements and exceptions to the consent requirements in these situations and the research team should contact the HAC Administrative Office.

What is In Vitro Fertilization?

In Vitro Fertilization is any fertilization of human ova, which occurs outside the body of a female, either through a mixture of donor human sperm and ova or by any other means.

NOTE: The Augusta VAMC has additional requirements and please see the Augusta VAMC web page for additional information.

What is a Fetus?

A fetus is defined as the product of conception from the time of implantation until delivery.

What is a Dead Fetus?

A dead fetus is a fetus which exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord if still attached.

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What is Delivery?

Delivery means the complete separation of the fetus from the woman by expulsion, extraction, or any other means.

What is a Neonate?

According to Stedman's Medical Dictionary, 27th edition, a neonate is an infant aged one (1) month or less.

What Is A Viable Neonate?

A viable neonate means to survive to the point of independently maintaining heart beat and respiration after delivery (given the benefit of available medical therapy).

What Is A Non-Viable Neonate?

Non-viable neonate means the same as a non-viable fetus and is not able to survive to the point of independently maintaining heart and respiration after delivery.

Who Do I Contact if I Have Any Questions?

For additional guidance, contact the HAC Administrative Office at HAC@mcg.edu or call the following extensions:

(706) 721-8397 for PIs whose last names begin with A-G

(706) 721-3110 for PIs whose last names begin with H-P

(706) 721-1482 for PIs whose last names begin with Q-Z

Although the above listing indicates the staff's primary PI assignments, all HAC Administrative Office staff can answer your questions. There may be situations when your questions may require consultation with the HAC or OHRP leadership.