藤原委員　提出

第6回臨床研究専門委員会	資料　7
平成20年2月13日	藤原

臨床試験登録についての意見

平成 20 年 2 月 13 日
国立がんセンター中央病院
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第 5 回委員会で「介入研究の臨床研究計画を事前に公表すること」に関連して、ＩＣＭＪＥが求めている臨床試験登録が「米国と世界のトップジャーナル（６つくらい？）」への掲載に必要なものであり、「公表は努力義務にしては」との議論がありました。

しかしながら、臨床試験登録は業績の発表という観点（被験者リクルートも促進されるというメリットもあります）より、publication bias を防ぐという被験者保護の観点から導入された概念であり、昨年９月には米国公衆衛生サービス法（Public Health Service Act(42 U.S.C.282)）で第Ｉ相試験以外の臨床試験の NIH への登録が義務づけられていたり、本委員会でも取り上げられた EU 臨床試験指令においても介入臨床研究については登録（Eudract number の取得）を義務づけていること、更にはＷＨＯが臨床試験登録の世界での統一化に動いていること等を考えると、「努力義務」よりは一段厳しい記述が臨床研究倫理指針には必要ではないかと思います。

登録の手間を懸念される方々もおられますが、別添のＷＨＯの登録に必要な必須項目を見てもおわかりのように、臨床研究に必要なプロトコールができていれば、すべて網羅されている内容しか求められておらず、手間はかからないと思います。

またＩＣＭＪＥ（International Committee of Medical Journal Editors）のサイト（http://www.icmje.org/）で確認したところ、臨床試験登録に関する要件（Obligation to Register Clinical Trials）は“Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication”Updated October 2007 の一項目であり、このＩＣＭＪＥの投稿規定を採用している学術雑誌は当該サイト（http://www.icmje.org/jrnlist.html）で確認したところ 660 誌にも昇っておりました。

なお、ＩＣＭＪＥが臨床試験登録先として認めるデータベースは：www.actr.org.au（オーストラリア、ニュージーランド）；www.clinicaltrials.gov（米国）；www.ISRCTN.org（ランダム化比較試験　英・カナダ）；www.umin.ac.jp/ctr/index.htm（日本）；www.trialregsiter.nl（オランダ）であり、（社）日本医師会　治験促進センター（https://dbcentre3.jmacct.med.or.jp/jmactr/）や（財）日本医薬情報センター（JAPIC：http://www.clinicaltrials.jp/user/cte_menu.jsp）の行っている登録システムは現在のところ含まれておりません。

以上

別添参照

World Health Organization

Trial Registration Data Set

Registration Data Set (Version 1.0)

	Item	Field Value	Definition/Explanation
1	**Primary Register and Trial ID #**	_____ Trial ID #	Name of Primary Register, and the unique ID number assigned by the Primary Register to this trial.
2	**Date of Registration in Primary Register**	_____ _____	Date when trial was officially registered in the Primary Register.
3	**Secondary ID#s**	Issuing Authority ID Number Click to add more …	Other identifying numbers and issuing authorities besides the Primary Register, if any. Include the sponsor name and sponsor-issued trial number (e.g., protocol number) if available. Also include other trial registers that have issued an ID number to this trial. There is no limit on the number of Secondary ID numbers that can be provided.
4	**Source(s) of Monetary or Material Support**	Name Click to add more…	Major source(s) of monetary or material support for the trial (e.g., funding agency, foundation, company).
5	**Primary Sponsor**	Name	The individual, organization, group or other legal entity which takes responsibility for initiating, managing and/or financing a study. The Primary Sponsor is responsible for ensuring that the trial is properly registered. The Primary Sponsor may or may not be the main funder
6	**Secondary Sponsor(s)**	Name Click to add more...	Additional individuals, organizations or other legal persons, if any, that have agreed with the primary sponsor to take on responsibilities of sponsorship. A secondary sponsor may have agreed • to take on all the responsibilities of sponsorship jointly with the primary sponsor; or • to form a group with the primary sponsor in which the responsibilities of sponsorship are allocated among the members of the group; or • to act as the sponsor's legal representative in relation to some or all of the trial sites; or • to take responsibility for the accuracy of trial registration information submitted.
7	**Contact for Public Queries**	Email, telephone number, or address	Email address, telephone number, or postal address of the contact who will respond to general queries, including information

			about current recruitment status
8	**Contact for Scientific Queries**	Email, telephone number, or address Affiliation	Email address, telephone number, or postal address, and affiliation of the person to contact for scientific queries about the trial (e.g., principal investigator, medical director employed by the sponsor). For a multi-center study, enter the contact information for the lead Principal Investigator or overall scientific director.
9	**Public Title**		Title intended for the lay public in easily understood language.
10	**Scientific Title**	 Acronym	Scientific title of the study as it appears in the protocol submitted for funding and ethical review. Include trial acronym if available.
11	**Countries of Recruitment**	_____	The countries from which participants will be, are intended to be, or have been recruited.
12	**Health Condition (s) or Problem(s) Studied**		Primary health condition(s) or problem(s) studied (e.g., depression, breast cancer, medication error). If the study is conducted in healthy human volunteers belonging to the target population of the intervention (e.g., preventative or screening interventions), enter the particular health condition(s) or problem(s) being prevented. If the study is conducted in healthy human volunteers not belonging to the target population (e.g., a preliminary safety study), an appropriate keyword will be defined for users to select.
13	**Intervention(s)**	Intervention name(s) Other details (e.g., dose, duration, etc.) Click to add more experimental interventions… Control Intervention name Other details of control (e.g., dose, duration, etc.) Click to add more control interventions…	Enter the specific name of the intervention (s) and the comparator/control(s) being studied. Use the International Non-Proprietary Name if possible (not brand/trade names). For an unregistered drug, the generic name, chemical name, or company serial number is acceptable. If the intervention consists of several separate treatments, list them all in one line separated by commas (e.g., "low-fat diet, exercise"). The control intervention(s) is/are the interventions against which the study intervention is evaluated (e.g., placebo, no treatment, active control). If an active control is used, be sure to enter in the name(s) of that intervention, or enter "placebo" or "no treatment" as applicable. For each intervention, describe other intervention details as applicable (dose, duration, mode of administration, etc)
14	**Key Inclusion and Exclusion Criteria**	Inclusion Criteria Exclusion Criteria	Inclusion and exclusion criteria for participant selection, including age and sex.
		  Choose one	A single arm study is one in which all participants are given the same intervention. Trials in which participants are assigned to receive one of two or more interventions are NOT single arm studies. Crossover trials are NOT single arm studies.

15	**Study Type**		A trial is "randomized" if participants are assigned to intervention groups using a method based on chance (e.g., random number table, random computer-generated sequence, minimization, adaptive randomization).
16	**Date of First Enrollment**	———	If the trial is being registered after recruitment of the first participant record actual date of Anticipated date of enrollment of the first participant.
17	**Target Sample Size**		Number of participants that this trial plans to enroll.
18	**Recruitment Status**	———————	Recruitment status of this trial. ● Pending: participants are not yet being recruited or enrolled at any site ● Active: participants are currently being recruited and enrolled ● Temporary halt: there is a temporary halt in recruitment and enrollment ● Closed: participants are no longer being recruited or enrolled
19	**Primary Outcome (s)**	Outcome Name Timepoints Click to add more outcomes…	Outcomes are events, variables, or experiences that are measured because it is believed that they may be influenced by the intervention. The Primary Outcome should be the outcome used in sample size calculations, or the main outcome(s) used to determine the effects of the intervention (s). Enter the names of all primary outcomes in the trial as well as the pre-specified timepoint(s) of primary interest. Be as specific as possible with the metric used (e.g., “% with Beck Depression Score > 10 ”rather than just “depression”). Examples: Outcome Name: all-cause mortality, Timepoints: 5 years; or Outcome Name: Mean Beck Depression Score, Timepoint: 18 weeks
20	**Key Secondary Outcomes**	Outcome Name Timepoints Click to add more outcomes…	Secondary outcomes are events, variables, or experiences that are of secondary interest or that are measured at timepoints of secondary interest. A secondary outcome may involve the same event, variable, or experience as the primary outcome, but measured at timepoints other than those of primary interest (e.g., Primary outcome: all-cause mortality at 5 years; Secondary outcome: all-cause mortality at 1 year, 3 years), or may involve a different event, variable, or experience altogether (e.g., Primary outcome: all-cause mortality at 5 years; Secondary outcome: hospitalization rate at 5 years). Enter the name and timepoint(s) for all secondary outcomes of clinical and/or scientific importance. Be as specific as possible with the metric used (e.g., “% with Beck Depression Score > 10” rather than just “depression”). Examples: Outcome Name: all-cause mortality, Timepoint: 6 months, 1 year; or Outcome Name: Mean

			glycosylated hemoglobin A1C, Timepoint: 4 and 8 weeks