From: s22
To: s22
Cc: s22
Subject: FW: Redesignation letter for Therapeutic Goods Authority, OLSS (AUS-47) as WHO collaborating centre for drug quality assurance [SEC=UNCLASSIFIED]
Date: Monday, 1 December 2014 9:28:47 AM
Attachments: Signed redesignation letter AUS-47.pdf
AUS-47 Redesignation form.pdf
AUS-47 Terms_and_conditions_for_WHOCCS.pdf

Fyi and congratulations!

s22
Head of Office
Office of Laboratories & Scientific Services

Phone: s22 Fax: s22
Mobile: s22
Email: s22 tga.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606 Australia
www.tga.gov.au

From: s
Sent: Friday, 28 November 2014 5:37 PM
To: s22
Cc: Lisa Kerr; s22
Subject: Redesignation letter for Therapeutic Goods Authority, OLSS (AUS-47) as WHO collaborating centre for drug quality assurance

Dear s22 ,

Please find attached an advance copy of redesignation letter (with attachments) for TGA as WHO collaborating centre for drug quality assurance for a period of four (4) years from 29 November 2014. Originals of the letter and attachments are being dispatched by regular mail.

Congratulations and I look forward to future collaboration with TGA. Warm regards,

s22
Team Leader
Essential Medicines and Health Techonology
Division of Health Systems
World Health Organization | Regional Office for the Western Pacific | Manila, Philippines
Tel: +63 2 5289026 | Mobile: +63 908 8944578 | E-mail: s22 @wpro.who.int | Web: http://www.wpro.who.int

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Document 2

WORLD HEALTH ORGANIZATION
REGIONAL OFFICE FOR THE WESTERN PACIFIC
ORGANISATION MONDIALE DE LA SANTE
BUREAU REGIONAL DU PACIFIQUE OCCIDENTAL
United Nations Avenue, P.O. Box 2932, 1000 Manila, Philippines

In reply please refer to: (WP) DCD/EPI/2014/001-A
Prière de rappeler la référence:

s22
Therapeutic Goods Administration
Office of Laboratories and
Scientific Services
Immunobiology and Biochemistry Group
P.O. Box 100
Woden ACT
Australia

15 AUG 2014

Dear s22

I would like to thank you for the valuable contribution made by your institution during its previous period of designation as WHO collaborating centre. I am pleased to inform you that the World Health Organization has redesignated the Therapeutic Goods Administration as a WHO Collaborating Centre for Quality Assurance of Vaccines and Biological Medicines, under WHO's reference number AUS-42.

As previously agreed, you will act as Head of the Centre. Should there be any change in the future, I would be grateful if you would inform WHO without delay.

The agreed terms of reference and workplan of the Centre are ... attached. We wish to emphasize that institutions designated as WHO collaborating centres are expected to implement the agreed workplan in a timely manner and to the highest possible standard of quality. Any issue that may affect the implementation of the agreed workplan should be brought to the attention of the WHO responsible officer, Dr Sergey Diorditsa, (632) 528 9745, diorditsas@wpro.who.int. For information on administrative matters, please visit the WHO website http://www.who.int/collaboratingcentres/information/en/.

We wish to also emphasize that institutions designated as WHO ... Collaborating Centres must also comply with the attached *Terms and conditions for WHO collaborating centres*. We wish to draw your particular attention to the fact that the WHO name and emblem may only be used by a WHO Collaborating Centre as described in those terms and conditions.

... ENCL.: As stated.

cc: The Acting Secretary, Department of Health
Attention: Assistant Secretary, International Strategies Branch, Canberra

Therapeutic Goods Administration
Woden

(WP)DCD/EPI/2014/001-A

15 AUG 2014

Finally, please note that institutions designated as WHO collaborating centres must complete a short online progress report form once a year. On the anniversary of the designation date, details will be sent to the email address of the Head of the Centre specified in the designation form.

The designation as a WHO Collaborating Centre will be effective for a period of four years, as from 16 August 2014, and will automatically end on 16 August 2018, unless redesignation has been approved by WHO before that date. During the period of designation, either party may revoke the designation at any time by giving three months advance notice in writing.

Again, I would like to express my appreciation for your past contribution and I look forward to our continuing successful collaboration.

Yours sincerely

s22

World Health Organization

Collaborating Centres REDESIGNATION FORM

The redesignation form consists of three parts:

Part I - Institutional Profile

Part II - Terms of Reference (TOR)

Part III – Workplan

This redesignation form below, together with the Terms and conditions for WHO collaborating centres will serve as the agreement between the proposed institution and WHO if the redesignation as WHO collaborating centre is approved by WHO. Completion and submission of the redesignation form, however, does not guarantee that the designation will be approved.

Folder eCC_00013080 is in stage Notification_Letter

Name of the University, Hospital, Research Institute, Academy or Ministry

Therapeutic Goods Administration (TGA)

Name of the Division, Department, Unit, Section or Area

Office of Laboratories & Scientific Services (OLSS), Immunobiology and Biochemistry Group

City	**CC Reference Number**
Woden	AUS-42

Title

WHO Collaborating Centre for the Quality Assurance of Vaccines and Other Biologicals

Part I - Institutional Profile

The majority of designations as WHO CC are given to a part (e.g. department, division, unit, etc) of an institution, as opposed to the institution as a whole. Example: the Department of Microbiology of the University of ABC. In those cases, when a question in the designation form refers to the "institution", please only provide information about the concerned part (e.g. the Department of Microbiology) of the institution and not about the institution as a whole (e.g. the University of ABC). Where information about the institution as a whole is being required, this will be clearly stated.

The term "WHO CC" means the (part of the) institution designated as a WHO collaborating centre while performing the agreed terms of reference and work plan with WHO (as opposed to the institution performing other activities outside the agreed terms of reference and workplan). Example: Department of Microbiology of the University of ABC, when working on activities included in this designation form and agreed with WHO.

A WHO CC is not a legal entity. The legal entity which controls and is responsible for the WHO CC is the institution or the ministry, academy, university, established research institute or hospital of which the institution forms part.

Address of the proposed institution

1.1 Street and number	P.O. Box 100
1.2 City	Woden
1.3 State/Region/Canton/Province	ACT
1.4 Postal Code	2606
1.5 Country	AUS

World Health Organization

Collaborating Centres
REDESIGNATION FORM

1.6 WHO Region	WPRO
1.7 Phone	(61-2) 6232 8400
1.8 Fax	(61-2) 6232 8442
1.9 Web site	http://www.tga.gov.au

Staff of the proposed institution

1.10 Name of the director of the institution as a whole

Professor John Skerritt

Head(s) of the proposed WHO collaborating centre

Salutation	First Name	Last Name	Email Address
Dr	s22	s22	s22 @tga.gov.au

Salutation	First Name	Last Name	Email Address
Dr	Lisa	Kerr	lisa.kerr@tga.gov.au

1.12 Please list the names of professional staff working at the proposed institution together with their professional qualifications (e.g. Dr John Smith MPH). Please do not include full resumes or biographies.

NAME, QUALIFICATIONS
Office of Laboratories ands Scientific Services (OLSS) Management
s22 Head, OLSS, BSc (Hons), PhD
Dr Lisa Kerr, Scientific Operations Advisor, BSc (Hons), PhD, MBA

Immunobiology Staff (Vaccines)
s22

Biochemistry Staff (Other Biologicals),
s22

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The officers listed above are the professional staff in OLSS who would contribute to the bulk of the work of the Collaborating Centre. In addition, the TGA and OLSS has a range of other professional, technical and administrative staff who could contribute to the work of the Collaborating Centre if required.

Sources of funding

Note: The reference to companies in this form includes trade associations and foundations closely associated with their commercial sponsors. The reference to "companies engaged in activities relating to tobacco" includes companies engaged in the manufacture, distribution and/or sale of tobacco or tobacco products and subsidiaries of such companies (including holding companies).

1.13 During the last two years, what percentage of the proposed institution's funding was core funding? Core funding refers to funding that is received by the proposed institution in a regular manner (e.g. a specific amount received annually from a secure source), as opposed to ad-hoc contributions that are received once or at irregular intervals.
over 75% regular (core) funding

1.14 Did over the last three years, does currently, or is there a prospect that, the institution as a whole will receive funds from one or more companies whose business activities are incompatible with WHO's work (e.g. companies engaged in activities relating to tobacco)?
Yes ☐ No ☑

If "Yes", please provide details (i.e. names of companies, their business activities, level of funding, for what such funding was, is being, or will be, used, together with an indication whether such funding has stopped (and if so, the year in which it stopped), or is current or prospective.

1.15 Does the proposed institution currently, or is there a prospect that the proposed institution will, receive funds from one or more companies that have, or may be perceived as having, a direct or indirect commercial interest in the activities being conducted by the proposed institution as part of its terms of reference as a WHO collaborating centre?
Yes ☐ No ☑

If "Yes", please provide details (i.e. names of companies, their business activities, level of funding, for what such funding is being, or will be, used, together with an indication whether such funding is current or prospective).

1.16 Does the proposed institution currently, or is there a prospect that the proposed institution will, perform research or other work commissioned by industry as part of its terms of reference as a WHO collaborating centre?
Yes ☐ No ☑

If "Yes", please provide details (i.e. description of the research or other work, names of companies by which the research or other work is being commissioned, the business activities of these companies, and a clarification of the amounts charged for this research or other work, i.e. whether these amounts are charged on a cost recovery basis or any other basis).

1.17 Does the proposed institution currently, or is there a prospect that the proposed institution will, receive unspecified funds from one or more companies which it is planning to use directly or indirectly for the implementation of the agreed terms of reference as a WHO collaborating centre?
Yes ☐ No ☑

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Collaborating Centres
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If "Yes", please provide details (i.e. the names of companies, their business activities, level of funding, for what such funding is being, or will be, used and whether the institution is dependent on the support of one or more of these companies for its continued operation).

1.18 Does the proposed institution currently, or is there a prospect that the proposed institution will, receive funding from one or more companies to support the salary of specific staff or posts working on the activities conducted as part of its terms of reference as a WHO collaborating centre?

Yes ☐ No ☑

If "Yes", please provide details (i.e. names of companies, their business activities, level of funding, for which staff or what posts such funding is being, or will be, used, and the functions of such staff and/or posts).

1.19 Did over the last three years, does currently, or is there a prospect that, any staff of the institution designated to work on the activities of the WHO collaborating centre, including the proposed head(s) of the WHO collaborating centre, have any other interactions, affiliations or relations with, or any other personal, professional, financial or business interests in, one or more companies that could give rise, or be seen as giving rise, to a conflict of interest?

Such a conflict could exist:
(i) if the company has, or may be perceived as having, a direct or indirect commercial interest in all or part of the activities being conducted by the proposed institution as a WHO collaborating centre;
(ii) if the business activities of the company are incompatible with WHO's work (e.g. companies engaged in activities relating to tobacco); or if the company has (or may be seen as having) a vested interest in exerting influence on the activities of the WHO collaborating centre and/or their outcome.

Interactions, affiliations, relations with, or other personal, professional, financial or business interests include, but are not necessarily limited to, collaborative projects or initiatives, employment, consultancy, investment interests (e.g. stocks, bonds, stock options, other securities, but not mutual funds, pension funds or similar investments that are broadly diversified), commercial business interests (e.g., proprietorships, partnerships, joint ventures), patents, trademarks, or copyrights (including pending applications), proprietary know-how in a substance, technology or process.

Yes ☐ No ☑

If "Yes", please provide details (i.e. names of the companies involved, their business activities, the nature of the interactions, affiliations, relations, or other personal, professional, financial or business interests, and the value of or income generated through such the interactions, affiliations, relations or other interests, together with an indication whether the interactions, affiliations, relations, or other personal, professional, financial or business interests in question have stopped (and if so, the year in which they stopped), or whether they are current or prospective).

1.20 Please attach a current organizational chart (1 page) of the institution as a whole, including its sub-parts such as divisions, departments, sections, unit or areas (whichever structure applies), indicating the part proposed as WHO collaborating centre.

tga-structure-130802.jpg

1.21 Please list major facilities and any specialized equipment available to the proposed institution (e.g. laboratories, training facilities, documentation centre), if applicable. Please do not list general office space or standard office equipment.

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TGA has laboratories which specialise in a range of regulatory sciences, particularly vaccine and biological medicine quality assurance, as well as some training facillities.

1.22 Does the proposed institution currently establish a smoke-free environment across its premises, which can be illustrated either through a documented institutional/departmental policy or through the existence of national/local smoke-free legislation? The smoke-free environment must apply to all indoor workplaces and public places of the institution's premises, and must entail a complete ban of smoking indoors and no areas designated for smoking.

Yes

☑ **The proposed institution agrees with the following Terms and conditions for WHO collaborating centres.**

Part II - Terms of Reference (TOR)

Please include the proposed terms of reference for the future collaboration between the proposed institution and WHO, as discussed prior to completing this form. In most cases, 1-3 TOR will be sufficient to provide a high-level framework of the future collaboration. For redesignations, the current terms of reference is automatically prefilled but can be revised as appropriate.

For detailed instructions on how to fill in this section please click on the link provided at the top of the form.

TOR 1 To contribute to strengthening institutional capacity of regulatory authorities through the regional NRA alliance framework in the Western Pacific Region or other regions.

TOR 2 To support WHO in developing international written standards and guidelines for regulatory evaluation of vaccines and biological medicines and implementing these standards into practice.

TOR 3 To contribute to the development of international measurement standards and reference materials for vaccines and biological medicines.

TOR 4 To provide scientific advice on seasonal and/or pandemic influenza vaccine virus strain selection.

TOR 5 To perform laboratory testing of the quality of vaccines and biological medicines.

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Part III – Workplan

Activity ID 21093	**Activity title**	NRA assessments
	Link to TOR	TOR1
	Name(s) of responsible staff at the institution	s22
	Type of activity	Providing technical advise to WHO
	Description of the activity and how it is implemented	Jointly, and/or at the request of WHO to provide Technical Assessors for NRA assessment missions.
	Expected deliverables	Contribution to WHO and Regional Alliance efforts to ensure that all vaccines in the Region – especially those in national immunization programs – are of assured quality.
	WHO Deliverable (Top Task)	4.3.3.H1 4.3.3.R1
	Name(s) of funding sources	WHO- subject to availability of funds TGA-staff time - subject to availability
	Activity timeframe	As requested by the WHO
	This activity has been specifically developed for the workplan of the WHO collaborating centre and does not constitute a standard activity of the institution without WHO involvement.	
Activity ID 21094	**Activity title**	Training
	Link to TOR	TOR1
	Name(s) of responsible staff at the institution	s22
	Type of activity	Training and education
	Description of the activity and how it is implemented	Jointly, and/or at the request of WHO, to provide training for appropriately qualified staff of national regulatory authorities in: • quality assurance and • evaluation of application dossiers
	Expected deliverables	Contribution to WHO and Regional Alliance efforts to develop systems and programs to build the capacity of NRAs to effectively regulate vaccines.
	WHO Deliverable (Top Task)	4.3.3.H1 4.3.3.R1
	Name(s) of funding sources	WHO- subject to availability of funds TGA - staff time - subject to availability
	Activity timeframe	As requested by the WHO
	This activity has been specifically developed for the workplan of the WHO collaborating centre and does not constitute a standard activity of the institution without WHO involvement.	

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Activity ID 21095	**Activity title**	Technical Advice
	Link to TOR	TOR2
	Name(s) of responsible staff at the institution	s22
	Type of activity	Providing technical advise to WHO
	Description of the activity and how it is implemented	Participate in development, review and implementation of written standards and guidelines for vaccines and biological medicines.
	Expected deliverables	WHO standards and guidelines are developed and maintained as best practice in vaccine regulation.
	WHO Deliverable (Top Task)	4.3.3.H1 4.3.3.R1
	Name(s) of funding sources	WHO- subject to availability of funds TGA- -staff time- subject to availability
	Activity timeframe	As requested by the WHO
	This activity has been specifically developed for the workplan of the WHO collaborating centre and does not constitute a standard activity of the institution without WHO involvement.	
Activity ID 21096	**Activity title**	Network of WHO Collaborating Centres for Biological Standardisation
	Link to TOR	TOR2
	Name(s) of responsible staff at the institution	s22
	Type of activity	Providing technical advise to WHO
	Description of the activity and how it is implemented	Participate in Network activities.
	Expected deliverables	Provision of technical and regulatory advice to Network activities and progression of the Network plans.
	WHO Deliverable (Top Task)	4.3.3.R1 4.3.3.H1
	Name(s) of funding sources	WHO- subject to availability of funds TGA- -staff time- subject to availability
	Activity timeframe	As requested by the WHO
	This activity has been specifically developed for the workplan of the WHO collaborating centre and does not constitute a standard activity of the institution without WHO involvement.	

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Activity ID 21097	**Activity title**	International Collaborative Studies
	Link to TOR	TOR3
	Name(s) of responsible staff at the institution	s22
	Type of activity	Providing technical advise to WHO
	Description of the activity and how it is implemented	Participate in international collaborative studies to calibrate the potency of physical reference preparations for vaccines and biological medicines.
	Expected deliverables	Laboratory testing results on the potency of candidate reference preparations. Coordination of collaborative studies to determine the potency of influenza reference reagents.
	WHO Deliverable (Top Task)	4.3.3.R1 4.3.3.H1
	Name(s) of funding sources	WHO- subject to availability of funds TGA- -staff time- subject to availability
	Activity timeframe	As requested by the WHO
	This activity has been specifically developed for the workplan of the WHO collaborating centre and does not constitute a standard activity of the institution without WHO involvement.	
Activity ID 21098	**Activity title**	Influenza vaccine strain selection
	Link to TOR	TOR4
	Name(s) of responsible staff at the institution	s22
	Type of activity	Providing technical advise to WHO
	Description of the activity and how it is implemented	Participate in WHO activities for the selection of influenza vaccine strains and to coordinate the Australian Influenza Vaccine Committee (AIVC).
	Expected deliverables	Influenza vaccine strain selection for northern and southern hemispheres.
	WHO Deliverable (Top Task)	4.3.3.R1 4.3.3.H1
	Name(s) of funding sources	WHO- subject to availability of funds TGA -staff time- subject to availability and activities associated with the Australian Influenza Vaccine Committee
	Activity timeframe	Annual for Northern and for Southern activities.
	This activity has been specifically developed for the workplan of the WHO collaborating centre and does not constitute a standard activity of the institution without WHO involvement.	

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Activity ID 21099	**Activity title**	Testing
	Link to TOR	TOR5
	Name(s) of responsible staff at the institution	s22
	Type of activity	Providing technical advise to WHO
	Description of the activity and how it is implemented	OLSS will test vaccines and biological medicines at the request of the WHO.
	Expected deliverables	Provision of laboratory testing results to the WHO.
	WHO Deliverable (Top Task)	4.3.3.R1 4.3.3.H1
	Name(s) of funding sources	WHO- subject to availability of funds TGA- -staff time- subject to availability
	Activity timeframe	As requested by the WHO.
	This activity has been specifically developed for the workplan of the WHO collaborating centre and does not constitute a standard activity of the institution without WHO involvement.	

TERMS AND CONDITIONS FOR WHO COLLABORATING CENTRES

1. The general conditions of becoming a WHO collaborating centre
2. Use of the WHO name, emblem and flag
3. Intellectual property
4. Interaction of WHO collaborating centres with industry and private sector in general
5. Research
6. Guideline development
7. Other Conditions

Definitions and notes

Unless otherwise stated, for the purpose of this document,

- the term "institution" means the part (e.g. department, division, unit, etc) of the institution (e.g. university, research institute, hospital or academy) or Government that is being proposed for re/designation. Example: Department of Microbiology of the University of ABC…

- the term "WHO CC" means the institution designated as a WHO collaborating centre while performing the agreed terms of reference and work plan with WHO (as opposed to the institution performing other activities outside the agreed terms of reference and workplan). Example: Department of Microbiology of the University of ABC… when working on two activities included in their designation form and agreed with WHO.

A WHO CC is not a legal entity. The legal entity which controls and is responsible for the WHO CC is the institution or the ministry, academy, university, established research institute or hospital of which the institution forms part.]

Through the signature of this form, a duly authorized representative of the institution proposed for (re)designation as a WHO CC (hereafter referred as "the head of the proposed WHO CC"), hereby accepts and agrees on behalf of the institution to comply with the following terms and conditions, in the event the proposal for re/designation is approved by WHO:

1. GENERAL CONDITIONS

Upon designation, the designated institution will be responsible for:

a) implementing the agreed plan of work in a timely manner and to the highest possible standards of quality;

b) bringing to the attention of the WHO responsible officer any issue that can delay or compromise the implementation of the workplan, and/or any change in the information provided in this form;

c) submitting annual progress reports via eCC on the anniversary of the designation date and as may be requested by WHO;

d) initiating discussions with the responsible officer at WHO at least six months prior to the expiration of the period of designation, with a view to evaluating any possible re-designation of the WHO CC.

2. USE OF WHO NAME, EMBLEM AND FLAG

As a general rule, a WHO CC may obtain permission to use WHO's name and emblem[1] only in relation to an activity included in the agreed work plan (as opposed to other activities that the institution may conduct outside the workplan). Use of the WHO name and/or emblem requires the prior approval of the WHO Director General on a case by case basis. Any authorization for use of the WHO name and emblem is granted only for the purpose for which such authorization has been requested and automatically comes to an end upon completion of the said purpose or expiration of the period of designation of the WHO CC, whichever occurs first.

To obtain permission to use WHO's name and/or emblem in relation to an activity from the work plan, the WHO CC should contact their responsible officer at WHO with a justification and a *mock-up of the proposed use* in line with the conditions set forth below.

General considerations

a) the WHO emblem and/or name should never be used in isolation. Instead, the exact title of the WHO CC (hereafter referred to as the "title"), as indicated in the official letter of designation and registered in the WHO CC global database (e.g. "WHO Collaborating Centre for Occupational Health") should be used, rather than the WHO name alone. If the WHO emblem is also to be used, it may only be placed directly next to the title;

b) The title (and emblem) should be discreetly used (and both have a similar size), and placed immediately underneath the name of the (relevant part of the) designated institution, which should have a more prominent position;

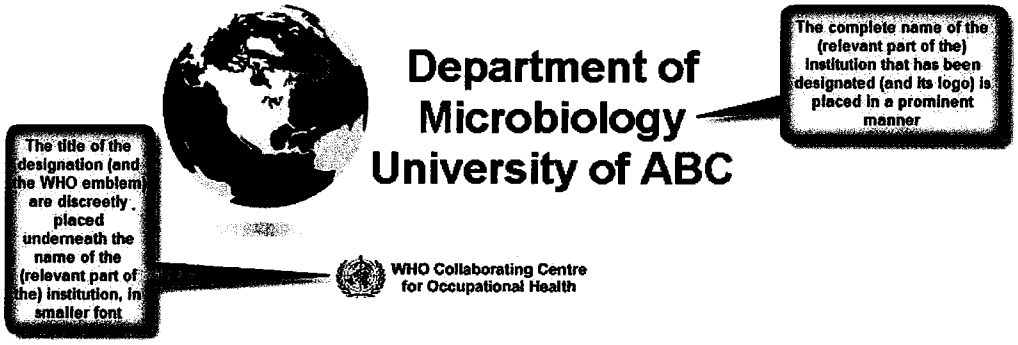
c) The characters of the title must be smaller than the characters of the name of the designated institution (or relevant part thereof), e.g. "WHO Collaborating Centre for Occupational Health" must be typed in smaller characters than "School of Occupational Health, ABC University".

d) All words in the title must be of the same font size, e.g. "WHO" may not be larger than "Collaborating Centre for Occupational Health".

[1] Emblem and logo are different things. The WHO logo incorporates the WHO emblem and the name of the Organization in a single design. Normally, WHO CCs are not allowed to use the WHO logo. Instead, they may be authorized to use the WHO emblem and title of their designation as a WHO CC following the rules stated in this document.

e) If, in addition to the title, the WHO emblem is to be used, the emblem of the designated institution should also be used, and the former should be of smaller size than the latter.

Example



Example

f) If the language used by the WHO CC is not one of the official languages of the World Health Organization (Arabic, Chinese, English, French, Russian and Spanish), or in case of designation by a WHO Regional Office, one of the official languages used by that regional office, then the WHO CC must also use one of those official languages .

2. 1 Use of the WHO name and emblem on letterheads

Subject to the general rule and considerations stated above, a WHO CC may use its official title and the WHO emblem on letterheads for correspondence related to the agreed activities.

2. 2 Use of the WHO name and emblem on a dedicated webpage

Subject to the general rule and considerations stated above, and the additional conditions stated below, a WHO CC may use its official title and the WHO emblem on a dedicated WHO CC Webpage.

Before submitting the request for permission, the responsible officer at WHO should receive a draft web page from the WHO CC to ensure that:

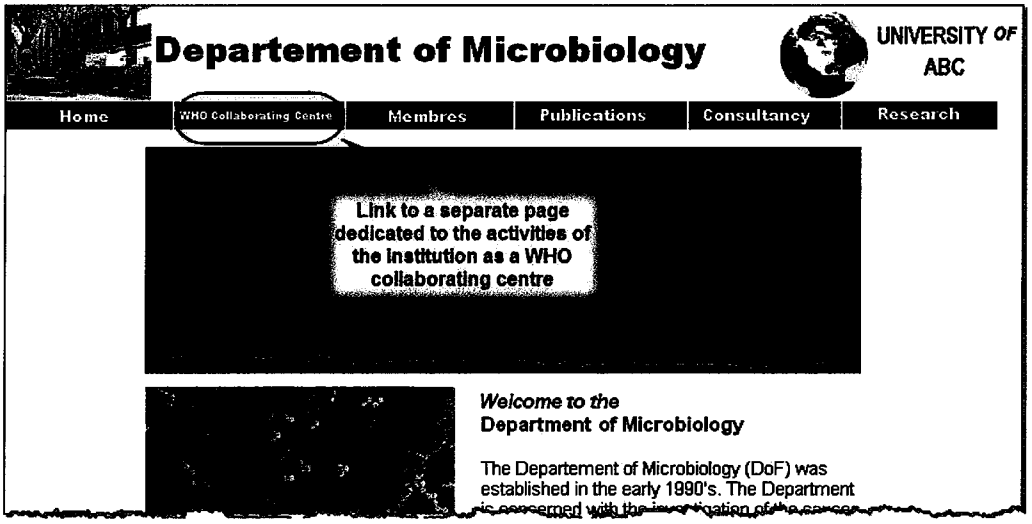
a) the WHO emblem is not used on the main web page of the designated institution (or part thereof). Instead, a discreet reference to the designation of the institution as a WHO CC may be included in the webpage of the institution, and that

reference could be linked to a separate page fully dedicated to the activities of the institution as a WHO CC;

b) the proposed web page is in accordance with the terms of reference and workplan of the WHO CC, i.e. it only refers to the activities of the institution in its capacity as a WHO CC as described in the terms of reference and workplan;

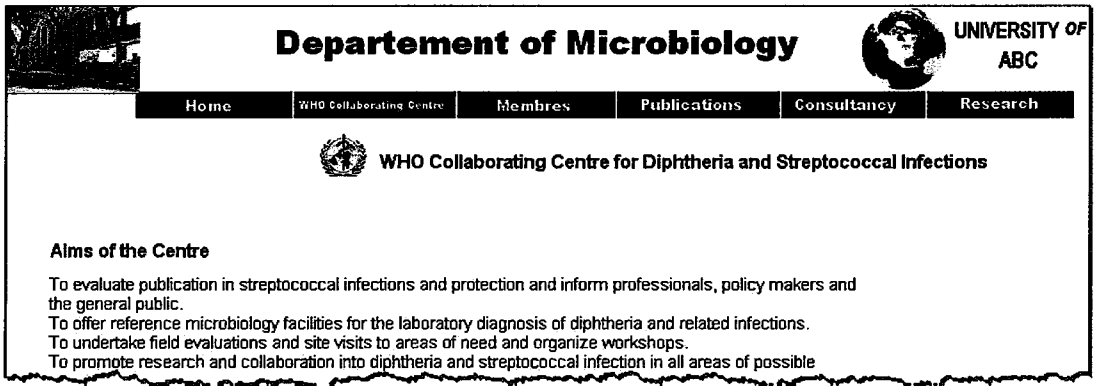
c) the content of the proposed web page is acceptable to WHO from a technical and scientific point of view;

d) if any financial support from the private sector is to be received for the development of the Webpage, this has to be consistent with the rules on interaction of WHO collaborating centres with the commercial private sector including in respect of the manner in which contributors are acknowledged.



Example above: main page of the Department of Microbiology of the University ABC.

Example below: page within the web site of the Department of Microbiology of the University ABC, especially dedicated to the activities in its capacity as a WHO CC for Diphtheria and Streptococcal Infections.



2. 3 Use of the WHO name and emblem on brochures, presentations and published material

Such use is subject to the general rule and considerations stated above and to a case by case approval by WHO.

2. 4 Flag

A WHO CC may submit a request for time limited use of a WHO flag at specific occasions (e.g. World Health Day). Such a request should be submitted to the WHO responsible officer. Approval, if granted, will be subject to the WHO CC displaying the flag in conformity with the WHO Flag Code and Regulations (sent along with the flag). At the end of the specific occasion for which approval has been granted, the flag must immediately be returned to the Organization.

2. 5 Business or visiting cards

The use of WHO's name or emblem on business or visiting cards of the staff members of the WHO CC is not allowed in any circumstance.

2. 6 Plaques

WHO does not normally authorize the use of plaques bearing its name and emblem by WHO CCs.

2. 7 Training diplomas and certificates

The WHO name and emblem may not be used on certificates of attendance, diplomas or similar awards to participants in training or other courses organized as part of a WHO CC's workplan.

3. INTELLECTUAL PROPERTY

This applies to the deliverables (outcomes) of the activities included in the workplan.

Summary table	**Product of the WHO CC,** and therefore WHO CC owns IP and gives licence to WHO	**WHO product,** and therefore WHO owns IP and gives WHO CC a licence
Copyrights (publications)	3.1.1	3.1.2
Patents (other type of deliverables)	3.2.1	3.2.2

3.1 Copyrights

3.1.1 As a rule, a product produced by the WHO CC as part of the agreed workplan and published under the institution's own name is the sole responsibility of the institution, and copyright will be vested in the institution, unless otherwise agreed. WHO is automatically granted a perpetual and irrevocable, non-exclusive, world-wide, royalty-free, sub-licensable right to use, change, adapt, translate, publish and

disseminate such work product in any manner and in any format in conjunction with the work of WHO. Any adaptation, translation, publication (including in scientific journals) and dissemination to be made by either party will be coordinated between them in order to avoid overlap. The institution will not publish in the name of WHO, nor use its title as a WHO CC and/or the WHO emblem in the product (book, article in a journal, etc), unless this has been specifically agreed with WHO, in which case the work product is subject to a special WHO's publication clearance procedures. In no case shall the name of WHO (either as an acronym or in full text) be used in the title of these products. If granted, the permission to publish in the name of WHO and/or use the title as a WHO CC and/or the WHO emblem ceases automatically upon termination or expiry of the institution's designation as a WHO CC.

3.1.2 However, if a work product is be developed by the WHO CC as a WHO product as part of the agreed workplan, then the copyright of such work product will automatically be vested in WHO, unless WHO requests otherwise. The institution (as a WHO CC) will be appropriately acknowledged for its contribution in connection with the product. WHO retains the right to amend the work product after consultation with the institution, to decide if and how the work product will be used and whether or not it will be published and disseminated. At the institution's request, WHO will give good faith consideration to granting the institution a non-exclusive, world-wide, royalty-free right to use, translate, adapt, publish and disseminate such work product as part of its agreed workplan as a WHO CC, or to use it for the development of other work products as foreseen in the WHO CC terms of reference. Any adaption, translation and publication (including in scientific journals) and dissemination will be coordinated with and requires the agreement of WHO in order to avoid overlap. Any licence granted by WHO will terminate automatically upon termination or expiry of the institution's designation as a WHO CC.

3.2 Patents

3.2.1. Unless otherwise agreed by the parties in writing, the ownership of any inventions, know-how, data and information and other results arising from any other study or trial carried out by the WHO CC, if exceptionally agreed as part of the workplan (see section 5 below) shall be vested in the institution, in accordance with and subject to the terms set forth below (unless otherwise agreed):

3.2.1(a) The results of the project may be freely used or disclosed by either party provided that, without the consent the other party, no use may be made for commercial purposes and confidentiality shall be maintained with respect to results that may be eligible for protection by proprietary rights. The institution will provide WHO with the results, in the form of relevant know-how and other information, and to the extent feasible, tangible products.

3.2.1(b) The industrial or commercial exploitation of any intellectual property rights, including the ownership of know-how, arising from the project shall be designed to achieve, in so far as circumstances permit, the following objectives in the following order of priority:
a. the general availability of the products of creative activity;
b. the availability of those products to the public health sector on preferential terms, particularly in developing countries;

c. the grant to each party of additional benefits, including royalties, account being taken of the relative value of each party's financial, intellectual and other contributions to the research.

3.2.1(c) The rights referred to above shall belong to the institution, or to the principal investigator if the institution and WHO so agree. To the extent that the former do not intend to exercise them, the rights shall be promptly transferred to WHO, if it so requests. Each party shall provide the other with its full cooperation to permit the effective exercise of the rights. The party in which the corresponding rights are vested may file applications for industrial property protection, promptly furnishing copies of the applications and other patent documents to the other party. All rights other than the right to file applications shall be exercised in accordance with an agreement which shall be negotiated in good faith between the institution and WHO.

3.2.1(d) In any publication by the institution or the principal investigator relating to the results of the project, the responsibility for the direction of the work shall not be ascribed to WHO. Unless WHO advises otherwise, all publications shall include a notice indicating that the underlying investigation was carried out by the Institution as a WHO CC. Two off-prints or copies shall be sent to WHO unless another number is stipulated.

3.2.2 However, the ownership of any inventions, know-how, data and information and other results arising from any study or trial carried out by the WHO CC as part of the agreed workplan, as a WHO study or trial, shall be vested in WHO and shall be held by the institution in confidence and not be used by it in any way without the prior written agreement of WHO.

3.3 Generic clause

In the absence of any different provision included in the designation form, any deliverable of any activity included in the designation form subject to copyrights will be ruled by paragraph 3.1.1, and any deliverable of any activitiy included in the designation form subject to patent rights will be ruled by paragraph 3.2.1.

4. INTERACTION OF WHO COLLABORATING CENTRES WITH THE COMMERCIAL AND PRIVATE SECTOR

Designation of an institution as a WHO CC is independent from any kind of financial support from WHO. In most cases, the WHO CC will be expected to cover the costs of the agreed activities through the core budget of the institution and if necessary, by mobilizing additional extra-budgetary resources. This does not prevent WHO from contributing financially in some cases, provided that funds are available and obligated for that purpose.

In order to safeguard the credibility, independence and objectivity of the work conducted by an institution as a WHO CC, WHO seeks to ensure that the interactions which this institution may have with the commercial private sector does not give rise to any real or perceived conflicts of interest in respect of the work of the WHO CC.

The commercial private sector includes:

a) companies;
b) associations representing companies or certain business interests ("trade associations"); and
c) foundations not at arms' length of their commercial sponsors.

For the purpose of this document, companies, associations representing companies or certain business interests ("trade associations"), and foundations not at arms' length of their commercial sponsors are jointly referred to as "companies".

Below are examples of the types of interaction that may give rise to a real or perceived conflict of interest in respect of the work of the WHO CC. Before the (re)designation of an institution as a WHO CC, the institution must:
- ascertain whether it and/or the responsible WHO CC staff are engaged in any interactions with the commercial private sector (particularly in respect of any activities that fall within the WHO CC's terms of reference and/or work plan); and
- if so, provide details thereof to WHO (including in particular, details about the identity of the companies in question, their business interests, and the activities, research and/or staff at the WHO CC which are concerned by the interaction).

Should WHO consider that an interaction gives rise to the risk of a real or perceived conflict of interest, every effort should be made to reach a mutually acceptable solution, consistent with the guidance provided in this section. In the event no such solution can be found, WHO will not be able to proceed with the proposed (re)designation of the institution as a WHO CC.

4. 1 Funding or other support from companies with incompatible business activities

The institution should not accept funding or other support (e.g. in kind or through secondment of employees) from companies whose business activities are incompatible with WHO's work (such as, for example, tobacco companies). This applies to both the activities of the institution as a WHO CC and any other activities of the institution as a whole.

4. 2 Funding or other support from companies with a direct commercial interest

The WHO CC should not accept funding or other support (e.g. in kind) from a company, if the company in question has, or may be perceived as having, a direct commercial interest in the outcome of that activity. For example, funds or other support should not be accepted from a manufacturer of insulin for an activity which (even generically) relates to the treatment of diabetes.

4. 3 Funding or other support from companies with indirect commercial interest

A WHO CC should exercise caution in accepting financing or other support from a company that has even an indirect interest in the outcome of an activity (e.g. in the case of an activity relating to the epidemiology of a disease, caution should be exercised in accepting funds or other support from a manufacturer of drugs for the

disease). In such cases, it is preferable to secure funding from multiple competing sources (i.e. so as to avoid a perceived close association with one particular company). In addition, the larger the proportion of the donation from any one source, the greater care that should be taken to avoid the possibility of a conflict of interest or appearance of an inappropriate association with one contributor.

4. 4 Unspecified support

In the event of an unspecified donation from a company, or group of companies, for the activities of a WHO CC in general (and not designated for a specific activity), the institution should ensure that the following is complied with:

a) The donation should not be used to support activities in which the company, or group of companies, has a direct commercial interest (see paragraph 4.2. above). In the event it is intended to use the donation to support activities in which the company, or group of companies, has an indirect commercial interest, donations should be sought from various sources having a similar interest; and it is preferable that support from multiple competing sources is secured (see paragraph 4.3 above). The larger the proportion of the donation from any one source, the greater the care that should be taken to avoid the possibility of a conflict of interest or appearance of an inappropriate association with one contributor.

b) The overall amount of unspecified support provided by the company, or group of companies, should not be so large that the WHO CC would become dependent on support from a single company, or group of companies, for its continued operations.

4.5 Support for activities related to the production of WHO guidelines or recommendations

As a general rule, a WHO CC should not accept any funds or other support from companies (regardless of their business interests) for activities related to the production of WHO guidelines or recommendations. The reason for this is that WHO's normative and standard setting work should be free from commercial concerns.

4.6 Funding to support the salary of specific staff or posts and secondment of company employees

Further, a WHO CC should not accept funds from companies to support the salary of specific staff or posts designated to the activities of the WHO CC (including short-term consultants), if the financial support could give rise to a real or perceived conflict of interest. For example, a conflict of interest would arise if the responsibilities of the staff member or post are directly or indirectly related to the business interests of the commercial contributor.

Similarly, a WHO CC should not accept the secondment of company employees to work on the activities of the WHO CC, if the company has a direct or indirect commercial interest in all or part of those activities.

4.7 Commissioned research or other work

The activities which an institution conducts as a WHO CC (as part of the WHO CC's terms of reference and/or work plan) should not include any research or other work commissioned by industry. In other words, WHO CCs should not, as such, perform research or other work which is contracted by companies.

4.8 Declaration of the interests of the director and other responsible staff

The institution should ensure and attest to WHO that the director and staff designated to work on the activities of the WHO CC do not have any interactions, affiliations or relations with and/or financial or other interests in companies (as defined above) that could give rise to, or be seen as giving rise to, a conflict of interest in respect of any of these activities.

In the event the WHO CC director and/or staff have any interactions, affiliations, relations and/or financial or other interests that could give rise to a real or perceived conflict in respect of any of the activities of the WHO CC, the institution should take appropriate measures to address and remove such conflicts. Examples of the type of interactions, affiliations, relations and financial or other interests that could give rise to, or be seen as giving rise to, a conflict of interest, can be found in the Declaration of Interest (DOI) for WHO experts, which can be found at http://www.who.int/collaboratingcentres/Declaration_of_Interests.pdf The WHO DOI is not, however, intended for use by the institution. The institution should make its own arrangements to ascertain, address and remove any possible conflicts which the WHO CC director and/or staff may have.

4.9 Information to be provided to WHO

In light of the above, before an institution can be (re)designated as a WHO CC, the head of the proposed WHO CC must ascertain whether:

a) the institution receives funding or other support from companies whose business activities are incompatible with WHO's work (such as, for example, tobacco companies);

b) the institution, as part of the work plan of the WHO CC, will conduct:

- activities that are funded or otherwise supported by companies (or trade associations or foundations closely associated with their commercial sponsors); and/or
- research or other work commissioned by industry; and/or

c) the institution receives funding to support the salary of specific staff or posts at, and/or the secondment of company employees for, the WHO CC.

In the affirmative, the institution should provide details (in the relevant sections of the re/designation form) about the identity of the contributors in question, their business interests, and the activities, research, staff and/or posts concerned, as well as any other information and/or clarification which WHO may reasonably require.

In addition, the head of the proposed WHO CC must ascertain whether the director and/or staff designated to work on the activities of the WHO CC have any interactions, affiliations or relations with and/or financial or other interests in companies which could give rise to a real or perceived conflict in respect of any of the activities of the WHO CC. In the affirmative, the institution must take appropriate measures to address and remove such conflicts.

The institution is required to attest to WHO that:

- the director and staff designated to work on the activities of the WHO CC have been required to declare any such interactions, affiliations, relations and financial or other interests; and that
- either no conflicts exist, or appropriate measures have been taken to address and remove them.

4.10 Evaluation by WHO and agreement on possible measures to be taken

The institution must make every effort to provide all relevant and potentially relevant information to WHO for evaluation, and where needed, to arrive at a mutually acceptable solution, consistent with the guidance provided in this section. For example, activities that give rise to a conflict of interest as described above or that have been commissioned by industry, will need to be deleted from the work plan, in order for a (re)designation to be approved. Similarly, WHO CC staff who have declared an interaction, affiliation, relation and/or financial or other interest in a company or group of companies that gives rise to a real or perceived conflict in respect of any activity of the WHO CC will need to recused from working on that activity.

With respect to those contributions from companies which are deemed acceptable, the WHO CC should -for reasons of transparency- always make a public acknowledgement. The basic and most common approach is to insert a discreet acknowledgement in the documentation relating to the activity concerned, including in any publication by the WHO CC of the outcome of this activity.

WHO may also require WHO CCs to publicly disclose the interactions, affiliations, relations and/or other interests of its director and/or staff that are considered to give rise to a conflict of interest.

Before accepting any contributions from companies, WHO CCs should seek the written assurance from the contributors in question that they will not use the results of the work that they have supported for commercial purposes or seek promotion of the fact that they have made a donation. However, they may make reference to donations in their corporate annual reports or similar internal documents.

WHO CCs should at all times maintain full and exclusive control over the activity to which a contribution relates, including over any report of the activity, its contents, whether it is published or disseminated in any form (e.g. electronically), and the timing of such diffusion.

5. RESEARCH CONDUCTED BY WHO CCS UNDER A JOINT WORK-PLAN

The terms of reference or work plan of a WHO CC should not include research involving human participants conducted by the WHO CC on its own accord. Instead, the terms of reference or work plan could provide that the centre will "participate in collaborative research under WHO leadership". Such activities will be conducted as WHO research, following WHO procedures and rules.

In order to fulfil WHO's responsibilities and oversee its involvement in research involving human participants, WHO has established a WHO Research Ethics Review Committee (ERC) to provide ethical review of research involving human participants funded or otherwise supported by WHO. As a result, in addition to the approval required for the designation or re-designation of a WHO CC, any research activity involving human participants included in the terms of reference or work plan of the WHO CC may require the approval of the WHO ERC. The WHO responsible officer will seek such approval/s, if necessary. Approval by an ethics body other than the WHO ERC does not exempt a research activity from WHO ERC review. The decision whether or not a particular activity involving human participants requires WHO ERC review and approval is made by the WHO ERC.

All research involving human participants for which WHO ERC approval is required, must conform to the requirements set forth at http://www.who.int/rpc/research_ethics/erc/en/index.html.

It is furthermore the responsibility of the WHO CC to safeguard the rights and welfare of human participants involved in research performed as part of the terms of reference or work plan, in accordance with the appropriate national code of ethics or legislation, if any, and, the Helsinki Declaration and any subsequent amendments. Research may only be undertaken where: (a) the rights and welfare of the research participants are adequately protected; (b) freely given informed consent has been obtained; (c) the balance between risk and potential benefits involved has been assessed and deemed acceptable by a panel of independent experts appointed by the institution; and (d) any special national requirements have been met.

It is moreover the responsibility of the institution to comply with the relevant national regulations pertaining to research involving human participants.

Without prejudice to obligations under applicable laws, the WHO CC is required to make appropriate arrangements to eliminate or mitigate the negative consequences to research participants, or their families in the case of death, injury or illness resulting from the conduct of the research. Such arrangements shall, to the extent feasible, include medical treatment and financial relief. The WHO CC should furthermore undertake to protect the confidentiality of the information relating to the possible identification of participants involved in such research.

Finally, the WHO CC should ensure that living animals, required for use as laboratory animals in research undertaken by the WHO CC, shall be handled in accordance with generally accepted principles for the humane treatment of such animals and the avoidance of unnecessary suffering.

6. GUIDELINES DEVELOPMENT

A WHO Guideline is a health information product containing recommendations. All WHO guideline development activities supported by a WHO CC as part of the agreed workplan must conform to the requirements set forth in the WHO Guidelines Review Committee (GRC) rules and procedures, unless the WHO guideline in question has previously been adjudicated by WHO as being exempt from GRC review.

7. OTHER CONDITIONS

7.1 Dissemination of results through WHO media

If any of the proposed activities provides that the results will be published by WHO, or disseminated through the WHO web site or through any other WHO media, the material to be published or otherwise disseminated will be subject to specific WHO clearance processes.

7.2 WHO funds

If any of the proposed activities mentions WHO as a source of funds, such financial contribution from WHO will be subject to the availability of funds.

7.3 Liability

The WHO CC shall be solely responsible for the manner in which the activities included in the terms of reference or work plan are carried out and accordingly shall assume full liability for any damage arising from these activities. Thus, WHO shall not be responsible for any loss, accident, damages or injury suffered by any person whatsoever arising in or out of the execution of these activities.

By completing and submitting this form, the head of the proposed WHO CC confirms that:

- to the best of his/her knowledge the information provided in this form is true and complete;and

- if there is any change in the information provided in this form, he/she will promptly notify the responsible officer of WHO.

If these conditions cannot be met, an institution cannot be (re)designated as a WHO CC. If these conditions cease to be met after designation, this should be immediately reported to the responsible officer of WHO.