MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER OF BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

Representation in Research
LGBTQIA+

Tool 4: SOGI Data Privacy Checklist

Introduction

Data privacy is critical not only for the safe and ethical conduct of clinical trials, but also for supporting and maintaining the trust of clinical trial participants. For clinical trial participants who may be discriminated against or otherwise harmed if their personal identifying information were to be disclosed, data privacy is even more important. In the Sexual Orientation and Gender Identity (SOGI) Data Collection Checklist we advocate for the collection of SOGI data, where appropriate and feasible.

In the SOGI Data Privacy Checklist, which is meant to accompany the SOGI Data Collection Checklist, we provide thinking prompts to support researchers, sites, sponsors, and others in maintaining privacy when collecting, storing, and sharing SOGI data (note especially those prompts in bold). We hope that you will use the prompts in considering how to make the research environment/site a welcoming place where individuals can trust that they and their data will be respected and protected, and how to implement safeguards to protect participant identity and privacy.

Checklist

Local and Site Environment

☐ **I have considered the local context, including relevant local, state,[1, 2] national,[3, a] and regional laws (including the [US] Health Information Privacy Protection Act/HIPAA[4] and the [European Council] General Data Protection Regulation[5] and the cultural environment, and how these may impact the safety and privacy of LGBTQIA+ participants.** Please note that it may also be helpful to speak to local public health departments, regulatory agencies, and regulatory experts at study sites, and to keep

[a] Please note that US Government documents listed as weblinks in this tool may not be available. Please see Tool 7, "Exit Survey inclusive of the LGBTQIA+ Perspective" for sample sexual orientation and gender identity (SOGI) questions and response options.

up to date on American Medical Association (AMA) policies.[6] **I have considered contingency plans** for jurisdictions with restrictive LGBTQIA+ policies.[b]

☐ **I have trained the clinical research team on where to find information and how to answer participant questions about safety and privacy.**

Options for Participants

☐ **I have assessed when it is appropriate to collect SOGI data in anonymous forms vs. separate forms with personal identifying information.[c]**

☐ **I have created an option for participants to opt out of answering any or all SOGI data questions and made clear in all participant-facing materials that this option may be exercised at any time during the trial.[7]** Please note, there may be cases where a participant shares their SOGI data but later decides to opt out.

☐ **I have made it clear in all communications with participants the ways in which our research team and organization can protect their privacy, and the situations in which we may not be able to protect their privacy.** Please note, for privacy reasons, carefully consider using HIPAA compliant end-to end encrypted information platforms [that are approved by your institution] for text messaging, email, and VPN connections.

[b] Contingency/security plans may build upon recommendations listed in this checklist and potentially include: minimizing data collection to only what is essential, storing and processing data within the jurisdiction to prevent cross-state and cross-border issues, restricting access to SOGI data to essential personnel only, using paper-based/non-electronic methods to record SOGI data, pronouns, and/or name changes, developing emergency data handling protocols (such as pausing data collection or securely transferring data to safer locations), and partnering with local organizations for legal guidance.

[c] For example, identifying information may not be collected for some qualitative research. Such research can be important to understanding local context and social determinants of health, community engagement and community priorities for research and trial conduct, reasons for participant under/representation, and the clinical care setting in which the tested products will be introduced.

Data Storage

- ☐ **I have a management plan for secure storage and transfer of data throughout the life cycle of the project**, including defined timeframes for keeping the data, and for deletion or disposition of the data at the conclusion of those timeframes.[8]

- ☐ I have a plan in place for deleting data not only at the conclusion of a trial, but also during a trial at a participant's request or if the participant drops out.

- ☐ **When it is necessary to have SOGI data linked to specific participants, I will de-identify participant data [e.g., introduce code numbers].**

- ☐ Where possible, I have created "backstops" in the medical records system to protect the participants' reported SOGI data (e.g., encryption, data segmentation, flags alerting that the data is confidential, user-defined options for different levels of visibility depending in the party viewing the records).[9]

- ☐ I have reviewed with legal counsel that the medical/lab and billing codes[d] to be utilized (e.g., codes for gender incongruence) are appropriate and would not inadvertently "out," compromise, or harm a participant.

Data Protection

- ☐ **I will make SOGI data available only through a controlled access environment and have considered which forms of data encryption would be most suitable.**

- ☐ I have separated research data from clinical medical records and implemented measures to protect SOGI data. Where that is not possible, the participant knows and agrees. Please note that researchers must obtain permission to share any data collected or produced by the study with the participant's medical provider/s.

[d] Some trial costs can go through institutional billing (that is not controlled by the investigator) to insurance companies, particularly in the case of trials that are comparing the tested intervention to the standard of care. Those billing systems may have codes or templates that are not optimally design to protect SOGI data.

☐ [Where possible] I have created an option for participants to opt out of sharing any or all data with other organizations and made that clear in all participant-facing materials. If the trial will be sharing data with other organizations or outside the state where the trial will be conducted, the clinical research team and Informed Consent Form will be explicit about that. The potential limits of data privacy should also be clearly communicated.

☐ In the event of a buy-out or merger, I/my organization will advocate for the new entity's commitment to the same privacy terms.

☐ [Where possible] I have planned opportunities for participants to give feedback on data privacy, and for regular review on the privacy of SOGI data for my study and at my site. If, for example, I start hearing from the transgender community that the data privacy protections are not sufficient or effective, I will listen carefully and adjust accordingly.

Site policies and staff training

☐ I attest that the study team and site have acted to **make this a welcoming environment and a place where individuals can trust that they and their data will be respected and protected**. These actions may include:[10]

- Developing study/site policy that respects LGBTQIA+ participants' rights to confidential care, in line with clinical, professional, and research practice and ethical guidelines, state and national laws, and the advice of legal counsel.
- Explaining clearly when, why, and how SOGI data will be collected and used.
- Taking training on and regularly practicing creating Safe Zones, working with Sexual and Gender Diverse (SGD) participants, and using respectful language and imagery.
- Describing, through as many communication modalities as possible (e.g., emails, posters, elevator video screens) what the site or organization is doing to create a welcoming environment.

- Sharing one's own name and pronouns. Asking about and using participants' pronouns.

Addendum for Pediatric Participants[11]

☐ I have reviewed clinical/professional practice/ethical guidelines and state/national laws, discussed with legal counsel, and implemented specific protections for pediatric participants. These may include:

- [To the greatest extent permissible by state/national law] I have set up the processes, physical space, and/or patient-preferred communication modalities to ask adolescents (age 11-17) about sexual orientation and gender identity in private, without a caregiver present.
- I have phrased SOGI questions in ways that are appropriate by age for children and adolescents, based on published guidelines and recommendations.[12, 13, 14]
- I have set up processes to ask adolescent pediatric participants which name and pronouns they want used and in which contexts (e.g., when caregivers are present, when non-medical staff are present).
- [To the greatest extent permissible by state/national law] I have set up processes to obtain consent from adolescent patients before entering SOGI information in their electronic health record and to clearly explain who is able to access their health record information.
  - Please note that participants in the U.S. may be covered under their parents' insurance until age 26. Therefore, any clinical trial costs that are billed to insurance may be visible to the parents of a participant who is under the age of 26. Similarly, if a parent is listed at a pharmacy to have permission to pick up prescriptions, those prescriptions, and the participant's prescription history may be visible to the parent.

References

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