**WHRI Website:**

**Research Project Template**

Please complete one form per research project/program you would like displayed on the WHRI website. This page will provide you with a space to help recruit participants, disseminate findings and showcase other knowledge translation activities resulting from the study. The content you provide in this form will be connected to the research team’s bios provided by the membership information. If any of these fields do not apply to this project, please leave them blank.

If there are supporting documents you would like embedded on the project page (i.e. consent forms) or if you have any questions regarding this form, please contact Nicole Prestley at [Nicole.Prestley@cw.bc.ca](mailto:Nicole.Prestley@cw.bc.ca) or by phone **604-875-2424 ext 4956**.

|  |  |
| --- | --- |
| **Title:**  (same as consent form) | A phase III, double-blind, randomized, controlled study to evaluate the safety, immunogenicity and efficacy of GlaxoSmithKline Biologicals’ HPV‑16/18 L1/AS04 vaccine administered intramuscularly according to a three-dose schedule (0, 1, 6 month) in healthy adult female subjects aged 26 years and above. |
| **Principal Investigator:** | Dr. Deborah Money |
| **Primary Contact:**  (name, title, phone, email) | Melissa Watt, Research Coordinator  604-875-2424, ext 4878  mwatt@cw.bc.ca |
| **About the Study:**  (100 words or less plain language summary) | The purpose of this research study is to look at the protection responses (immunity), safety (reactions) and efficacy of the vaccine in women who are 26 years of age and older. |
| **Why is this research important?** | Cervical cancer (lower part of the uterus or womb) is the second cause of death in women worldwide. While not many Canadian women die of cancer of the cervix because of our screening programme (regular Pap smear) there are major emotional and medical burdens when diagnosed and treated for this cancer. Studies show that 98% of cancers of the cervix are found in women that have an infection called human papillomaviruses (HPV). Preventing HPV infection would prevent most cases of cervical cancer. |
| **Study Status:**  (e.g. recruiting, data analysis, manuscript development, complete) | Complete |
| **Who can participate:**  (short description, attach consent form) | Healthy women, 26 years of age and older who:   * The investigator believes that she can and will comply with the requirements of the protocol. * Have an intact cervix. * Have a negative urine pregnancy test. * Is of non-childbearing potential or, if of childbearing potential, she must be abstinent or must be using an effective method of birth control for 30 days prior to the first vaccination and must agree to continue such precautions for two months after completion of the vaccination series. |
| **Study Results/Publication:** | <https://clinicaltrials.gov/ct2/show/NCT00294047?term=Cervarix&rank=33> |
| **Co-Investigators:** | Dr. Simon Dobson  Dr. Thomas Ehlen  Dr. Dianne Miller  Dr. Julie van Schalkwyk |
| **Funded by:** | GlaxoSmithKline (GSK) |
| **Partners:** |  |
| **Other Attachments:**  (e.g. Newsletters, videos) |  |