Documentation of IRB Review and Approval:
Department of Defense

Additional Criteria for Department of Defense (DOD) Research (Check if "Yes" or "N/A". All must be checked)	
☐	The study has received department scientific review approval.
☐	The research does NOT involve Prisoners of war or detainees as subjects.
☐	Military personnel will not be paid for research conducted while on duty.
☐	If the research involves DOD-affiliated personnel as subjects, when applicable, the following is required: (Check if "Yes." All must be checked): ☐ If the research includes risks to their fitness for duty (e.g. health, availability to perform job, data breach), language regarding this risk as well as the instruction that they should seek command or Component guidance before participating. must be included in the consent document ☐ Research involves greater than minimal risk: ☐ An ombudsman, who does not have a conflict of interest and is not part of the study team, has been identified and appointed by the IRB. The person should be named in the Research Activity section of PittPRO. ☐ The recruitment section indicates that the ombudsman will be present during the recruitment to explain that participation is voluntary and that the information provided about the research is consistent with the IRB-approved script and materials, including digitally provided material. The ombudsman should be available to address concerns about participation. Note: At the discretion of the IRB, an ombudsman may also be appointed for studies involving minimal risk. ☐ If the study involves Large-scale genomic data (LSGD) collected from DoD-affiliated personnel (including the secondary uses or sharing of de-identified data or specimens) then the following is required: • The research will apply an HHS Certificate of Confidentiality and CoC language has been included in the consent document. • Administrative, technical, and physical safeguards have been considered, as the disclosure of the data may pose a risk to national security.
☐	If the research involves intervention or interactions with cognitively impaired subjects, there is anticipated direct benefit to the subject.
☐	Military and civilian supervisors, officers, and others in the chain of command will not influence the decisions of their subordinates regarding participation in research.
☐	Military and civilian supervisors, officers, and others in the chain of command will not be present at any recruitment sessions or during the consent process for any DoD-affiliated personnel.
☐	When a subject is a Service member, all Research Component, and/or National Guard members in a federal duty status are considered to be adults. If a Service Member, Research Component, or Guard member in federal duty status, student at a Service Academy, or trainee is under 18 years of age, the recruitment process and the necessity of including such member as a human subject is considered during IRB review.
☐	The consent includes language regarding provisions for research-related injury follows the requirements of the DOD component.
☐	Research involving fetal tissue must comply with the US Code Title 42, Chapter 6A, Subchapter III, Part H, 289g: The Secretary may not conduct or support any research or experimentation, in the United States or in any other country, on a nonviable living human fetus ex utero or a living human fetus ex utero for whom viability has not been ascertained unless the research or experimentation 1) may enhance the well-being or meet the health needs of the fetus or enhance the probability of its survival to viability; or 2) will impose no additional risk of suffering, injury, or death to the fetus and the purpose of the research or experimentation is the development of important biomedical knowledge which cannot be obtained by other means. NOTE: This is in addition to compliance with the PA Abortion Control Act.
☐	If the research involves human subjects who are not U.S. citizens or personnel of the DOD, and is conducted outside the United States, its territories, and its possessions: ☐ The permission of the host country has been obtained. ☐ The laws, customs, and practices of the host country and the United States will be followed. ☐ An ethics review by the host country, or local IRB with host country representation, will take place.