COLUMBIA UNIVERSITY INSTITUTIONAL REVIEW BOARD POLICY

SEEKING CONSENT FOR RESEARCH PARTICIPATION ON THE DAY OF AN ELECTIVE SURGERY OR PROCEDURE

I. SCOPE:

This Policy applies to all research involving human subjects, including behavioral, social science, epidemiological, and biomedical research, and sets forth Columbia University Institutional Review Board's requirements for human subjects research for which consent is sought on the same day as an elective procedure.

II. EFFECTIVE DATE: September 29, 2010

III. BACKGROUND:

The Code of Federal Regulations requires that "…an investigator shall seek…consent only under circumstances that provide the prospective subject…opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence."

Most patients experience some anxiety in the hours immediately before an invasive procedure. This anxiety is heightened by a disruption of normal eating and drinking regimens, and sometimes other pre-operative procedures. This vulnerability increases the possibility for coercion or undue influence. In these situations, obtaining informed consent prior to the day of the procedure is preferable.

However, for some research conducted on the same day as an elective procedure, researchers can not prospectively identify and contact potential research subjects. In such instances, restricting research subjects to those who can be prospectively identified and contacted may render the research impracticable or would introduce bias into the subject pool.

IV. POLICY:

The Institutional Review Board (IRB) aims to avoid seeking consent for research on the same day as elective procedures when possible, and provide adequate protections when such consent is necessary.

A. Minimal Risk Research

For minimal risk research, seeking same day consent is allowable following appropriate IRB review, if the research may not otherwise be practicably conducted.

For protocols that meet the criteria for expedited review, such review may be conducted by the chairperson.

B. Research Posing a Minor Increment Above Minimal Risk

For research posing a *minor increment above minimal risk*, seeking consent on the day of an elective surgery or procedure may be approved on a case by case basis by the convened IRB, through full board review. The following criteria should be considered when reviewing such requests:

1) The research poses only a minor increment more than minimal risk, as determined by a full board review.
2) The IRB protocol application must explicitly request permission to obtain same-day consent, and must describe the proposed consent process, including who will seek consent, and how this process will fit in with the schedule of clinical care.
3) Same-day consent must be found by the IRB to be necessary to the research and to not place undue pressure on individuals to participate.
4) The consent process must begin with a specific statement about day of procedure approach, and include a clear opportunity to decline participation (e.g. "We understand that some people will not want to discuss clinical research while they are waiting for a procedure. If you do not want to discuss this research study, you do not need to do so.")
5) The patient/potential subject will be encouraged to invite an accompanying relative or friend to participate in discussions of research options.
6) All potential subjects must be offered sufficient time to review the consent form and consider research participation before being asked for their decision.
7) Whenever possible, an IRB approved information sheet should be mailed to potential research subjects prior to the procedure date containing the following information: 1) that the patient may be approached to consider research participation, 2) a description of the difference between research and standard practice, and 3) a description of the voluntary nature of research participation.
8) Consent must never be sought when a potential subject has received medications that may alter his/her cognitive state. Discussion should take place while the patient is still in possession of glasses, hearing aids, or other necessary devices.
9) Documentation in the research record must include the time at which the consent process started and the time at which consent was obtained.

C. Research that is Greater than Minimal Risk (more than minor increment above minimal risk)

The IRB will consider research protocols that involve greater than a minor increment above minimal risk on a case by case basis. In general, such protocols will not be allowed to obtain informed consent on the same day of the elective surgical procedure.

However, there may be some research protocols that may provide potential therapeutic benefit and for which seeking consent prior to the day of the procedure may not be feasible. At a minimum, all of the above protections will need to be considered.