# EMRAD FAIR PROCESSING & CONSENT STANDARD OPERATING PROCEDURES

## 1. INTRODUCTION

1.1. This Standard Operating Procedure (SoP) complements the EMRAD Data Processing Protocol (DPP), which contains the principle that patient information will be collected and jointly processed by EMRAD consortium members using implied consent. This is based on:

- The patient has consented to their data being processed by agreeing to a diagnostic test/intervention[1]
- The processing is necessary for medical purposes, and is undertaken by a health professional, or by someone who is subject to an equivalent duty of confidentiality.

## 2. OBJECTIVE

2.1. The objective is to ensure that all EMRAD consortium members agree and apply a consistent consent model for the collection and processing of EMRAD patient data that satisfies the:

- Data Protection Act 1998
- Access to Health Records Act 1990
- Common Law Duty of Confidentiality
- Confidentiality: NHS Code of Practice
- Caldicott Principles.

## 3. SCOPE

3.1. This SoP addresses:

- Consent for data processing for direct care purpose
- Consent for data processing for non-care purposes
- Patients who dissent, or withdraw consent, to joint data processing.

## 4. RESPONSIBILITIES

4.1. The EMRAD Management Board will ensure that:

- Non-care data processing is lawful, seeking expert advice as necessary
- Explicit patient consent is obtained for use of EMRAD patient information for non-care purposes

4.2. SRO from each EMRAD consortium member will ensure that:

- All EMRAD patients are informed about how their information will be used
- Records are kept of patients who dissent to their data being processed within EMRAD

## 5. DOCUMENTATION

5.1. The documentation required to maintain a consistent consent model includes:

- Standard wording on EMRAD patient letters

[1] In the case of a patient lacking capacity for any reason, a clinical decision will be made in the patients' best interests according to existing legislation and guidance.

- Patient information leaflets and consent forms where explicit patient consent is required
- Records of patients who dissent.

## 6. PROCEDURES

**Consent for data processing for direct care purpose**

6.1. The public fair processing notices of EMRAD consortium members must contain the following statement:

> *This Trust is part of a group of NHS hospitals in the East Midlands that have a shared NHS radiology system, which is used by our healthcare professionals to access your radiology records. If necessary, your radiology records may also be accessed by healthcare professionals in other NHS hospitals in the East Midlands or NHS Service Providers, to ensure you receive consistent, safe and effective clinical care and treatment, irrespective of where you receive your care. If you have any concerns about providing information or how we use it, please discuss this with radiology staff so that you fully understand the potential impact on your care or treatment.*

6.2. The same statement should appear in all radiology appointment letters.

6.3. The EMRAD Live Services Team will monitor consistent use of this terminology by EMRAD Trusts.

**Consent for data processing for non-care purposes**

6.4. Use of EMRAD patient data for non-care purposes typically falls into 3 categories:

- **Clinical audit** – permitted without further patient consent as long as the audit is conducted by those involved in patient care.

  NB. The Clinical Audit Support Network for the East Midlands (CASNET) is currently drafting a set of agreed SOPs for performance and registration of clinical audits within/ across the EMRAD consortium which require access to the EMRAD patient record. These will be available on publication and it is expected that all clinical audits will adhere to these.

- **Research** – typically requires explicit patient consent[2]. Applications must be approved by the relevant Research and Ethics Committee (REC). This may either be the local Trust REC, or the regional REC, dependent on the scope of the research project. Any project which requires access to the EMRAD patient record should be approved by the regional REC. A patient information leaflet and consent form, specifically for the research project, must clearly indicate what information will be collected and who will have access to it.

- **Service evaluation/improvement** – unless there exists a legal basis for processing patient identifiable information, only anonymised data may be used for this purpose. All such processing requests must be registered at regional level with the EMRAD live services team, such that (if requested) any other EMRAD consortium Trust can have assurance that the shared record is being processed appropriately by the Trust/s.

**Patients who dissent, or withdraw consent, to joint data processing**

6.5. If a patient expresses concern about their information being jointly processed by EMRAD Trusts, or withdraws their consent, the following steps should be followed:

[2] Or Section 251 approval (of the NHS Act 2006)

i. A nominated responsible clinician[3] should explain to the patient the clinical benefits of their information being readily accessible to healthcare professionals across the region

ii. If not acceptable, explain that an imaging examination will not be able to be performed in an EMRAD Trust. Such cases are expected to be exceedingly rare. These events must be promptly recorded using the Trusts' designated risk log (e.g. DATIX) as a clinical incident, such that these events can be appropriately monitored.

6.6. Patients who withdraw consent must be told that any records created prior to the point of withdrawal cannot be removed, but that future records will be maintained in accordance with the patient's wishes.

[3] In practice this is expected to be the senior radiographer or radiologist in the department at the time.