ADIRONDACK HEALTH

TITLE:	Expedited Review Procedures	POLICY #: SOP-11
FOLDER NAME:	Institutional Review Board (IRB)	PAGE: 1 OF: 2
PREPARED BY:	Patricia Druzba, Ph.D. Chair, Institutional Review Board (IRB)	
EFFECTIVE DATE: 1/15	REVIEWED/REVISED: 2/16	
APPROVED BY: Patricia Druzba, PhD (Chair, IRB) Patricia Druzba PhD Chandler Ralph (CEO/President)		

POLICY:

In the event that a project involves no more than minimal risk to a potential subject and the research procedures are one or more of the categories listed below, an expedited review process may be available. Generally, an informed consent must still be used.

1. A protocol for the collection of blood specimens from healthy, nonpregnant adults weighing more than 110 pounds in amounts less than 550 ml per 8 week period and fewer than 2 times per week is eligible for expedited review.
2. A protocol for the collection of blood specimens from other adults and children at a rate of 3 ml/Kg or 50 ml, whichever is less, over an 8 week period may be eligible for expedited review after discussion with the Chair of the IRB.
3. A study of human specimens collected by a non-invasive procedure may be given expedited approval if not collected under general anesthesia or sedation. The general rule is that the collection process may not exceed the process that would be done under standard of care procedures. For example, buccal and mucosal skin cells collected by scraping, swabbing, mouth wash or skin swab would be appropriate for expedited review.
4. Collection of data through routine non-invasive procedures such as sensors applied to the body or used at a distance and do not introduce significant amounts of energy into the subject or an invasion of the subject's privacy, weighing or testing sensory acuity, MRI, ECG, EEG, thermography, detection of naturally-occurring radiation, ERG, US, diagnostic infrared imaging, doppler blood flow, echo, moderate exercise, muscular strength testing, body composition assessment, flexibility testing are some of the categories which may be included in an expedited reviewed protocol, if appropriate to the subject population.
5. Data that have already been collected as part of routine medical care and are already "on the shelf" are appropriate for expedited review.
6. Collection of data from voice, video, digital or image recordings generally can follow expedited review procedures.
7. Collection of data on group characteristics or behavior, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices or research involving surveys, oral history, focus group, program evaluations, human factor evaluations and quality assurance methodologies may be appropriate for expedited review.

8. Continuing review of research previously approved by a convened IRB is allowed under expedited review. Providing, the study is permanently closed to new enrollment, all subjects have completed all phases of the investigational interventions, no new significant risks have been identified, and the remaining research activities are limited to data analysis.

REFERENCES:

CFR (Code of Federal Regulations): 21 CFR 50.24, 21 CFR 56.110
NYCRR: N/A
HFAP: N/A