

Data Access Policy for the Cleft Care UK (CCUK) Resource

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The Cleft Care UK Study Team

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Introduction

This document sets out the data access policy for the resource arising from the study entitled "Cleft Care UK" (CCUK). The objective of this study was to investigate the impact of reconfigured cleft care in the United Kingdom. This study was carried out 15 years after an initial survey commissioned by the Clinical Standards Advisory Group (CSAG 1998) led to government recommendations on centralisation.

Study Methods

CCUK is a multi-centre cross sectional study of five year olds born with non-syndromic unilateral cleft lip and palate. The study recruited children born between 01/04/2005 and 31/03/2007 in cleft centre audit clinics. Consent was obtained for the collection of routine clinical measures (speech recordings, photographs, models, oral health assessment and audiology, height, weight, head circumference) and research measures eg psychosocial and satisfaction. The methods for each clinical measure followed those of the earlier survey as closely as possible. Details of methodology, participant characteristics and outcome measures are described in "A cross-sectional survey of five-year-old children with non-syndromic unilateral cleft lip and palate: Cleft Care UK". (Orthodontics & Craniofacial Research. Persson M, Sandy JR, Waylen A, Wills AK, Al-Ghatam R et al <http://onlinelibrary.wiley.com/doi/10.1111/ocr.12104/full>)

The study protocol, consent form, patient information leaflet and questionnaires were approved by the local research ethics committee (REC number: 13/SW/0064).

Resource Management

Dr Sam Leary is the Director of the resource. The resource includes all data derived from the CCUK study. The management of the resource is the responsibility of the Cleft Care UK Study Team. This group currently comprises of Stu Toms. The final decision lies with the Director.

Sharing data with researchers

The resource is set up as a supported access resource rather than as an open access resource. The following sections describe the process of accessing and sharing the data and the procedures in place to monitor output. Cropped, anonymised photographic images and CCUK and CSAG 1998 models are available onsite at Bristol.

Submitting a proposal

If you decide that you would like to access the resource, you should contact the CCUK Study Team on cleftcareuk@uhbw.nhs.uk

We welcome informal enquiries addressed to the CCUK Study Team before submission of formal proposals. Once you are ready to submit a formal proposal you should complete the proposal form. This will ask you to state the aims and hypotheses of the study and to list the variables you require. The CCUK Study Team will reply within one month of your proposal submission date to inform you of the outcome and to provide advice on the next stages.

Data Provision

When the CCUK Study Team have approved your project, a standard dataset will be provided to you, usually within a month of all paperwork being completed. You will not be provided with statistical, methodological, or other support without prior agreement.

Derived Variables

Any derived variables (such as data obtained as part of a new data collection exercise or newly derived variables coming from secondary analyses) that you or your team create as part of any research project must be returned to the CCUK Study Team with appropriate documentation. These will be incorporated into the main resource and made available to all researchers once the protected period of approved use has ended. Failure to return derived variables may risk your future access to the resource.

Paper submission and Publication

The Director and/ or one or more nominated member(s) of the CCUK Study Team should also be included as an author on papers using data from the CCUK resource. The designated author from the CCUK Study Team will read all papers to check confidentiality is protected and to ensure that the paper will not bring the study into disrepute. The CCUK Study Team member will also provide advice and feedback.

All full papers must be sent to the CCUK Study Team for approval along with a completed papers checklist prior to journal submission. The CCUK Study Team expect to process all papers within one month of receipt.

Researchers should let the CCUK Study Team know when a paper is accepted (copy of acceptance letter and accepted manuscript) and send through an electronic copy of the final published version. If your work on the resource was funded by bodies that require open access to publications arising from their funding, it is your responsibility to ensure papers are freely available.

We will maintain a list of papers arising from the resource. We request that we are provided with an electronic copy of any reports and other publications that use the CCUK resource as soon as possible. We also request that we are provided with an electronic copy of any theses that use the CCUK resource as soon as possible after a degree is awarded. We do not need to see conference submissions prior to submission but a copy should be sent to the CCUK Study Team once submitted.

Publicity policy

All press releases on research arising from the resource should be seen and approved by the CCUK Study Team. We may write press releases on certain articles and ask the lead author on the paper and host organisation's public relations team to be available to deal with media enquiries and interviews; we will give as much notice of such actions as possible. We may also ask authors to prepare a précis of important papers to include in reports to funders and future applications for future core support.

Intellectual property

Intellectual property in the data and samples that make up the CCUK resource is vested in University Hospitals Bristol and Weston and managed by the CCUK Study Team. As such any requests to access the data and/or samples must be made through the CCUK Study Team.

Any data generated through an approved project must be made available to the CCUK Study Team where it will form part of the CCUK resource to enable it to be used by the research community. Any intellectual property generated using the CCUK resource ("Foreground IP") will belong to UH Bristol.

Acknowledgements

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