

The Select Agent Laboratory:

- *at the intersection of research, preparedness and safety*

Nancy Connell, PhD
Professor and Vice-chair for Research
Department of Medicine
UMDNJ-New Jersey Medical School
Director, UMDNJ Center for BioDefense

- **Safety-**
 - Regulations**
 - Training**
 - Inspections**
 - Preparedness**
 - planning, training, exercising**
 - Research**
 - “dangerous experiments’**
 - Fink and other reports**
 - ABSAA**
 - Codes of conduct**
 - Roles of the safety officer**

Training

- BSL3 training
 - Incident command
 - First aid
 - Examinations
 - Experience
 - Responsibility

Preparedness

- “planning, training, exercising”
walk-throughs, table tops, and full-scale
Power outages, floods, accidents, fire,
health emergency, theft
Students, certificates, electives

Scenarios and Exercises

- Operation Smokescreen

Operation Secure Access

Operation Secure Egress

Research

Four dangerous experiments

- *Legionella* (?) expressing myelin (Soviet)
Fatal autoimmune disease in guinea pigs

More virulent strain of *B. anthracis* (Soviet)(US?)
B. cereus gene for lipase expressed in *B. anthracis*

Defeating mousepox vaccination (Australian)
Entromelia virus expressing IL-4

Synthesis of polio virus de novo (US)

Controlling dangerous pathogens

- **Monitoring and verification protocols: BWC**
Domestic: CDC permits do not cover prior possession
Comprehensive international oversight of work with biological pathogens
Model: Recombinant DNA Advisory Committee?
Protective oversight regime: consequential regulation
Adequate protection against interference with scientific exploration

Poste's list of activities

Stealth viral vectors

Novel genes

Novel proteins

Novel organisms

Host range expansion

Host immune evasion

**Agents that induce immune
hyperresponse**

Recombination: benign X virulent

Latent/triggerable infections

Reviewing and Publishing Research Results

- The new system also would include the review of study results from any experiments of concern that are approved. But the issue of whether these results should be published needs to be resolved within the scientific community – *not by government policy*, the committee emphasized.

Restrictions on release of information

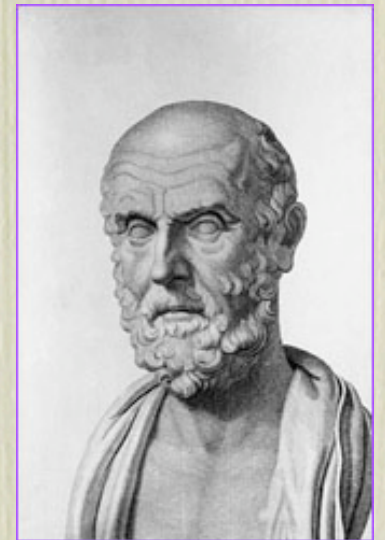
- **Mousepox/IL-4 case: should these data not have been published?
Who reviews and decides?
How can lack of publications be compensated?**

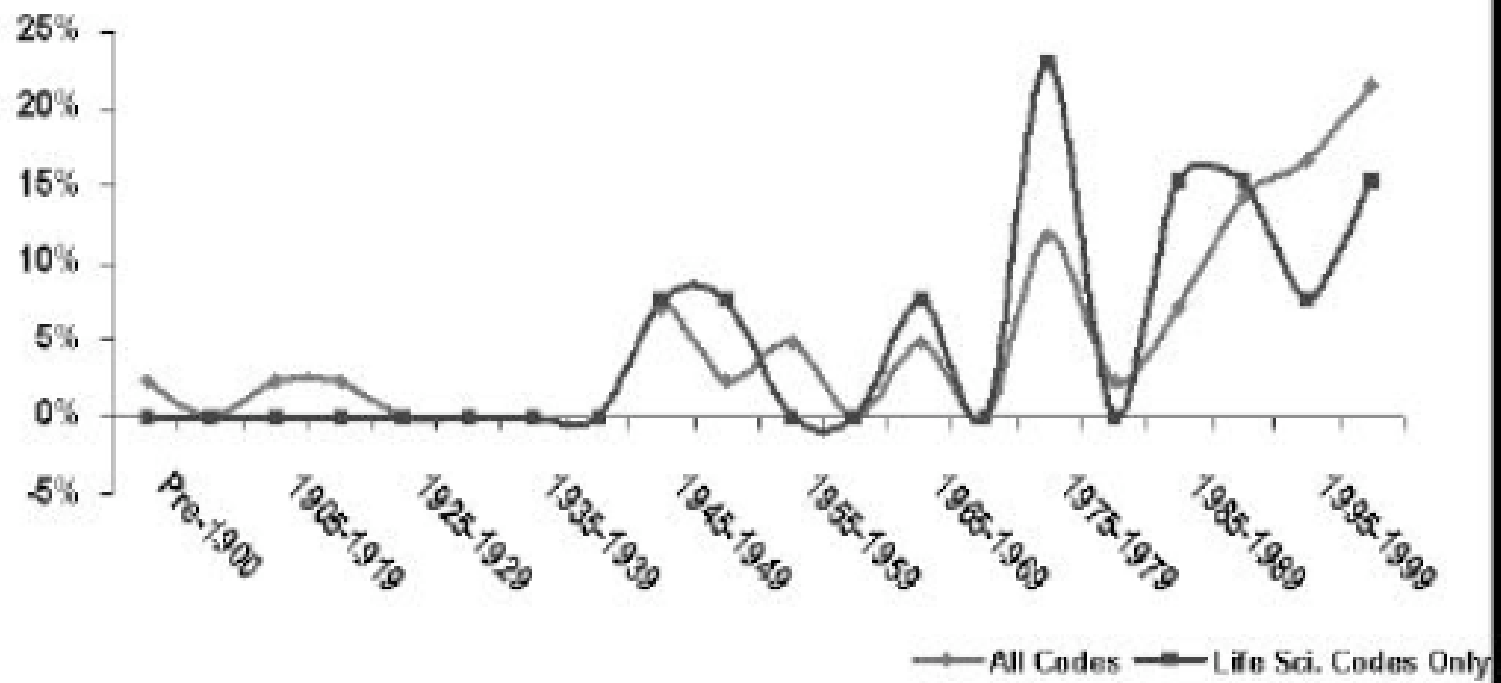


CODES OF
CONDUCT
AND
WHISTLEBLOWER
PROTECTION

Codes of Conduct: history

- XIX: Codes within professions (medicine, law)
- Hippocratic Oath
- 1948 Physician's Oath: World Medical Association
- Nuremberg Code (post WWII)
- Helsinki Declaration 1964
- IRBs in various countries





From the US document submitted at the June 2005 Meeting of Experts

- **...[U]nless some principles of conduct are established for the men and women who manipulate the materials of nature, anarchy will develop, and with anarchy, disaster.”**

-

- **New Scientist, editorial “Wanted - Code of Conduct” (1968)**

-

-

BW-related Codes, pre-2000

- **ASM 1985: 'discourage any use of microbiology contrary to the welfare of humankind'**
- **CRG 1989: pledge for scientists not to participate knowingly 'in research and teaching that will further the development of chemical and biological agents'.**
- **Student Pugwash 1990: promote ethical reflection. It included the promise that individuals 'will consider the ethical implications' of their work.**
- **Pugwash: Joseph Rotblat furthered a call for a type of Hippocratic Oath for scientists.**

Codes, pre-2000

- International Network of Engineers and Scientists for Global Responsibility (INES)
- BMA 1999: Professional scientists and physicians have an ethical responsibility to reinforce the central norm that biological and genetic weapons are unacceptable.
- Scientists' and Engineers' Pledge to Renounce Weapons of Mass Destruction. (Los Alamos Study Group, the Natural Resources Defense Council, Tri-Valley CAREs, and Western States Legal Foundation)



ICRC

“The responsibility to prevent hostile uses of biotechnology lies with each State.

But it extends beyond governments to all persons, especially to military, scientific and medical professionals and those in the biotechnology and pharmaceutical industries”.

ICRC: Biotechnology, weapons and humanity: an informal meeting of government and independent experts, Montreux, Switzerland, 23-24 September 2002.)

2002, continued

- **UN General Assembly and Security Council** endorsed recommendation that codes of conduct be established across those areas of research relevant to weapons of mass destruction.
- **Joint Code of Conduct statement for Biodefense Programs and the Council for Responsible Genetics** ‘Call for a Ban on the Genetic Alteration of Pathogens for Destructive Purposes’.
- **Tibor Toth/BWTC series of “Meetings of Experts”** In 2005, the topic for the meeting will be ‘The content, promulgation, and adoption of codes of conduct for scientists’.
- **The 18th Workshop of the Pugwash Study Group on the Implementation of the Chemical and Biological Weapons Conventions**

Codes 2003

- **Policy Working Group on the United Nations and Terrorism, a UN Inter-Agency Consultative Meeting**
- **British Society for General Microbiology issued a Policy on Scientific Publication, Security and Censorship.**
- **Wellcome Trust stated a code could play an important role the self-governance of the international scientific community by making it 'aware of potential risks and concerns relating to terrorist misuse of research, and of the regulatory and ethical responsibilities that they hold.'**
- **The UK House of Commons Science and Technology Committee urged British learned societies and funding councils to 'consider introducing an overt ethical code of conduct' linked to professional membership analogous to the Hippocratic Oath.**

Codes, 2003

- Statement on Health Security, members of the **Asia-Pacific Economic Cooperation** agreed to 'establish an effective code of domestic ethical and operational conduct for bio-scientists or promote such codes where they already exist'.
- the **UNESCO's** World Commission on the Ethics of Scientific Knowledge and Technology (COMEST)
- **National Research Council** report Biotechnology Research in an Age of Terrorism

Codes, 2004

- **US National Science Advisory Board for Biosecurity (NSABB) include developing 'Professional codes of conduct for scientists and laboratory workers that can be adopted by professional organizations**
- **International Physicians for the Prevention of Nuclear War lent its support to establishing 'a code of ethics ... guided by the Precautionary Principle.'**
- **The United Nations Security Council adopted Resolution 1540 in April that called for states to develop 'appropriate ways to work with and inform industry and the public regarding their obligations under' international WMD-related laws.**

Interacademy Panel (IP)

- awareness
- safety and security
- education and information
- accountability
- oversight

2004

- Royal Society “Do no harm”
- Tucker (Monterey Institute of International Studies): all researchers funded in the biodefense program be required to sign a code of ‘required to sign a code of conduct, similar to the Hippocratic oath, that precludes them from deliberately developing agents with enhanced pathogenicity or other harmful properties and requires them to report any deviations from this norm’.
- ICRC, Pax and Sunshine Project

Codes 2005

- **New Defence Agenda's** Bioterrorism Reporting Group encouraged 'ethical codes of conduct for scientists working in sensitive bio-technologies sectors'.
- Atlas and Somerville's paper in Science
- "International Forum on Biosecurity", a member of the International Council for Science called for the implementation of existing and new codes of practice.

Codes, 2005

- In April, the International Institute for Strategic Studies (IISS) and the Chemical and Biological Arms Control Institute launched the charter-based International Council for the Life Sciences.
- In May, the UK Council for Science and Technology launched a consultation on its Rigour, Respect, and Responsibility: A Universal Code of Conduct for Scientists, which though not specifically covering biological weapons may play an important role for British government scientists.
- June 2005 BTWC Meeting of Experts

Codes, 2005

- International Union of Microbiological Societies
- June 30-July 1, the US National Science Advisory Board for Biosecurity
- September 2005 the UK Biotechnology and Biological Sciences Research Council, the UK Medical Research Council and the Wellcome Trust published a joint policy statement on managing risks of misuse associated with grant funding activities
- University of Virginia Tech Biosecurity Summit held in May.
- November issue of Nature, a leading scientist in the field of synthetic biology called for a code of ethics for bioengineering
- IAP-BWTC meeting of experts

DoD's Code

- **A DoD Code of Conduct?**
 - **DoD is committed to the legal, ethical, and appropriate operation of its biological defense research and development activities**
 - **DoD believes that it has important elements of a code already in place through regulations**
 - **DoD will continue to examine ways to improve its biosafety and biosecurity programs – possibly with improvement to training modules related to ethical practices in biological research and development**
 - **DoD takes its commitment to the BWC seriously and constantly examines its programs and activities to ensure optimal compliance**
- **Seattle workshop, May 17-18, 2005**

From: **Meeting of Experts Geneva, 13-24 June 2005: Documents submitted by the United States, not edited.**

DHS's Codes

- **Codes of Conduct**

DHS takes its BWC obligations seriously and will ensure that its programs fully comply with the BWC and related statutes.

- **Programs are vetted in a rigorous Department-level compliance review and are consistent with U.S. laws and policies pertaining to biological research. U.S. laws, regulations, guidelines, and DHS agency procedures contain ethical guidelines for our day-to-day activities.**

- **DHS is developing a training module for researchers that focuses on ethical imperatives.**

DHS continually examines ways to improve its biological research, safety, and security training, and welcomes the opportunity to participate in discussions on codes of conduct.

From: Meeting of Experts Geneva, 13-24 June 2005: Documents submitted by the United States, not edited.

Article VI.1 of the BWTC

Any State Party to this Convention which finds that any other State Party is acting in breach of obligations deriving from the provisions of the Convention may lodge a complaint with the Security Council of the United Nations. Such a complaint should include all possible evidence confirming its validity, as well as a request for its consideration by the Security Council.

**Whistleblowing and disclosure:
protection of the concerned
citizen-scientist**

Whistleblower: “a person who tells someone in authority about something illegal that is happening, especially in a government department or a company.”

Cambridge International Dictionary of English

Whistleblower: An employee who refuses to engage in and/or reports illegal or wrongful activities of his employer or fellow employees.

Black's Law Dictionary

National whistleblower protection legislation

UK:

The Public Interest Disclosure Act of 1998

Australia:

1996: five acts in different states, inconsistent approaches

US:

**The False Claims Act (qui tam)
Sarbanes Oxley Act**

Nigeria: Independent and Corrupt Practices Commission

HongKong: Political and Economic Risk Consultancy

Transparency International

TI is an international coalition concerned with combating corruption as part of the larger struggle against misconduct and misappropriation.

In a report published in March 2005,

- **whistleblower protection needs substantial improvement: Argentina, Australia, Canada, Czech Republic, Denmark, Germany, Italy, Mexico, the Netherlands, Norway, Poland, Spain, Sweden and Switzerland.**
- **whistleblower protection may need to be strengthened: Belgium, Finland, France, Greece, Japan, Korea, New Zealand, Slovak Republic and the UK.**

National Whistleblower Center



The National Whistleblower Center (Center) is a nonprofit, tax exempt, educational and advocacy organization dedicated to helping whistleblowers. Since 1988, the Center has used whistleblowers' disclosures to improve environmental protection, nuclear safety, and government and corporate accountability.

Other Protection Agencies

- EU Ombudsman
- International Agency Corruption conference
- Office of Research Integrity
- False Claims Act Resource Center
- Public Concern at Work (UK Public Interest Disclosure Act)
- Mainstreaming ethics in the African Public Service (Addis Ababa, UNECA, 2005)

ICRC:



“Voicing concern”

Those working in life sciences who voice concern and take responsible action require and deserve political and professional support and protection.

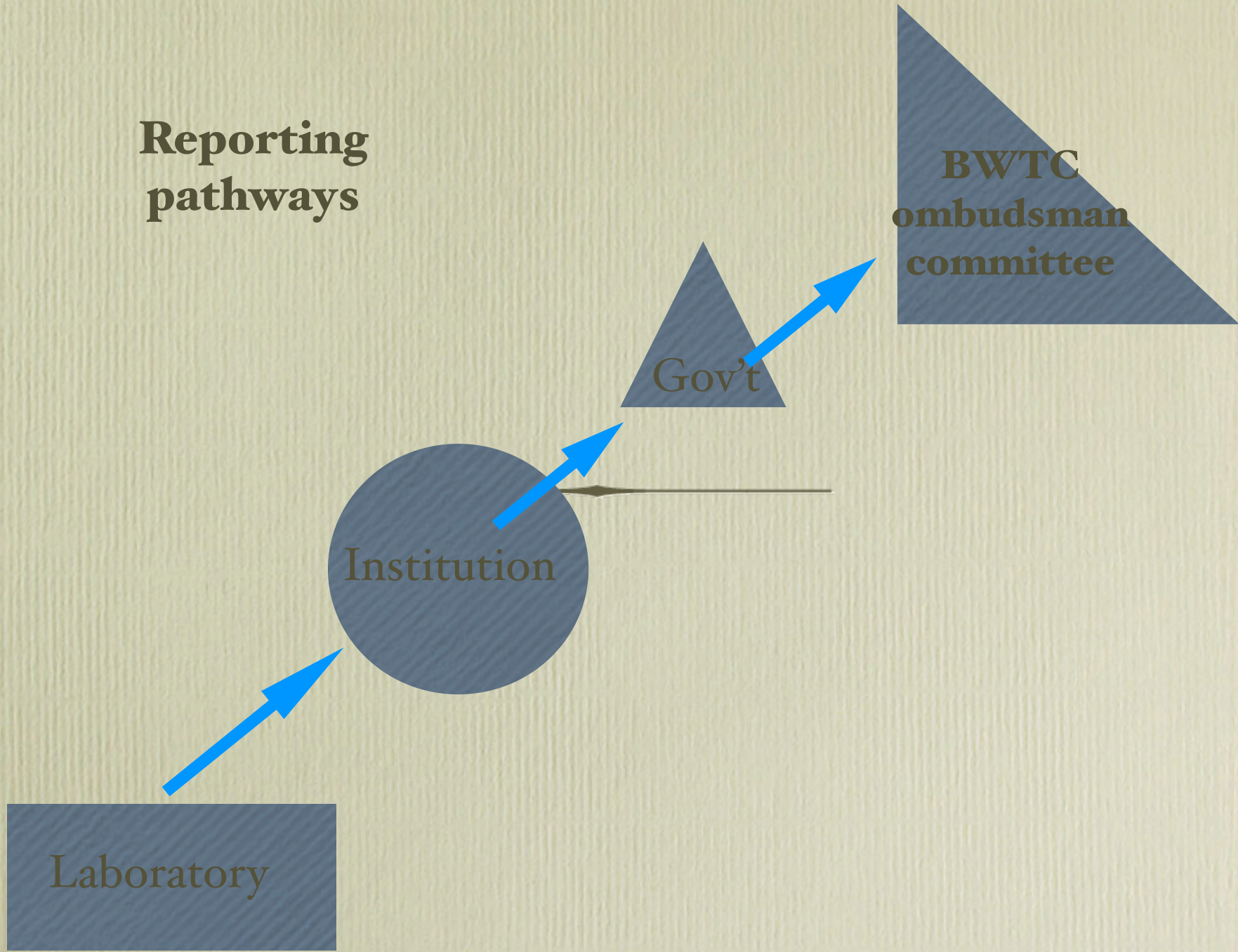
Action points:

- Encourage people who work in the life sciences to voice concern about issues relating to poisoning and the deliberate spread of infectious disease.**
- Ensure that adequate mechanisms exist for voicing such concerns without fear of retribution.**

First, what are the possible events or situations that might lead a responsible individual to make the decision to report an activity?

- 1. lack of biosafety compliance**
- 2. lack of security compliance**
- 3. experimental procedures that lead or might lead to the generation of dangerous strains or toxins ("the seven experiments of concern")**
 - How to make vaccine ineffective
 - Alter host range of pathogen
 - Enhance virulence of pathogen
 - Confer resistance to useful antibiotics & antivirals
- 4. use of science in ways that might contravene BWTC**

Reporting pathways



Institution

Gov't

BWTC
ombudsman
committee

Laboratory



What can the
European Ombudsman
do for you?



*The European Ombudsman
A guide for citizens
EN*

EU Ombudsman: Nikiforos Diamandouros elected April 2003



The European Ombudsman

COMPLAINT ABOUT MALADMINISTRATION

[Please continue on a separate sheet if necessary and enclose all the documents necessary to support your complaint.]

- From (name):
On behalf of:
Full postal address (including postcode and country):

Tel:
Fax:
E-mail:
- Against which European Union institution or body do you wish to complain ?

<input type="checkbox"/> The European Commission	<input type="checkbox"/> The Committee of the Regions of the European Union
<input type="checkbox"/> The Council of the European Union	<input type="checkbox"/> The European Central Bank
<input type="checkbox"/> The European Parliament	<input type="checkbox"/> The European Investment Bank
<input type="checkbox"/> The European Court of Auditors	<input type="checkbox"/> The European Personnel Selection Office
<input type="checkbox"/> The Court of Justice of the European Communities*	<input type="checkbox"/> The European Anti-Fraud Office
<input type="checkbox"/> The European Economic and Social Committee	<input type="checkbox"/> Europol
	<input type="checkbox"/> Other Union body (please specify)

*except in its judicial role
- What is the decision or matter about which you complain ? When did it come to your attention ?
- What result do you hope to achieve with your complaint ? What are your claims ?

- Have you already contacted the Union institution or body concerned in order to obtain redress ?

Yes (please specify) No
- If the complaint concerns work relationships with the Union institutions and bodies: have you used all the possibilities for internal administrative requests and complaints provided for in the Staff regulations ? If so, have the time limits for replies by the institutions already expired ?

Yes (please specify) No
- Has the object of your complaint already been settled by a court or is it pending before a court ?

Yes No

Complaints to the European Ombudsman (and any annexed documents) are normally dealt with publicly.

"Dealing publicly" with a complaint means that any member of the public may have access to the complaint and its annexes. If the Ombudsman opens an inquiry, the opinion of the institution or body concerned on the complaint, any observations on the opinion made by the complainant, as well as other documents mentioned in Article 13 of the Implementing Provisions (available on the Ombudsman's Website) are public documents to which any member of the public may have access on request. The Ombudsman's decisions on complaints are published in his Annual Report and on his Website, with the complainant's name removed.

A complainant has the right to request that his or her complaint be dealt with confidentially. If confidentiality is requested, there is no public access to the complaint or to the other documents mentioned above. However, even a confidential complaint must be sent to the Union institution or body concerned, if the Ombudsman begins an inquiry. The Ombudsman's decisions on confidential complaints are published in his Annual Report and on his Website, after the removal of any information which could lead to the identification of the complainant.

Complaints to the Ombudsman may contain personal data relating to the complainant, or to a third party. The processing of personal data by the European Ombudsman is governed by Regulation (EC) N° 45/2001.⁽¹⁾ Unless the complainant requests confidentiality, he or she is understood to consent for the purposes of Article 5 (d) of Regulation (EC) N° 45/2001 to the Ombudsman dealing publicly with any personal data which the complaint may contain.

⁽¹⁾ Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data. Official Journal L 8/1, 12/01/2001.

- Please select **one** of the following two options:

Please treat my complaint publicly
 I require that my complaint be treated confidentially
- Do you agree that your complaint may be passed on to another authority (European or national), if the European Ombudsman decides that he is not entitled to deal with it ?

Yes No

Date and signature:

Establish a mechanism for whistleblower protection in the context of the BWTC

Oversight Committee:

- a. anonymous reporting (as opposed to confidentiality)**
- b. legal advice: lack of consistency among States Parties**
- c. avenues of protection for disclosure**

Ombudsman: ombudsman is an official charged investigating and addressing complaints reported by individual citizens.