



Ethical research guidelines for wastewater-based epidemiology and related fields

Version 1.0

2015

Ethical research guidelines for sewage epidemiology

Developed jointly by the University of Tasmania, the University of Queensland, Mario Negri, the University of Amsterdam, Universidad Jaume, Saarland University, Universiteit Antwerpen, Imperial College London, Leuphana Universität, the University of Applied Sciences, the Norwegian Institute for Water Research, and the University of Bath.

Endorsed March 2016

Contributing authors

Jeremy Prichard, Wayne Hall, Ettore Zuccato, Pim De Voogt, Nick Voulvoulis, Klaus Kummerer, Barbara Kasprzyk-Hordern, Angelo Barbato, Alberto Parabiagli, Barbara Kasprzyk-Hordern, Felix Hernandez, Janelle van Wel, Kevin V Thomas, Karl Fent, Marie Mardal & Sara Castiglioni.

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1.0 Purpose and scope of this document

This document provides guidelines for researchers in a new field that applies analytical chemistry techniques to analyse samples of sewage water. The field is variously called 'wastewater-based epidemiology' (WBE)*, 'wastewater analysis', 'sewage-based epidemiology', and 'sewage epidemiology'. WBE is used for a wide variety of purposes that include estimating:

- Rates of consumption of illicit drugs, alcohol, tobacco, licit pharmaceuticals and foodstuffs;
- Human exposure to pollutants.

Where illicit substances are concerned, studies have been conducted on major drug types, including cannabis, cocaine, heroin and other opioids, and amphetamine-type stimulants. While most studies have concentrated on mapping population drug consumption, several studies have applied WBE in specific settings with small catchment areas, such as prisons, hospitals, schools and workplaces. This emerging field has attracted multiple research teams in Europe, North America and Australia and its broad, interdisciplinary focus means that disciplines contributing to this research include chemistry, biology, mathematics, economics, engineering, epidemiology, forensic sciences, social science, law and criminology.

To date there has been little oversight by research ethics committees because WBE data are not collected on individuals. Only one human research ethics committee has required review of a WBE drug study and it approved the study as low-risk. Other human research ethics committees have declined to review WBE studies on the grounds that they raise no ethical issues. It is reassuring that human research ethics committees have concluded that WBE studies involve very low ethical risks. But some level of caution is required in the absence of supervision by ethics committees.

These ethical guidelines were developed by researchers in Europe and Australia and they abide by internationally recognised ethical principles.¹

Guidelines will assist to promote an ethical research culture among WBE teams and scholars involved in the publication process. An ethical research culture will maximise ethical practice, minimise risks for vulnerable people and other groups, and help to maintain the good reputation of the field. These guidelines are designed to be interdisciplinary and reflect as much as possible the international characteristics of this

¹ E.g. as expressed in Australia's *National Statement for Ethical Conduct in Human Research*; <https://www.nhmrc.gov.au/guidelines-publications/e72>

* WBE is now the agreed term for the field.

field of research. The guidelines also aim to promote ethical research (including in publication processes) with minimal detail and restrictions.²

The objective of these guidelines is to outline the main potential ethical risks for WBE research and to propose strategies to mitigate those risks. Mitigating risks means reducing the likelihood of negative events and/or minimising the consequences of negative events.

Like other ethical documents, these WBE guidelines provide principles and approaches that should be adaptable to most situations encountered by researchers. It is beyond the scope of these guidelines to provide an exhaustive list of all potential risks, covering all possible scenarios in different countries. See further 2.1, below.

The WBE ethical guidelines will be ‘living’, meaning they can be updated periodically. This is a very important point. It enables the WBE field to adapt the guidelines – for instance because the field develops in new ways, or because WBE researchers identify new ethical risks or beneficial mitigation strategies (see below, 2.3 Revision of these guidelines).

2.0 Governance

2.1 Responsibilities of researchers and institutions

As ethical *guidelines* only, this document is non-binding. However, these guidelines should be viewed in the wider context of research governance. WBE researchers should consider these guidelines *in combination with laws and regulations of their country, and, protocols stipulated by their university or place of employment*. WBE researchers in different institutions and in different countries will find details of research ethics and protocols that are not contained in these guidelines, eg protocols relating to how long data needs to be retained and when it needs to be destroyed.

² The idea for these guidelines arose from the EMCDDA Testing the Waters Conference, Portugal May 2013, and a subsequent publication in *Science and the Total Environment* 472 (2014) 550-555.

The broad ethics landscape is summarised in the following extract. It underscores the responsibility of individual researchers and their institutions:

Responsibility for the ethical design, review and conduct of human research is in fact exercised at many levels, by: researchers (and where relevant their supervisors); [human research ethics committees] and others conducting ethical review of research; institutions that set up the processes of ethical review, and whose employees, resources and facilities are involved in research; funding organizations; agencies that set standards; and governments. *While the processes of ethical review are important in this field, individual researchers and the institutions within which they work hold primary responsibility for seeing that their research is ethically acceptable.*³ [emphasis added]

One implication of this responsibility is that WBE researchers ought not to assume that external requests, for example those coming from law enforcement agencies, necessarily satisfy principles of ethical research.

2.2 Reference to these guidelines in publications, correspondence with journals & in ethics applications

WBE researchers may choose to refer to these guidelines in their publications, indicating that principles and risk mitigation strategies were adopted or adhered to. The guidelines may also be used in correspondence with journal editor regarding appropriate publication processes (eg for protecting anonymity). WBE researchers who are applying for ethics approval from human research ethics committees (eg in their universities or research institutions) ought to reference these guidelines within their application.

2.3 Revision of these guidelines

These guidelines will be housed on the website of *COST – European Cooperation in Science and Technology* (www.cost.eu), which is supported by the *EU Framework Horizon Program 2020*. The authors of these guidelines will revise the guidelines as deemed necessary. WBE researchers are encouraged to suggest revisions to the guidelines by emailing Professor Ettore Zuccato ettore.zuccato@marionegri.it, Professor Pim de Voogt W.P.deVoogt@uva.nl, Professor Wayne Hall w.hall@uq.edu.au or Dr Jeremy Prichard jeremy.prichard@utas.edu.au.

³ NHMRC (2007). National Statement on Ethical Conduct in Human Research. Canberra: Australian National Health and Medical Research Council: 4.

2.4 Promulgation of these guidelines

These guidelines are, in a sense, the product of the WBE field and they belong to the WBE field. Their usefulness and effectiveness depends on the support of WBE researchers globally. WBE researchers are encouraged to promulgate these guidelines in the best ways they see fit. For example, the guideline's URL could be:

- Displayed on research websites, or on WBE researchers' personal web pages
- Listed in academic publications
- Given to early career academics and postgraduate students
- Provided to human research ethics committees in universities or other institutions.

3.0 Ethical context

In human research fields the term "participant" applies to any individual who chooses to be involved in a study as well as individuals whose data are used to conduct research. In some circumstances it is feasible that legal entities, such as corporations, may be research participants. Research is to be cognisant of:

- potential harms to participants and non-participants (including emotional and economic harm)
- respecting participants' autonomy
- potential benefits for participants and society.

Three recurrent ethical concerns in human research are ensuring participants provide informed consent, specifying the circumstances in which de-identified data may be used without participants' consent, and protecting the confidentiality of sensitive information. In most WBE drug research the impingement on participants' autonomy is minimal, the participants are at low risk of harm and, broadly, WBE research aims to benefit society. However, the potential risk of harm may be heightened in certain situations, as discussed below. While attention to date has focussed particularly upon WBE and illicit drug use, new and emerging ethical issues are likely to arise from WBE data on health and disease as well as indicators of pollution.⁴

⁴ In the unlikely event that SE researchers were interested in studying samples flowing from private residences without the consent of the occupants, a full research ethics application will almost certainly be required from a registered human research ethics committee. See further *2.1 Responsibilities of researchers and institutions*.

3.1. Risks arising from general population studies

While the media play an important part in democratic societies, in our view erroneous or sensationalised media communication may:

- result in minor emotional harms for vulnerable groups, such as shame or embarrassment (e.g. through reporting drug consumption in a suburb or district with high levels of social disadvantage);
- amplify stigmatization and labelling of vulnerable groups, influencing how they are treated by society and the state;
- generate political incentives to ‘get tough’ on drug use and crime, displacing more effective policing strategies and bringing more drug users into the criminal justice system.

Local councils or regional authorities, companies, industry and other legal entities could foreseeably be economically harmed through similar sorts of miscommunications of WBE results. For example, sensationalised reporting of drug consumption at a regional tourist event attended by young people could result in economic loss for the region. In a similar fashion, event organisers of music festivals may be economically harmed through miscommunications of WBE data.

Sampling from a sewage treatment plant (STP) without the consent of relevant authorities may constitute an offence (eg trespass) or a breach of regulation. This may affect the reputation of the WBE field and affect the willingness of authorities to support or collaborate with WBE researchers.

3.2. Risks arising from site specific studies (e.g. prisons, schools, hospitals & workplaces)

Site-specific WBE research has good potential to benefit *participants* and the community. However, in the prison setting potential risks include:

- the introduction of austere anti-drug strategies by prison authorities (e.g. eliminating contact visits for inmates’ families) in reaction to WBE data on drug consumption. It may be legitimate for authorities to use such measures. However, if the measures are triggered by WBE research, and if these measures cause harm (even emotional distress), then the WBE study may have inadvertently breached ethical standards by causing harm to participants who *did not provide consent*.
- stigmatisation of inmates, ex-inmates and their families. Mismanagement of WBE research findings may lead to media reports on prison drug consumption that embarrass inmates or contribute to negative community sentiments about the rehabilitation and reintegration of ex-prisoners back into society.

In studies of schools and workplaces apparent risks are:

- stigmatisation and labelling through media reporting for children, parents, teachers and workers of specific schools and workers at other workplaces;

- adverse effects for the reputation of a school or workplace;
- economic harm for workplaces;
- the introduction of austere or unfair working conditions.

Other negative outcomes might occur if particular buildings or workplaces (eg hospitals) if they are erroneously identified as causing environmental damage or pollution.

Clearly sampling from a particular building (eg prison, school, workplace, hospital, music festival etc) without consent may be an offence or a regulatory breach. Either situation may affect the reputation of the WBE field and affect the willingness of authorities to support or collaborate with WBE researchers.

4.0 Mitigation strategies

4.1 Research planning

Anonymising data. By considering the issues raised in these guidelines, WBE teams may be able to adopt simple strategies that mitigate risk and that are tailored to their specific social and cultural circumstances. For example, mixing samples obtained from multiple sites may ensure that only aggregate data can be reported (e.g. thereby hiding the results of a particular suburb, workplace or school). Or it may be feasible to simply omit the name and location where the research was conducted. It is not suggested that these become standard practices for the WBE field – only that they may be considered necessary in some circumstances.

Plans for effective communication of research outcomes to media. Research planning should entail some consideration of how findings might be interpreted within the socio-political context of the study. Attention needs to be given to how media outlets might misrepresent findings and how policy makers may feel they have to respond. Research planning may include deciding how results may be clearly and concisely communicated to the media and in a way that convinces media outlets to highlight the benefits of the research instead of blaming the behaviours of participants.

Seeking approval of a human research ethics committee (HREC). Consistent with section 2.1 *Responsibilities of researchers and institutions*, above, WBE researchers hold responsibility for determining whether they are required by their university or workplace to seek HREC approval for their planned studies. Typically HREC are happy to respond to queries about the need for ethics approval. (Some HREC have automated online ‘ethics checkers’.) In some cases, even if ethics approval is required, the process will be relatively simple (eg for ‘minimal risk applications’).

The likelihood that WBE researchers will need HREC ethics approval increases for all site-specific studies (eg prisons, schools, workplaces, hospitals, music festivals etc). In

addition, the HREC in each country will know of particular laws and regulations that apply to certain groups of people. For example, regulations in some countries (but not others) may require that WBE researchers secure the consent of the parents of school children before they undertake a school-focused study.

It is worth highlighting that approval from a HREC may have strategic benefit for WBE researchers. In addition to peace of mind for the research team, the ethics approval may be useful in establishing relationships with stakeholders because it demonstrates the preparedness of the WBE team. The process of seeking for ethics approval is also an effective way to plan aspects of research projects and to develop procedures tailored to specific contexts. See further below regarding using HREC approval to manage stakeholder expectations (section 4.2).

4.2 Identifying and managing stakeholders

General population studies. Care needs to be taken in studies of the general population to seek approvals from ‘relevant authorities’ that own, control or operate STPs or related facilities. Failing to do so may constitute an offence or a breach of a regulation (see further 3.1), or may bring the field into disrepute. When seeking consent, WBE researchers should disclose the nature and purpose of the analyses. In other words, when authorities consider providing consent they should be given enough information to understand whether the study concerns illicit drugs use, health, the environment or a combination of these things.

Caution is necessary if WBE researchers are approached by agencies to conduct analyses (eg in a certain area). It is important to verify whether the agency making the request is in fact a ‘relevant authority’. If not, in most cases no analyses should be conducted until approval is granted from a relevant authority.

Site-specific studies (prisons, schools etc). Clearly the same principles apply to studies of prisons, schools, workplaces, hospitals and so forth. However, in these contexts the guidelines recommend that consent should be sought from the relevant stakeholder (eg prison director, school principal) *regardless of whether the agency has any control over the STP or related facility.* (For example, some STPs that service prison complexes are completely external to the prison building and are operated by different authorities. It could also be the case that sewage leading from a particular building, like a school or workplace, can be lawfully accessed at a point outside of the building property.⁵)

⁵ Eg see analyses of Australian property law and sewage facilities in Griggs, L, Henning, T & Prichard, J, (2012) ‘Does the Despoiler of Water Have a Proprietary Right in the Commingled Product? Implications for Property Law and Criminal Procedure’, *Monash University Law Review*, 38(3) pp. 35-54.

Understanding stakeholders. Before embarking on collaborative research with a stakeholder like a prison, school, or workplace, it is advised that WBE researchers seek to understand the stakeholder's ethical practices. For example, if research is to be conducted at a workplace, does that workplace have a history of treating its employees fairly, or has it demonstrated a willingness to treat its workforce harshly (e.g. by sacking employees, docking pay, or setting difficult work requirements). Where prisons are concerned, a careful assessment of prison drug policies would be wise. This point is particularly pertinent if WBE research teams are invited to do research in countries with poor respect for prisoners' human rights. Of course WBE researchers cannot control the behaviour of stakeholders. However, they may be able to *mitigate* risks by avoiding collaborations with stakeholders who, on available advice or evidence, appear unlikely to respect the ethical boundaries of the WBE researchers.

WBE researchers will have to determine as best they can how to assess a stakeholder's practices on a case-by-case basis. However, the following suggestions may be useful:

- use a search engine to source public criticism of a stakeholder (eg by human rights agencies, child protection agencies, ombudsman, or lawyers) or formal findings of misconduct (eg anti-discrimination authorities or workplace tribunals)
- read an agency's mission statement or annual reports
- conduct preliminary meetings with an agency
- ask researchers from other disciplines who may know about an agency's reputation and ethical practices.

In early discussions with stakeholders, WBE researchers ought to explain the ethical boundaries to which they must adhere. Researchers may find that HREC oversight is strategically useful in managing stakeholders' expectations. This is because the WBE researchers can state that the research depends on non-negotiable ethical protocols being followed and that breaches of protocols may bring an end to the study – a decision which would be made by a third party (the HREC).

4.3 Adopting media communication protocols

As noted earlier, a key focus of planning WBE research would be to ensure the anonymity of regions where special sensitivities may apply, such as marginalised residential districts, prisons, schools and workplaces. All members of a WBE team should be made aware of communication protocols, such as those relating to research publications, non-academic publications, public forums, and interaction with the media. Although 'media communication protocols' may sound complex, in most instances they will simply involve deciding:

- what cannot be communicated (eg information that gives away the identity of a suburb or a prison); and / or
- who in a WBE team is the media contact person.

Media communication protocols may be critical even where WBE researchers' only public output is in academic publications. In other words, risks do not only arise when WBE researchers directly engage with the media (eg through radio, television or print).

Boundaries between scholars' private communications and their research is normally uncontentious. However, in some circumstances WBE researchers may need to be wary about commenting about sensitive research-related issues on social media (eg Twitter, Facebook, Netlog). This is because these forums can be open to the general public and consequently comments from particular researchers can legitimately be reported by media outlets.

4.4 Protecting anonymity through the scientific publication process

The WBE publication process should retain scientific rigour while protecting the anonymity of disadvantaged suburbs, prisons, schools and so forth. In discussions with WBE authors, journal editors and peer reviewers should be amenable to devising practical systems of protecting anonymity in publications – not as standard practice for WBE research but only when the systems are deemed necessary because of the ethical context. It may be that WBE authors propose such systems. On the other hand, editors or peer reviewers may be the first to detect genuine ethical risks. In this way the publication process can provide an important service to WBE scholars. Where journal editors are unfamiliar with WBE research, scholars in this field may help to raise awareness of the ethical issues by giving editors copies of these guidelines.

Without limiting other potential strategies, it is feasible that data could be provided to peer reviewers that is not included in a publication. For example, in WBE publications it is typical to report the estimated population size of the catchment studied. Yet, in some circumstances such information could be used to identify a vulnerable region or group that the researchers would prefer remained unidentified. In these scenarios all data

could be scrutinized through the peer review process. However, in the resulting publication the risk of identifying the site could be minimised by only reporting population rates (e.g. per 100,000 people). After publication, any WBE scholars who wished to see the complete population estimates could contact the authors. This would dramatically reduce any risk that the scientific report was misinterpreted or misused by media sources.

5.0 Useful sources and other materials

- World Medical Association, *Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects*
<http://www.wma.net/en/30publications/10policies/b3/>
- Australian Government, National Health and Medical Research Council, *National Statement on Ethical Conduct in Human Research (2007) - Updated May 2015* <https://www.nhmrc.gov.au/book/national-statement-ethical-conduct-human-research>