Description

The file below (IRB Case Presentation Analysis) is the word document template you must use to submit your assignment. Be sure to remove the instruction comments before submitting your final document. PLEASE ADD YOUR NAME TO THE DOCUMENT TITLE BEFORE SUBMITTING YOUR ASSIGNMENT. IRB.Case.Presentation.Analysis.Template.docx The expected learning outcome is for the student to be able to critically evaluate the ethical/regulatory issues and impact of a case study. In preparation for the assignment it is strongly recommended that you read/review the following:

 Emanuel, E. J., Grady, C., Crouch, R. A., Lie, R. K., Miller, F. G., & Wendler, D. (Eds.). (2011). The Oxford Textbook of Clinical Research Ethics. New York, NY: Oxford University Press. ISBN-13:9780199768639

Oxford – Ch 57 Legal and Regulatory Requirements Standards of Informed Consent (pg 613); Ch 64 Appropriate Ethical Standards (pg 711); Ch 65 Benefits to Host Country (pg 710); Ch 67 Responsiveness to Host Community Health needs (pg 737)

Developing a Well-Reasoned Response to a Moral Problem in Scientific Research by Muriel J. Bebeau, University of Minnesota http://www.indiana.edu/~koertge/Sem104/Sem104Bebeaustu.html (Links to an external site.)

The file below is an example of a case presentation. This file is provided only as a reference. It is being provided so you can see the critical thinking that should be reflected in a case analysis. Sample Case Presentation Analysis.pdf INSTRUCTIONS (PLEASE READ CAREFULLY): Submit a four (4) page analysis of the case that is outlined below. Spelling and grammar count, so be sure to check/review your paper prior to submission. Use APA formatting for citations and references (must have at least 3) to support your arguments. The reference page is not included in the page count. In the introduction paragraph, include your position on whether or not the IRB should approve the study. What are the ethical issues and points of conflict in this case? (one full page, double spaced, and bulleted) Who are the interested parties affected by the issues/conflicts and what are their reasonable expectations? (one full page, double spaced, and bulleted) If the interested parties acted on their expectations what would be the probable consequences? REMEMBER: Consequences can be multifaceted. (one full page, double spaced, and bulleted) What are the obligations of the Amazing IRB? (one full page, double spaced, and bulleted) The Case: IRBs in Conflict Researchers in a developing nation in South America (SA) have been studying a hereditary disorder found only in an isolated, indigenous population living deep in the jungle. They now hope they can identify the gene(s) that may be associated with the disorder in order to identify causative factors and to find interventions and targeted therapies. To accomplish this, they will need to collaborate with a qualified US researcher, Dr Herod I. Tarry. Dr Tarry is a world-renowned molecular biologist who is utilizing a genomic technology that is not widely available. The SA researchers would send subject blood samples to Dr Tarry's US lab for testing. The SA researchers submitted a protocol amendment to the South America Institutional Review Board (SAIRB), which is the IRB of record for the study. The protocol amendment added Dr Tarry to the study team and added the genomic research. In addition, the SAIRB-approved informed consent form (ICF) was revised to include information about the blood draw for genomic analysis. The SA researchers’ revised protocol and consent form were approved by the SAIRB in compliance with South America's research regulatory requirements. Per his institution’s requirements, Dr Tarry must get approval for his work on the international study from the institution’s IRB (Amazing IRB). Dr Tarry submits the SAIRB-approved documents in a proposal to the Amazing IRB. Dr Tarry is asked to present the SA hereditary disorder study at the next convened meeting for Amazing IRB.

The Amazing IRB members are not receptive to the proposal, in large part due to the perceived quality of the ICF. The SAIRB-approved ICF is a single-spaced, typed page (about 550 words). It includes a description of the study, the procedures (including the blood draw for genomic analysis), risks, benefits, and confidentiality protections. However, the details are more limited than the Amazing IRB usually sees. While the consent technically meets all the required US regulatory elements for informed consent, the Amazing IRB members feel it is far below US standards for consent documents. Dr Tarry acknowledges the consent document is not written like consents are in the US. He states he is not consenting subjects for this study and he will not have any contact with them. He points out to the IRB members that the consent document is acceptable by the SA research regulatory standards and he hopes the Amazing IRB will approve the study and the consent as is. In final comments, he notes his role in the research can be very beneficial to the study population and as such it is extremely important for him to participate in the genomic research.