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Iranian Journal of Psychiatry and Behavioral Sciences (IJPBS) Policy Regarding Clinical Trial Registration

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Through recent decades, several attempts have been made to counteract selective report of clinical trial results by investigators of many countries. They decided to register these trials to permit every trial's existence be part of the public record, and the many stakeholders be able to explore the full range of clinical evidence. Iranian Ministry of Health and Medical Education proposed comprehensive trials registration in accordance with international standards, and established the policy of prospective clinical trial registration on December 22nd 2009. This policy was supported and adopted by members of the Iranian Committee of Medical Journal Editors (ICMJE). To welcome the new act, Iranian Journal of Psychiatry and Behavioral Sciences (IJPBS) elaborates the timelines for initiation of this new policy.

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Introduction

The International Committee of Medical Journal Editors (ICMJE) defines "clinical trials" as any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. These interventions include but are not restricted to drugs, cells and other biological products, surgical and radiologic procedures, devices, behavioral treatments, preventive care, process-of-care changes, and so on (1,2).

Unfortunately, it is mentioned that many researchers and medical journals report the results of clinical trials selectively, which distorts the body of evidence available for decision-making in clinical settings. They typically are less enthusiastic about negative trials showing inferiority of a new treatment in comparison to a standard one. Indeed, they are generally most excited about the publication of positive and non-inferiority trials that show either a large effect of a new treatment or equivalence of two approaches to treatment. Moreover, trial results that place financial interests at risk are particularly likely to remain unpublished, irrespective of their scientific interest (1).

Fortunately through recent decades, several attempts have been made to counteract the "privacy" with which some clinical trials are conducted. American, and then European investigators decided to register their trials in an accessible manner to the public repository to permit every trial's existence be part of the public record, and the many stakeholders in clinical research be able to explore the full range of clinical evidence. Since 1997, they have done it at www.clinicaltrials.gov and www.controlled-trials.com websites respectively. Afterwards, some other countries such as India, China, Sri Lanka, and some Latin American countries participated in the movement of clinical trials registration. This movement was the subject of a declaration issued in September 2004 by members of the ICMJE (1,3).

The World Health Organization (WHO) initiated the International Clinical Trials Registration Platform (ICTRP) in May 2007 to harmonize the standards of trial registration and reporting, and coordinate the international efforts for registering clinical trials. The ICMJE participated in, and supported the WHO ICTRP project (4). Later, Journals were classified as "requiring trial registration for publication" or "with no information about registration" (5).

Recently the Iranian Ministry of Health and Medical Education proposed comprehensive

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trials registration in accordance with international standards as a solution to the problem of selective awareness of clinical trials, and established the policy of prospective clinical trial registration on December 22nd 2009. This policy was supported and adopted by members of the Iranian Committee of Medical Journal Editors (ICMJE).

Recently the Iranian Ministry of Health and Medical Education proposed comprehensive trials registration in accordance with international standards as a solution to the problem of selective awareness of clinical trials, and established the policy of prospective clinical trial registration on December 22nd 2009. This policy was supported and adopted by members of the Iranian Committee of Medical Journal Editors (ICMJE).

All stakeholders-investigators, research organizations and institutions, journal editors, lawmakers, consumers, and others - are now well aware of the importance of the registration of clinical trials, and concern to find information about these trials worldwide (6,7).

Clinical trial registration is fundamentally an ethical issue (7), and has a number of advantages, including governmental, academic, and private funding bodies' assistance to make more informed decisions in sponsoring new trials to reduce unnecessary duplication of work. In this way, registration makes it easier to signify the priorities in health care system and guide investigators to those topics. Also it helps investigators in designing, performing, and, analyzing clinical trials. A registry makes barrier to publication bias and selective reporting of positive findings and underreporting of negative undesirable findings, which distort efficacy and safety profiles of the research. Helping systematic reviewers becoming informed of ongoing trials and assistance of peer reviewers and editors in the assessment of manuscripts on completed clinical trials to be informed of published trials and ongoing works in a given topic are other benefits of clinical trial registration. On the other hand, patients who are interested and might be eligible in participation in a clinical trial and access to new therapies are informed, and their tendency to contribute will be increased (3,8).

The Iranian Registry of Clinical Trials (IRCT) which has been confirmed by WHO is accessible to the public at no charge, electronically searchable, and open to all prospective registrants. It is worth mentioning that there are some problems in registering. Some researchers believe that public registration of clinical trials will destroy their competitive edge by allowing competitors full access to their research proposals. Unfamiliarity of the Iranian researchers about the registry rules, unnecessary bureaucratic delays and Internet connectivity problems are some other major barriers in this field. Sometimes the registry site rejects the trials and requests some details of information, whereas, the IRCT should contain the minimum core of trial information. Moreover, the IRCT should possess a mechanism for ensuring data validity.

Search within the content of IRCT website is possible for members of public. All investigators and researchers can register their trials in this site from all over the world. The main objectives of this site are increasing public awareness of their importance, informing public of the ongoing trials, and implementing the ICMJEs' initiative for mandatory registration of trials before the enrollment of the first patient.

According to IRCT website, chief investigators or representatives of the sponsor are among people who are eligible to register a trial. Eligible people need to register with IRCT web-site, set up an account, and then enter all the required information. The information will be verified by IRCT staff. When all information is complete, they will be given their registration ID with IRCT. They then need to keep their trial record up to date and make changes -if needed- by updating their trials when any of the characteristics of their trial such as design or timings have changed (2). This process is only for the purposes declared on the website and does not in anyway convey any other notion such as ownership, and so on (2).

To welcome the new act of the Iranian Ministry of Health and Medical Education, regardless of its success, Iranian Journal of Psychiatry and Behavioral Sciences (IJPBS) elaborates the timelines for initiation of this new policy, because medical journals have a

responsibility to promote ethical issues as well as to encourage publication of clinical trial research. So the IJPBS will consider a clinical trial only if it has been registered. The IJPBS does not advocate one particular registry, but authors are required to register their trials in a registry that meets the IRCT criteria.

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