

From: dheaton@ncat.edu
Sent: Tuesday, September 16, 2008 5:54 PM
To: Chi Anyansi-Archibong
Subject: Re: IRB on Qualitative/Case method research

Hi Dr. Archibong,

I spoke with the IRB chair, Dr. Karen Smith-Gratto who states case studies should be reviewed by the IRB. This is because you cannot assume that a case study is not human subjects research. If it meets the definition of a human subject being studied (a living individual) and meets the definition of research (a systematic investigation) then it requires IRB approval. The number of living individuals being studied does not determine if IRB approval is required. At the very least, the IRB must be consulted for a determination of exemption, the regulations do not recommend and our policy does not allow for faculty to make the determinations on their own.

Also, I looked up case studies in the IRB Management book which refers to case reports. It also states that the first step is to determine whether the project contains both of the elements from the regulatory definition of research. In the author's opinion the number of participants is not a defining factor. It is the use of statistical method and test for prognostic factors that are the distinguishing features. It goes on to state that care should be taken to distinguish a case report from a "N-of-1" research study in which there is manipulation of an intervention to produce generalizable knowledge.

I can share more from the book which is a notable reference if you need.

Thanks for your patience

Donna Eaton

"Chi Anyansi-Archibong" <archiboc@ncat.edu>

To <dheaton@ncat.edu>

cc

09/16/2008 10:05 AM

Subject IRB on Qualitative/Case method research

Hi Donna:

Is it possible to respond to my request regarding the above—my report on the policies is due tomorrow.

Thanks

Chi

Chi Anyansi-Archibong, Ph. D.
 Professor, School of Business and Economics
 Coordinator, University Global Studies Certificate Program
 Institution Leader, LANGURE/Research Ethics
 Coordinator, Business Environment
 North Carolina A&T State University
 Phone: 336-334-7656 ext.4025 or 334-7104
 Fax: 336-334-7093 or 256-0802
 Email: archiboc@ncat.edu or chi.archibong@hotmail.com
www.ncsu.edu/langure

