PUBLIC CONSULTATION FOR MANAGING UNSOLICITED COMMERCIAL MESSAGES AND THE PROVISION OF GUIDANCE TO SUPPORT INNOVATION IN THE DIGITAL ECONOMY

Submitted by

***Science, Health and Policy-relevant Ethics in Singapore* (SHAPES),**

on behalf of the Centre for Biomedical Ethics, NUS

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The clarifications we seek relate to exceptions for the requirement to obtain consent, as per your request for feedback in:

PART IV: SECOND, THIRD AND FOURTH SCHEDULES TO THE PDPA

9. Solicitation of feedback on exceptions to consent

Our submission relates to exceptions for the requirement to seek and obtain consent primarily in the research context. Please note that we also take this opportunity to seek clarifications around consent waivers as discussed in the Human Biomedical Research Act (HBRA) to ascertain if the two Acts differ in their treatment of the same issue. In total, we ask you to consider four issues (A-D) below:

A. We seek clarification on the intended meaning of:

Paragraph 2(c) of the THIRD SCHEDULE on USE OF PERSONAL DATA WITHOUT CONSENT

and

Paragraph 4(c) of the FOURTH SCHEDULE on DISCLOSURE OF PERSONAL DATA WITHOUT CONSENT.

Below we have extracted the points of concern from Paragraph 2(c) of the THIRD SCHEDULE of USE OF PERSONAL DATA WITHOUT CONSENT for illustrative purposes. Please note that we have bolded the wording for emphasis. The bolded and underlined sections are the issue we wish to query.

This same query also applies to Paragraph 4(c) of the FOURTH SCHEDULE on DISCLOSURE OF PERSONAL DATA WITHOUT CONSENT.

> 1. An organisation may use personal data about an individual **without the consent**
>
> of the individual in any of the following circumstances:
>
> (i) subject to the conditions in paragraph 2, **the personal data is used for a**
>
> **research purpose**, including historical or statistical research;
>
> 2. Paragraph **1(i) <u>shall not</u> apply <u>unless</u>**
>
> **(c) the personal data <u>will not be used</u> to contact persons to ask them to**
>
> **participate in the research**;

The conjunction *unless* is used to connect two sentences. The first of these sentences always has a verb in the negative (i.e. "paragraph 1(i) shall not apply…") and the second of these sentences, following the conjunction *unless*, <u>always</u> has a verb in the affirmative. The resultant meaning conveyed is: *A will happen only if B happens*.

Paragraph 2(c) of the THIRD SCHEDULE of USE OF PERSONAL DATA WITHOUT CONSENT and Paragraph 4(c) of the FOURTH SCHEDULE on DISCLOSURE OF PERSONAL DATA WITHOUT CONSENT follow the conjunction *unless* but contain a verb in the negative. This results in possible misinterpretation.

As a result of this grammatical oversight, it is not clear whether personal data **can** be disclosed and used without consent to contact persons to ask them to participate in the research or whether personal data **cannot** be disclosed and used without consent to contact persons to ask them to participate in the research.

To further clarify the concerns raised by the current articulation of these paragraphs, we provide examples below:

1. Is it permissible for researchers working at a hospital to use patient contact details to contact patients for the purpose of inviting them into a study, if the patients did not previously give explicit consent to be contacted for research, but did give consent to be contacted for clinical purposes?
2. What if the researcher is also a member of the clinical team caring for that particular patient?
3. Is it permissible for researchers at a hospital to contact individuals using a database provided by a partner organisation, such as an activity centre, where the partner organisation did not seek explicit consent from the individuals to be contacted to take part in a research study but said that their information would be shared for "data analysis and evaluation" purposes? If it is permissible, what limits, if any, should be applied with respect to that data? Can all the data, including health and financial data, and contact details of family members be shared with the hospital?

Such queries may arise despite one's familiarity with Section 18. Under *Division 2 – Purpose* of the PDPA. We believe that clarification of the point we raise above will greatly increase researchers' ability to comply with the PDPA.

In addition, we note that the SECOND SCHEDULE on the COLLECTION OF PERSONAL DATA WITHOUT CONSENT remains silent on the **collection** of personal data for the purpose of contacting participants for involvement in research.

B. We seek additional clarification on a different point in the same paragraphs:

Paragraph 2(d) of the THIRD SCHEDULE on USE OF PERSONAL DATA WITHOUT CONSENT and Paragraph 4(d) of the FOURTH SCHEDULE on DISCLOSURE OF PERSONAL DATA WITHOUT CONSENT both make reference to "…the benefits to be derived from the linkage are clearly in the public interest." However, guidance on how 'public interest' is to be understood and determined is not provided in the ADVISORY GUIDELINES ON KEY CONCEPTS IN THE PDPA (revised 27 July 2017) or the PRACTICAL GUIDANCE TO QUERIES BY MEDICAL RESEARCH INSTITUTION (where the same statement is repeated but not clarified).

We acknowledge the difficulty in making such determinations but believe that the lack of guidance will ultimately lead to inconsistencies, within and across organisations, in

determining how the benefits to be derived from the non-consensual linkage of data are clearly in the public interest.

For consent waivers, the Human Biomedical Research Act requires that "the human biomedical research or health information research would reasonably be considered to contribute to the greater public good." Does the PDPC view this to be the same standard as "…the benefits to be derived from the linkage are clearly in the public interest."?

C. We suggest the development of a dedicated biomedical research guidance document

In August 2016, the PDPC released a 'Practical Guidance to Queries by a Medical Research Institution," which included very helpful information on how to interpret the 'impracticability' criterion in paragraph 2 of the THIRD SCHEUDLE, as well as the use of 'third-party keys' for anonymization.

This document, however, does not appear in the list of main guidance documents, and is very difficult to access on the PDPC website unless you know exactly where to look. We suggest that this information, in combination with the above points and other issues related to biomedical research, be collated into an omnibus guidance document for the biomedical research sector. It could be supplemented with realistic examples, as are contained in other advisory guidance documents. This would be an invaluable reference point for biomedical researchers, research institutions and IRBs tasked with ensuring privacy protection in biomedical research.

In addition, perhaps more could be done by the PDPC to empower IRBs and research institutions that have supervisory authority over a variety of social sciences research that fall outside the scope of the HBRA.

D. We suggest protection for data made publicly available via a data breach

Paragraphs 1(c) of the SECOND SCHEUDLE, 1(c) of the THIRD SCHEUDLE, and 1(d) of the FOURTH SCHEDULE exempt publicly available data from the consent requirements, and paragraphs 12.57-12.67 of the Advisory Guidelines on Key Concepts in the PDPA provide useful clarifications. However, that language suggests no protection for the use, storage and disclosure of personal data that is unlawfully made public via a data breach (see for example the Ashley Madison breach where very personal information pertaining to individuals engaging in extramarital affairs was publicly posted online). Further use of such data by third parties could embarrass or harm individuals who had a reasonable expectation of data protection safeguards when it was originally provided.

We therefore suggest that the guidance or regulatory language be amended to explicitly prohibit the collection, use and storage of data without consent whose public release was unlawful, even if the group using the data was not involved in the breach itself. This would, for example, prohibit researchers from making use of such data without consent, which would be in line with the ethical norms of privacy and confidentiality that should be respected and enforced.

In fact, it is perhaps useful to also include accidental or mistaken disclosure of personal information in the public domain. While paragraphs 12.52 to 12.67 are practically sensible, an individual should have the ability to remove personal information from further disclosure or use, perhaps through a public notice of some sort that the personal information – now removed from the public domain – should no longer be used by anyone or any entity who has or should have been put on notice of the retraction. This is somewhat linked to the idea of 'the right to be forgotten' in the EU's GDPR, and since local entities may well collect personal data from European sources or about individuals under EU jurisdiction, it should be considered by the PDPC.

Conclusion

We recognise that the main focus of the current PDPC Consultation is on consolidating legislation governing unsolicited messages. Given, however, the PDPC's request for feedback on exceptions to consent, we viewed this as an opportune time to query the issues discussed above. The SHAPES team and other members of the Centre for Biomedical Research are willing to discuss these issues further (including issues beyond the exceptions to consent, as relevant to research) and to provide our expertise in this area of policy development and legislation should this be of assistance to the PDPC.

We thank you very much for the opportunity to contribute to this consultation.