

GUYANA

No. 9 of 2008

REGULATIONS

Made Under

THE MINISTRY OF HEALTH ACT 2005
(Act 6 of 2005)

IN EXERCISE OF THE POWERS CONFERRED UPON ME BY SECTIONS 4 (c), (w)
AND 10 OF THE MINISTRY OF HEALTH ACT 2005, I HEREBY MAKE THE
FOLLOWING REGULATIONS:-

- Citation. 1. These Regulations may be cited as the Medical Research Involving Human Subjects Regulations 2007.
- Interpretation 2. In these Regulations-
- No. 6 of 2005. (a) "Act" means the Ministry of Health Act 2005;
(b) "Committee" means the Committee established by the Minister to oversee the compliance of these Regulations;
(c) "ethical principles" means the principles and policies governing medical research involving human subjects laid down and implemented by the Minister ;
- Regulation of human subject research. 3. (1) Any person engaged in medical research involving human subject, shall-
- (a) be responsible for protecting the rights and welfare of all human subjects involved in that research which they sponsor or conduct;
 - (b) encourage and promote a research atmosphere that safeguards the rights and welfare of human subjects;
 - (c) respect the generally accepted scientific standards with respect to the safeguard, health and integrity of human subjects;
 - (d) ensure that before human subjects are involved in research which they sponsor or conduct, proper consideration be given to-
 - (i) the risk to the subjects;
 - (ii) the anticipated benefits to the human subjects and others;
 - (iii) the importance of the knowledge that may reasonably be expected to result out of the research;

- (iv) a consent process;
- (v) special safeguards, whenever appropriate, for protecting human subjects such as children, prisoners, pregnant women, refugees, mentally challenged persons, rural populations and economically or educationally disadvantaged persons; who may be vulnerable to coercion or undue influence.
- (vi) an appropriate administration overview to ensure that the principles referred to in paragraphs (i) to (v) are applied effectively.

Powers of the Minister.

4. The Minister may-

- (a) lay down and implement the ethical principles;
- (b) establish the Committee;
- (c) appoint the Chief Medical Officer or other senior medical officer as the chairperson of the Committee;
- (d) prescribe the terms of reference of the Committee so as to enable it to discharge the functions in conformity with the written laws;
- (e) ensure participation in the Committee of the private sector, civic society and any other person or body of persons concerned or affected by the implementation of these Regulations;

Reports by the Committee.

5. (1) The Committee shall submit a report to the Minister regarding its activities for each year within thirty days after the end of each calendar year.

(2) The Committee shall be answerable and accountable to the Minister and shall submit to the Minister any interim report or explanation or statement on any matter as required of it.

Made on this the 17 day of December 2007



MINISTER OF HEALTH