Guidance on the Use of Participant Identifiers on Study Documents

Purpose

This guideline is intended to outline the Island Health Research Ethics Boards (REBs) perspective and recommendations on the use of participant identifiers (e.g. initials, names, unique study identification) on research study documents which includes all formats including electronic.

Background

The issue of whether or not to use participant initials on trial documentation such as the case report forms (CRF) or consent forms is not one that is unusual to Island Health. Many involved in clinical research have struggled with the question of using personally identifiable information during the conduct of research that could be made available outside of the study site. Some examples include:

- Austria, Norway, Finland and Hungary (to name a few) have data protection legislation that clearly restricts the capture of Date of Birth (DOB) and participant initials;
- In Germany initials and DOB may appear on lab reports which remain on site as source data, but any data going into the electronic data capture (EDC) and database must be anonymized or pseudonymized;
- Ethics Committees (REBs) for research in certain countries (e.g. Belgium and Spain) request that personal data such as DOB and initials are not collected at all.

There are two fundamental requirements of Good Clinical Practice (GCP) that can cause a dilemma for researchers and REBs alike when they are trying to ensure the protection of personal information.

1. All clinical trial information is to be recorded, handled, and stored in a way that allows its accurate reporting, interpretation, and verification.
2. The requirements for confidentiality of records that could identify participants to be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirements(s).

Some clinical research sites recognize that collecting participants' initials and full DOB on CRF's could either directly identify participants, or could identify participants when this information is combined with other publicly available information. This has resulted in their decision to remove participants' initials and a full DOB to reduce the risk of identification of the participant.

However, Health Canada and FDA regulations do not dictate how participant files are maintained as far as identifiers are concerned. All regulatory agencies accept that the clinical sites and study Sponsors take appropriate measures to ensure the confidentiality of participant records. While it is not forbidden for Sponsors to maintain files with participant names, most Sponsors prefer to have initials at the most or numbers or other identifiers so that major procedures are not required to maintain that confidentiality. That is why most Sponsors use initials or a code (participant identification number) instead. The Sponsor's only need for actual identification of the participant is when they, or their contractors, are monitoring and auditing the sites, so they can assure the participants exist and that the data accrued and reported is accurate and pertains to the individual in question (as required under point 1 above).

The overarching ethical concern regarding use of participant identifiers in research is around participant confidentiality. The use of a unique study identifier in conjunction with their name or other personally identifying information on a study document creates additional linkages which may break confidentiality if compromised. This speaks to the need for the unique study identifier of a participant not be listed on consent documents which may include a participant's signature. Additionally, study participant initials are also preferred not be listed on consent documents. Island Health REBs however, may exercise the right to consider the use of identifiers (e.g. initials, partial DOB) on consent documents whereby potential harms of using additional identifiers are well understood in relation to the risks and safety of not using them. When this is the case, the collection, use, transfer and storage of such information must be disclosed in the study consent documents.

Island Health REBs Recommendation:

The Island Health REBs will request through provisos the following:

1. The unique study identifier assigned to a participant should not be included on consent documents.
2. When there is planned disclosure of any personal identifiers (e.g. names, partial or full DOB, or initials) outside of the local study site, or if such personal identifiers are used on study documents or any research-related information, this must be justified to the REB, and if permitted, disclosed to participants in consent documents.
3. Protection of the confidentiality of documents containing the personal identifiers, and the connection between them and the unique study identifiers must be ensured by the researchers which includes the study team supporting the research.

Tools and Resources

The TCPS 2 defines “Personal Information” as, “Identifiable information about an individual“ (e.g. names, date of birth, or initials). Identifiable information” is defined as, “Information that may be reasonably expected to identify an individual, alone or in combination with other available information. Also referred to as “personal information.” These definitions are applied by the Island Health REBs.

The BC Clinical Common Consent Form Template should be used for clinical research studies. It includes the following template wording that can be referred to or used:

> You will be assigned a unique study number as a participant in this study. This number will not include any personal information that could identify you (e.g., it will not include your Personal Health Number, SIN, or your initials, etc.). Only this number will be used on any research-related information collected about you during the course of this study, so that your identity will be kept confidential. Information that contains your identity will remain only with the Principal Investigator and/or designate. The list that matches your name to the unique study number that is used on your research-related information will not be removed or released without your consent unless required by law.

And under the Confidentiality section:

> If there is planned disclosure of personal identifiers (e.g. names, date of birth, or initials) outside the local study site, or if such personal identifiers are used on study documents or any research-related information or are part of the unique identifier, this must be justified to the REB on the application and, if permitted, the required wording below must be amended as necessary.

The TCPS2, Article 3.2 states several requirements of consent documents including:

> i. an indication of what information will be collected about participants and for what purposes; an indication of who will have access to information collected about the identity of participants; a description of how confidentiality will be protected (Article 5.2); a description of the anticipated uses of data; and information indicating who may have a duty to disclose information collected, and to whom such disclosures could be made;