Who can serve as the consent witness for surrogate consent at RWJUH

The policy regarding who can serve as the surrogate consent witness at RWJUH is a RWJUH policy, not an IRB policy. This occurred because the hospital was concerned about the staffing that would be required to comply with the requirements for witnessing surrogate consent. The demands to witness surrogate consent are greater than for simply witnessing consent of someone who is fully capable of providing his/her own consent. That is, the witness of a surrogate consent must be present for the whole consent process, which can take considerable time. Therefore, the hospital did not want staff (e.g. nurses, residents, etc.) to be taken away from other critical duties for the length of time required to fulfill the surrogate consent witness process. Thus, RWJUH administration has determined that the only RWJUH personnel they will allow to be a surrogate consent witness is pastoral care. In addition, the state statute requires the witness be someone who is not involved in the study and who is familiar with the elements of informed consent. To meet the latter requirement, the RWJUH pastoral care department was trained by our IRB director, Donna Hoagland, in the elements of consent. Should an investigator want to initiate an alternative plan for witnessing inpatient surrogate consent, that investigator would need to submit their plan with the surrogate consent modification request. The plan would need to include the following; designate witnesses not involved in the study, a plan to train witnesses in the elements of informed consent, and identify back-up personnel in case those designated as witnesses are not available. Currently all initial applications and modification requests to use surrogate consent are being reviewed at the full board Executive Committee.

With regard to the use of translations for surrogate consent, the state statute requires both a fully translated consent and a full verbal translation. The statute does not allow the use of the English short form or the use of only a verbal translation. Presumably the PI would have a translator present if English is not the surrogate’s language. Therefore, the witness would not need to be fluent in the surrogate’s language any more than the PI would need to be. Rather, a certified translator would be present and translate for both the PI and the witness to hear.

For outpatient surrogate consent situations, the PI will need to develop a plan for witnessing surrogate consent abiding by the same guidelines as indicated for inpatient witness. Pastoral care is not designated for outpatient surrogate consent unless the outpatient clinic is located at the hospital. Otherwise, it will be up to the PI to develop an acceptable plan for witnessing surrogate consent.