

***Data Sharing
Policy & Management***

Potential ethical issues

Participants and communities

- Autonomy
 - Broad consent
 - Category consent
 - Case-by-case consent
- Privacy, confidentiality and anonymity
- Implications of data release and feedback
- Governance

Ethical review

- Differing approaches to data
 - Destruction following research
 - Maintenance for a set period of time
 - Maintenance indefinitely for internal use
 - Managed open access
 - Open access
- Consent
- Governance
- Protections

Governance

- Governance
 - Open access / curated open access
 - Curation
 - Representation of local populations
 - Roles of committees that review research
 - Data release policies
 - Data access agreements
 - Conditions of access
 - Conditions of use (including commercial use)

Issues in Data Sharing Management

Commentary: data sharing in South East Asia

Louis Grue and colleagues describe their experiences of sharing data in an international research collaboration

Louis Grue *clinical project manager*¹, Sophia Siddiqui *deputy branch chief*², Direk Limmathurotsakul *assistant professor*³, Armaji Kamaludi *country coordinator for SEAICRN-Indonesia*⁴, Muhammad Karyana *chair, INA-RESPOND Indonesia*⁴, Chuen-Yen Lau *medical officer*²

Including data sharing in protocols

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Researchers from different countries may have varying experience and requirements for data sharing. When we were planning to make our data open access, it became apparent that Indonesia had several regulations on data sharing that needed to be considered. Investigators from Thailand and Vietnam had differing ideas and understanding of what, how, and when data should be shared. Some investigators supported sharing the entire dataset in a repository while others preferred to limit it to the data that would be included in the planned manuscripts. Opinions also differed regarding unrestricted access to the data versus monitored and refereed access.

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Although datasets can be held by the principal investigator and disseminated to those who want access, this increases the demands on the investigator long after the study has ended. The websites currently available to house datasets vary in cost (from free to around \$3000 (£2400; €2700) and capabilities. The more expensive options allow the originators of the data to have more control over access. This has clear resource implications.

Investigators must not only determine how data are accessed but also the duration for which the data will remain available on these sites, and allocate funds. It is also imperative to identify someone from the outset as the custodian of the dataset, especially in a multicentre trial. This person is responsible for posting the data in a useable format, monitoring, answering queries, and maintaining the dataset, all of which require time and resources.

Issues in Data Sharing Management

Informed consent

Even when the published data are deidentified, patients have a right to know how data from their study participation will be used and attitudes towards sharing of data vary. Some will see it as adding value to their study participation⁷ whereas others may view it as an invasion of privacy. They may want their information to be used only for a particular purpose.⁸

Information about plans to share data should be provided to potential participants in the consent. This should cover confidentiality as well as the plan for data storage and data sharing,⁹ including the potential risks.

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Responsibilities of data users

Standard processes for data sharing and acquisition would accelerate progress in developing platforms that facilitate better use of stored data.¹⁰ Currently the burden of open access data sharing is disproportionately placed on the investigators generating the data. It seems appropriate to establish ways to share these responsibilities with those using the dataset. This would help to reduce the anxiety and mistrust that less experienced investigators may have with the idea of open access data sharing and facilitate collaboration.

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Educating investigators about data sharing

As with any new initiative, education is important in the understanding and acceptance of open access data sharing. Investigators with knowledge of the rationale, concerns, and requirements should have access to the tools to educate and inform their collaborators about the concept, its applications, and implementation.

Data Sharing Setup

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A1. Title of the Study in Thai and English

Thai: การพัฒนากระบวนการแบ่งปันข้อมูลวิจัยโดยคำนึงถึงหลักจริยธรรม:

การสำรวจทัศนคติของผู้ที่มีส่วนเกี่ยวข้องในการแบ่งปันข้อมูลในหน่วยวิจัยเวชศาสตร์เขตร้อนขนาดใหญ่

English: Developing ethical data sharing processes: examining the views of stakeholders in a large tropical medicine research unit.

A3. Principal Investigator Name Dr Phaik Yeong Cheah

With permission from PI

Data Sharing Setup

คณะผู้สนับสนุนทุนวิจัยจาก Wellcome Trust มีวิสัยทัศน์ในการที่จะพัฒนาการแบ่งปันข้อมูลวิจัยเพื่อปรับปรุงระบบสาธารณสุข**
ให้ดียิ่งขึ้น โครงการวิจัยชิ้นนี้มุ่งที่จะหาหลักปฏิบัติที่สำคัญของการแบ่งปันข้อมูลอย่างมีจริยธรรมในหน่วยวิจัยเวชศาสตร์เขตร้อน
ขนาดใหญ่ โดยจะดำเนินการวิจัยเชิงประจักษ์ (Empirical Research) ในประเทศไทย อินเดีย เวียดนาม เคนยา และแอฟริกาใต้
เพื่อสำรวจความคิดเห็น และสร้างความเข้าใจอย่างลึกซึ้งในเรื่องของจริยธรรมในการแบ่งปันข้อมูลวิจัย (ethics of data sharing)

ในปัจจุบัน ยังไม่ค่อยมีการศึกษาเกี่ยวกับปัจจัยเสี่ยงที่มีต่อเรื่องจริยธรรมในการพัฒนานโยบายการแบ่งปันข้อมูลมากนัก
จากตัวอย่างของการแบ่งปันข้อมูลในการวิจัยทางพันธุกรรม ปัญหาด้านจริยธรรมได้ถูกค้นพบเป็นอย่างมาก โดยเฉพาะอย่างยิ่ง
ในเรื่องต่างๆดังนี้

- ความเป็นส่วนตัวหรือการเก็บรักษาความลับ (privacy, confidentiality)
- การเก็บข้อมูลจำนวนมากและการนำข้อมูลมาใช้ในอนาคต
- การนำข้อมูลของประชาชนและสมาชิกในครอบครัวของผู้ที่เกี่ยวข้องมาเผยแพร่
- ความจำเป็นที่จะต้องทำให้เกิดความสมดุลระหว่างงานวิจัย และการให้การคุ้มครองกับผู้ที่เกี่ยวข้องต่างๆ

- การพัฒนากลไกการจัดการที่เหมาะสม
- ความไว้วางใจ
- การขอความยินยอม
- หลักแห่งเสรีภาพส่วนบุคคล (autonomy of research)

- การใช้ประโยชน์ทางการค้า (commercialization)
- ความสำคัญทางจริยธรรมของการเก็บรักษาข้อมูลที่ปลอดภัย

ดังนั้นจึงมีความจำเป็นอย่างยิ่งที่จะต้องมียานวิจัยที่จะช่วยนำทางไปสู่การพัฒนาของการแบ่งปันข้อมูลในกลุ่มประเทศดังกล่าว
ให้เกิดประสิทธิภาพ มีจริยธรรม และมีการแบ่งปันข้อมูลอย่างยั่งยืน

Data Sharing Setup

Thai: ประเด็นปัญหาทางจริยธรรมที่เกี่ยวข้องกับการขอความยินยอมอันเนื่องจากการดำเนินนโยบายการแบ่งปันข้อมูล

English: Ethical Challenges related to consent following implementation of a new data sharing policy

A3. Principal Investigator Name: Dr Phaik Yeong Cheah

With permission from PI

Data Sharing Setup

นับตั้งแต่เดือนมกราคม พ.ศ. 2559 เป็นต้นมา ทางหน่วยวิจัยเวชศาสตร์เขตร้อนมหิดล-ออกซ์ฟอร์ด (MORU) ได้ทำการริเริ่มปรับใช้นโยบายการแบ่งปันข้อมูล โดยได้มีการจัดตั้งคณะกรรมการเพื่อการเข้าถึงข้อมูลขึ้น (Data Access Committee - DAC) เพื่อจัดการและดูแลการเข้าถึงข้อมูลอย่างเป็นระบบและมีประสิทธิภาพ ซึ่งตามแผนนโยบายนี้ รูปแบบชุดข้อมูลการวิจัยจะสามารถเข้าถึงได้ผ่าน 3 กลไกหลักดังต่อไปนี้

1.) ฐานข้อมูลออนไลน์แบบเปิด (Online Open Access)

อาทิเช่น ข้อมูลเสริม (supplementary files) สำหรับวารสารทางวิชาการ ในกลไกนี้ MORU มิได้มีอำนาจในการควบคุมการใช้ข้อมูลในเชิงทฤษฎี เนื่องจากชุดข้อมูลนี้คือฐานข้อมูลที่ได้รับการตีพิมพ์จากทางวารสารวิชาการ

2.) ข้อมูลนำฝากภายนอก ที่มีได้รับการประเมินในแต่ละกรณี (External repository without case-by-case assessment)

ในกลไกนี้ ชุดข้อมูลที่นำส่งต่อผู้รับฝากภายนอกจะได้รับการเข้าถึงโดยผู้ใช้ที่ลงทะเบียนและแสดงความยินยอมตกลงกับเงื่อนไขของทางผู้รับฝากข้อมูล โดย MORU มิได้มีอำนาจควบคุมการใช้ข้อมูลเชิงทฤษฎีของผู้ใช้ที่ลงทะเบียนกับทางผู้รับฝาก ผู้ใช้ข้อมูลจะถูกกำกับโดยเงื่อนไขของหน่วยงานที่รับฝากข้อมูลนั้น

3.) การขออนุมัติจากคณะกรรมการเพื่อการเข้าถึงข้อมูล (Application to the Data Access Committee)

ด้วยกลไกนี้ ผู้ประสงค์ใช้ข้อมูลต้องยื่นแบบฟอร์มคำร้องและลงนามในข้อตกลงการใช้ข้อมูล คำร้องขอใช้ข้อมูลจะได้รับการอนุมัติจากทางคณะกรรมการเป็นรายกรณีโดยพิจารณาจากเงื่อนไขและมาตรฐานที่อ้างอิงตามแบบฟอร์มคำร้อง

Data Sharing Setup

Best Practices for Ethical Sharing of Individual-Level Health Research Data From Low- and Middle-Income Settings

Susan Bull¹, Phaik Yeong Cheah^{1,2}, Spencer Denny³, Irene Jao⁴, Vicki Marsh^{1,4}, Laura Merson⁵, Neena Shah More⁶, Le Nguyen Thanh Nhan⁷, David Osrin⁸, * * Decha Tangseefa⁹, Douglas Wassenaar³, and Michael Parker¹

Core Considerations in Ethical Data Sharing

Taken together, the analyses of the five individual studies suggest four key factors as important considerations in judging whether any particular data-sharing initiative is likely to be an example of good data-sharing practice and likely to command support in the development of models of data-sharing practice. These are the value of data sharing, minimizing harm, promoting fairness and reciprocity, and trust.

Box 1

Key considerations in good data-sharing practice:

The value of data sharing

Minimizing harm

Promoting fairness and reciprocity

Trust

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The Value of Data Sharing

Echoing a broad consensus in the published literature, there was general support at all five empirical study sites for data sharing among the stakeholders, particularly among senior and junior researchers. Attitudes of community members and participants were typically more cautious, although support for data sharing often grew as they became familiar with the concepts involved, the potential advantages of sharing, and safeguards that could be implemented to address concerns. What this suggests is that for all stakeholders, an assessment of the potential benefits of data sharing is likely to be an important factor in the question of whether or not it constitutes an example of good data-sharing practice.

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Minimizing Harm

Concerns about minimizing harms of research focused on ensuring that participants' interests were not adversely affected when individual-level data were shared. At all sites, protecting participants' privacy and ensuring that identifying data remained confidential were considered to be of key importance by all stakeholders, reflecting a consensus in the reviewed literature (Bull, Roberts & Parker, 2015). However, reflecting the broader discussions of harm in the literature outlined above, de-identification of data was not necessarily considered sufficient in itself to minimize the risk of harm. Risks of harm were associated both with the sensitivity of the data sets collected and with the uses that could be made of the data.

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Promoting Fairness and Reciprocity

At all sites, the importance of ensuring that data-sharing practices did not increase existing inequalities was considered fundamental, reflecting discussions in the literature about the need for data sharing to be ethical and equitable. Participants focused not only on the importance of protecting stakeholders from harm but also promoting their relevant interests. In such discussions, community stakeholders noted that their contributions to the development of a valuable resource suggested that the resource should be used to directly or indirectly benefit their community.

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Trust

The final core theme that arose in conversations with stakeholder groups at all sites was the importance to participants, communities, researchers, and the wider public of ensuring that data were shared in both a trusted and trustworthy manner, reflecting discussions about sample and data sharing in the literature (Erlich et al., 2014; Kaye, Heeney, Hawkins, de Vries, & Boddington, 2009; Murtagh et al., 2012; Tindana, Molyneux, Bull, & Parker, 2014). Data sets, primary researchers, secondary data users, and data-sharing policies and processes all needed to be trusted for effective and ethical data sharing.

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Ethical Data Sharing: Ways Forward

Seeking Consent to Data Sharing

There was substantial variation in views within and between sites about best practices in seeking consent to prospective data sharing. Two related topics emerged as core considerations: the ethical acceptability of broad consent to data sharing, and the nature and extent of information to be provided to participants about data sharing if consent is to be considered appropriately informed.

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Ethical Data Sharing: Ways Forward

While views differ about whether requesting broad consent to unspecified future research is respectful of participants and can be sufficiently informed to be valid, it is clear that broad consent approaches are increasingly widely accepted (Caulfield, 2007; Sheehan, 2011). In this study, the ethical acceptability of broad consent to future research purposes attracted varying views from stakeholders within and between sites. Many arguments in favor of broad consent were pragmatic, with researchers referring to the difficulty and expense of recontacting research participants, perhaps repeatedly, for consent to specific secondary research proposals. Requirements to recontact participants for specific consent were also considered to have ethical implications in settings where web-based interfaces for ongoing management of consent to sharing were not practicable.

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Governing Data Sharing

When considering how best to manage data sharing, researchers at each site expressed a strong preference for sharing data within collaborative relationships. This was the most familiar form of sharing for most researchers and considered important to enable them to fulfill obligations to minimize potential risks of sharing and appropriately promote participants' interests. Researchers noted that sharing data within collaborations supported trust building and capacity development.

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Data-Sharing Policies

To inform best practices in sharing data from clinical and public health research, stakeholders identified a number of areas where policies and standard operating procedures would be valuable. Priority topics to address included the following:

- Quality control and preparation of qualitative and quantitative data sets for sharing, including guidelines for de-identification of data.
- Preparation of metadata to accompany data sets, including metadata about the context in which the data were collected.

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- The design and conduct of consent processes, including core information to be provided to research participants.
- Information that secondary researchers seeking to access data sets should provide.
- Conditions that secondary researchers should be obliged to comply with when accessing, analyzing, and reporting data, including acknowledgment of the primary data source and researchers.
- The composition and conduct of bodies overseeing data release.
- Guidelines for prioritization of data sets for release and criteria for determining how specific data sets should be released.
- Guidelines for case-by-case review of data-access applications where appropriate.

Perceptions about Data Sharing

**Perceived Benefits, Harms, and Views
About How to Share Data Responsibly:
A Qualitative Study of Experiences With
and Attitudes Toward Data Sharing
Among Research Staff and Community
Representatives in Thailand**

Phaik Yeong Cheah^{1,2}, Decha Tangseefa³, Aimatcha Somsaman¹,
Tri Chunsuttiwat¹, François Nosten^{1,2}, Nicholas P. J. Day^{1,2}, Susan Bull²,
and Michael Parker²

Suggestions for Best Practices in Data Sharing

Resources and capacity to ensure good quality data. Many of the researchers we interviewed were of the opinion that good quality data were a prerequisite for effective and useful data sharing. They took the view that there is an urgent need for capacity building around data-curation, management, and analysis in low-income settings, and that this needed to be addressed before seriously considering data sharing. Participants emphasized the importance of establishing high standards of good practice if potential benefits of data sharing are to be realized.

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and Michael Parker²

Consent. All of those interviewed were concerned to ensure that the interests of research participants and communities were protected, and most saw effective valid consent as a key element in ensuring that this was the case. Different models of consent were discussed in the interviews and focus groups discussions; however, no agreement was reached on what would be the best approach. It was agreed by all respondents that research participants should have some say about what happens to their data. How this should be done in practice was more complicated.

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Governance. Given the potential harms that data sharing might bring about, participants felt that for data sharing to be successful, it needs to be appropriately governed, managed, and funded. The discussion of data governance focused primarily on the strengths and weaknesses of open versus managed access approaches to data sharing.

Open access. Very few researchers were in favor of having the entire data set, including unpublished data, publicly available without any controls. This was primarily because of concerns about the potential harms described above.

Managed access. The vast majority of those interviewed thought that given the potential harms of open access to data sets, a managed approach in which a governance committee or trusted gatekeeper vetted requests for access to data and ensured appropriate attributions would be preferable.

Data Sharing Policy & Management

MORU Tropical Network Data Sharing Policy 6th January 2016 version 1.0

1. Introduction

The MORU Tropical Network recognizes the value of sharing individual level data. We aim to ensure that data generated from all our research are collected, curated, managed and shared in a way that maximizes their benefit. When sharing data we have an obligation to ensure that the interests of research participants, researchers and other stakeholders are appropriately protected.

MORU is committed to ensuring that data sharing is planned for in the inception of a study: including during negotiations with funders and collaborating sites, during evaluation of compliance with local and international ethics and regulatory requirements, and during the design and conduct of consent processes.

From January 2016 data management for all research studies will include preparation for data sharing. Data will be made available within six months of publication.

Data Sharing Policy & Management

4. Key Principles and Considerations

When sharing research data we aim to **maximise its scientific utility** through ensuring that data are high quality, shared in appropriate formats and accompanied by relevant and comprehensive associated information such as protocols, case report forms and data dictionaries. We aim to **minimize potential harms of sharing and protect the interests of relevant stakeholders** including research participants, communities and researchers by ensuring that data are released via governance methods with appropriate levels of oversight and conditions of use. MORU **remains the custodian of shared datasets** and will monitor applicants' uses of data as appropriate. We aim to share data in a **fair manner** that does not exacerbate existing inequalities and will prioritise the health interests of those in low and middle income settings. Our data sharing governance is designed **to build and sustain stakeholders' trust** in data sharing. Our sharing policies and processes aim to be **fair, accountable and transparent as well as proportionate and responsive** to the contexts in which the data were collected.

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5. Process

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A. Data Access Committee

Oversight for data sharing within MORU is the function of the Data Access Committee (DAC). Members of the DAC are appointed by the Science & Strategy Committee.

The DAC on behalf of MORU is responsible for:

- (i) Facilitating data access
- (ii) Reviewing applications for sharing of datasets submitted to DAC
- (iii) The custodianship and stewardship of the data, the oversight of the quality of the data shared, and compliance with funders' policies and this data sharing policy.

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B. Data access routes

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These include:

1. **Online open access:** e.g. as supplementary files to a journal article. With this method of access MORU has no oversight or control of secondary uses made of the data.
2. **External repository without case-by-case assessment**
With this method datasets submitted to a repository may be accessed by registered users who have agreed to the repository's terms and conditions of use. With this method MORU has no oversight or control over secondary uses made of the data by registered users. Uses made of the data will be restricted by the terms and conditions of the repository.
3. **Application to the Data Access Committee – for published and stand-alone datasets (e.g. PhD projects)**
With this method applicants complete an Application Form and data access agreement. Applications are considered by the DAC on a case-by-case basis informed by the terms of reference and the application checklist. The type of agreement that applicants are asked to complete depends on the dataset requested.

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4. Application to the Data Access Committee – for partially published, complex and sensitive datasets

With this method applicants complete an application form and data access agreement. Applications are considered by the DAC on a case-by-case basis informed by the terms of reference and the application checklist. The type of agreement that applicants are asked to complete depends on the dataset requested. Consideration is likely to involve consultation with principal investigators, relevant collaborators and other experts. Additional specific conditions of access may be implemented including collaboration and cost-recovery for preparation of datasets.

5. Limited release

Data may be judged as low priorities for release due to limited scientific value.

Queries and applications for datasets should be directed to Dr. Phaik Yeong Cheah at phaikyeong@tropmedres.ac



Discussion

- IRB and Data Sharing Committee relationship?
 - Governance of data sharing platform
 - Informed consent of potential profit of data /specimen use
- Data sharing committee for Mahidol research?
- Other comments on governance of data sharing