CHAPTER 1

Informed Consent and Clinical Trial Participation: Perspectives from a Ghanaian Community

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Introduction

Clinical research continues to expand globally. Lower-income countries have become popular destinations for research institutions and pharmaceutical companies in which to conduct clinical trials (Ballantyne 2010; Emanuel et al. 2004; Glickman et al. 2009). To illustrate, Ghana, a country relatively new to clinical research (Ogutu et al. 2010; Ghana-Michigan Collaborative 2010), reported having thirteen registered clinical trials in operation in 2012, according to the government's Food and Drug Board that regulates this work (Food and Drug 2012). Of these trials, twelve were sponsored by non-African institutions, with the remaining one funded by a Tanzanian research institution (Food and Drug 2012).[1] The pharmaceutical industry is aware that running trials in the lower-income countries is more cost effective than in higher-income countries (Petryna 2007; Schuklenk 2010). In lower-income countries like Ghana, participants are often targeted as preferable, "treatment-naïve" trial candidates, meaning individuals who have not been exposed to drugs that could potentially interfere with clinical trial results (Frimpong-Mansoh 2008; Mbuagbaw et al. 2011; Petryna 2007). Although the financial compensation given to lower-income country participants in clinical trials may be higher than what they typically can expect to receive in annual income, participants from low-income countries still receive relatively low compensation compared to their counterparts in wealthier nations

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(Glickman et al. 2009; Brody 2002). This creates an economically beneficial arrangement for the pharmaceutical industry; lower research costs allow for increased profits margins (Petryna 2009). As various reports have shown, international clinical research is thriving financially and experiencing increasing revenues (Gatter 2006; Moses et al. 2005). According to PharmaTimes, revenues from the clinical trials market are expected to surpass $65 billion by 2021 (Mansell 2011). As the demand for pharmaceutical drugs and interventions grows, more international clinical research will be needed to meet this demand; consequently, greater numbers of global citizens will be needed to fill positions as trial participants in the various phases of research.[2]

The growing need for trial participants, combined with several notable moral atrocities that have plagued clinical research in Europe and North America (i.e. the German Nuremburg experiments and the US Tuskegee syphilis study), have led many critics to call for stronger participant protection mechanisms in international clinical research (Lorenzo et al. 2010; Moreno 2007). They believe this will help lower risk and mitigate the potential for the exploitation of "vulnerable" populations through participation in biomedical research (Dixon-Woods et al. 2006; Resnik 2009; Shamoo and Resnik 2006). While acknowledging this need for improved governance of international clinical trials and ensuring safety for participants involved in them, recent literature has been critical as well toward traditional protectionist approaches such as those seen in the informed consent process, arguing that they tend to be too heavily focused on the individual (Miller and Boulton 2007) and one's right to autonomy. One of the main arguments against such approaches is that they do not adequately, if at all, take into account the wider social context in which research and decision making take place (Felt et al. 2009). This includes clinical research in impoverished areas that have weak health system infrastructures and a lack of resources. Increasingly, there have been calls for more robust ethical research frameworks against the background of the increased shift of clinical trials to low-income countries (Buchanan et al. 2008; Levitt and Zwart 2009). In constructing these ethical frameworks, there is a need to ensure that they are contextually sensitive and inclusive to the views and concerns of research participants and the general public. Thus there is a clear need to critically consider how protection mechanisms currently used in international clinical research are implemented, negotiated, and enacted, including the use of traditional informed consent.

Informed consent of individuals from low-income countries engaging in internationally sponsored clinical research has been problematized by a number of publications (Krosin et al. 2006; London et al. 2012; Mystakidou and Panagiotou 2009; Tindana, Kass, and Akweongo 2006; Van Loon and Lindegger 2009). Commentators have voiced concerns regarding the ability