



## Guidance for Clinical Researchers | Equity, Diversity and Inclusion Considerations

The mission and purpose of an institutional Research Ethics Board (REB) is to ensure the ethical acceptability of research conducted within the jurisdiction of or under the auspices of an institution. [TCPS2 Article 6.1] Determination of ethical acceptability requires that the REB consider the core principles of Respect for Persons, Concern for Welfare and Justice. [TCPS2 Article 1.1] Consistent with the principle of justice, human participant research should aim to be broadly inclusive and representative of the population whose conditions are the focus of study ( unless justified by scientific, ethical, or safety concerns) without exclusion on the basis of attributes such as culture, language, religion, race, disability, sexual orientation, ethnicity, linguistic proficiency, gender or age. [TCPS2 Ch. 4 Article 4.1]. While not specifically referenced in the TCPS2, attributes such as sex and gender identity should also not be unjustifiably excluded. Justice refers to the obligation to treat people fairly and equitably. Fairness entails treating all people with equal respect and concern. Equity requires distributing the benefits and burdens of research participation in such a way that that no segment of the population is unduly burdened by the harms of research or denied the benefits of the knowledge generated from it. [TCPS 2 Ch.1 Article 1.1 Framework – Justice]

Increasingly funders and publishers are requiring that health researchers, particularly those who are sponsoring regulated clinical trials, include equity, diversity and inclusion considerations at the time that they develop the study protocol. This compels researchers to know the demographics of their participants. Depending on the research being conducted what is collected and how will vary. For example, current FDA demographic categories are often required for clinical trials [see [FDA Draft Guidance](#)], however when not mandated by regulations, other descriptors may be more appropriate for research [see [National Academies of Sciences, Engineering, and Medicine](#) and [CMAJ Guidance](#)]. UBC's REB's support this development and will review all research studies taking into account the considerations itemized below.

### 1. When should researchers be thinking about equity, diversity and inclusion considerations during their research?

Diversity based considerations should be taken into account by all researchers in every research study in relation to:

- a. **Study aims and participant selection.** Researchers should be able to explain why they chose the proposed study population. They should be able to directly comment on the choice of demographic characteristics, the proposed study population and its appropriateness given the research question, including whether there has been any community consultation and how the sample reflects the population of interest.

Researchers should consider geographic and cultural norms in the context of their research, the expectations and sensitivities of involved participants, and consider the norms of their specific field of research

- b. **Criteria for inclusion and exclusion.** Researchers should be able to justify any exclusions based upon scientific, ethical or safety concerns. [Box 5.2 of the Ethics Application] When necessary, researchers should think about alternative approaches to minimize risk that do not rely on exclusion to enable a diverse participant sample..
- c. **Recruitment.** Researchers should investigate recruitment procedures that consider specific approaches to engage underserved populations which should be determined based upon the most current Canadian and/or Provincial data. ( \* See note in [glossary](#) pertaining to determination of underrepresented / underserved populations. )
- d. **Study Conduct.** Researchers should ensure that study procedures are flexible and accommodate the needs of underrepresented groups ( \* See note in [glossary](#) pertaining to determination of underrepresented / underserved populations) For example, they should provide translations wherever possible and ensure that all participant facing materials conform to the requisite level of literacy.
- e. **Remuneration for participation.** Remuneration should be adequate to cover costs, culturally and practically appropriate and participants from underrepresented groups may require special consideration.
- f. **Return of study results.** These should be returned in a manner that meets the needs of the populations studied
- g. **Recruitment and accrual goals in the context of continuing review.** When completing annual reviews researchers should consider whether the study has or is on track to fulfill its recruitment and accrual goals, including those related to demographic distribution. If this is not happening, researchers should consider whether corrective actions could be implemented.
- h. **Identifiability.** When collecting demographic information, researchers must consider how collecting demographics can compromise identifiability of data by giving additional data points that may promote reidentification

## 2. Limitations on the role of individual researchers and the REB in relation to social justice concerns

REBs have traditionally focused on review of specific study aims and objectives. However, there is increasing pressure at all levels to consider social justice and human rights concerns, particularly in health care research. Although the value of **individual** study data for social justice, health equity purposes may be limited, there are some potential benefits that may be

derived and asking such questions should not be precluded. The questions should be structured in accordance with recommended standards and the reason for the collection of such data must be clearly explained to all potential participants. See for example [CIHI Standards](#)

### 3. Recommendations for Data Collection

#### A. UBC's REBs acknowledge that there are a variety of different reasons why racebased/ethnicity/cultural identity data might need to be collected.

Some of the reasons for which researchers might want to collect information on ethnicity and/or race are to:

1. Identify or investigate the relation between genetic background and risk for disease, prognosis of disease, or response of disease to therapy.
2. Select for a group of people with an a priori higher incidence of genetic variants or haplotypes to test hypotheses about risk for disease, prognosis of disease or response of disease to therapy.
3. Identify or investigate social affiliations of people in particular geographical locations.
4. Identify or select for social factors possibly related to self-reported race or ethnicity that may be predictive of discrimination or socially-affected access or response to health care services that may affect risk for disease, prognosis of disease or response to therapy.

#### B. REB Recommended Categories of questions concerning race and ethnicity [See [Glossary of Terms](#)]

Researchers should know the reasons why ancestry or self-reported race and ethnicity data need to be collected in the context of their study and how they will be used in analysis of the data, so that the demographic questions asked will be relevant to the study purpose. These reasons should be transparent to research participants and relevant communities in keeping with the principles of informed consent. Given the underlying complexity of self-reported race and ethnicity terminology and given the various different reasons for which researchers might want to collect race/ethnicity identity data, UBC REBs recommend use of the following categories of questions:

##### 1. Biological relatedness: Ancestry

We can speak of two kinds of ancestry – genealogical ancestry, the family history reconstructed by eliciting a pedigree, based on an individual's knowledge of their family history, and genetic ancestry, based upon the results of genetic testing. (Questions referring to place assumes reproductive relationships among individuals in the same town, city or region.)

These data can be captured by:

- Asking questions such as: Where are your ancestors (e.g. parents, grandparents, etc.)
- Asking questions based on categories related to place

- Asking questions based upon pedigrees
- Conducting genetic testing

## 2. Social Affiliation – Ethnicity

Ethnicity is a form of relatedness based on a person's social or cultural affiliations, connecting them to contemporaries as well as ancestors. Individuals may be able to have multiple ethnic affiliations. A person's ethnicity is situationally determined by the individual making the claims of affiliation and their audience who may accept or reject those claims.

These data can be captured by:

- Asking questions such as: What social, cultural or ethnic identities do you have?
- Creating new or unique labels for ethnic categories that are relevant to the study population

## 3. Discrimination – Racialized Groups

Identifying groups affected by discrimination is an administrative process that often uses census categories to gather information to inform social policy. While they are of some use in sociological, anthropological, economic and political analysis, because groups identified in this way reflect social conceptualizations of categorizing people, they have limited value in identifying individuals' biological or self-identified ethnic affiliation because they serve as surrogate markers at best.

These data can be captured by:

- Asking questions such as: Are you a member of a racialized community, or a group that has suffered from discrimination
- Referencing relevant indicators such as visible minority, colour, or community that are often used as the basis for discrimination, social interaction or access to services.

## C. Other Considerations

1. In order to mitigate the potential risk of harm to a particular group or groups of underrepresented people, when appropriate, researchers engage with communities to ensure their needs/wishes are met in relation to the use of data collected in the research.
2. Document in the **informed consent** form the reason why ancestry, ethnicity, and racialized group data are required to be collected in the study, and allow their collection to be optional whenever possible (e.g., whenever these data are not essential to the analysis of the data in order to answer the study question)

3. If the research requires demographic data for social/political reasons, e.g. investigation of access to care, quality of care, evidence of discriminatory practices etc. use an approach that would allow comparisons with previously published data and/or that reflect common social views of racialized groups and ethnic categories. [Statistics Canada Guidance](#) and the CIHI Standards linked above.
4. When collecting data on (socially defined) or racialized groups and/or ethnicity for the purpose of inclusiveness in the research, use categories that would be relevant in the community(ies) from which the study sample will be drawn. In doing so, estimate the proportion of the major racialized and/or ethnic groups in the population such that the recruitment strategy can be designed to obtain a somewhat representative and therefore inclusive sample. To the extent that it is feasible to do within the specific context of the research, consider geographic and cultural norms in the context of the research, the expectations and sensitivities of involved participants and consider the norms of the specific field of research.
5. If you are interested in enriching the study sample for one or more groups with higher or lower prevalence of genetic or environmental backgrounds, consider designing screening and demographic data collection questions that would best meet the goals of the research, rather than resorting to the vaguely understood terms for race and ethnicity. For example, for a study of inherited long QT syndrome, approaching a subset of the First Nations population known to have a relatively high incidence of this syndrome.
6. For whatever reason demographic data are being collected, researchers and institutions must ensure that the **reasons** why the data are being collected are explained to participants. They must also provide participants with information concerning who will be analyzing the data and for what purposes, i.e. what is the intended use of the data. If the intention is to collect the data to help ensure representation and equity in research participation and the data are going to be used by health care administrators or others to achieve this purpose, this should be stated in the consent form. If there is no plan at the time of the study to use the data, the informed consent form should state something like..."it is anticipated that these data will be used in the future to provide empirical evidence as to which populations are under-represented or underserved within \_\_\_\_\_ health authority / BC. " UBC's REBs will ask researchers which groups the Health Authority/Province has empirical evidence for to demonstrate which populations are under-represented or underserved within their Authority. Researchers are expected to use the most current evidence that is available.
7. When collecting demographic information, researchers must consider how collecting demographics can compromise identifiability of data by giving additional data points that may promote re-identification

8. When collecting demographic data, options such as “population group not listed, specify, don’t know, prefer not to answer and multiple/mixed and a self-description fill in response can enhance participant comfort.
9. Research that focusses on a particular participant group should use language that is most appropriate for that group. If you are in doubt about the appropriate terms, consult with the participant communities before constructing your demographic survey.
10. If participants may be excluded due to demographic questions about ethnicity or languages spoken, explain this up front and place “excluding” questions at the beginning of your survey. It is frustrating for participants to be “bumped’ out of a survey after they have spent time answering the questions because their demographic group is over-represented. (The Research Participant Complaint line has received calls from survey takers who believed they were prevented from receiving compensation after completing a survey, because the last questions in the survey identified them as being of the “wrong” ethnicity.)

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Sources:

Carleton University Research Ethics Guidelines on the use of race and ethnicity in demographics:  
<https://carleton.ca/researchethics/wp-content/uploads/Research-Ethics-Guidelines-on-the-use-of-Race-and-Ethnicity-in-Demographics.pdf>

Science: Justice, diversity and research ethics Review, Strauss, White and Bierer, 19 March 2021 Vol. 371, Issue 6525, pp. 1209-1211 <https://www.science.org/doi/abs/10.1126/science.abf2170>  
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Canadian Institute of Health Information: Proposed Standard for collection of race-based data:  
<https://www.cihi.ca/sites/default/files/rot/proposed-standard-for-race-based-data-en.pdf>

Annual Review of Anthropology: Population Demography, Ancestry, and the Biological Concept of Race, Van Arsdale, Adam P, October 2019, Vol. 48, pp. 227-241:  
<https://www.annualreviews.org/doi/abs/10.1146/annurev-anthro-102218-011154>



## Glossary of Common Terms

**Underserved, underrepresented and marginalized populations:** Within Canada and BC, these groups generally can include: indigenous people, women, people with disabilities and gender and sexually diverse peoples. While researchers are encouraged to obtain data from such groups, in the health research context, determining the relevant proportion of these groups relative to the health condition, treatment or service being studied can be best identified by current Canadian and/or BC data which may not be readily accessible. UBC's REBs encourage BC's Health Authorities and the Ministry of Health to fund researchers to undertake studies that will provide current information on underserved, underrepresented and marginalized populations within the regions of the province, so that such information can be routinely used by BC's health researchers. Race and ethnicity are problematic terms which have been defined in a multiplicity of ways often perpetuating systemic racism and white privilege. UBC's REBs encourage researchers to review both current anti-racism literature and the relevant literature in their field, to deepen their understanding about how best to apply the terms and concepts in their research.

Race and Ethnicity are two distinct constructs. While sometimes used interchangeably, researchers should understand the specific concept that they are interested in investigating so that the appropriate questions and language are used.

**Race** is a socially constructed system of classification based on antiquated and discredited theories of biology, and is no longer considered to be based on science or biology, but on societal distinctions (Gould 1994).

Research since the 1900s has demonstrated that populations could not be classified as biologically distinct races (Lewontin 1972) and recent population genetic studies have determined that there is more internal biological variation within populations than between "racial" groups (Van Arsdale 2019).

Race continues to be used in popular discourse, which can contribute to social, economic, and political discrimination. It is also used for administrative purposes (U.S. Census Bureau 2022).

**Ethnicity:** As stated in the Statistics Canada reference guide: "Ethnic origin refers to a person's "roots" and should not be confused with citizenship, nationality, language or place of birth..." [Ethnic Origin Census Guide and BREB guidance] Ethnic groups share "common identity, heritage, ancestry or historical past, often with identifiable cultural, linguistic and/or religious characteristics.

Ethnicity is a form of relatedness based on a person's self-identified social or cultural affiliations, connecting them to contemporaries as well as ancestors. Individuals may have multiple ethnic affiliations. These various ethnic identities may be contextually relevant in different social and research settings (Barth 1969). This requires researchers to frame their questions to elicit the information on ethnicity that would actually be relevant to their research.

**Racialization or ethnicization:** "In [sociology](#), racialization or ethnicization is a political process of ascribing [ethnic](#) or [racial identities](#) to a relationship, social practice, or group that did not identify itself as such. Racialization or ethnicization often arises out of the interaction of a group with a group that

it [dominates](#) and ascribes a racial identity for the purpose of continued domination and [social exclusion...](#)"

Although census and related categories of race and ethnicity are used extensively in different areas of research, including medicine, the actual intended use of these categories by public bodies is to gather information to inform social policy (US Census Bureau 2022) . While these are of some use in sociological, anthropological, economic, and political analysis, they have limited value in identifying individuals' biology or social affiliations because they serve as surrogate markers for genetic, behavioural and environmental differences at best.

**Racialized group:** A social construct describing groups that have racial meanings associated with them that affect their economic, political and social life. This term is sometimes preferred over "race" because it acknowledges the process of racialization. Gathering information on self-identified membership in a racialized group may be used for administrative purposes or to determine underserved groups or those with unmet needs. (Gans 2017).

**Genealogical Ancestry:** Genealogical ancestry establishes claims to affiliations and ancestors and their social groups through family histories and pedigrees. Genealogical ancestry may reflect cultural and behavioural characteristics, as well as some genetic and epigenetic characteristics (Benn Torres 2020; Van Arsdale 2019; National Academies of Sciences 2023).

**Genetic Ancestry:** Genetic ancestry is a relatively new means of characterizing individuals' biology, based on DNA testing using SNPs, panels of selected genes, and whole genome sequencing. In clinical settings it may identify individuals who are related, in order to investigate inherited conditions, or to determine susceptibility to diseases, prognosis of diseases, and response to drug and other therapies. Genetic ancestry through pedigrees and DNA testing provides a more useful means of capturing the biological relatedness among individuals than the vague notion of race. Genetic Ancestry cannot be used to establish ethnic affiliation, which is a social attribute (Benn Torres 2020; Van Arsdale 2019; National Academies of Sciences 2023).

**Indigeneity:** Indigeneity: Indigenous is a global term that refers to the Original Peoples of a country ([Ontario, 2021](#)). In Canada, Indigenous typically refers to people of First Nation, Inuit, and/or Métis descent "regardless of where they reside and whether their names appear on an official register." Indigenous groups have distinct histories, cultures, languages ([TCPS2, Chapter 9](#)), and distinct traditional knowledge, perspectives, and worldviews). For the purposes of REB review, Indigenous is assumed to mean Canadian Indigenous peoples.

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- Benn Torres, Jada. 2020. "Anthropological Perspectives on Genomic Data, Genetic Ancestry, and Race." *American Journal of Physical Anthropology* 171:74-86.
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- Lewontin, Richard C. 1972. "The Apportionment of Human Diversity." In *Evolutionary Biology*, 381-398.



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National Academies of Sciences, Engineering, and Medicine. 2023. *Using Population Descriptors in Genetics and Genomics Research: A New Framework for an Evolving Field*. Washington, DC: The National Academies Press.

U.S. Census Bureau, Population Estimates Program (PEP). 2022. "Race." accessed 2022-07-05.

<https://www.census.gov/quickfacts/fact/note/US/RHI325221#:~:text=OMB%20requires%20that%20race%20data,sixth%20category%20%2D%20Some%20Other%20Race.>

Van Arsdale, Adam P. 2019. "Population Demography, Ancestry, and the Biological Concept of Race." *Annual review of anthropology* 48 (1):227-241. doi: 10.1146/annurev-anthro-102218-011154.