THE ANALYSIS OF COMPLIANCE OF BIOETHICAL NORMS OF SIGNING THE INFORMED CONSENT DURING ORGANIZING CLINICAL TRIALS OF DRUGS

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Clinical trials (CT) are the essential step in development of medicines in the whole world, which goes before its registration and wide medical usage. Informed consent (IC) is a process that allows a patient or a healthy volunteer reaffirm their will freely to participate in CT. The volunteers should understand all the procedures and risks of participating in CT. Such information is provided by a researcher to a potential volunteer during signing the IC.

The interview of 44 volunteers was held for the evaluation of volunteers' awareness during signing the IC.

The questionnaire for respondents consisted of two parts: the first part had general questions and questionnaire that allowed volunteers to assess themselves their knowledge of terms which could be got across during CT, and the second – test questions of closed type for evaluating real knowledge of terms. The verification of the test in the questionnaire was conducted by the key.

The analysis of results showed that from 44 volunteers more than a half (52.27%) were aged 36 – 45 years. 52.17% of respondents aged 36 – 45 years took part in 3 – 5 CT, 60% of volunteers aged 18 – 25 years – in 1 – 2 CT. The majority of respondents (86.36%) didn't have questions during reading the information, but 34.09% asked questions about unfamiliar or unclear terms, the answers on the raised questions were provided to 56.82% of cases and were satisfactory to 68.18% of respondents.

The statiscal analysis by Student's test of relations between volunteers' self-rating and evaluation of their real knowledge of CT's terms was carried out. It showed that the volunteers' self-rating is significantly higher than their test results ($P=0.29<p\text{-level}=0.05$).

The results of analysis demonstrate the necessity of the proper explanation of terms by researchers to volunteers and then making sure by asking volunteers questions how well they understand the received information. In future it is planned to analyze the impact of different factors on degree of the IC information understanding during signing it by the volunteers.