

Fr. Grzegorz Mazur, O.P.

*The Nature and Limits of Proxy Consent to Experimentation on Human Subjects*

**ABSTRACT**

This study aims to offer a comprehensive understanding rooted in a sound Catholic anthropology and moral theory of the meaning and limits of proxy consent to experimentation on human subjects. In particular, it seeks to articulate the rationale justifying such consent in both therapeutic and nontherapeutic settings. In doing so, it rejects the notion of autonomy, reduced to pure self-determination and endorsed by today's mainstream bioethics literature as a basis for surrogate decision-making. Given its indifference to both the good and truth, autonomy so construed presupposes a highly reductionist account of freedom by which it undermines human dignity and ultimately neither satisfactorily protects the research subjects nor furnishes the proxies with reliable guidance. The remedy to these flaws is to be found in the Golden Rule compatible with the standards of objective morality and hence recognizing the basic inclinations of human nature toward objective goods perfective of human persons. As such, the Rule proves well-equipped to underpin a sound notion of proxy consent to experimentation on human subjects.

Regarding nontherapeutic settings an additional scrutiny of the amount of risk involved is necessary, as the risk-benefit ratio frequently invoked to justify a higher-risk therapeutic research does not exist in its nontherapeutic counterpart. In this context, the minimal-risk standard has been commonly proposed by present-day bioethicists as a benchmark by which to measure the moral validity of proxy consent in nontherapeutic research. Still, while certain authors repudiate nontherapeutic research regardless of the risk involved, others extend its justifiability so as to include also so called *slight increase over minimal risk*. This study discusses all these positions

and develops one that builds upon the comprehensive, objective view of the human good. Consequently, it offers a qualified justification of proxy consent to nontherapeutic experimentation with human subjects provided that no significant risk is involved. Such risk is justified because it does not threaten the subject's good. In addition, participation of the incompetent subject in nontherapeutic research can be defended by pointing to the relationship between the individual good and the common good. The common good respects the good of the subject, and since it is shared, it becomes part of the subject's own good as well.