

**International Agency for Research on Cancer**



**World Health  
Organization**

**POLICY ON CLINICAL TRIALS REGISTRATION AND  
PUBLIC DISCLOSURE OF RESULTS**

**November 2018**

The present Policy regarding registration and public disclosure of results of clinical trials coordinated by IARC or clinical trials in which IARC is a collaborator, has two different aims:

- To align IARC research policies with the WHO Information Note 19/2018 pertaining to the registration and public disclosure of results of clinical trials, and to describe the disclosure requirements in respect of clinical trials coordinated by IARC or in which IARC is a collaborator, as set forth in the [WHO Statement on Public Disclosure of Clinical Trial Results](#) and since the publication of the [WHO Joint Statement on public disclosure of results of clinical trials](#) of May 2017.
- To clarify the application, expectations and responsibilities for the implementation of the new WHO guidance on registration and public disclosure of results of the clinical trials.

This Policy is based on the Declaration of Helsinki (clause 36<sup>1</sup>) and aligned with the WHO taking a leadership position in advocating for prospective registration and timely results reporting. It has been WHO policy since 2005 that before any clinical trial is initiated (at any Phase) its details are to be registered in a publicly available, free-to-access, searchable clinical trial registry complying with WHO's international agreed standards ([www.who.int/ictrp](http://www.who.int/ictrp)).

**All IARC intervention studies** meet WHO's definition of clinical trial for registration purposes (please see below) and **must be registered before initiating the first recruitment of subjects**. Failing to comply with the WHO's position will expose IARC to reputational risk.

### What is a "clinical trial"?

The WHO definition of a clinical trial for the purposes of registration is "*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*".

Clinical trials may also be referred to as *intervention trials*. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioural treatments process-of-care changes, etc. This also comprises in the case of IARC preventive interventions including screening, early detection or implementation trials.

See [www.who.int/ictrp](http://www.who.int/ictrp) for information on clinical trial registration with any one of the Primary Registries in the WHO Registry Network or an ICMJE<sup>2</sup> (International Committee of Medical Journal Editors) approved registry.

Considering the above definition and **in respect of clinical trials coordinated by or in collaboration with IARC** since the publication of the WHO Joint Statement of 18 May 2017, the **below disclosure requirements shall be considered:**

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<sup>1</sup> See <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>, "Research Registration and Publication and Dissemination of Results".

<sup>2</sup> See <http://www.icmje.org/icmje-recommendations.pdf>: "The ICMJE will not consider as prior publication the posting of trial results in any registry that meets the criteria noted ... and encourages authors to include a statement with the registration that indicates that the results have not yet been published in a peer-reviewed journal, and to update the results registry with the full journal citation when the results are published."

1) Summary results<sup>3</sup> of clinical trials should be posted on the results section of the primary clinical trial registry within 12 months from primary study completion<sup>4</sup>. Where a registry is used without a results database available, the results should be posted on a publicly available institutional website. The Sections/Groups having their own webpage or project webpage on the IARC website should publish the results on these sites.

2) In addition, clinical trials summary results<sup>3</sup> should be submitted for publication in a peer reviewed journal within 12 months of study completion in accordance with IARC open access policy and should be published within 24 months of study completion.

3) The latest version of the clinical trial protocol should be made publicly available no later than the time at which the summary results are posted on the results section of the clinical trial registry.

This includes amendments approved by the IARC ethics committee (IEC) and the ethics committees/institutional review boards of the collaborating Institutions. The protocol and amendments should either be uploaded in electronic document formats such as pdfs, or as a link to electronic document formats. Access to a sufficiently detailed clinical trial protocol is necessary in order to be able to interpret summary results.

4) The Trial ID or registry identifier code/number should be included in all publications of clinical trials, and should be provided as part of the abstract to PubMed and other bibliographic search databases for easy linking of trial related publications with clinical trial registry site records. This is essential for linking journal publications with registry records.

5) Past trials can be registered and reported retroactively. Reporting of previous trials enhances the value of that research; therefore, the contribution made from reporting previous trials, whatever their results, will be considered in the assessment of funding proposals by all signatories to the May 2017 WHO Joint Statement (this includes for example, the Bill and Melinda Gates Foundation, DFID, the European Commission for Horizon 2020 Societal Challenge and Health Demographic Change and Wellbeing and the Wellcome Trust). When principal investigators apply for new funding, they may be asked to provide a list of all previous trials for which they were principal investigator within a specified timeframe and their reporting status, with an explanation where trials have remained unreported. All IARC scientists responsible for previously completed but unreported sponsored or supported trials are encouraged to take measures to publicly register and disclose the summary results of such trials. If journal publication has not been pursued for such long completed trials, an option is to retrospectively register the clinical trial in [clinicaltrials.gov](http://clinicaltrials.gov) and upload summary results to the registry entry.

6) [These expectations should be included in the agreements concluded by IARC](#) in respect of such trials. This includes Collaborative Research Agreements (CRAs), and other types of agreement established by IARC for clinical trials.

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<sup>3</sup> "Summary results" are defined as the main findings from analyses conducted on data, and should include the following as a minimum: participant flow, baseline characteristics, primary and secondary outcome measures, and adverse events including all serious adverse events and important anticipated or unanticipated adverse event. See <http://www.who.int/ictrp/network/trds/en/> for additional information and [here](#) for examples.

<sup>4</sup> "Primary study completion" is defined as the last data collection time point for the last subject for the primary outcome measure.

## **Important Note**

The registration of clinical trials with a clinical trial registry and the publication of clinical trial results should not prejudice the confidentiality of information, which is proprietary to IARC, parties collaborating with IARC and/or third parties. In the case of results that may be capable of industrial or commercial exploitation, confidentiality shall be maintained for a period of up to twelve months in order to enable patent rights to be safeguarded or to allow alternative forms of legal protection to be explored. Unless it is mutually agreed that confidentiality beyond a period of twelve months is necessary and consistent with the public interest, the parties shall not be bound by any obligation to keep the results confidential.

## **Responsibilities for clinical trials coordinated by IARC or in which IARC is a collaborator**

The IARC scientist responsible for the submission of a proposed clinical trial to be coordinated by IARC or in which IARC would be a collaborator (i.e. the IARC PI), is also responsible for promoting compliance with the expectations set forth in this Policy. This includes communicating these expectations to, and following up with, relevant third parties (e.g. collaborators, funders, trial sponsors) and ensuring that these expectations are included in the corresponding agreement(s).

Where compliance does not occur within the deadlines set out in this Policy, the reasons should be documented by the PI, and the public disclosure timelines can exceptionally be extended by IARC in writing with an additional period of no more than 12 months.

When compliance does not occur within the extended deadline, the IARC PI is required to report this (together with the reasons) to the IEC Secretary for discussion with the IARC Director. IARC may decide to publicly disclose such non-compliance on the IARC website. As non-compliance may also constitute breach of the corresponding agreement(s), the IARC PI should consult with the IEC Chair and members regarding appropriate action.

The IEC will prepare a list of all the Committee's approved clinical trials and amend its SOPs in agreement with the expectations set forth in this Policy, to integrate compliance with clinical trial registration and results reporting requirements (including the timeliness thereof) as a monitoring element. The updated IEC SOPs will include the following requirements:

- To give an undertaking to register the trial before initiating the first recruitment of subjects. The final IEC approval for any clinical trial will be conditional to the inclusion of the clinical trial registry ID in the Annual Report to the IEC; and
- To include the final version of the protocol in the Annual Report to the IEC and overall compliance to the above listed expectations.

## **Responsibilities when co-authoring publications on the outcomes of clinical trials funded and/or supported by third parties**

The IARC scientist(s) co-authoring the publication is(are) also responsible for encouraging compliance with the expectations set forth in this Policy and WHO Information Note 21/2016. This includes communicating these expectations to, and following up with, relevant third parties.

When compliance does not occur within the extended deadline, the IARC scientist(s) should consider withdrawing co-authorship in consultation with the IARC Director.