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FAQs on the Consent Document for Biomedical Studies

1. I am conducting biomedical research only at the University of Miami (UM). What consent document do I use?

If you will not be conducting research procedures at Jackson Health Systems (JHS) and all of the research procedures will be done at the UM, you should use the Five-Part Biomedical Consent Template for the UM (HRP 502a1).

2. I will identify and/or recruit subjects from JHS but I will perform all other research procedures at the UM. What consent document do I use?

If the only procedures you will conduct at JHS is subject identification and recruitment, and all other research procedures will be done at the UM, you should use the Five-Part Biomedical Consent Template for the UM (HRP 502a1). If you plan to post fliers at a JHS facility, you need to obtain approval of the flyer from the Jackson Clinical Trials Office. If you plan to identify potential subjects by reviewing health information at a JHS facility, you must obtain a waiver of authorization from the UM IRB. When you use JHS records to identify potential subjects, you must maintain a list of the patients whose record you accessed. JHS will request the list to meet its regulatory obligations under HIPAA to account for disclosures of protected health information.

3. I am conducting biomedical research only at a JHS facility. What consent document do I use?

If you will not be conducting research procedures at the UM and all research procedures will be done at a JHS facility, you should use the Five-Part Biomedical Consent Template for JHS (HRP 502b1).

4. I am conducting the same biomedical research protocol at both the UM and JHS facility. What consent document do I use?

If you are conducting the same research at both the UM and JHS Facility, then you should use the combined UM/JHS consent document (HRP 502a3).

5. I was approved to use JHS medical information to identify potential subjects for research that I am performing at the UM. Since my research is being done only at the UM, the consent document and authorization language does not mention JHS. I need more health information on routine procedures done at JHS for which the patient has already been scheduled for or in an unforeseen adverse event/serious adverse event where the patient chooses JHS as it's primary care center. What do I do?

The waiver of authorization for recruitment you received from the IRB does not allow you to access a subjects' health information after the subject enrolls in your study. You must obtain the subjects' signature on JHS form, "Authorization for Release of Confidential Medical Records" before you request the subjects' health information from the JHS Medical Records Department.

6. What consent do I use if my study is observational at both UM and JHS?

If the study is observational where data is being collected on routine procedures at both UM and JHS, use the part 5 Biomedical Consent hrp-502a3 template.

7. What consent do I use if my study is observational at JHS only and research procedures are at UM?

If the study is observational where data is being collected on routine procedures, include language in the consent that at JHS there will be only data collection from the EMR and use the part 5 Biomedical Consent hrp-502a3 template.