INFORMATION SHEET FOR EATING DISORDER SERVICES

Title of project
The Eating Disorders Clinical Research Network (EDCRN).

Introduction
We would like to invite your service to join the Eating Disorders Clinical Research Network (EDCRN) research project. Please read below to find out more about what your participation will entail and the benefits of taking part.

What is the purpose of the project?
The purpose of the project is to collect and record information about eating disorder symptoms, treatment, outcomes, demographics, risk factors and physical health markers in participating eating disorder services across the UK. This information will be collected through questionnaires, blood tests and other physical tests. The information will be recorded in the secure EDCRN online platform which can be accessed, at varying levels, by clinicians, service leads, patients and (if applicable) parents and/or guardians.

This will help us to understand who is being seen in eating disorder services. We will also be able to learn which treatments patients are getting and how well these treatments work. Standardising the information that is collected and recorded across services will facilitate further research into the factors influencing eating disorder development. We hope that this in turn will lead to better, more personalised treatments. Services will be able to access all data relating to their service and will be able to view summary information at national level for all sites participating in the Network.

The project is currently scheduled to run until 29th October 2026 but may be extended.

How will we securely manage data?
Data security is always a primary consideration in NHS settings. Data for your patients will be securely processed by Prescribing Services (ECLIPSE) an NHS-authorised data processing organisation which currently manages data for around 30 million patients registered by primary care in England.

Information will be systematically collected, recorded and presented in the secure EDCRN platform which is provided by ECLIPSE.

What data will we use?
The EDCRN dataset comprises patient and parent/guardian-reported questionnaire data, and clinician-reported information on eating disorder presentation and diagnosis, biomarkers (where available) and other physiological data (e.g. weight). All data will be recorded via the EDCRN platform. Services will have instantaneous access to the information provided by patients and parents/guardians, and clinicians will be able to use the platform to review patient progress.

What does joining the EDCRN entail?

By joining the EDCRN, your service will collect the EDCRN dataset from patients* and parents/guardians who agree to take part, using the EDCRN platform to record and view this information. Relevant health and care information from other health services will be integrated (subject to patient permissions and where available) automatically into the patient record. Your service will have live access to the information provided by patients and caregivers, allowing clinicians to review patient progress in real time.

Many of the items contained in the EDCRN dataset are currently being collected by eating disorder services using local systems or approaches (e.g., using Microsoft Forms or in paper format). The EDCRN platform is intended to replace these forms of data collection.

To note: the EDCRN platform *will not* replace electronic patient record systems (e.g. ePJS) in place for your service. Clinical notes and other administrative details (appointments, correspondence) will continue to be recorded and take place through these local clinical systems and the EDCRN team will not have access to those clinical records.

Should your service opt to participate in the EDCRN, access to the platform will be granted at varying levels depending on role.

- **Clinicians:** individuals with direct clinical responsibility for patient care will be able to access identifiable data for all patients under their care. They will also have the ability to view aggregate data for all patients participating in the national EDCRN via dashboards available within the EDCRN platform.
- **Service leads:** nominated representatives** within the service will have advanced permissions enabling them to export identifiable data for all patients in the service. They will also be able to grant EDCRN access permission to the clinicians within their service.

Clinicians with direct responsibility for patient care can sign up to the EDCRN platform directly following the steps outlined below. Services will be required to provide the details of personnel who require access to advanced 'service lead' permissions before these can be granted.

**Barring those who opt-out.*
***Number to be confirmed by the size and needs of the services but expected to be in the range of 2-5.*

Clinician registration
To register as an individual, users should email support@prescribingservices.org requesting access to ECLIPSE and providing details as follows:

- Applicant name
- Applicant nhs.net email address
- Applicant mobile number (for 2 factor authentication)
- Applicant job description (nurse, HCA, Psychologist etc)
- Name of Service
- Trust name
- Trust/Service ID

An ECLIPSE support team member will contact a data controller at the named service to confirm that the applicant should be given access to the patient record. Once conformed the applicant will receive login details and instructions to access ECLIPSE via their nhs.net email account.

Alternatively, a data controller at the service can email ECLIPSE to request access for multiple eligible staff members.

Patient contact

Your service will be asked to share information about the EDCRN with new patients. Generally this would occur when booking the patient's initial assessment. Along with information about the assessment appointment, new patients should be sent the following EDCRN information:

- Participant information sheet (see information pack)
- Informed consent form (see information pack)
- EDCRN text for inclusion in initial communication (see below for standard and adapted versions)

Patients would then provide intake information and complete questionnaires online through the EDCRN platform before attending their initial appointment with your service. The assessing clinician would be able to see their responses on the EDCRN platform.

General text to include in your initial communication to patients, e.g., within an assessment confirmation letter:

[NAME OF SERVICE] is part of the Eating Disorder Clinical Research Network (EDCRN, for short). The EDCRN is working with services like ours to standardise the information collected on eating disorder treatment and outcomes. This information will be collected on an online platform. We are encouraging all patients in our service to sign up to the EDCRN.

You can read more about the EDCRN in the [ATTACHED/ENCLOSED] information leaflet. If, after reading this, you are interested to take part, we encourage you to register a profile on the EDCRN platform at: [INSERT WEBSITE LINK] and complete the initial questionnaires.

To register a profile, you will need to provide:

- *Your NHS Number [INSERT PATIENT NHS NUMBER]*
- *Your date of birth*
- *Your phone number or email address (a code may be texted or emailed to you on this number or email so that you can verify your account).*

If you do not want to participate in the EDCRN, please let us know.

Text for parents/guardians referring a child (u-16):

[NAME OF SERVICE] is part of the Eating Disorder Clinical Research Network (EDCRN, for short). The EDCRN is working with services like ours to standardise the information collected on eating disorder treatment and outcomes. This information will be collected on

an online platform. We are encouraging all patients and parents/guardians in our service to sign up to the EDCRN.

You and your child can read more about the EDCRN in the [ATTACHED/ENCLOSED] information leaflets. If, after reading this, you and they are interested to take part, we encourage you to register profiles on the EDCRN platform at: [INSERT WEBSITE LINK] and complete the initial questionnaires.

To register a profile, you and your child will need to provide:

- *Your child's NHS number*
- *Your Child's date of birth*
- *Your **own** NHS Number (required to link your details to that of your child within secure NHS systems)*
- *Your **own** date of birth*
- *Your phone number or email address (a code may be texted or emailed to you on this number or email so that you can verify your account).*

If you and/or your child do not want to participate in the EDCRN, please let us know.

Patient registration

Once patients have registered on the EDCRN platform (using the details listed above), their information will be accessible to the nominated service lead(s). Participants will be invited to complete demographic details and questionnaires prior to their assessment (see the "EDCRN dataset" document included in the information pack for more details). This information will be made available to clinical teams in real time and can be reviewed ahead of the patient's initial assessment. Clinical teams can access the patient's record by entering the patient's NHS number. Permissions can be granted to clinicians with direct responsibility for patient care by nominated service lead(s) as deemed appropriate. This is intended to account for changes in clinical teams due to staff turnover. Clinicians with access to patient records in their service will then be able to search for the patients they are working with (for assessment and/or treatment) and add these patients to their home dashboard if they wish.

Prior to treatment commencing

Once patients have had their initial assessment* and been accepted for treatment, the service should assign them a clinician as normal. The assessor or an appropriate representative should complete the baseline clinician-reported data on the EDCRN platform and request biomarkers (e.g., blood tests) as specified in the "EDCRN dataset" document. Results of these biomarkers should be entered onto the EDCRN platform by an appropriate representative in the service. Patients will be able to view this information when they log into the platform.

**Patients who do not complete the assessment questionnaires and demographic details should be requested to do so at the initial meeting. If they choose not to take part in EDCRN, local service protocols should be followed, e.g., the service may choose to offer paper forms or another means of collecting intake information.*

During treatment

From the time that a patient starts treatment, clinicians should encourage them to complete questionnaires as outlined in the EDCRN dataset. Patients will also receive

automated alerts via the platform reminding them to complete questionnaires. Clinicians should request applicable biomarkers and upload the results to the EDCRN platform as outlined in the EDCRN dataset. Once recorded, the information will be visible to patients* and clinical teams via the EDCRN platform. Clinicians can review questionnaire responses ahead of meeting with patients.

**We recognise that some of the data may prove triggering to patients. Patients will have the option of hiding data items (for example, weight) if they would prefer not to see these.*

Discharge
A patient's discharge from the service marks the final data collection point at which their details are visible to the service in an identifiable way. Patients can choose to complete follow-up questionnaires for a period of up to 5 years post-discharge. This will be managed under a separate opt-in consent process. Aggregate data from follow-up questionnaires will be available for services like yours to access.

Follow-up questionnaires
Once patients are discharged, they (and parents/guardians as applicable) will be invited to complete follow-up questionnaires for up to 5 years following discharge via a separate opt-in consent process. Treatment teams ***will not*** have access to individual-level data collected through the follow-up questionnaires. Treatment teams will be able to view de-identified follow-up data at aggregate level for all patients who 1) received treatment at your service and 2) are participating/have participated in the EDCRN.

The EDCRN dataset
The EDCRN dataset comprises both essential and optional items. Optional data items can be customisable to the needs of your service. Equally, patients can choose to complete optional questionnaires which feel particularly relevant to them. To note: even where an item in the dataset is marked as essential, patients can choose not to complete these (or have a particular clinical test) if they feel uncomfortable doing so.

Considerations for patients under 16
Information about the EDCRN should be sent to the same person who is sent details about the service and assessment. In many cases, for patients under 16, this will be a parent or guardian. Sometimes, a child or young person may self-refer*. The EDCRN will follow the principle of Gillick Competence. Patients considered capable of consenting to treatment and creating a profile on the platform will be able to do so without requiring explicit consent from a parent or guardian. Parents/guardians *can* provide consent for their child via the online platform enabling them to create a profile and complete pre-assessment questionnaires. Where a parent *does not* provide consent, the child's capacity to participate in the EDCRN should be determined at assessment. Treatment teams will be able to override the parental consent tick box on the EDCRN platform which they can activate at any point from when a patient logs their details.

**Where a patient under the age of 16 has self-referred for treatment, they should be considered capable of providing informed consent and therefore should not have to wait until assessment to have their profile activated by the service.*

Sharing records with a parent/guardian(s)
Patients of all ages may choose to share their record with parents/guardians. This should be discussed with patients at assessment or their first treatment meeting. Express

permissions will be required from *all* parties (including clinicians or nominated service leads) via online consent protocols within the EDCRN platform before these records can be shared. Parents/guardians who register profiles will also be invited to completed caregiver questionnaires. Only one parent/guardian per patient should complete the questionnaires. This is explained in patient and parent/guardian information materials.

Considerations for adult patients lacking capacity to consent
Capacity will be assumed by a patient's ability to set up a profile, provide consent online and answer questionnaires. Due to the nature of the project, it won't be possible for us to include adults who lack capacity to consent in the EDCRN.

Withdrawals
If a patient wishes to withdraw from the EDCRN, they can communicate this to the research team by email, post or by selecting the 'withdraw' option on the EDCRN platform. They will also have the option to request that any pre-existing data which has not already been used for analysis and/or distributed to other researchers be deleted.

Patients are encouraged to speak with their treatment team prior to withdrawal but this is not a requirement. Once we have actioned the withdrawal request, your service will be notified by a member of the research team.

National Data Opt-Out
Patients (and parents/guardians as applicable) who are part of the National Data Opt-Out may still participate in the EDCRN. If a patient chooses to register a profile and complete questionnaires, this will be considered an indication of their interest in participating and will supersede their participation in the National Data Opt-Out for the purposes of this study. This is explained in participant information materials.

Transfers to a new service
If a patient moves to another service which is part of the EDCRN, they will have the option of transferring their record to the new service. This will give the new treatment team access to all existing data pertaining to the patient which has been recorded on the EDCRN platform. The existing serviced will retain access to all data collected prior to the patient's transfer.

Participation in EDGI
One of EDCRN's primary aims is to recruit 1000 patients into the Eating Disorders Genetics Initiative UK (EDGI UK). EDGI is a pre-existing research study which aims to better understand the genetic and environmental links to eating disorders and help develop better treatments.

Each service participating in Phase 1 of EDCRN – including yours – will be asked to try and recruit 125 patients to EDGI UK. This involves supporting participants to provide informed consent and register an account on the EDGI UK site and facilitating the collection of biological (blood and saliva) samples. Clinicians or service leads should click the 'recruited to EDGI' box on the EDCRN platform once a patient opts to take part. This will enable the EDCRN and EDGI teams to perform data linkage and reimburse participants for the additional time involved in EDGI participation. Costs relating to the recruitment of these participants will also be reimbursed to your service via the SoECAT mechanism, as outlined in the Organisation Information Document (OID).

An advantage of linking EDCRN and EDGI data is that, for the first time, it will be possible to consider whether genetic markers predict response to psychological treatments.

Saliva sample: EDGI participants can provide a saliva sample in their own time. Participants will be sent a non-invasive saliva kit (IsoHelix saliva kit for DNA analysis) through the post using HTA (Human Tissue Act, [2004]) approved procedures, as per the manufacturer's instructions. They will complete saliva collection in their own homes (or another location of their choice) and then return the kit through the post using a postage-paid envelope, again following the manufacturer's protocol. Participants who are receiving treatment as inpatients may ask for your help in posting the saliva sample.

Blood sample: A (maximum 50ml) blood sample should be taken by your service by a qualified, trained member of staff/trained phlebotomist (or by the patient's GP if no onsite phlebotomy services are available) and requested by the clinician at the same time as other biomarkers being routinely collected as part of the patient's treatment. Blood samples should be taken at two timepoints – at admission and at the end of treatment/near discharge. Materials for collection and storage of samples will be provided. This includes a pre-addressed, pre-paid mailing kit which should be transported to the NIHR Maudsley Biomedical Research Centre.

Participant incentive: The 1000 EDCRN participants (125 per service) recruited to EDGI will receive a £20 incentive for their time in the form of a voucher. The research team will arrange for the voucher to be sent to participants by email or post once they have taken part in the study.

Recruiting additional participants: When the recruitment target of 1000 EDCRN participants into EDGI has been met, further EDCRN participants can also optionally sign up to EDGI providing saliva samples instead of blood. These will be accrued via NIHR Clinical Research Network (CRN) mechanisms to each Trust (if applicable) but will not be part of the SoECAT mechanism.

Further information about EDGI can be found in the *EDGI Guidance for Local Delivery Teams* document included in the local information pack.

Who is funding and organising the study?

This study is being funded by the Medical Research Council [grant number MR/X030539/1], the Medical Research Foundation and the National Institute for Health and Care Research (NIHR). The funding period is 30th October 2023 – 29th October 2026.

This project is sponsored by King's College London and South London and Maudsley NHS Foundation Trust and is being led by Professor Gerome Breen (King's College London) and Dr Karina Allen (South London and Maudsley NHS Foundation Trust.

Who has reviewed this study?

This project has been reviewed by [Insert REC name and number / other relevant regulatory authorities]

Where will data be stored?

Data will be retained for 15 years in highly restricted format in accordance with funder requirements and King's Records and Data Retention Schedule: https://www.kcl.ac.uk/professional-services/business-assurance/corporate-records-

management More information about data processing and storage can be found in the Data Protection Impact Assessment, available in the local information pack.

If your service downloads your service-level data from EDCRN, this should be stored and retained in line with your local Trust Information Governance policy and not shared outside of your Trust information system.

What will happen to the results of the project?

The information collected through the EDCRN will be used to improve our understanding of who is being seen in eating disorder services and how effective eating disorder treatments are for different patients. All analyses will use pseudonymised data, with no identifiable patient information being shared. Results will be considered on average across the national Network, but we may also look at regional and service-level differences. **No individual service will ever be identified or identifiable when we report EDCRN data.** Services will be described using an ID number. Learnings from the Network will be published in journal articles and presented at conferences. Published findings will be made available on the EDCRN website.

Services will be able to analyse and report on their own service-level data however they choose. This may include publications, internal summaries or presentations. Again, all use of your data should comply with your local Trust Information Governance policy.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions:

- EDCRN@kcl.ac.uk (study team email)
- Anna.carnegie@kcl.ac.uk (Study Coordinator)
- Gerome.breen@kcl.a.uk (Principal Investigator)
- karina.allen@slam.nhs.uk (Principal Investigator)

Who should I contact for further information?

If you have any questions or require more information about this project, please contact the research team using the following contact details: EDCRN@kcl.ac.uk You can use this contact information at any point during the study.