

HOW TO SUBMIT A RESEARCH PROTOCOL

The documents below may be submitted electronically to the Human Protections Administrator, Ericka Seidemann, at ericka.seidemann@womans.org, and Shonta Wallace, IRB and R&D Secretary, at Shonta.wallace@womans.org.

If you are unsure if your study qualifies as exempt, expedited, or full board, please submit the documents as listed for exempt studies and you will be notified of any other necessary requirements.

For exempt studies:

- Initial study application (under Forms)
- Study protocol (see Protocol Template under Forms)
- Informed consent document (see Consent Template under Forms), if applicable
- Cover sheet for the informed consent document (see Cover Sheet Template under Forms)
- HIPAA authorization (under Forms), if applicable
- Any screening forms, survey forms, data forms, case report forms
- Any instructional or informational material given to participants
- Signed Department Approval Forms for any additional hospital departments involved in conducting the study (under Forms)
- Financial Conflict of Interest Disclosure signed by all investigators, if the study is funded (under Forms)
- If a waiver of HIPAA authorization is requested, submit either a Disclosure for >50 Participants or a Disclosure for <50 Participants, as applicable (under Forms)

For expedited studies:

- Initial study application (under Forms)
- Study protocol (see Protocol Template under Forms)
- Informed consent document (see Consent Template under Forms), if applicable
- Cover sheet for the informed consent document (see Cover Sheet Template under Forms)
- HIPAA authorization (under Forms), if applicable
- If a waiver of HIPAA authorization is requested, submit either a Disclosure for >50 Participants or a Disclosure for <50 Participants, as applicable (under Forms)
- Any screening forms, survey forms, data forms, case report forms, advertisements
- Any instructional or informational material given to participants
- Signed Department Approval Forms for any additional hospital departments involved in conducting the study (under Forms)
- CITI training certificates for all investigators and study staff, if not previously submitted
 - CITI training in human subject research is found at citiprogram.org
- Investigator Agreement signed by all investigators (under Forms), unless previously submitted
- A *curriculum vitae* for each investigator, including copies of any licenses
- Financial Conflict of Interest Disclosure signed by all investigators, if the study is funded (under Forms)

For full board studies:

- Initial study application (under Forms)
- Study protocol (see Protocol Template under Forms)
- Informed consent document (see Consent Template under Forms), if applicable
- Cover sheet for the informed consent document (see Cover Sheet Template under Forms)

- HIPAA authorization (under Forms), if applicable
- Any screening forms, data forms, case report forms
- Any instructional or informational material given to participants
- Signed Department Approval Forms for any additional hospital departments involved in conducting the study (under Forms)
- CITI training certificates for all investigators and study staff, if not previously submitted
 - CITI training in human subject research is found at citiprogram.org
- Investigator Agreement signed by all investigators (under Forms) , unless previously submitted
- Financial Conflict of Interest Disclosure signed by all investigators, if the study is funded (under Forms)
- A *curriculum vitae* for each investigator, including copies of any licenses
- Two copies of the Investigator's Brochure , if applicable
- Human Resource requirements for non-employee study personnel collecting data or consenting participants on campus, which may include confidentiality statements, proof of training, and appropriate vaccinations
- Proof of IDE/IND (for investigational drug or device studies)
- Radiation Safety Committee approval for studies involving radiation exposure, other than for diagnostic or treatment procedures