

Informed consent waiver:

This study was given an informed consent waiver by meeting the following criteria. The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirements to obtain informed consent, provided the IRB finds and documents that ALL of the following criteria are met:

1. The research involves no more than minimal risk to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The research could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Further, the analyses were conducted by using 2 teams of investigators. Team 1 did have access to patient identity and collected the data from the medical records. Team 2 entered the data into the statistical software databases, and the analyses were independently conducted.

