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Researchers Without Borders?: Limiting Obligations of Ancillary Care Through the Rescue Model

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OUTSIDE PERSPECTIVE

Researchers Without Borders?: Limiting Obligations of Ancillary Care Through the Rescue Model

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With the expansion of clinical research in developing countries, there is a need to explain obligations that researchers have to their subjects beyond those required by the study protocol. This paper outlines a model founded on the duty to rescue that provides ethical clarification of the obligations of ancillary care.

I. INTRODUCTION

The burgeoning business of clinical research has an increasing prevalence in developing countries, where it is easier to recruit a large number of participants and costs are drastically reduced.[1] When educated and well-funded research teams venture into communities with few resources and almost no education, the imbalance raises ethical questions far more frequently than in the context of research in developed countries. Questions arise over what the researchers owe to the host population and what obligations they have to the individual research subjects. The burdens undertaken by the host country and the risk undertaken by the individual subjects are distinct and may be addressed under different ethical frameworks.[2] This paper seeks to provide guidance with regard to the obligations researchers owe individual subjects.

Some scholars advocate that researchers owe ancillary care to research subjects. Ancillary care is the provision of care to research subjects that is beyond the requirements of what is needed to reach scientific validity and research objectives, or prevent and rectify research-related injuries.[3]

Differing models of ancillary care have been suggested, most of which focus on the researcher-subject relationship and the duties that arise from it.[4] This approach can create problems of when obligations end,[5]

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[1] Angela Ballantyne, *'Fair Benefits' Accounts of Exploitation Require a Normative Principle of Fairness: Response to Gbadegesin and Wendler, and Emanuel et al.*, 22 BIOETHICS 239, 240 (2008).

[2] Proposals of reasonable availability suggest that companies from developed countries should not be allowed to subject populations in poorer countries to the risks of a trial when researchers will simply take the new medical intervention back to their own country to sell for profit. Ezekiel Emanuel et al., *Moral Standards for Research in Developing Countries: From "Reasonable Availability" to "Fair Benefits"*, 34 HASTINGS CTR. REP. 17, 18 (2004) [hereinafter *Moral Standards*]. When a developing country is exposed to the risks of research with few benefits in return there is an unethical risk of exploitation. *Id.* Therefore, those supporting reasonable availability feel the population that participates in the trial deserves access to the medical intervention they are helping to generate. *Id.* Others argue that because exploitation is about how much one receives, not merely what each party receives, reasonable availability is but one of the benefits that a community may receive to avoid exploitation. *Id.* at 20. Instead the Fair Benefits framework allows for the community to receive other benefits rather than requiring reasonable availability. *Id.* at 22.

[3] Henry S. Richardson & Leah Belsky, *The Ancillary-Care Responsibilities of Medical Researchers*, 34 HASTINGS CTR. REP. 25, 26 (2004).

[4] *See id.* at 27–28 (describing the foundation of the partial-entrustment model); Neal Dickert & David Wendler, *Ancillary Care Obligations of Medical Researchers*, 302 J. AM. MED. ASS'N 424, 426 (2009) (stating that the source of ancillary care obligations is the researcher-subject relationship).

[5] *See* Richardson & Belsky, *supra* note 3, at 30 (finding that ancillary care requirements only apply to those needs discovered through study procedures).

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as well as what acts may fulfill ancillary care obligations.[6] This paper seeks to address whether an obligation to provide ancillary care exists, and then it proposes a model based on the duty to rescue.

It is not difficult to imagine that any given research subject in a developing country may have a plethora of health care needs during their enrollment in the study. Yet, to mandate care for individual subjects could severely deplete the budgets of many research trials and may dissuade researchers from conducting studies in developing countries thereby preventing the benefits that can arise from this important work. Determining what obligation, if any, researchers have to address subjects' medical needs and what limitations exist is imperative to conducting ethical research in developing countries.

II. PRINCIPLES OF ETHICAL RESEARCH

The very definition of research is to create generalizable knowledge for the benefit of society.[7] This point is critical when considering the weight of potential obligations researchers have to individual subjects.[8] As such, ethical principles of autonomy, justice, and beneficence are largely in place to protect the rights of individuals while pursuing this objective, rather than producing significant requirements of positive action toward individual subjects.

For example, respecting a subject's autonomy requires informed and voluntary consent and the ability to withdraw from the study at any time.[9] Justice requires a fair distribution of benefits and burdens, ensuring that one group of people is not undertaking all the risk while another group is positioned to receive the benefits.[10] Beneficence obligates the research team to maximize the possible benefits and minimize the possible harms.[11] Given that beneficence creates a positive obligation, the consequences of that positive action must be sufficiently outweighed by the amount of benefits created.[12] Therefore, beneficence is thought to be satisfied if the study has a favorable risk-benefit ratio.[13] This determination is made by Institutional Review Boards (IRBs) prior to enrollment and, therefore, cannot and should not factor in potential ancillary care, which may or may not be provided. And while all of these principles are critical to performing ethical research, especially in the backdrop of a developing country, they traditionally have created very few requirements with regard to individual subjects.

However, from beneficence stems secondary ethical principles of nonmaleficence, reciprocity, and rescue, which do create obligations to individual subjects. Since nonmaleficence is a negative duty that merely restricts conduct based on a responsibility not to inflict harm on others,[14] it cannot require positive actions of ancillary care. Reciprocity does require a proportional return of benefits to research subjects for their voluntary enrollment in the study;[15] however, reciprocity does not specify the type of benefit that must

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[6] *See* Dickert & Wendler, *supra* note 4, at 425 (discussing the potential for ancillary care obligations to extend beyond health care services).

[7] NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR PROTECTION OF HUMAN SUBJECTS OF RESEARCH § A (1979) [hereinafter BELMONT REPORT]. *See also* Ezekiel J, Emanuel, David Wendler, & Christine Grady, *What Makes Clinical Research Ethical?*, 283 J. AM. MED. ASS'N 2701, 2701 (2000) ("the overarching objective of clinical research is to develop generalizable knowledge to improve health and/or increase understanding of human biology."); Michelle N. Meyer, *The Kindness of Strangers: The Donative Contract Between Subjects and Researchers and the Non-Obligation to Return Individual Results of Genetic Research*, 8 AM. J. BIOETHICS 44, 44 (2008) ("by definition research seeks not to serve the interests of participants but to create generalizable knowledge designed to benefit society and future participants.").

[8] *See* BELMONT REPORT, *supra* note 7, at § A (differentiating between clinical practice and clinical research).

[9] Emanuel, Wendler, & Grady, *supra* note 7, at 2706.

[10] BELMONT REPORT, *supra* note 7, at § B(3).

[11] *Id.* at B(2).

[12] TOM L. BEAUCHAMP & JAMES F. CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS 166 (Oxford University Press, 5th ed. 2001).

[13] Emanuel, Wendler, & Grady, *supra* note 7, at 2705–06.

[14] BEAUCHAMP & CHILDRESS, *supra* note 12, at 113, 115.

[15] *Id.* at 174.

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be received.[16] Therefore, monetary compensation, aggregate study results, or access to medication or care that subjects would not ordinarily receive, which is certainly likely in developing countries, would satisfy this requirement.[17] Furthermore, if subjects are to receive a benefit in exchange for their participation in the study, presumably every subject should receive the same benefit.[18] Since ancillary care may not be necessary for every subject, and reciprocity can be fulfilled by other means besides ancillary care, this is not a sufficient justification for the creation of an obligation.

The duty to rescue is unique in that it lies with all moral agents.[19] The duty to rescue creates an ethical obligation to help a person in need when no one else can help and aid can be provided without serious risk to the rescuer.[20] Subjects in developing countries are more than likely to have various health needs due to a lack of health care resources. Since the duty to rescue applies to everyone, positive obligations of rescue already lie with the research team. Moreover, researchers who choose to conduct trials in developing countries place themselves in a position to help their research subjects and thereby separate themselves from the general public.[21] The question then becomes not whether this duty to rescue provides obligations to provide ancillary care, but what care must be provided and who is eligible to receive it. When examining ancillary care through the lens of the duty to rescue, the obligations and necessary limitations become quite clear.

III. THE RESCUE MODEL

Any ancillary care obligation must fit within the ethical research framework of trying to attain generalizable knowledge, rather than to undermine it.[22] The clear limitations of obligations to individual subjects found in the ethical foundations of research strongly support this notion. After all, it is ethically impermissible to commit resources to certain subjects if it were to prevent completion of the study and answer the research question.[23] For the subjects who may not need ancillary care, there is an ethical obligation to complete the study to justify the risks they undertook by entering the trial.[24] Applying a duty to rescue, which does not require action if there is a risk of harm, to ancillary care means the provision of care would not be obligatory if providing it would be detrimental to the study itself.

This point is critical given the need to establish clear boundaries around the ancillary care obligation and is one that appears to be ignored by those discussing ancillary care but choose to ignore the duty to rescue underpinnings.[25] The duty to rescue requires an action to help another when it is within the

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[16] Leslie A. Meltzer, *Undesirable Implications of Disclosing Individual Genetic Results to Research Participants*, 6 AM. J. BIOETHICS 28, 28 (2006).
[17] *Id.* at 29.
[18] *Id.*
[19] Richardson & Belsky, *supra* note 3, at 26.
[20] *Id.*
[21] Roger Brownsword, *The Ancillary-Care Responsibilities of Researchers: Reasonable but not Great Expectations*, 35 J. L. MED. & ETHICS 679, 685 (2007).
[22] *See* Maria W. Merritt, Holly A. Taylor, & Luke C. Mullany, *Ancillary Care in Community-Based Public Health Intervention Research*, 100 AM. J. PUB. HEALTH 211, 214 (2010) ("A necessary condition for the ethical justification of health research with human subjects is the study team's ongoing fulfillment of the obligation to produce high-quality, scientifically valid results.").
[23] *See* Meyer, *supra* note 7, at 45 (discussing the paradox of expecting subjects to be motivated to volunteer for research because of its ultimate goal, meanwhile requiring duties of researchers to individuals that would undercut the devotion of maximum available resources to the research ends).
[24] *Id.*
[25] *See* Merritt, Taylor, & Mullany, *supra* note 22, at 212 (asserting that the duty to rescue is fundamental and, yet, has been underanalyzed in the ancillary care literature). *See also* Leah Belsky & Henry S. Richardson, *Medical Researchers' Ancillary Care Responsibilities*, 328 BRITISH MED. J. 1494, 1494 (2004) (finding that a general duty to rescue creates too broad an obligation that may drain limited human and financial resources). They also imply that obligating researchers under a duty to rescue fails to

rescuer's capacity.[26] Therefore, a study with a small budget would not be required to provide care, such as surgical treatment, that would drain resources needed to complete the trial. Acting within one's capabilities would not only limit obligations due to budget constraints, but certainly a research team would also not be expected to provide care they were not sufficiently trained for either.[27]

The rescue model's ability to limit obligations that jeopardize the overall goal of the study prevents the need to create an inflexible link between the scope of care and the study protocol.[28] For example, if a child enrolled in a malaria study appears to have an infected leg wound, a research team with the capabilities to care for the leg wound would be required by obligations of rescue to care for the infection despite being unrelated to the study protocol.[29] By anchoring ancillary care obligations to the duty to rescue rather than to the researcher-subject relationship, as other prominent models do,[30] the rescue model also avoids the uncomfortable idea that this same child's infection may be ignored simply because the researcher only has met with the child once. The duty to rescue allows for obligations to be enhanced by special relationships,[31] while those subjects that are seen only briefly are still treated as whole persons rather than a means to an end.[32] Therefore, any medical need the researcher becomes aware of during an interaction with a study subject is eligible for ancillary care.

While a subject who meets with the research team only briefly should be eligible for ancillary care, it is imperative to limit who the researchers owe obligations to. The limits of a researcher's requirement cannot extend beyond those who volunteer for the study. After all, the discussion involves care that is ancillary to that which the study would already be providing. This also appropriately eliminates the possibility of fulfilling ancillary care obligations by providing services outside the scope of care for a pressing health need, and it justifiably prevents obligations from being fulfilled by providing any benefits to those outside of the research study.[33]

Delineating a scope of ancillary care that includes any medical need of a subject who volunteers for a study is bound to seem unnecessarily broad, and has the potential to produce untenable burdens given the context of developing countries. However, describing the conditions eligible for ancillary care and those a

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acknowledge the goal of generalizable knowledge. *Id.* Again, the limits found within the duty to rescue that restrict actions that would harm the study team's ability to achieve their research goals avoid both of these problems.

[26] *See* BEAUCHAMP & CHILDRESS, *supra* note 12, at 170 (stating that a poor swimmer has no obligation to swim out and try to save someone drowning). However, there is a moral obligation to tell a lifeguard if one is nearby. *Id.*

[27] This should not be used by researchers as an excuse to avoid providing ancillary care. If it can be reasonably assumed that the research team will be presented with certain health conditions, they should have someone appropriately trained to address those conditions if it is within their budgetary constraints.

[28] *See, e.g.,* Richardson & Belsky, *supra* note 3, at 30 (describing the scope of their partial-entrustment model being limited by the nature of the study).

[29] This example is utilized by Dickert & Wendler to distinguish their model from the Richardson & Belsky model, which they feel inappropriately narrows the scope by requiring a relation to study procedures. Dickert & Wendler, *supra* note 4, at 426.

[30] *See id.* at 426 (finding that Richardson & Belsky's belief that ancillary care obligations stem from the researcher-subject relationship is an accurate assessment).

[31] *See* Ernest J. Weinrib, *The Case for a Duty to Rescue*, 90 YALE L. J. 247, 247 (1980) (discussing the creation of a duty to rescue in special relationships). Special relationships include husband and wife, shipmaster and crew, proprietor and customer, carrier and passenger, educator and pupil, and employer and employee. *Id.* at n.1.

[32] *See* Richardson & Belsky, *supra* note 3, at 29 (stating the importance of researchers treating subjects as whole persons instead of means to an end).

[33] *Contra* Dickert & Wendler, *supra* note 4, at 425 (describing ancillary care obligations being fulfilled by providing training to address unemployment). The rescue model removes the possibility of fulfilling obligations without providing care for health needs because other issues that may be addressed, such as unemployment or insufficient education, do not constitute an urgent need for care that would give rise to a duty to rescue to prevent immediate harm. Additionally, the notion that providing employment training to fulfill obligations of ancillary care run counterintuitive to the "care" aspect of the obligation, which presumably limits ethical requirements to medical care needed by research subjects.

researcher are required to provide care for are distinctly different.[34] Rescue obligations arise when care is needed and can be provided without presenting significant harm or burdens to the rescuer,[35] which in this case is the research team who is attempting to complete a specific study goal. This fundamental principle essentially creates an inherent cost-benefit analysis in the rescue model that allows researchers to determine if the benefits of providing the care sufficiently outweigh the harms, costs, or burdens that are likely to incur to the overall study.[36]

With a strong possibility that many specific needs may arise in the study population, it is unlikely the research team will be able to address them all.[37] Therefore, it is essential that the team be able to appropriately discern what ancillary care requirements are of the highest priority.[38] At the same time, "these efforts must not tax the workers' ability to carry out their primary research-related assignments."[39] And while this balance may prove difficult at times, it is not unmanageable to the point of eradicating an ethical obligation.

IV. ADDRESSING POTENTIAL CONCERNS

THERAPEUTIC MISCONCEPTION

Anytime research starts to delve into providing care outside of what is required by the research protocol, there is concern over the possibility of misleading subjects and potential volunteers into entering trials for the wrong reasons. A therapeutic misconception occurs when research subjects fail to grasp the differences between the aims of clinical research and ordinary personal care, and thereby ascribe therapeutic intent to research procedures.[40] While the individual subjects' personal health certainly is not irrelevant, the ethical principles of research described earlier are in place to protect individual rights rather than require positive actions to enhance each subject's well-being. This leaves the researcher to pursue the primary goal of generalizable knowledge, and distinguishes researchers from physicians.[41]

The chief concern with therapeutic misconception is that it may distort the subject's ability to provide informed consent, a cornerstone of ethical research and a requirement under principles of autonomy.[42] In a developing country, where subjects may be undereducated and in need of health care resources, the chances of a therapeutic misconception exponentially increase.[43] Consequently, a determination must be made whether this concern rises to the level of limiting or preventing an ethical requirement to provide ancillary care.

Important to this consideration is the fact that a therapeutic misconception does not mean the subject does not understand the nature and purpose of the research or the procedures involved.[44] In fact, a

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[34] *See id.* at 427 (explaining why expanding the scope of the Richardson & Belsky model does not necessitate expanding the care a researcher must provide).
[35] BEAUCHAMP & CHILDRESS, *supra* note 12, at 171.
[36] *See id.* at 171 (affirming that rescue cannot be required if significant risks, costs, or burdens are created that offset the benefit).
[37] Merritt, Taylor, & Mullany, *supra* note 22, at 215.
[38] *Id.*
[39] *Id.* at 214.
[40] Charles W. Lidz & Paul S. Appelbaum, *The Therapeutic Misconception: Problems and Solutions*, 40 MED. CARE V–55, V–57 (2002).
[41] Paul S. Appelbaum et al., *False Hopes and Best Data: Consent to Research and the Therapeutic Misconception*, 17 HASTINGS CTR. REP. 20, 20 (1987).
[42] Sam Horng & Christine Grady, *Misunderstanding in Clinical Research: Distinguishing Therapeutic Misconception, Therapeutic Misestimation, & Therapeutic Optimism*, 25 IRB: ETHICS & HUM. RES. 11, 12 (2003).
[43] *See* Paul S. Appelbaum, Charles W. Lidz, & Thomas Grisso, *Therapeutic Misconception in Clinical Research: Frequency and Risk Factors*, 26 IRB: ETHICS & HUM. RES. 1, 6 (2004) (finding that lower education and poorer health contribute to misconstrued beliefs about research trials).
[44] Lidz & Appelbaum, *supra* note 40, at V–57.

therapeutic misconception has been well documented in numerous trials in the United States despite the best efforts of the staff to fully educate and inform subjects of a study's purpose and procedures as well as the fact that the aim is not to provide benefits to the individual subjects.[45] Yet clinical trials continue. We should not allow the therapeutic misconception to void the obligation to provide ancillary care in developing countries.

Researchers should attempt to inform potential subjects of the risks and benefits of the research, without including ancillary care, in as culturally competent a manner as possible. However, with limited health care resources in many developing countries, it is highly probable that the research trial may present the best means of receiving medical care, even without ancillary care provisions.[46] The hope of receiving some benefit from a research trial, known more accurately as therapeutic optimism, is distinctly different than a therapeutic misconception and is not ethically problematic.[47] As a result, anxiety about potential therapeutic misconceptions cannot prevent ancillary care requirements.

IRB REVIEW

IRBs are tasked with determining whether a particular trial has a risk-benefit ratio favorable enough to enroll subjects.[48] IRBs are often criticized for inconsistent decisions.[49] It is not always clear what constitutes acceptable risks and potential benefits,[50] and adding a moral obligation to provide ancillary care may add to the complexity of that question. Furthermore, there is the troubling potential for IRBs to erroneously consider the provision of ancillary care as a benefit to be weighed in the risk-benefit equation.

When examining potential benefits, IRBs should only consider benefits that subjects receive from the procedures necessary to complete the research objectives.[51] Extraneous benefits, including ancillary care, cannot be considered because increasing care unrelated to the research study could ensure that risky research that would otherwise be impermissible may be approved.[52] Therefore, if IRBs are applying this standard appropriately, then the provision of ancillary care would provide no concern for the authorization of overly risky research. However, this is not always the case. IRBs frequently consider benefits accrued from procedures unnecessary for research purposes.[53]

While this certainly presents a legitimate concern, it does not seem to insist that ancillary care should not be provided. Similar to concerns over a therapeutic misconception, apprehension over IRB review should not be used as an excuse to avoid a moral obligation of rescue. Rather, education of IRBs and re-emphasizing the ethical guidelines they are expected to adhere to should be sufficient to warrant supplying ancillary care. The fear of overly risky research being inappropriately approved due to ancillary care

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[45] *See* Paul S. Appelbaum, *Clarifying the Ethics of Clinical Research: A Path Toward Avoiding the Therapeutic Misconception*, 2 AM. J. OF BIOETHICS 22, 23 (2002) (suggesting that over a variety of trials in the United States, as many as 70% of subjects suffered from a therapeutic misconception). *See also* Paul S. Appelbaum et al., *supra* note 41, at 23 (describing the surprisingly high prevalence of therapeutic misconception in a study where the entire project was reviewed extensively over several days).

[46] Ballantyne, *supra* note 1, at 242.

[47] Horng & Grady, *supra* note 42, at 14.

[48] Ezekiel J. Emanuel et al., *What Makes Clinical Research in Developing Countries Ethical? The Benchmarks of Ethical Research*, 189 J. INFECTIOUS DISEASES 930, 934 (2004).

[49] Charles Weijer & Paul B. Miller, *When are Research Risks Reasonable in Relation to Anticipated Benefits?*, 10 NATURE MED. 570, 570 (2004).

[50] *Id.*

[51] Emanuel et al., *supra* note 48, at 934.

[52] Emanuel, Wendler, & Grady, *supra* note 7, at 2705.

[53] *See* Seema Shah et al., *How do Institutional Review Boards Apply the Federal Risk and Benefit Standards for Pediatric Research?*, 291 J. AM. MED. ASS'N 476, 480 (2004) (discussing studies showing a majority of IRBs considered psychological counseling, which was unnecessary for the ultimate research goal, as a benefit to the subject).

should be further diminished by the fact that while a research team must anticipate and prepare for providing this care, they do not need to detail the exact care that will be given in a protocol.

DISCOURAGING FUTURE RESEARCH IN DEVELOPING COUNTRIES

While some research conducted in developing countries may be driven by the desire to cut costs or even avoid certain regulations, there are plenty of studies that provide real and much needed benefits to underserved populations. Whether the benefits they receive are from the trial itself or from a fair benefits framework,[54] developing countries are in need of any help they can get. Therefore, it is imperative that researchers not be overburdened with obligations that may discourage their work, an outcome that could leave needy populations worse off.[55]

While requiring ancillary care does increase obligations of researchers in developing countries, applying the rescue model effectively avoids the dilemma of possible discouragement.[56] The rescue model allows the researcher's interest, which is the research goal, to remain the primary focus. In fact, it requires the research to be the focal point. The rescue model allows researchers to fulfill an ethical obligation of rescuing those in need while preventing onerous requirements that derail the study. The application of an effective cost-benefit analysis ensures that only urgent, necessary care that will have a significant impact on a subject's health will be obligatory.

V. CONCLUSION

Issues arising from conducting research in populations riddled with health needs are likely to become more prevalent as trials in developing countries expand. As such, the need for clearly delineated obligations and limitations to research subjects cannot be understated. The rescue model establishes an ethical base in the duty to rescue, a moral obligation that already exists for researchers. The rescue model creates a requirement of providing ancillary care that fits within the current ethical research framework, rather than producing a paradigm shift to generate obligations to individual subjects from principles historically thought to protect individual rights. Additionally, it allows for a broader scope of care to be eligible while a cost-benefit analysis ensures that the goal of producing generalizable knowledge is maintained as the primary focus. Thus, ethical obligations to all research subjects are fulfilled while the benefits to society, and those populations in need, may still be sought.

[54] *See generally Moral Standards*, *supra* note 2, at 22 (describing the fair benefits framework).
[55] Dickert & Wendler, *supra* note 4, at 425.
[56] *See* Merritt, Taylor, & Mullany, *supra* note 22, at 215 (stating the importance of identifying a model that recognizes ancillary care obligations without creating disincentives for research on conditions that afflict the poorest populations).