Human Cell Atlas – Ethics Toolkit –Template Consent Form Pediatric
v.1.0 (July 18th, 2022)

Pediatric consent tools

Human Cell Atlas

Reference Notes on Template Consent Form - Research with Leftover Newborn Blood Spots (parental consent/legally authorized representative consent)

Important notes on the current version of this template:

- Open-access and managed-access: Template proposed language for sharing of datasets under both a fully open-access mechanism and a managed-access mechanism. **Presently, the HCA DCP only supports datasets that have been consented for fully open-access. Only data meeting open-access tier consent language can currently be submitted.** However, it is recognized that some datasets may not be able to be released under a fully open-access tier (for e.g. due to ethical, legal or institutional limitations). Some projects collecting data to build next phases of the HCA may not be able to deposit certain datasets in open-access tier and need to obtain consent for managed/controlled access. In some jurisdictions, this may include datasets from pediatric participants. While these datasets will have to be deposited in other repositories at the present time, they could eventually be included in next phases of development of the HCA DCP. Therefore, the proposed templates contain language for managed-access datasets, to allow such datasets to be deposited in the HCA, once managed-access is supported.
- Data protection regulatory requirements: These templates were developed to apply to *consent to participate in a research project*, which may not be equivalent to consent requirements under other types of legislation (e.g. consent to data processing under your local laws or in Europe, under the GDPR). Therefore, users of these documents should always verify with their institution whether additional information needs to be provided to participants to comply with data protection regulations, including standards applicable to data from children.

  For information on points-to-consider regarding the General Data Protection Regulation (GDPR) and genomics researchers, see the Global Alliance for Genomics and Health (GA4GH), GDPR Forum.

- Consent requirements: The HCA does not require projects to use the proposed template language. It is only provided for informational purposes, and its use does not guarantee compliance with your local requirements. However, it is strongly suggested that projects depositing datasets to the HCA DCP include minimal **Core Consent Elements** (see separate document) in their consent documents.
- Update to document: This document may be updated in the near future to account for the evolution of the HCA DCP, but this will not affect the management of datasets already submitted to the HCA.

This document is part of the HCA ethics toolkit. It includes core elements for consent to contributing to the HCA, as well as language specific to collecting or using already collected newborn blood spots and associated data from pediatric participants. The language in this document is intended to provide an example for research, and can be modified to reflect local consent requirements.

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Who is this document useful for?

- This document is intended to provide template language for researchers/research studies intending to collect/use already collected newborn blood spots and associated data from pediatric participants in order to generate gene expression data and submit these datasets to the HCA DCP.

How do I use this document?

- Most countries collect newborn blood spots at birth as part of pediatric care. The purpose is to screen for at-risk, asymptomatic newborns for immediately treatable conditions.
- The clauses below provide examples of language illustrating core elements to enable the contribution of leftover newborn blood spots and their data to the HCA. These can be modified and adjusted to comply with your institutional requirements and existing templates.
- Sections highlighted are meant to indicate text that should be customized based on the drafter's project-specific context.

Who do I contact if I have questions?

For any questions about this document, you can contact the HCA Ethics Helpdesk at:
ethics-help@humancellatlas.org

Template Consent Form - Research with Leftover Newborn Blood Spots

- **YES**, my baby's blood spots may be used for health research through your [Institution]. By ticking this box you understand:
  - Unused blood spots are stored using a code and not your child's name. The spots are forever at a secure site [Institution].
  - Stored blood spots may be used by the [Institution] lab for quality control and to help ensure that newborn screening detects those at risk. Stored blood spots may also be used for research approved by an ethics committee. Blood spots can only be used for studies to better understand disease or improve the public's health.
  - Researchers at your [Institution] will sequence the genetic information of the unused blood spots and deposit this data into the Human Cell Atlas (HCA) open access database. Researchers from around the world will be able to access this data to do research. The HCA will not control the kinds of individuals or projects that may use the data in its public (open access) part.
  - Many types of laboratory methods are used to study biological factors like geneticsor environmental factors like metal and toxins. Genes are the basic 'instruction book' for the cells that make up our bodies. Genes are made out of DNA, and all of the DNA in each cell is called the genome. Different genes are turned on in different types of cells. In order for them to be turned on, another type of molecule called RNA copies certain parts of the DNA. RNA acts as a 'messenger' to send the genetic information that is turned 'on' in different kinds of cells. The HCA will use different types of genetic sequencing technologies to study RNA.
  - The risk for using your baby's blood spots in research is that your child could be identified. This risk is very low. Many steps are taken to protect privacy. Details that could identify your child or family are removed before your child's blood spots are given to researchers.
  - Most likely you or your child will not benefit from blood spot research.
  - Participation is voluntary. You can call [Institution] at any time if you change your mind. There is no penalty or loss of benefits for saying no or changing your mind.

- **NO**, my baby's blood spots may not be used for health research. By ticking this box you understand:
  - Blood spots will be stored forever but not used for research. These stored blood spots may still be used by the [Institution] lab for quality control studies and to help ensure that newborn screening detects those at risk.