Persons Placed in Social Protection Institutions as Subjects of Clinical Research by International and Serbian Regulations

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Abstract—Subject of the paper is analysis of the position of persons placed in social protection institutions as subjects of clinical research. In its first part, authors determine who belongs to the category of these subjects and what reasons make them vulnerable, more sensitive than other people in this context. In the second part of the paper, they elaborate efficiency of additional protection forms provided to these subjects by international regulations and regulations of the Republic of Serbia – solutions of which are mutually different. Result of made analysis is a proposal of new, in the authors’ opinion most appropriate model of protection of persons in question within clinical researches.

Keywords—medical law; clinical research; vulnerable subjects; persons placed in social protection institutions.

I. INTRODUCTION

Clinical trials of new medicines in human beings are unavoidable stage of their future safe application; therefore, there is no medicine progress without clinical research or survival of mankind. Although their importance is indisputable, clinical research in human being cannot be performed without its consent [1], because right to autonomy and self-determination regarding body is one of the fundamental human rights. Although consent [2] is the most important measure of human being’s protection from possible misuses within clinical research, numerous research scandals all over the world [3] showed that such protection is not sufficient for certain categories of persons. Certain persons for their personal features, social position, living circumstances or for other reasons are more vulnerable and more susceptible to misuses by others; therefore, it is believed that beside consent additional terms guaranteeing their protection have to be fulfilled for their participation in research (minors, pregnant women, refugees, prisoners, etc.). They are named vulnerable subjects [4]; common feature for them is: presumably, mentioned reasons are cause of their diminished capability to protect personal interests, and this is manifested in compromised capability of giving voluntary consent to participation in research [5].

Analysis of one of vulnerable subjects’ categories position was selected for the topic of the paper as least elaborated one – persons placed in social protection institutions. Reason for selection of this topic are new regulations of the Republic of Serbia which classify mentioned persons in a separate category, regulating their position in a unique manner, unlike international regulations in the field of clinical research. International regulations categorize many persons placed in different institutions of social protection as vulnerable subjects; however, they are not treated as separate category whose “common denominator” is also a cause of their specific sensitivity and that is exactly their stay in specific conditions of these institutions – on the other hand, this was done within Serbian regulations (for justified reasons). Our first step in going to be to establish who belongs to this category of subjects and what is causing their specific sensitivity and need for additional protection in research. Then, we will analyze measures for their protection foreseen by the most relevant international regulations in this field, as well measures prescribed by Serbian legislator differing than international once. On the basis of the comparison of these solutions, and having in mind also causes of specific sensitivity of this category of participants in research, we will try to identify the most acceptable model of their protection.

II. WHO BELONGS TO THE CATEGORY OF PERSONS PLACED IN SOCIAL PROTECTION INSTITUTIONS?

In order to apply measures of additional protection within research over persons placed in social protection institutions, it is primarily necessary to establish who belongs to this category of subjects. Since none of regulations in the field of clinical research we will analyze does contain regulations referring to that, answer to this question has to be sought in laws regulating work and types of social protection institutions in each state individually.

Having these regulations in mind, as in most of the countries, in Serbia following persons can be classified in this group of persons: 1) children with no parents’ care living in centers for neglected children; 2) elder, powerless and disabled persons who cannot live without assistance of other persons placed in proper institutions; 3) mentally ill persons placed in adequate institutions, because either their relatives are not able to take care of them or for mandatory medical treatment; 4) in the widest possible sense, here also belong homeless persons and „children from the street” occasionally staying in so-called “hangouts” (when it is very cold, or to get meal...) – and for this they are different than other persons from this group staying in institutions continuously, in shorter or longer period of time or even for their life time.
vulnerable group will be provided with reasonable availability of tested method; expected risk of non-
serious position; for that reason, it is necessary to prescribe additional terms which have to be fulfilled for their participation in research or to prescribe other measures of their protection from misuses [8] – and this will be object of our observations in the following chapter of the article.

IV. PROTECTION OF PERSONS PLACED IN SOCIAL PROTECTION INSTITUTIONS BY INTERNATIONAL AND SERBIAN REGULATIONS

A. International Regulations

Only two of several international documents regulating the field of clinical research categorize as vulnerable subjects some of subjects we have classified in that category, and who are usually placed in social protection institutions. That is the International ethical guidelines for biomedical research involving human subjects [9] (hereinafter: the Guidelines); in the comment of its Guideline 13 regulating position of vulnerable subjects, following persons are listed, among others: residents of nursing homes, homeless persons and refugees or displaced persons. Same persons are also mentioned in the point 1.16 of the Guideline for Good Clinical Practice [10] (hereinafter: GCP). Difference between these two regulations is that GCP does not foresee any measures of special protection for these persons as participants of researches.

The Guidelines, however, allow participation of all vulnerable subjects in research – including persons in question here – only if there is a „special justification“ for that and with the fulfillment of several additional terms in comparison to terms related to subjects who are not in the list of vulnerable ones and for whose participation their valid consent is sufficient. These terms are: research cannot be equally well conducted in „less vulnerable subjects“; research objective is to gain knowledge relevant for the health needs of typical or unique vulnerable subject group; research participants, but also other members of the vulnerable group will be provided with reasonable availability of tested methods; expected risk of non-therapeutic research is minimal, with the option of its slight increase with the approval of ethical committee; and, when research is going to be participated by persons who cannot give their consent, consent has to be given by their legally authorized representative (comment to the Guideline 13).
Highest degree of protection for persons placed in social protection institutions is certainly provided by the first of listed terms which foresee their participation in research only when research cannot be successfully conducted in other persons who are not on the list of vulnerable ones or are in other ways less vulnerable. That means these persons will not participate researches if there is the other subject fulfilling participation criteria who is at the same time not refugee, homeless person, disabled or powerless person, etc. or other subject who is one of mentioned persons but does not reside in adequate institution relying on the assistance of the state and society. Since there are many subjects as such, this term means that situations which will require participation of persons placed in social protection institutions in clinical research will be rare. But, the problem may appear with the situation where there are two subjects suitable for conducting the same trials and one of them is vulnerable because he lives in institution of social protection and the other one is vulnerable for some other reason or several different reasons simultaneously [11]; this situation requires assessment who of them is „less vulnerable", and such situation is difficult and disputable and can end harmfully for the person whose position is assessed. Also, it is possible that there will be no „less vulnerable“ subject (ex. trial has to be conducted in disabled persons whose condition requires accommodation in adequate institution). That means persons placed in a social protection institution can find themselves in a situation where research needs to be conducted in them because there are no „less vulnerable“ subjects or because it is assessed that they are exactly „less vulnerable“ in the concrete situation. If that happens, even cumulative fulfillment of all other terms for protection foreseen by the Guidelines cannot solve the problem that research will be participated by the person accompanied by high probability that his consent will not be reflection of his sincere will but a consequence of unacceptable motives (fear of worst care, stress, gratitude to the society, etc.). Namely, fulfillment of other terms: that research will bring health benefit for the vulnerable group subject represents (not necessarily also for the subject) and that tested therapy will be additionally available; that risk of non-therapeutic research subject participates in is minimal [12] and that subject's legally authorized representative agrees with its participation in the research when that is necessary – does not represent any protection of person placed in social protection institution if subject's consent (or representative's consent) is not expression of his true will. Such person ceases to be subject but becomes an object of the research – and that is unacceptable. Therefore, we think protection provided by the Guidelines to persons placed in social protection institutions is incomplete and insufficient.

B. **Serbian Regulations**

According to regulations of the Republic of Serbia contained in the Medicines and Medical Products Act [13] (art. 63, par. 1, point 3), persons placed in social protection institutions cannot participate clinical trials under no terms. This form of protection disables participation of mentioned subjects on the basis of their consent, which we cannot actually consider voluntary and acceptable, for already stated reasons – and that is the good side of it. Bad side of such protection is that it disables participation of mentioned persons in research even when consent is an expression of their true will, not consequence of (wrong) belief that society expects gratitude in the form of “sacrifice for general interest" by exposure of their health to a risk researches bear. Such protection is based on irrefutable presumption that consent of persons placed in social protection institutions is never expression of their real will, and this is a disputable position. That is particularly relevant for therapeutic research where consent can be motivated by hope that research will contribute to healing of the subject. Such protection is also problematic from the aspect that researches can be conducted only in certain categories of persons placed in social protection institutions (ill persons, disabled persons). Ban of their participation actually means also no possibility to conduct clinical research of medicines intended to their illness.

V. CONCLUDING REMARKS

Consent is not sufficient term for participation of persons placed in social protection institutions in clinical trials both by international and Serbian regulations. Difference is in a form of additional protection provided to these persons. While Guidelines allows their participation in research with fulfillment of special terms intended to minimize this practice, Serbian law bans their participation. As it can be seen from previous analysis, both forms of protection have certain shortcomings. Protection provided by the Guidelines can lead to situations where these persons participate in research although it is not known is their consent expression of the true will or it was given for other motives – thus, protection is incomplete. Protection foreseen by the Serbian law removes shortcomings of the protection provided by the Guidelines, but has unacceptable results in some situations for what we consider it exaggerating.

Having in mind reasons which make these subjects vulnerable, in our opinion, more acceptable model of protection could be obtained by combination of presented solutions: participation of persons placed in social protection institutions in research should be banned in principle except if research conducting is not possible in other persons for medical reasons. Even then consent is not sufficient until an expert (psychologist) does not verify in the interview with the subject (and its legally authorized representative, if there is one) is given consent an expression of the true will and not given for unacceptable motives.If an expert assesses that consent was not an expression of a true will of the subject – he cannot participate the research irrespective how it is important for science and society, because this would be opposite to ethical principle by which interest of the subject is more important than interest of the society.

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