QOMS Rare Bening Lesions of the Jaws registry – user guide

This document was developed to guide organisations who wishes to take part / contribute to the QOMS Rare Bening Lesions of the Jaws (RLJ) registry.

PROJECT DETAILS

Project Title: Rare Bening Lesions of the Jaws

Project Lead: Michael WS Ho (michael.ho2@nhs.net)

Project manager: Fabien Puglia (baomsprojectmanager@baoms.org.uk)

Project rollout Date: December 2023 **Review date:** End of 2024

Funding / Lead organisation: British Association of Oral and Maxillofacial Surgeons (BAOMS) |Royal College of Surgeons of England | 38/43 Lincoln's Inn Fields | London WC2A 3PE | E: office@baoms.org.uk

WHAT DO I NEED TO DO TO BE ABLE TO CONTRIBUTE TO THE RLJ REGISTRY?

- The first thing to do is to contact your hospital / trust / health board's information governance / audit department to enquire what the steps to register this project are.
    - You will probably be asked to complete and sign forms (e.g., a data protection impact assessment or DPIA). If that's the case, the information below should help you to start completing the document but remember to contact the project manager to help you.
    - Your hospital / trust / health board might also ask to sign a data sharing agreement. That is not a problem. We can either use a template provided by them or by QOMS. The project manager can help you with that too.
- Once your local approval has been sorted, contact the project manager to help you to get access to the registry and to obtain your (unique) QR code to manage online consent.

RATIONALE OF THE PROJECT

Numerous benign lesions, cysts or solid tumours may present in the jaws. They may be of either odontogenic (tooth-forming, in the dental alveolus) or non-odontogenic (mainly bone) origins in the mandible and maxilla. From a diagnosis perspective, these lesions may have similar imaging features and their location, margins, internal contents, and effects on adjacent structures are important features to diagnose them. These rare benign lesions and tumours of the jaws (RLJ) can vary in behaviour, and despite their benign diagnosis, some can grow rapidly and result in destruction of surrounding structures. Some patients may require complex treatment to adequately treat these lesions/tumours adequately. In recent years / decades, less invasive and adjunctive treatments have become available to reduce the morbidity associated with surgical treatment. The long-term safety and efficacy of these emerging modalities are still unclear. As the molecular and genomic pathogenesis of these lesions is better understood, there might yet be the potential for more personalised treatment approaches to optimise treatment strategies for patients.

WHO CAN CONTRIBUTE TO THE RLJ REGISTRY?

Although led by BAOMS, the registry is not only open OMF surgery departments or surgeons but also to other surgical/medical specialties (ENT, Oncology…) treating patients affected by these conditions.

WHAT IS QOMS?

The Quality and Outcomes in Oral and Maxillofacial Surgery (QOMS) project is the quality improvement and clinical effectiveness programme for Oral and Maxillofacial Surgery (OMFS), initiated by the British Association of Oral and Maxillofacial Surgeons (BAOMS).

QOMS operates a series of clinical registries across several OMFS subspecialties) and the dental specialty of oral surgery. The RLJ registry is an additional registry under the QOMS umbrella. It follows the same principles as other QOMS registries (see below for details).

INFORMATION GOVERNANCE FOR THE SGC

- The RLJ registry is NOT a research project but an audit / service evaluation, it therefore does not require ethical approval (see Appendix 1).
- Population: Patients newly diagnosed with or currently treated for a primary or recurring rare lesion or tumour of the jaws.
    - This means also that the RLJ may collect data about children and other vulnerable patients if they have been diagnosed or are being treated for RLJ.
- Collection of patient identifiable information: Yes.
- Lawful basis for the collection and processing of personal data (GDPR):
    - Article 6(f): processing is necessary for the purposes of the legitimate interests pursued by the controller or by a third party, except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject which require protection of personal data, in particular where the data subject is a child.
    - Processing of special categories of personal data – Article 9(h): processing is necessary for the purposes of preventive or occupational medicine, for the assessment of the working capacity of the employee, medical diagnosis, the provision of health or social care or treatment or the management of health or social care systems and services on the basis of Union or Member State law or pursuant to contract with a health professional and subject to the conditions and safeguards referred to in paragraph 3;
- Condition to satisfy the Common Law Duty of confidentiality: Consent
  Patient consent will be sought before the start of data collection.
- The RLJ registry is fully consented. A patient information leaflet is available in Appendix 2.
    - Data collection for a patient should not start before they are consented.
    - A parent or a legal guardian should give consent on behalf of the child if aged under 16 years. There is no system in place to reconsent paediatric patients once they reach 16 years of age.
    - The consent asks for people to positively opt in and also give separate distinct options to consent separately to different purposes and types of processing.

- For England and Wales only. Because the RLJ registry is consented, the National data opt-out does not apply. Participating patients retain all their patient's rights including to object to the processing of their data, and to withdraw at any point without giving reason.
- Your organisation is the data controller, while BAOMS and any subcontractors are the data processors.

WHY IS THE RLJ REGISTRY CONSENTED?

1. For potential secondary research, patients need to consent researchers to access images, blood and tissue etc samples collected during in course of their treatment.
2. Establishing multidisciplinary collaborations at a regional (Integrated Care Board) and national levels. The aims are (1) to review the registry activities and any related operational issues discussed and (2) to discuss complex patient cases as requested by their primary clinicians.

ARRANGEMENTS FOR THE RLJ

- Data is collected and stored in an instance of the Research Electronic Data Capture (REDCap) system, hosted and managed by the Barts Cancer Research UK Centre (BCC), Queen Mary University of London (QMUL).
    - The Barts CR-UK Centre (BCC) have a NHS Digital DSPT toolkit and an ISO 27001 certification.
- Data collection is done directly either by dedicated members of staff (data coordinators) or by surgeons.
- Data processing: see data flow in Appendix 3.
- Data retention: 10 years after the end of collection of follow-up data. Data retention for the registry will be reviewed on a regular basis.
- Data access is under access control policy:
    - Each participating hospital will have a designated clinical lead (at the consultant level). They are given full access (including patient identifiable information) to the records entered in the registry for their own institution only. They are able to view, edit and download that data to use it locally.
    - Access to the whole dataset is limited to the project manager (Fabien Puglia), who is a non-clinical member of the QOMS team. Other members of the QOMS team only have access to anonymised information.
- Access to the central dataset by any third party (individuals/institutions) requires a formal request, via the online data request form.
    - Applicant must demonstrate that they will adhere to relevant information governance regulatory framework.
    - Applications are reviewed by the RLJ working team (as described in the QOMS "Data Request" SOP).
    - If the application is approved, no identifiable information will be shared with the third party and a summary of their proposal will be published on the QOMS page on the BAOMS website.

DATA COLLECTION PROCESS

- **Consent:** The consent process is managed online (REDCap). The patient information leaflet should be made available in both printed and electronic format. If managed online, a copy of the signed consent form is emailed to the patient (providing a valid email address has been provided). Alternative solutions must be put in place at participating hospitals in case this arrangement is not possible.
- **Clinical data:** Data collection is done directly either by dedicated members of staff (data coordinators) or by surgeons. Each user is provided with a unique username and password to access the online registry. User's access to data is limited to data collected in a user's institution.
- **Imaging and biological samples:** Any imaging or biological samples collected as part of patient's diagnosis, treatment or follow-up, will be made available to be reviewed by a panel of expert and used for secondary research. No new samples are to be collected as part of the registry.

WHO HAS REVIEWED THE RLJ REGSITRY?

The RLJ registry was developed by a multidisciplinary team of surgeons, and pathologists. A group of patients was convened to discuss the set up and plans for the registry. The arrangements and security have been reviewed by this hospital / Trust / Health Board.

DATA OWNERSHIP

Participating organisations will retain the ownership of the data they entered, while the ownership of the central dataset will be with BAOMS. BAOMS will curate data on behalf of participating organisations.

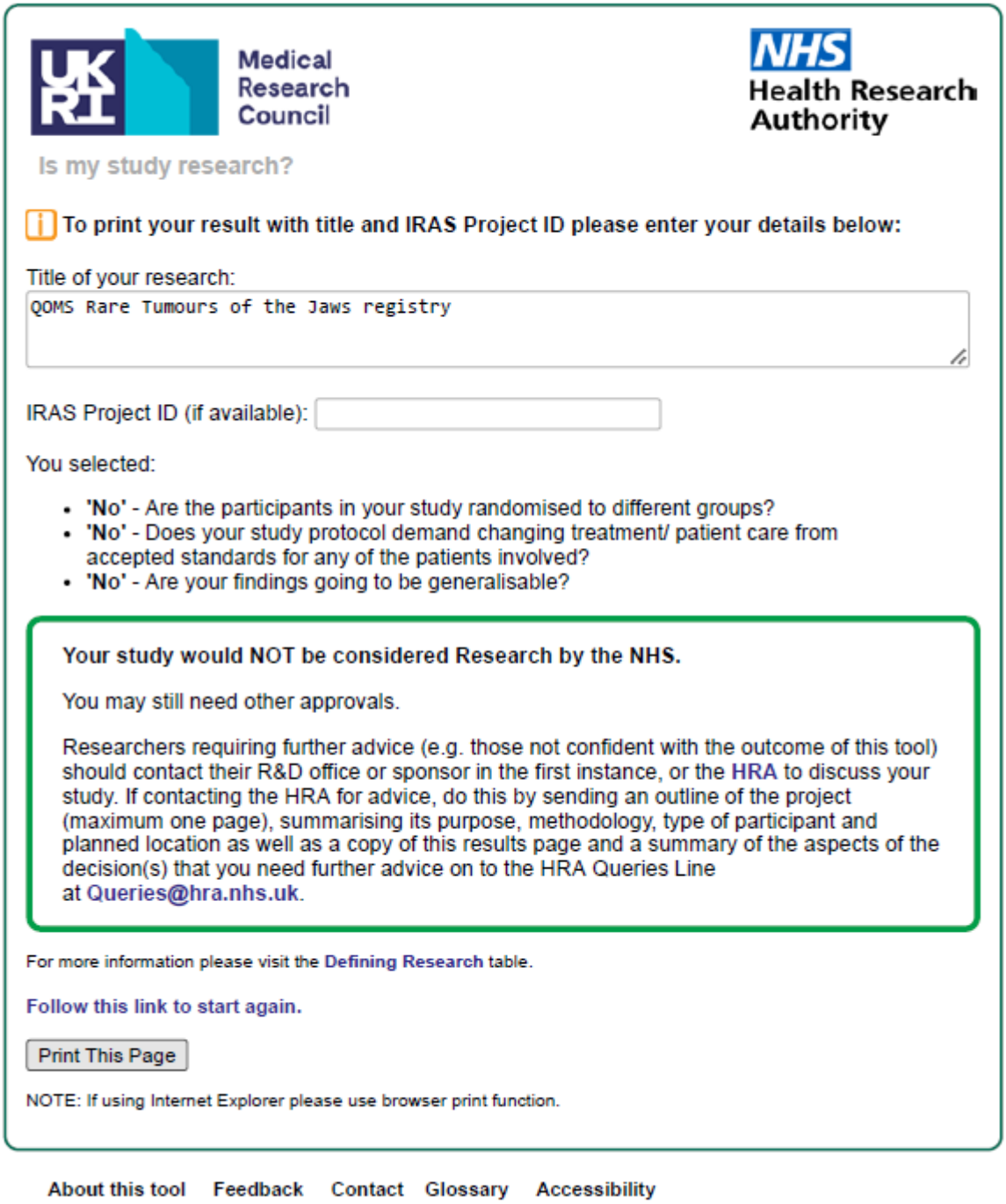
PUBLICATION POLICY

The British Journal of Oral and Maxillofacial Surgery (BJOMS) will have first refusal of any peer reviewed output from this initiative.

Individuals responsible for collecting data will be acknowledged as “collaborators” and listed in publications.

APPENDICES

APPENDIX 1. HRA MRC TOOL KIT "IS MY STUDY RESEARCH?"



Medical Research Council

NHS Health Research Authority

Is my study research?

To print your result with title and IRAS Project ID please enter your details below:

Title of your research:

QOMS Rare Tumours of the Jaws registry

IRAS Project ID (if available):

You selected:

- **'No'** - Are the participants in your study randomised to different groups?
- **'No'** - Does your study protocol demand changing treatment/ patient care from accepted standards for any of the patients involved?
- **'No'** - Are your findings going to be generalisable?

Your study would NOT be considered Research by the NHS.

You may still need other approvals.

Researchers requiring further advice (e.g. those not confident with the outcome of this tool) should contact their R&D office or sponsor in the first instance, or the HRA to discuss your study. If contacting the HRA for advice, do this by sending an outline of the project (maximum one page), summarising its purpose, methodology, type of participant and planned location as well as a copy of this results page and a summary of the aspects of the decision(s) that you need further advice on to the HRA Queries Line at Queries@hra.nhs.uk.

For more information please visit the Defining Research table.

Follow this link to start again.

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APPENDIX 2A. PATIENT INFORMATION LEAFLET

Version 1.0 Date: 20/09/2023

You have been given this leaflet because you have been diagnosed with a rare benign lesion or tumour of the jaws. The surgeons and other health professionals who care for you would like to invite you to take part in this registry dedicated to similar conditions to yours.

Please read this leaflet carefully. It explains who we are, what we are doing and how we treat your information to ensure confidentiality and anonymity.

WHY WAS I GIVEN THIS LEAFLET?

Benign lesions and tumours of the jaws are a rare and relatively varied group of conditions. Because they are rare, they are not very well understood and there are various recommendations for their management. One possible approach to this challenge is to collect information about these conditions in a specialised registry. A clinical registry collects organised information about patients affected by a condition and the treatment received. This can be used to find patterns in disease presentation, treatment outcomes and ultimately improve patient care.

WHY ARE YOU COLLECTING THIS INFORMATION?

We would like to find out how your condition was treated and followed up, if you have experienced any complications or recurrence. We would like to understand how frequent these tumours are and how they are treated in the UK. We hope this information about patients and their treatment will help clinicians and healthcare commissioners understand more about the best treatment for those tumours and improve care for patients in the future.

WHAT WOULD TAKING PART INVOLVE?

Taking part in this registry will not take up any of your time after you have consented to the study. Your surgical team will collect data directly from your medical records and pass it onto us securely.

WHAT INFORMATION ABOUT ME ARE YOU COLLECTING?

To be able to follow-up your progress over time, we need to collect your NHS number, date of birth and information about your conditions, treatments, and long-term outcomes. We would also like your permission to access and share any imaging or biological specimens routinely collected as part of your diagnosis, treatment or follow-up, to be reviewed by a panel of experts and potentially used for secondary research.

WHAT WILL HAPPEN TO MY INFORMATION?

Your information will be collected and stored on secure computers managed by the Barts Cancer Research UK Centre at Queen Mary University of London (BCC, QMUL). Access to your information will be restricted to your clinical team and a limited number of approved members from QMUL and the project team. No identifiable information will be shared.

IS MY INFORMATION SAFE?

Yes, your information is safe. Very strict rules and secure procedures are in place to ensure that your information is kept safe. The systems and procedures in place at QMUL comply with international

standards and QMUL continuously monitor and adapt them as necessary to maintain security over the lifetime of the project.

Because this information is valuable, it may also be used for secondary research e.g. evaluation of treatment outcomes, surveillance strategy and translational studies. Should this be the case, data that can directly identify you (e.g. NHS or CHI number) will never be shared.

How long will my data be kept for?

Your information will be kept for 10 years after the end of data collection. Afterwards, it will either be anonymised (i.e., NHS number, date of birth… will be deleted) or completely deleted.

Can I not take part to this registry?

Participation is voluntary and you can change your mind at any time without it affecting the care that you receive.

If you decide to not take part, when you complete the consent form, simply select "I do not agree". This way, we will keep a record of your decision and we will not ask you again at a later stage.

If you change your mind about taking part, you can withdraw at any point without providing any reasons. Simply contact your treating team or email the project team and put "Opt-out" in the subject line (see email address below). You will be asked whether you want all your information removed or whether you are happy for us to keep the information we have so far but no new information will be collected.

Who is organising and funding this study?

This project was designed by oral and maxillofacial surgeons in collaboration with pathologists. The British Association of Oral and Maxillofacial Surgeons (BAOMS) leads this project and as data controller, is responsible for looking after your information and using it appropriately. The costs for the project are being supported by BAOMS (Registered charity number: 1062067).

Who has reviewed this initiative?

This project has been reviewed by clinicians and a group of patients and carers, and the audit department of this hospital and authorised by this hospital for data protection and security prior to their participation.

What if there is a problem?

You also have the right to lodge a complaint with the Information Commissioner's Office (ICO), the supervisory authority in the UK responsible for the implementation and enforcement of data protection law, if you have concerns about the way your personal data is being handled. You can contact the ICO via telephone (0303 123 1113) or email (W: https://ico.org.uk/concerns/).

Finding out more

If you would like further information or have any questions, please contact:

British Association of Oral and Maxillofacial Surgeons | Royal College of Surgeons of England, 38/43 Lincoln's Inn Fields, London WC2A 3PE | Project Team's email: qoms@baoms.org.uk | W: https://bit.ly/qoms-at-baoms

APPENDIX 2B. CONSENT FORM

Version 1.0 Date: 20/09/2023

Consent form for patients aged 16 years and above, deemed to have capacity to consent

Before signing this consent form, please read the accompanying patient information leaflet (version: XX, Date: DD/MM/YYYY) carefully and ask questions to your clinical team. Once you are satisfied, please complete the consent form below to show whether or not you consent to the collection of your personal information and sign this form.

Please **initial** the boxes below

1.	I confirm that I have read and understand the patient information leaflet (version XX, date: DD/MM/YYYY) describing the registry and potentially associated work and have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	☐
2.	I am fully aware that the project collects personal information about me and that I will remain anonymous.	☐
4.	I understand that I have the right to withdraw my consent at any time without giving a reason and that my care will not be affected.	☐
5.	I agree to having my personal health data stored in this database at the Barts' Cancer Centre	☐
6.	I agree to have images and samples of my blood/tissue collected from any procedures that would have been undertaken as part of my treatment, to be accessed for review and secondary research.	☐
7.	I understand and agree that data from the study can be used in future research and that data would be completely anonymised.	☐
8.	I am fully aware that data collected will be stored securely, safely and in accordance with Data Protection Act (2018) and the General Data Protection Regulation (GDPR).	☐
9.	a. I AGREE to take part in this project and for my information to be collected.	☐
	b. I DO NOT AGREE to take part in this project and for my information to be collected	☐

_____	_____	_____
Name of Participant	Signature	Date
_____	_____	_____
Name of the person taking consent	Signature	Date

If you would like further information or have any questions, please contact:

BAOMS | Royal College of Surgeons of England, 38/43 Lincoln's Inn Fields, London WC2A 3PE |Tel: +44(0) 207 405 8074| Project Team: qoms@baoms.org.uk | W: https://bit.ly/qoms-at-baoms

One copy of this form should be given to the patients, one copy kept in the patient's note and the original copy kept by the treating team.

Note: provision will be made to allow for consenting of paediatric patients (less than 16 years of age)

APPENDIX 3. DATA FLOW