

LOCAL CONTEXT SUPPLEMENT

15.307 (HRP-508)

(For use as applicable e.g. with multi-centered, or industry sponsored protocols, etc.)

Please answer all applicable questions below (**remove** all instructional text in blue):

1. Study Site

Provide the specific name of all departments, hospitals, inpatient services or outpatient clinics, schools or other locations where subjects will be recruited, consent process will take place, treatment will occur, medical records will be accessed and/or stored, and other research-related activities will occur. For example: University Radiology Group at 10 Plum Street, Ambulatory Surgical Pavilion at 10 Plum St., University Hospital, CAB Suite 4100 Department of OB/GYN, Somerset Medical Center, Local Private Physicians Offices, etc.

[Add Your Answer Here]

2. Site Specific Protocol Differences (if applicable)

Note any differences between what is stated in the general protocol and what activities will or will not be conducted at Rutgers sites. (For example: If the general multi-site protocol offers optional elements or if the Rutgers study sites will not be participating in certain aspects of the study.)

[Add Your Answer Here]

3. Subject Recruitment and Enrollment Considerations

[Note: Recruitment and enrollment design considerations are extremely important for assuring human subjects' protections, including their voluntary & informed consent, privacy of person and confidentiality of data, and equitable access to research.]

[Add Your Answer Here]

3.1 Subject Recruitment

Describe how and when individuals will be recruited to participate in the study. Specify who and how investigators will be involved in subject recruitment and the consent process. Explain how individuals will be approached, what collateral materials will be used to recruit them (e.g., flyers, internet, letters from physicians), and the context of the offer of participation (location, timing of offer, and decision deadline). Provide copies of all recruitment materials in an appendix to the protocol. Indicate the number of subjects to be approached for recruitment, allowing for screen failures and/or drop outs. Carefully consider if and when others (e.g., family members) become secondary subjects as a result of the information provided by the primary subjects and how such persons will be protected and informed consent secured, if applicable. Determine in advance how many times you need to contact (mail, email, phone) a patient to recruit them for a study. Be sure to factor in possible low response rates when you make that calculation. Since the IRB must pre-approve any/all contact with subjects, accurately calculating the number of times you need to make outreach minimizes the need to submit protocol modifications to the IRB.

Please Note: Only persons authorized to have/view patients' protected health information may contact patients to participate in research (i.e., their own physician). However, some practices consider all patients' as 'their' patients. If that is the case, you must demonstrate it is

documented somewhere in the patients' records that they have been notified of this relationship. Any mailing to patients recruiting them for research must include the name of all physicians involved in the practice on the correspondence letterhead.

[Add Your Answer Here]

3.2 Consent Procedures

Describe the consent procedures to be followed, including how, when, where and by whom informed consent will be obtained and documented. [Example: The study will be explained to the potential subject by the Principal Investigator, the consent will be read, and their questions will be answered. If they wishes to enroll, the subject will sign the consent form. The study staff obtaining consent will also sign and date the consent form, and a copy will be given to the subject.] Be mindful to create an environment that supports voluntary and informed decision-making and include additional safeguards for persons likely to be vulnerable to coercion or undue influence. Procedures must reflect that informed consent will be sought from each prospective subject or the subject's representative. A copy of the consent document(s) you will use must accompany your IRB application. Under certain circumstances, a waiver of consent or waiver of documentation of consent may be appropriate. If so, a request for a waiver must be submitted to the IRB for their consideration/approval. **[Note:** Informed consent is not an event but a process. Study staff should periodically check with subjects to answer any further questions they may have about the study or their rights while participating in it.]

[Add Your Answer Here]

3.3 Non-English-Speaking Subjects

Indicate what language(s) other than English are understood by prospective subjects or representatives.

[Add Your Answer Here]

- **Process for Non-English-Speaking Subjects**

If subjects who do not speak English will be enrolled, describe the process to ensure that the information about the research—oral or in writing—that is provided to subjects will be in that language. Indicate the language that will be used by those obtaining consent.

[Add Your Answer Here]

- **Short Form Consent for Non-English Speakers**

Indicate whether you will be using a consent short form for non-English speakers. [See Toolkit items 6.202 (HRP-317) and 16.360-16.377 (HRP-507).]

[Add Your Answer Here]

3.4 Adults Unable to Consent / Decisionally Impaired Adults

[To complete this section, see HRPP Guidance: Surrogate Consent Process and Toolkit 7.001 (HRP-013).]

- **NJ Law-Assessment of Regaining the Capacity to Consent**

Describe your plans for obtaining an assessment of the decision-making capacity of subjects, including a process for the selection of an attending physician not connected with the study to make this assessment. [See 6.203 (HRP-390) Determining Decisional Capacity.]



[Add Your Answer Here]

▪ **Capacity to Consent**

Describe your plans for obtaining surrogate consent and consent for subjects who regain capacity. [See 6.204 (HRP-391) Selecting a Surrogate.]

[Add Your Answer Here]

a. **NJ Law-Selecting A Witness**

Describe the process for selecting this witness. [For studies at RWJUH, the Chaplain is the designated witness for studies utilizing surrogate consent.]

[Add Your Answer Here]

b. **Removing a Subject**

Describe your plans to safely remove a subject from the research if the subject expresses dissent to continued participation or if a surrogate withdraws consent.

[Add Your Answer Here]

4. **For Chart or Electronic Medical Record Review**

For Chart Reviews indicate every institution's records that will be accessed. For example, Rutgers paper medical records, University Hospital paper medical records, RWJUH paper medical records, RWJUH at Somerset, etc.

If electronic records will be accessed clarify the name of the electronic database, whose database it is, and where it is located.

Indicate how the PI will know what records to access. For example, will someone provide a list of what records to access and if so who will provide the list, or will a query be created to create a list and if so who will set the query, will medical records provide a list of names? If some other method will be used to identify what records to access, provide details of how this will occur and by whom

[Add Your Answer Here]

5. **Drug/Device Accountability (if applicable)**

5.1 **Indicate the specific location where study drugs/devices/biologicals will be stored:**

[Add Your Answer Here]

5.2 **Indicate how storage location will be secured:**

[Add Your Answer Here]

5.3 **Indicate who will be responsible for study drug/device/biological preparation:**

[Add Your Answer Here]

5.4 **Indicate who will dispense subject drug/device/biological to the subject(s):**

[Add Your Answer Here]

6. **Data Handling and Storage**



Describe data entry, editing and methods for quality assurance. Indicate how information will be recorded (e.g., electronically, audio, paper), where data will be stored, who will have access, and how subject's privacy and confidentiality of health information will be protected during collection, storage, use, or transmission (e.g., flash drives, internet) of data.

If data will be transferred or transported from one local site to another or from one local site to Rutgers, please specify who will transfer the data and how. For example, if data will be transferred/transported from the Newark Campus to the New Brunswick Campus or from a private physicians office to a Rutgers building please provide details of who will transfer/transport the data and how.

[Add Your Answer Here]

7. Sample/Specimen Collection, Processing, Handling and Storage (if applicable)

If samples/specimens will be collected at another location (either another Rutgers location or other local site), specify who will collect the specimens, who will process them, how they will be transported, who will transport them, and where they will be stored. Please note any personnel transporting biological materials will need to provide documentation of the appropriate Biosafety training.

[Add Your Answer Here]

8. Approvals

Describe any approvals that will be obtained prior to commencing the research. (e.g., Data Use Agreements, Material Transfer Agreements, funding agency agreements, Bio-Safety Approvals, Radiation Safety Approval, etc.). **UPLOAD a copy of all approvals and agreements to e-IRB+ Section 10.0 Supporting Documents.**

[Add Your Answer Here]

Need Help?

Visit the [Human Research Protection Program \(HRPP\) website](#) to obtain referenced [Toolkit Forms & Templates](#) to obtain referenced Guidance documents. Contact the IRB Office if you need additional help IRBOffice@research.rutgers.edu.