C. Proposed Protocols for ESWL

Craigavon Stone Treatment Centre

Agreed method of working at Urology Stone MDT on

For review 3 months after start date of working at stone MDT.

1. **Staff Nurse checking in and out of Patient**
    1. Patient to Arrive 45 minutes prior to treatment and hand in patient consent and contraindications signed form (Sent by post prior to appointment)
    2. On arrival patient is asked to produce a Urine sample (and pregnancy test for child baring age 12 -55 years of age IRMA guidelines. QUOTE)
    3. In the patient consultation room, consent form checked signed. Contraindications to ESWL form checked with patient again and nurse signs check list to confirm.
    4. Medications given as per protocol (30 minutes before ESWL , ref evidence meds onset of action)
    5. Following completion of ESWL, patient to remain in waiting room, given light refreshments and observed for 30 minutes.
    6. Bloods pressure, Heart rate, respiratory rate and oxygen saturation checked prior to discharge.
    7. Radiologist books patient for either;
        1. Follow-up imaging as indicated by stone meeting or
        2. Re-book slot for ESWL and inform patient of date and time, included in discharge letter (add to hospital W/L)
    8. Upon discharge copy of discharge and medications given and explained, ESWL post procedure advice sheet given.

2. **Medication Protocols**

    1. Patient to receive medication pathway set and prescribed at Thursday morning stone meeting
    2. Nurse to check with patient allergies/ check contraindication
    3. Pathway 1,2,3,4 Nurse led, Pathway 5 Doctor led

	Pathway 1	Pathway 2	Pathway 3	Pathway 4	Pathway 5
30mins prior to ESWL, oral medications	Paracetamol 1g	Paracetamol 1g, Diclofenac Potassium 50mg oral	Paracetamol 1g, Diclofenac potassium 50mg oral	Paracetamol 1g	Doctors led, meds advised
Breakthrough pain relief during ESWL	Not suitable	Not suitable	Penthrox 3ml inhaler	Penthrox 3ml inhaler	Penthrox or Alfentinal

3. i. **Radiographer ESWL treatment and discharge letter**
    A. Patient consent form counter signed by radiographer
    B. Stone to be treated as per Stone meeting outcome letter or as per stone clinic outpatient letter.
    C. Stone localised using USS and/or fluoroscopy
    D. Ramping as per protocol

E. Following completion of patients dedicated treatment hour please fill **lithotripter e-discharge to state**

1. Patient full name, date of birth, address
2. Radiographer and nurse full name
3. Urologist responsible for patient
4. Blood pressure before/ during/after
5. Medication given prior, during and discharge from treatment
6. Number of shocks, energy and power
7. Stone location
8. Pain encountered during treatment
9. Fragmentation
10. **Until the software changes below have been made, please use the free text comment box to fill out <u>either</u>** a. Rebooked for second treatment to same stone
    b. Rebooked for third treatment to same stone
    c. Rebooked for fourth treatment to same stone
    d. Rebooked for treatment to concurrent stone
    e. Follow-up imaging 6weeks (option x-ray, USS, both or CTKUB)
    f. Re-discuss at MDT meeting due to treatment failure or complication
    g. Stone clinic review

Software changes proposed;

i. Hounsfield units of stone being treated
ii. Validated Pain score 0-10
iii. Treatment limited due to: drop down box
    a) Pain
    b) Nausea and vomiting
    c) Other patient factors
    d) Time constraints
iv. Stone to skin distance (cm)
v. Accurate stone size from original CT (mm)
vi. Number of treatments to stone
vii. Record of other stones present (green colour on diagram, red treated stone)
viii. Allergies (free text)
ix. Free text comments
x. Drop down selection of follow-up
    a) Rebooked for second treatment to same stone
    b) Rebooked for third treatment to same stone
    c) Rebooked for fourth treatment to same stone
    d) Rebooked for treatment to concurrent stone
    e) Follow-up imaging 6weeks (option x-ray, USS, both or CTKUB)
    f) Re-discuss at MDT meeting due to treatment failure or complication
    g) Stone clinic review

<u>e-discharge is then uploaded to ECR (copy to patient/GP/patients notes)</u>

ii. **Auxiliary Nurse during treatment**

A. Ensure patient comfort on table; supervise patients to prevent moving off the table during a treatment. Allow patient to play music they have brought in and use the earphones if patient has brought their own with them.

B. Undertake continuous observations of **heart rate** and **oxygen saturation** during Penthrox use, and ask radiologist to stop treatment and retrieve staff nurse from adjoining room if patient concerns raised, such as increased MEWS.

C. **Blood pressure** check every 15 minutes during Penthrox treatment, or more regular if required.

iii. **Staff nurse**

A. To provide Penthrox medication as breakthrough pain relief to suitable patients.

4. When Help is needed

1. **Treatment Query;**
   - Urgent advice needed then contact Mr Young on Mobile Personal information redacted by USI
   - Call Urology Registrar on call if Mr Young unavailable
   - If unable to contact then call consultant on-call via switch board (0)

2. **Unwell patient;**
   - Contact the Registrar on Call for Urology on bleep Irrelevant redacted or mobile through switch board. If unable to contact call the Consultant on-call.

Cardiac Arrest or Peri-arrest Dial 6666 and state 'cardiac arrest, stone treatment centre' Then call Urology Doctors.

Nurse Checklist for Stone Treatment centre

Admission: Date: _____ **Patient Label:**

Time: _____

Signed: _____

Print Name: _____

Prior to treatment	YES	No	Comment if required
Confirm patient details			
Confirm patient understands treatment and any questions			
Chaperone present			
Review medication list			
Allergies (incl latex)			
Medications stopped as advised			
Able to take NSAIDs			
Urinalysis (POCT urine if symptomatic of UTI, Immunosuppressed)			(See flow chart)
Pregnancy test (12 to 55 years of age)			
Safety checklist from patient:			
Anticoagulation stopped as per protocol			List medication held:
Artificial heart valve			If yes give antibiotic prophylaxis Check anticoagulation protocol
Pacemaker or defibrillator			Electrophysiologist check/programme pre and post ESWL **YES/NO**
Artificial joint or mobility concern			
Abdominal aneurysm			Proceed only if aneurysm discussed at MDT and ESWL recommended. **YES/NO** Otherwise, cancel ESWL and discuss at Stone MDT
Neurosurgical Abdominal shunt			Cancel treatment and discuss at Stone MDT
Neurostimulator or other abdominal implant			If aware at MDT and ESWL to proceed **YES/NO** Implant not to be in focal zone of treatment
Pregnancy test positive			Cancel if positive and discuss at Urology Stone MDT
Pre ESWL Medications given and signed for			
Counsel on use of Penthrox (if indicated)			
Consent form check – radiographer countersigned			

During treatment	YES	No	Comment if required
Penthrox used			
Comments			

Observations

Admission

BP: **Pulse:** **Sats on air**: **Temperature:**

During Treatment

Time	BP	Pulse	Sats on air	Other (if required)

After treatment and on discharge

BP: **Pulse:** **Sats on air**: **Temperature:**

After treatment	YES	No	Comment if required
Post ESWL information given			
Medications for discharge			
Chaperone			
Anticoagulation to restart			Restart date as per protocol/ warfarin clinic organised **YES/NO**
e-Discharge letter for GP and patient			
Follow up arrangements made by radiographer			

Discharge: Date: _____

Time: _____

Signed: _____

Print Name: _____

Management of blood pressure Prior to ESWL Treatment

Acute episodes of hypertension may arise in a variety of clinical settings due to the exacerbation of a pre-existing chronic hypertensive condition or as *de novo*. Emergency, intensive care, anaesthesia, and surgery are among the clinical settings where prompt recognition and treatment of acute hypertensive episodes (AHE) is of paramount importance. A variety of surgical and medical events may trigger intense sympathetic activity, resulting in sudden elevations in blood pressure (BP).

Table 1

Classification of Blood Pressure for Adults Aged ≥18. **(Pre-ESWL)**

Category	Systolic Blood Pressure	Diastolic Blood Pressure	
Normal	<120	<80	Proceed with ESWL.
Pre-hypertension	120–139	80–89	
Hypertension-Stage I	140–159	90–99	Proceed with treatment with ESWL. Advise patient to have BP rechecked with GP.
Hypertension-Stage II	≥160	≥100	Return to GP for checking and managment
Hypertensive Urgency	>180	>120	Contact oncall doctor #1144 – to discuss with medical team.
Hypertensive Emergency	>180	>120 and target organ damage	

Adapted from Chobanian, 2003.

Tulman DB, Stawicki SPA, Papadimos TJ, Murphy CV, Bergese SD. Advances in Management of Acute Hypertension: A Concise Review. *Discovery medicine*. 2012;13(72):375-383.

d. ESWL Medications

(Pain Relief and Antibiotics)

PATHOGENESIS OF PAIN DURING ESWL

The pain experienced by a patient receiving ESWL is multifactorial, but broadly speaking can be split into patient factors and lithotripter factors.

Patient Factors	Lithotripter Factors
Cutaneous superficial skin nociceptors*	Lithotriptor type^
Visceral nociceptors such as periosteal, pleural, peritoneal*	Size and site of stone burden^
Musculoskeletal pain receptors*	Location of shockwave focal stone^
Pain tolerance	Size of focal zone^
Pre-existing injury	Cavitation effects^
	Shockwave peak pressure^
* (Weber A, 1998)	Entry of shockwaves at skin^
	Coupling
	(Basar H, 2003)

To achieve the desired number of shockwaves delivered to a stone, at a suitable power, to generate a reasonable level of energy delivery to treat the stone requires the practitioner to limit the pain experienced by the patient.

Although many papers have been written on ESWL and pain relief, to date a consensus on what to prescribe has not been reached. The search for the ideal pain medication regime therefore continues.

Pain Medication ESWL pathway Craigavon Stone Treatment Centre (still active October 2017)

Current Medication:

a. Prior to treatment: **1 gram oral Paracetamol**
20mg Piroxicam oral (FELADINE MELT)

These are both given as long as there are no contraindications prior to procedure. Currently there is no set time prior to treatment for when given, hence a patient may take the medication and proceed straight to ESWL treatment.

b. Post Procedure : **Paracetamol 1 gram oral, QDS, 3 days**
Diclofenac 50mg, oral, tds, PRN, 3 days
(Alternative to diclofenac is codeine phosphate 30-60mg, oral, QDS, PRN, 3 days)

Pre-medication Onset of action

Paracetamol:

Paracetamol is readily absorbed from the gastrointestinal tract with peak plasma concentrations occurring about 30 minutes to 2 hours after ingestion. It is metabolised in the liver (90-95%) and excreted in the urine mainly as the glucuronide and sulphate conjugates. Less than 5% is excreted as unchanged paracetamol. The elimination half-life

varies from about 1 to 4 hours (emc+, 2016)

Piroxicam:

Piroxicam is a Non-steroidal Anti-inflammatory, with a half-life of 3-4 hours, and duration of action of up to 2 days, with some effect being reported up to 7-10 days (British Medical Association , Fourth edition, 2012). The Piroxicam Melt has a fast absorption and is not influenced by the fasting state (Gorham, 2013).

The FDA gives two explicit warnings on the use of NSAIDS (Not Aspirin) (DRUGS.COM , 2017)

WARNING: RISK OF SERIOUS CARDIOVASCULAR AND GASTROINTESTINAL EVENTS

Cardiovascular Thrombotic Events

- Nonsteroidal anti-inflammatory drugs (NSAIDs) cause an increased risk of serious cardiovascular thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in treatment and may increase with duration of use. *[see Warnings and Precautions (5.1)]* .
- Piroxicam Capsules USP is contraindicated in the setting of coronary artery bypass graft (CABG) surgery *[see Contraindications (4) and Warnings and Precautions (5.1)]*.

Gastrointestinal Bleeding, Ulceration, and Perforation

- NSAIDs cause an increased risk of serious gastrointestinal (GI) adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients and patients with a prior history of peptic ulcer disease and/or GI bleeding are at greater risk for serious GI events *[see Warnings and Precautions (5.2)]* .

Pubmed Search for Piroxicam use for ESWL

Search terms included 'ESWL', 'SWL', 'Extracorporeal shockwave lithotripsy' and 'Piroxicam'

9 papers were returned

7 papers were discarded as they did not directly compare piroxicam in a trial or present study evidence for its use.

The remaining 2 papers were clinical trials, a randomized placebo-controlled study and a randomised comparison trial.

Andreou et al undertook a Randomized study comparing piroxicam analgesia and tramadol analgesia during outpatient electromagnetic extracorporeal lithotripsy, 2006. They randomised 171 patients into 2 groups of 40mg IM Piroxicam and 100mg IV tramadol. The tramadol group had more side effects, but both forms of medication were deemed suitable pain relief for ESWL according to the visual pain score and researches analysis (Andréou A, 2006).

Aybek et al undertook a randomized, placebo-controlled study, comparing 30 patients receiving IM Piroxicam 40mg

vs 30 patients receiving IM saline as the placebo control. Medications were given as IM injection to the gluteal muscle 45 minutes before ESWL. Medication vs no medication demonstrated a significant difference on a verbal rating pain scale (Aybek Z, 1998).

The 2 papers which looked at piroxicam and ESWL did not look at the oral route and were not using the current generation or modality of shock generation used at Craigavon Area Hospital.

Outcome:

Data is therefore required for oral Piroxicam use as a pre-medication for ESWL. We conducted a prospective study in Craigavon, comparing 100 patients in relation to energy received to stone and premedication given.

Comparison Study of Piroxicam and Paracetamol vs Paracetamol

for ESWL pain relief medication.

Craigavon Stone Treatment Centre

Aim

Does the combination of oral Piroxicam and Paracetamol premedication for ESWL increase the power and energy delivered to renal and ureteric stones when compared to Paracetamol alone?

Background

The Craigavon Area Hospital Stone Treatment Centre generally follows the recommendations for ESWL based on the European Urology guidelines for Urolithiasis (European Association of Urology , 2017). It was noted the most common reason for limitation of ESWL treatment was pain experienced by the patient. The department had been traditionally using the NSAID piroxicam 20mg oral fast tab and 1 gram of oral paracetamol as pre-medication for ESWL. This had been given to the patient on average 30 minutes before their ESWL treatment.

Piroxicam is non-selective non-steroidal anti-inflammatory drug (NSAID), meaning it has action on COX-1 (Cyclo-oxygenase-1) and COX-2 enzyme inhibition. The COX-1 and COX-2 enzyme catalyzes the synthesis of cyclic endoperoxides from arachidonic acid to form prostaglandins. Prostaglandins mediate the inflammatory, fever and pain sensation (Day RO, 2013). COX-1 is distributed throughout the body, with higher concentration in kidney, stomach, endothelium and platelets. Prostaglandins produced via this pathway control renal perfusion, promote platelet aggregation and gastric protection. Whilst COX-2 is found in macropharges, leukocytes, fibroblasts and synovial cells, with the prostaglandins produced mediate inflammation, fever, and pain and inhibit platelet aggregation (Longo D, 2012).

There are several non-prostaglandin pathways NSAIDS may act upon, but further study in required to explain the mechanism of action and the importance (Soloman, 2017). The combination of paracetamol and the NSAID

Ibuprofen has been proved to be of benefit in a Cochrane review, for the treatment of post-operative pain (Derry CJ, 2013). There is however clear variation in the individual patient response to NSAIDs in both therapeutics and adverse effects, and some patients seem to respond better to one drug than to others, and responses differ between patients. These differences have been attributed to variations in mechanism of action to COX enzyme inhibition different capacities for altering non-prostaglandin-mediated biologic events; and differences in pharmacodynamics, pharmacokinetics, and drug metabolism, including pharmacogenetic factors (Soloman, 2017).

The pain experienced by a patient receiving ESWL is multifactorial, but broadly speaking can be split into patient factors and lithotripter factors.

Table 1.

PATHOGENESIS OF PAIN DURING ESWL

Patient Factors	Lithotripter Factors
Cutaneous superficial skin nociceptors*	Lithotriptor type^
Visceral nociceptors such as periosteal, pleural, peritoneal*	Size and site of stone burden^
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* (Weber A, 1998)	Entry of shockwaves at skin^
	Coupling
	(Basar H, 2003)

To achieve the desired number of shockwaves delivered to a stone, at a suitable power, to generate a reasonable level of energy delivery to treat the stone requires the practitioner to limit the pain experienced by the patient.

Although many papers have been written on ESWL and pain relief, to date a consensus on what to prescribe has not been reached. The search for the ideal pain medication regime therefore continues.

A Pubmed search for the use of oral Piroxicam as pre-treatment medication for ESWL returned no studies. Search terms included 'ESWL', 'SWL', 'Extracorporeal shockwave lithotripsy' and 'Piroxicam', 9 papers were returned, 7 papers were discarded as they did not directly compare piroxicam in a trial or present study evidence for its use. The remaining 2 papers were clinical trials, a randomized placebo-controlled study and a randomised comparison trial, but neither studied the use of Piroxicam as an oral medication (Andréou A, 2006) (Aybek Z, 1998). Data is therefore required for oral Piroxicam use as a pre-medication for ESWL.

Method,

Data on a prospective 150 patients receiving ESWL for renal and upper ureteric stones was collected in2017. The departments guidelines for pain relief was followed, offering all patient pre-medication with paracetamol and piroxicam, with those contraindicated to piroxicam due to allergy, previous stomach ulcer, NSAID ingestion that day or personal choice only receiving Paracetamol or nothing. Oral medication was given on average 30 minutes prior to treatment by the staff nurse, in a separate room to the lithotripter and blinding radiographer who delivers the ESWL treatment.

All patients were treated by the same EDAP TMS Sonolith i-sys, which is a new generation electroconductive lithotripter. All patients were aimed to have 1000J delivered to a renal and 1400J to a ureteric calculi, with a frequency of 1.2Hz as standard. The power to the calculi was aimed at reaching 100%, requiring 3000 maximum shocks up to a one hour treatment session. Treatment can be stopped if stone successfully treated at a lower energy.

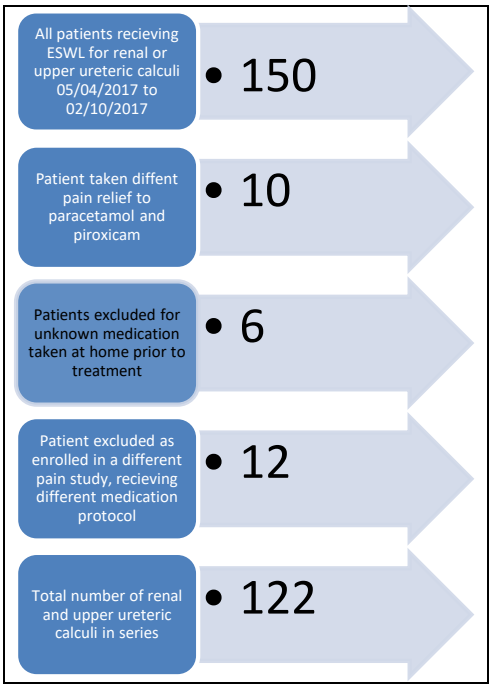


Table 2. Patients excluded from study

Results,

Table 3. Renal and upper ureteric calculi

Medication	Number of Patients	Average age and (range)	Power (%) average and (range)	Energy average and (range)
20mg Piroxicam and 1g Paracetamol	62	50.3 (24-80)	59.4 (16-100)	689.6 (55-1000)
1g Paracetamol	56	54.4 (28-81)	60.8 (12-99)	788.8 (145-1000)
No Medication	4	65.5 (60-74)	51 (38-59)	899.25 (713-1000)

The statistical analysis of prioxicam and paracetamol vs paracetamol alone demonstrated no significant difference for the power or energy delivered to renal or ureteric calculi.

Discussion

The medication groups were well matched for age and number, 62 patients received piroxicam and paracetamol with an average age of 50.3 years and, 56 patients with an average age of 54.4 years received paracetamol only. The average power and energy was less in the joint paracetamol and piroxicam group then the paracetamol group alone. There is no significant difference between the two pain reliefs it would appear based on the treatment parameters.

There were too few patients in the no medication group to really comment, with only 4 patients, who received less power to the calculi on average then the medication groups, but received more energy due to a higher number of shockwaves.

The reason for no difference between the two medicated groups is probably due to the time of onset of the piroxicam. Although the 20mg piroxicam melt used and has a fast absorption rate (Gorham, 2013) it has a variable action of onset and take up to 2 days for a steady state with a half-life of 3 -4 hours (British Medical Association , Fourth edition, 2012). The medication may have greater benefit therefore if it was started the day before or even two days before treatment, and then possibly continued as part of the post procedure pain relief for a number of days. This however would increase cost and the complexity of prescribing the medication prior to attendance at the Stone Treatment Centre for ESWL. Further limitations of the study would include the small numbers in each group and the lack of a validated pain score. Since piroxicam activity can last up to 7-10 days a pain score once the patient had returned home may have been of benefit.

The current use of Piroxicam 20mg 30 minutes prior to ESWL should therefore be discontinued. If an NSAID is to be continued as a pre ESWL pain relief medication then an intramuscular NSIAD or Per Rectum NSAID may be of greater effect (ref). Other fast acting oral NSIAD medications would warrant further evidence for their use with ESWL, as more practical and acceptable form of medication for the patient.

ESWL Treatment Breakthrough Medication:

Currently no breakthrough pain medication is given during ESWL treatment at Craigavon Stone Treatment Centre. Thus patient's treatments can be limited due to pain. A Prospective study was conducted looking at patient who did not receive any break though medication and the average power able to be achieved, if treatment was limited due to pain as per radiographer and a visual analogue scoring system for pain experienced during by the patient during treatment.

Results

A break though pain medication was sought. Since the ESWL treatments are Nurse and radiographer led, then type and route of drug is limited. IV morphine is currently not allowed to be given by a nurse, and the nurses also do not have prescribing rights.

A novel solution is therefore required, and so following consultation with A+E, Penthrox 3ml Inhaler as a

breakthrough medication is a consideration. The alternative pathway would be to include a Doctor with treatment session so IV morphine could be given as and when required, however this would increase the cost of the service and impact negatively to another aspect of the urological activity. Could the numbers requiring breakthrough pain medication be reduced further by altering or adding to the current regime, this is a further topic for research and is an ongoing topic of research in the sphere of ESWL.

In order to trial the use of Penthrox as breakthrough medication the drug had to be first approved at the drug and therapeutic committee at Craigavon Area Hospital. A review of the drug, including current use and safety was conducted, as well as the environment for its use.

Penthrox was given approval for use from the Craigavon Hospital Drug and Therapeutics Committee (DTC) in February 2017. An initial 50 units (Penthrox 3ml inhaler) were to be purchased by the hospital and a further 20 units were to be provided by Galan free of charge. There were all then registered to the pharmacy department and requested for use at the Stone Treatment Centre when required.

Southern Health and Social Care Trust

New Product Application Form

This form must be completed to provide the SHSCT Drug and Therapeutics Committee (DTC) with information about the proposed product. Applications may only be made by Trust Consultants.

Requests must be sent to Dr Tracey Boyce c/o DTC Secretary, CAH Pharmacy Dept., at least **2 weeks** prior to the Drug and Therapeutics Committee meeting.

*** * Please note that incomplete forms will be returned to the consultant concerned ****

Section 1: Background information

Generic name of medicine: Methoxyflurane

Brand name/ manufacturer: Penthrox

Formulation: 3ml Methoxyflurane (99.9%), liquid to be used in an inhaler

Route of administration: Inhaler with carbon filters for exhaled gases.

Proposed indication: Breakthrough pain relief for extracorpeal shockwave lithotripsy (ESWL) of renal and ureteric stones

Dose information: 3ml Penthrox, not to exceed 6ml on single administration, not to exceed 15ml in a week.

Section 2: Place in treatment algorithm

Please specify the criteria for patient selection:

Patients have 1g Paracetamol and NSAIDS (currently oral piroxicam 20mg, may change to PR Diclofenac 75mg) 40 minutes prior to starting ESWL treatment of stone.

If treatment limited due to pain, then breakthough pain relief to be given in the form of 3ml Penthrox as inhaler under supervision by a staff nurse. **Only one inhaler of 3ml to be given to each patient over their treatment hour as needed, and no more than one per hour to be used in the treatment room**. Currently no breakthrough pain relief is available and so some treatments are limited or require more treatments. No breakthrough pain relief potentially increases the need for more costly treatment in main theatre, such as Flexible Ureterenoscopy, which also carries greater risk of patient complication compared with ESWL.

Penthrox **would not be given** to patients with clinically evident cardiovascular or respiratory instability, any history of anaesthetic allergy, alcohol abuse, isoniazid, phenobarbital, rifampicin, clinically significant renal impairment (e.g. CKD stage IV, V).

Section 3: Summary of evidence on clinical effectiveness issues

What are the principal trials supporting the indication(s) described above and the overall results regarding efficacy? Please provide copies of up to 3 (maximum) relevant references, preferably including comparative data trials.

http://www.sciencedirect.com/science/article/pii/S027323001630126X

Derivation of an occupational exposure limit for an inhalation analgesic methoxyflurane (Penthrox®)

John Frangos, , Antti Mikkonen, Christin Down
Golder Associates, 570 – 588 Swan Street, Richmond, Victoria, 3121, Australia
Received 4 March 2016, Revised 9 May 2016, Accepted 11 May 2016, Available online 13 May 2016

Highlights
• Dose response analysis using clinical toxicity data is exemplified.
• Exposure limit for methoxyflurane of 15 ppm (8 h TWA) was derived.
• Occupational exposure estimates are well below the proposed MEL.

The peak is always less than 15 ppm in a treatment room under the following conditions:

1 vial per hour at an air change per hour (ACH) OF 1.15; and
2 vial per hour at ACH of 1.95.

Abstract
Methoxyflurane (MOF) a haloether, is an inhalation analgesic agent for emergency relief of pain by self administration in conscious patients with trauma and associated pain. It is administered under supervision of personnel trained in its use. As a consequence of supervised use, intermittent occupational exposure can occur. An occupational exposure limit has not been established for methoxyflurane. Human clinical and toxicity data have been reviewed and used to derive an occupational exposure limit (referred to as a maximum exposure level, MEL) according to modern principles. The data set for methoxyflurane is complex given its historical use as anaesthetic. Distinguishing clinical investigations of adverse health effects following high and prolonged exposure during anaesthesia to assess relatively low and intermittent exposure during occupational exposure requires an evidence based approach to the toxicity assessment and determination of a critical effect and point of departure. The principal target organs are the kidney and the central nervous system and there have been rare reports of hepatotoxicity, too. Methoxyflurane is not genotoxic based on in vitro bacterial mutation and in vivo micronucleus tests and it is not classifiable (IARC) as a carcinogenic hazard to humans. The critical effect chosen for development of a MEL is kidney toxicity. The point of departure (POD) was derived from the concentration response relationship for kidney toxicity using the benchmark dose method. A MEL of 15 ppm (expressed as an 8 h time weighted average

(TWA)) was derived. The derived MEL is at least 50 times higher than the mean observed TWA (0.23 ppm) for ambulance workers and medical staff involved in supervising use of Penthrox. In typical treatment environments (ambulances and treatment rooms) that meet ventilation requirements the derived MEL is at least 10 times higher than the modelled TWA (1.5 ppm or less) and the estimated short term peak concentrations are within the MEL. The odour threshold for MOF of 0.13–0.19 ppm indicates that the odour is detectable well below the MEL. Given the above considerations the proposed MEL is health protective.

Emergency Medicine Journal

Emerg Med J 2014;**31**:613-618 doi:10.1136/emermed-2013-202909

- Original article

STOP!: a randomised, double-blind, placebo-controlled study of the efficacy and safety of methoxyflurane for the treatment of acute pain

OPEN ACCESS

Frank Coffey[1], John Wright[2], Stuart Hartshorn[3], Paul Hunt[4], Thomas Locker[5],Kazim Mirza[6], Patrick Dissmann[4]

Abstract

Objective To evaluate the short-term efficacy and safety of methoxyflurane for the treatment of acute pain in patients presenting to an emergency department (ED) with minor trauma.

Methods STOP! was a randomised, double-blind, multicentre, placebo-controlled study conducted at six sites in the UK. A total of 300 patients, 90 of whom were adolescent patients (age 12–17 years), were randomised 150:150 to receive either methoxyflurane via a Penthrox inhaler or placebo. The primary end point of the study was the change in pain intensity as measured using the visual analogue scale (VAS) from baseline to 5, 10, 15 and 20 min after the start of study drug inhalation. Patients were supplied with one inhaler containing 3 mL methoxyflurane or 5 mL placebo after enrolment and initial assessments. Age group (adolescent/adult) and baseline VAS score were controlled for in the statistical analyses.

Results A total of 149 patients received methoxyflurane, and 149 patients received placebo. Demographic and baseline characteristics were comparable between the groups. Methoxyflurane reduced pain severity significantly more than placebo ($p<0.0001$) at all time points tested, with the greatest estimated treatment effect of −18.5 mm (adjusted change from baseline) seen at 15 min after the start of treatment. Methoxyflurane was well tolerated, with the majority of adverse reactions being mild, transient and in line with anticipated pharmacological action.

Conclusion The results of this study suggest that methoxyflurane administered via the Penthrox inhaler is an efficacious, safe, and rapidly acting analgesic.

Trial registration number: NCT01420159.

Anaesthesia
Journal of the Association of Anaesthetists of Great Britain and Ireland

Self-administered methoxyflurane for procedural analgesia: experience in a tertiary Australasian centre

1. A. L. Gaskell Research Fellow[1,*],
2. C. G. Jephcott Consultant[2],
3. J. R. Smithells Consultant[2] and
4. J. W. Sleigh Consultant, Professor[2,3]

Version of Record online: 15 FEB 2016

DOI: 10.1111/anae.13377

Summary

Methoxyflurane, an agent formerly used as a volatile anaesthetic but that has strong analgesic properties, will soon become available again in the UK and Europe in the form of a small hand-held inhaler. We describe our experience in the use of inhaled methoxyflurane for procedural analgesia within a large tertiary hospital. In a small pilot crossover study of patients undergoing burns-dressing procedures, self-administered methoxyflurane inhalation was preferred to ketamine-midazolam patient-controlled analgesia by five of eight patients. Patient and proceduralist outcomes and satisfaction were recorded from a subsequent case series of 173 minor surgical and radiological procedures in 123 patients performed using inhaled methoxyflurane. The procedures included change of dressing, minor debridement, colonoscopy and incision-and-drainage of abscess. There was a 97% success rate of methoxyflurane analgesia to facilitate these procedures. Limitations of methoxyflurane include maximal daily and weekly doses, and uncertainty regarding its safety in patients with pre-existing renal disease.

Section 4: Summary of evidence on comparative efficacy

What are the advantages of this medicine compared to other treatments? Consider medicines already recommended in the Regional Formulary or in the same therapeutic class.

Rapid onset

Patient controlled

Compared with the opiate alternatives there would be no need for a second staff nurse present. The stone centre is run by x1 staff nurse, x1 HCA, X1 radiographer.

Section 5: Summary of evidence on comparative safety

What are the advantages/disadvantages of this medicine in relation to patient safety compared to other treatments?

Self-administered by patient in the form of an inhaler

Rapid onset of analgesia (6 – 10 breaths)

Shorter recovery time then traditional opiate based medication

After 30 minutes of observation can be discharged and can safely return to highly skilled psychomotor skills tasks such as driving and daily work the same day.

Not for use in patients with clinically evident cardiovascular or respiratory instability, any history of anaesthetic allergy, alcohol abuse, isoniazid, phenobarbital, rifampicin, clinically significant renal impairment (e.g. CKD stage IV, V).

NOTE: The cardiovascular and respiratory caution may well be historic to its use as an anaesthetic agent as no clinically significant changes were observed for vital signs (heart rate, respiratory rate, BP or temperature).

H F Oxer, 'Effects of Penthrox® (methoxyflurane) as an analgesic on cardiovascular and respiratory functions in the pre-hospital setting, Volume 24 Number 2; April 2016, Journal of Military and Veterans' Health'.

Regarding potential occupational exposure the number of air changes per hour has been calculated by the estates department. Only one 3ml vial per patient may be used and not more than one vial per hour to be used in the treatment room. To achieve a peak of always less than 15 ppm in the treatment room then 1 vial per hour at an air change per hour of 1.15 needs to be achieved (Frangos et al, see Section 3, Summery of Evidence)

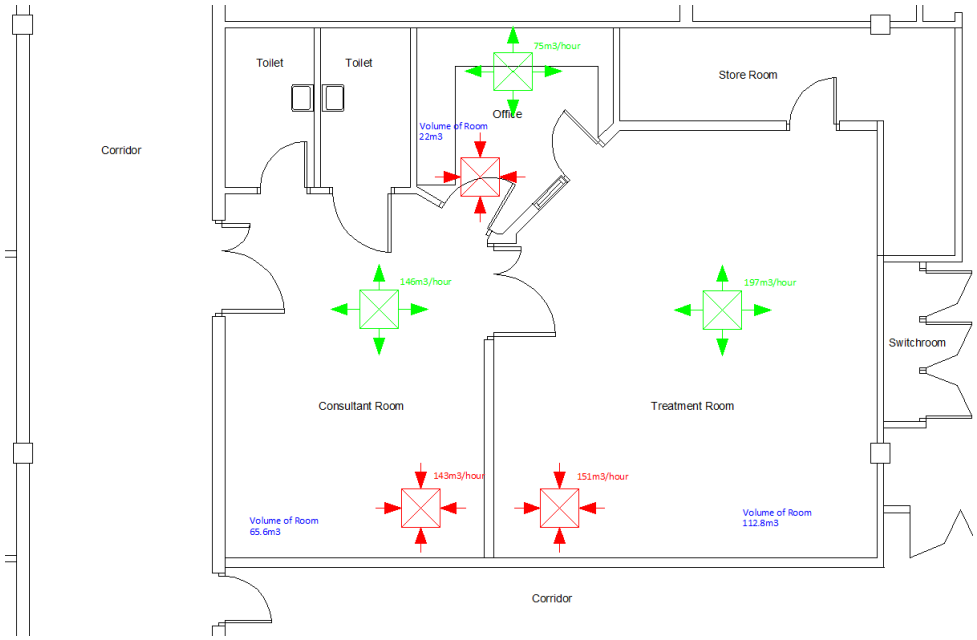
The room was tested on the 09/02/2017 by the Estates department and the treatment room meets the standard required, with an air change per hour of 1.75.

Craigavon Area Hospital – Stone Treatment Centre Ventilation Report

Measured on 9th February 2017 by Ruairi King, Estates Department

Survey conducted to measure the number of air changes per hour within each room. This information is required to determine the use of a new inhaler type pain relief at the centre.

Stone Treatment Centre Plan showing supply and extract grilles with corresponding air flows.



$$Air\ changes/hour = \frac{Volume\ of\ air\ supplied/hour}{Volume\ of\ room}$$

Treatment room:

$$Air\ changes/hour = \frac{197}{112.8} = 1.75$$

Consultant room:

$$Air\ changes/hour = \frac{146}{65.6} = 2.23$$

Office:

$$Air\ changes/hour = \frac{75}{22} = 3.41$$

The ventilation system supplying air to the Stone Treatment Centre is not connected to the Hospitals Building Management System (BMS); therefore its status cannot be monitored by the Estates Department.

It is necessary to install airflow sensors which connect to the BMS so that the status of the ventilation system can be monitored and logged in case of faults etc.

An indicator should also be installed within the treatment centre showing the status of the system and alarm when

there is a fault or when there is no air flowing. This is needed to safeguard staff and patients when using the new inhaler type of pain relief.

Section 6: NICE and Scottish Medicines Consortium (SMC) Adjudications

Has NICE considered this product: Yes / No
If yes – what was the outcome? If No – is NICE currently considering the item?

Nice contacted Galen in 2016 as they are considering reviewing the medication as per Dr Sarah Dolan 06/02/2017.

Penthrox was highlighted on a NIHR horizon scanning document in February 2016: http://www.hsric.nihr.ac.uk/topics/methoxyflurane-penthrox-for-emergency-relief-of-moderate-to-severe-pain/

Has the NICE guidance been endorsed in Northern Ireland: Yes / No

Has SMC considered this product: Yes / No
If yes – what was the outcome?
All Wales Medicines Strategy Group concluded that Penthrox was exempt from review as it is a medicinal gas: http://www.awmsg.org/docsnoindex/awmsg/June%202016.pdf

Penthrox is classed as a medicinal gas, and therefore exempt from review by SMC as per Dr Sarah Dolan from Galen 06/02/2017 – see exclusion criteria no. 7 in SMC publication: Guidance for medicines out with SMC remit.

Section 7: Financial Information

	No. of patients in SHSCT eligible for treatment per annum	Cost per annum (£) per patient	Total annual cost (£)

Secondary Care		Current ESWL capacity is 9 patients per week. At present 9 x52 = 468 potential stone treatments per year. (not taking into account public holidays)	£17.89 + VAT	£61138 + VAT Used as Breakthrough pain, 73% would require Penthrox, therefore 73% of 468 = 342 patients). Based on ESWL questionnaire of pain during treatment 10/02/17, currently on-going.
Primary Care				
Cost of the therapy to be 'replaced' if applicable	Secondary Care	**<u>Potential cost savings</u>** if further treatments of ESWL prevented by use of the pain relief, or potential failure of treatment requiring more expensive ureteroscopy or PCNL.		
	Primary Care			
TOTAL NET COST:				£8372.52
Other Cost Implications e.g. Additional Medicine Therapy, X-rays, Lab Tests, etc.	Please state:			

If additional funding is required to purchase this product within the Trust please give details of how this will be found (e.g. current approved business case, agreed reduction in bed-days /beds, stopping use of another product)

Increased funding is likely to be required to fund the medication, but it will have a **knock on effect to save money** from the reduction in further procedures and waiting list. The aim would also to provide emergency treatment, so reduce the cost and burden on the emergency operating theatre.

The use of Penthrox as breakthrough pain relief could increase the number of patients receiving a full treatment of ESWL and therefore reduce the need for secondary procedures such as Ureteroscopy or PCNL, both of which are more costly.

Koo and Young from Craigavon Area Hospital, published in the British Journal of Urology in November 2010 calculated the overall cost of Flexible ureteroscopy (FURS) to be £2602, compared to £426 for ESWL. If each patient had one treatment of ESWL instead of FURS, then £2176 could be saved, or to use the operating time for a different case and possibly decrease the waiting list.

Only 2.8 patients would need to be prevented from having a further surgical procedure (FURS) **by having successful ESWL to match the cost of 342 patients receiving Penthrox**. (Based on 342 patients x £17.89 Penthrox cost).

Many patients may have reduced number of ESWL treatments, as a greater energy can be delivered to the stone on initial treatment then the current average.

From the 4th Jan 2017 to 6th Feb 2017, 22 patients out 31patients treated by ESWL had limited treatment received, with the most common reason being pain.

Section 8: Declaration of Interests

SHSCT Gifts and Hospitality and Standards of Conduct Policy/ Declaration of interest (Procurement)

The lead consultant(s) responsible for completing this application to the Drug and Therapeutics Committee are asked to declare and describe to the Chairman, any involvement that they may have with the relevant pharmaceutical company, or with the manufacturers of any comparator products.

This includes direct or indirect financial gain that they have received from the pharmaceutical company where this amounts to *greater than £500 p.a. within the last 2 years*. Such interests may be direct (e.g. lecture or consultancy fees, sponsorship for postgraduate educational activity) or indirect (egg. departmental donations, research contracts, funded staff support).

Do you have an interest in the pharmaceutical industry as described above? **No** (please delete as necessary)
If Yes, name of Pharmaceutical Company(ies):
Nature of involvement or assistance: Direct and/or indirect – specify (the amount of money involved does not have to be declared):

Signatures (please note all must be complete before application accepted by DTC)

Name of Consultant: Mr Michael Young Date: 10/02/2017
(please print name)

Signature of Consultant: _____

Associate Medical Director

Name: _____ Date: 10/02/2017
(please print name)

Signature of AMD: _____

Assistant Director/Director

Name: _____ Date: 10/02/2017
(please print name)

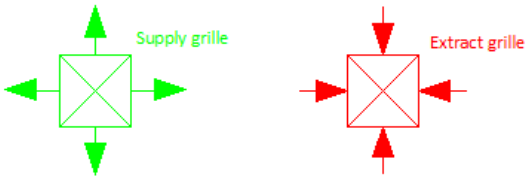
Signature of AMD: _____

Outcome of DTC

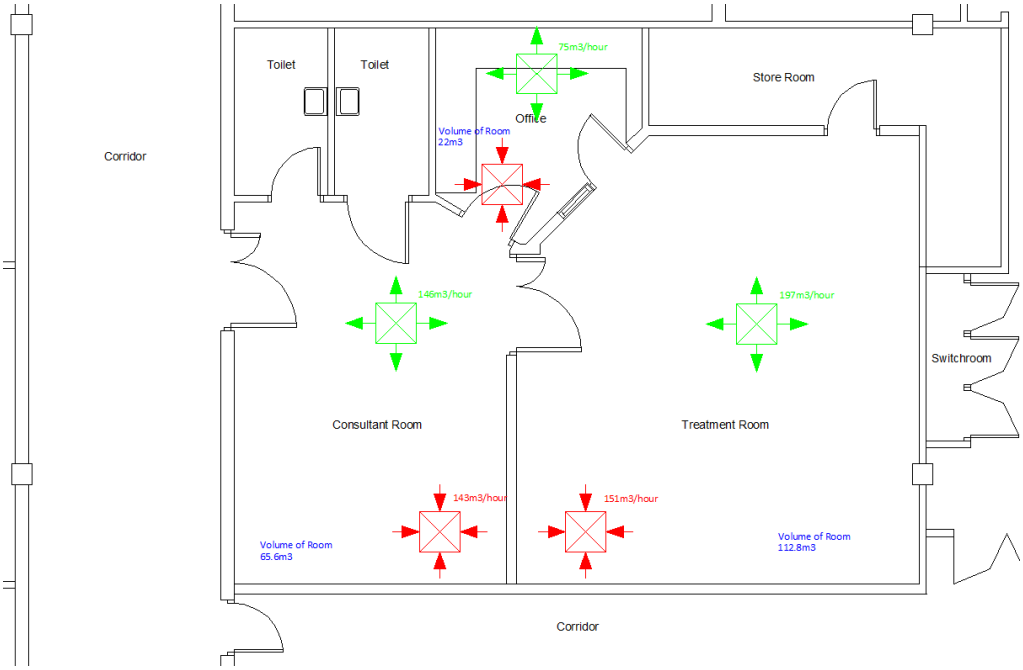
Craigavon Area Hospital – Stone Treatment Centre Ventilation Report

Measured on 9th February 2017 by Ruairi King, Estates Department

Survey conducted to measure the number of air changes per hour within each room. This information is required to determine the use of a new inhaler type pain relief at the centre.



Stone Treatment Centre Plan showing supply and extract grilles with corresponding air flows.



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It is necessary to install airflow sensors which connect to the BMS so that the status of the ventilation system can be monitored and logged in case of faults etc.

An indicator should also be installed within the treatment centre showing the status of the system and alarm when there is a fault or when there is no air flowing. This is needed to safeguard staff and patients when using the new inhaler type of pain relief.

The DTC required further evidence to be produced following the use of Penthrox for ESWL break through pain relief. Data was prospectively collected on the standard pre-medication given (paracetamol, piroxicam), a pain visual rating index, if breakthrough Penthrox was received, power and energy delivered to the stone and if pain limited treatment (this could be decreased power or energy delivered compared to standard expected, e.g. 1000j to renal and 1400j to ureteric stones).

Prior to use of the Penthrox the medical prescribing doctor has to check for contraindications to its use. Prior to use of Penthrox each patient is given an information sheet containing action, contraindication and side effects, as well as how to use the device. This was developed in conjunction with Galan the manufacturer. All patients were advised to attend with a chaperone. This is more from a safety standpoint that ESWL can produce small fragments and potential colic and may well be best not to drive themselves home.

To standardise the information given to the patients a standard script was developed by the nurses to explain how to use the drug. On average the script take 75 seconds to run and demonstrate how to use the Penthrox device.

Observations during Penthrox use were discussed and agreed at a Urology Stone Meeting MDM August 2017 to include continuous saturation and heart rate monitor and BP every 15 minutes.

Following ESWL treatment patients receive a minimum of 30 minute observation, including re-checking of observations prior to discharge. A Penthrox advice card is given to the patient as part of their discharge pack.

Pain Intensity Score During ESWL Questionnaire (To be completed by Staff Nurse following ESWL)

Patient to give score immediately following completion of ESWL.

Patient Age

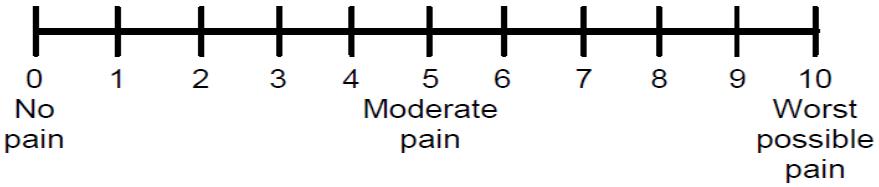
Patient gender Male Female (circle answer)

Type of pain relief given,

Paracetamol Piroxicam Diclofenac Codeine Phosphate Penthrox (circle answer)

1. **How would you rate your pain DURING your ESWL treatment (show to patient)**

0–10 Numeric Pain Rating Scale



2. **Any nausea/ sickness experienced during treatment? Yes No (circle answer)**

3. **Renal or Ureteric stone (circle answer)**

4. **Mean Power achieved …… Total energy delivered……**

5. **Did pain limit treatment Yes No (circle answer)**

Many thanks

PENTHROX 3ML Inhaler Breakthrough Pain Relief

1. Patient unable to Tolerate ESWL treatment, STOP TREATMENT

2. Check no contraindications (Table 1) to Penthrox (ideally checked before ESWL started)

Table 1.

Penthrox Contraindications: (Galen Ltd)

Contraindications

- Clinically significant renal impairment , (e.g. eGFR <30, Stone Treatment Centre)
- Patients who have a history of showing signs of liver damage after previous methoxyflurane use or halogenated hydrocarbon anaesthesia
- Malignant hyperthermia: patients with known or genetically susceptible to malignant hyperthermia or a history of severe adverse reactions in either patient or relatives
- Use as an anaesthetic agent
- Hypersensitivity to PENTHROX or any fluorinated anaesthetic
- Altered level of consciousness due to any cause including head injury, drugs or alcohol
- Clinically evident cardiovascular instability
- Clinically evident respiratory depression

Galen Ltd . (n.d.). *Penthrox, Methoxyflurane*. Retrieved March 21, 2017, from Penthrox: https://www.penthrox.co.uk/hp/information/safety/contraindications/

3. If no contraindication give 3ml Penthrox inhaler as per instruction 8-10 breaths (see table 2)
4. Radiographer to resume ESWL and begin power ramping
5. Patient to self-administer further Penthrox, 2-3 breaths as required.
6. Once Penthrox treatment complete inhaler, carbon filter and drug bottle to be placed in sealed plastic bag provided and placed in clinical waste.
7. Clinical waste to be disposed of from Stone Treatment Centre every day Penthrox is in use.

Only use with the air exchange ventilation system operating.
Periodic assessment of air exchange ventilation system required by Estates Department to ensure air changes/hours of >1.15

Nurse Administration protocol:

- Patient informed of possible Penthrox use prior to entering ESWL treatment room (patient information leaflet in pre-procedural pack and in waiting room) and demonstration given by nurse using a training pack.
- Script for explaining PENTHROX usage to patient (takes 75seconds to explain):
    - **'Hold the green inhaler in the opposite hand to the side of your treatment**
    - **Place the inhaler into your mouth and create a tight seal with your lips**
    - **Take 3 gentle breaths in AND out through the inhaler**
    - **Keep inhaler in your mouth and breath normally in AND out for 5 more loading breaths then remove it from your mouth**
    - **If you experience pain during the procedure then reinsert the inhaler into your mouth and resume normal breathing in AND out through the inhaler device until you feel more comfortable.**
    - **If you need a stronger dose you can place your finger over the clear plastic hole and continue your normal breathing in AND out through the inhaler.**
    - **Please take your Penthrox throughout the procedure as you need it.**
    - **It is normal to experience some discomfort during this procedure. It has been described as a similar sensation to being flicked with an elastic band.**
    - **Do you have any questions about using the Penthrox inhaler'?**

- See Penthrox package for explanation of assembly of delivery device.
- ESWL treatment to stop if patient not tolerating treatment.
- Give the inhaler to the patient and use the directional script above to aid use.
- Radiographer should restart treatment 60seconds after first Penthrox inhalation breath.
- See flowchart for example of use.
- Encourage patient to continue using inhaler as required, including covering the dilution hole to deliver a stronger dose during treatment.
- If patient not tolerating treatment despite optimal use of inhaler then pause treatment and deliver a further five loading breaths, repeat this step to a maximum of x3 as required.
- Discontinue treatment if not tolerated/ patient requested

Patient who are unable to tolerate ESWL treatment, pause treatment, and if no contraindications use Penthrox

Initial loading with Penthrox (3 inhalation breaths and 5 loading breaths in and out of the inhaler).

Radiographer restarts ESWL treatment 60 seconds after first inhalation breath of Penthrox .

Throughout Penthrox treatment monitor

1. Heart Rate and Saturation using continuous monitor
2. Blood pressure every 15 minutes

Patient to continue taking normal breaths in and out through the inhaler **as required** for pain relief.

If stronger dose required, instruct patient to cover dilution hole whilst continuing normal breathing in and out through inhaler.

Patient not tolerating treatment despite optimal use of inhaler:

Stop treatment and reload with 5 breaths in and out of inhaler.

Radiographer to restart ESWL 60seconds after first breath taken.

If after 3 cycles patient not tolerating treatment then abandon treatment.

Patient tolerating treatment:

Continue same usage as required until treatment completed

Note: stop treatment at any point if patient requests.

Pain Relief Future Considerations

It is important to optimise the pain relief so ESWL treatments are not limited by this factor. Pain from ESWL is multifactorial, as seen in the section on 'Pathogenesis of pain during ESWL'. Such is the case therefore any changes which are made to the delivery of the treatment should be made in isolation and proved the change to be an improvement (e.g. change in medication only and then study, not change in medication and coupling medium).

	Patient Factors	Nurse Factors
Premedication:	• Pain relief to act within 1 hour or 30 minutes of pre-ESWL procedure. • Medication to give adequate pain relief during ESWL for a 1 hour session. • Have limited side effect profile and able to be prescribed for the majority of patients who attend for ESWL	• The ideal medication should be able to administered by a single staff nurse • If nurse prescribing is started then medications able to be prescribed by a nurse with prescribing rights
Breakthrough Medication	• Pain relief to act within a short time to allow ESWL treatment to resume. • Medication to give adequate pain relief during ESWL for a 1 hour session. • Have limited side effect profile and able to be prescribed for the majority of patients who attend for ESWL	• Can be given with only one staff nurse present • Allows a discharge following procedure of 45 minutes maximum • If nurse prescribing is started then medications able to be prescribed by a nurse with prescribing rights
Discharge Medications	• Provides adequate pain relief for renal colic • Have limited side effect profile and able to be prescribed for the majority of patients who attend for ESWL	• Able to be dispensed the day of ESWL • If nurse prescribing is started then medications able to be prescribed by a nurse with prescribing rights

Urology Stone MDM: Recommendations for changes in Pain Relief Medication or Delivery of ESWL

Medication or change in delivery of ESWL	Reason for Change	Method of action	Evidence (Such as Pubmed search or review article or guidelines)	Method to study change	Result and Outcome
Penthrox 3ml Inhalor (Methoxyflurane)	Introduced as a trail for breakthrough medication during ESWL. No breakthrough medication used prior to this.	Methoxyflurane can cause dose-related nephrotoxicity a clinical study identified that nephrotoxicity occurred at doses in excess of 2.5 MAC-hours These doses were reached when methoxyflurane was used for anaesthesia. As a result of this clinical study a safe upper limit for methoxyflurane exposure was determined to be 2 MAC-hours – doses below 2 MAC-hours have not been associated with nephrotoxicity. Methoxyflurane administered via the PENTHROX inhaler (3 mL dose) equates to approximately 0.3 MAC-hours.[3] PENTHROX was approved by the regulatory	Please refer to the Penthrox Drugs and Therapeutics Committee (DTC) submission	Keeping Paracetamol 1g oral and Piroxicam 20mg oral fast tab as premedication for ESWL. Penthrox used for breakthrough pain relief. When used as a breakthrough medication during ESWL, does it allow completion of treatment and provide adequate pain relief?	Results to be submitted to the Craigavon DTC and disseminated at the Urology Stone MDM.

		authorities for use in the UK and Ireland in late 2015			

Antibiotic Prophylaxis ESWL

In keeping with European Association of Urology (EAU) Guidelines, prophylactic antibiotics are given to patients,

1. Infection stones
2. Bacteriuria (European Association of Urology , 2017)
3. Stone Treatment Centre Guidelines also includes patients who are relatively immunocompromised, such as steroids, immune modifying drugs.

- The standard at CAH STC is 500mg oral Ciprofloxacin prior to ESWL.

Recommendation for future practice would be to modify antibiotic prophylactic to urine sensitivities. This would require those patients needing antibiotic prophylaxis to have a urine culture one or two weeks prior to treatment.

A Pubmed search of 'ESWL' or Shockwave Lithotripsy' and 'Antibiotic', Prophylaxis', Urine Culture'

Returned 10 papers

Excluded was 1 case report

e. Craigavon Area Hospital ESWL TMS i-sys Sonolith lithotripter Adult Protocol

(In addition to the TMS i-sys Sonolith manual, EDAP TMS 2012)

Stone and side for treatment	As per MDT indication, check ESWL request for stone and laterality. Recommended number of treatments and follow-up plan included
Pain Relief	As pre-prescribed by Stone MDT (nurse to check allergies prior to administration)
Breakthrough pain relief	As per pre-prescribed MDT (nurse to check allergies prior to administration)_ Stop ESWL to initialise break through medication and restart at last tolerated power level
Imaging	USS or Fluoroscopy or both. Regular imaging (constant if USS) to check stone position for treatment. **Stop treatment if satisfactory stone treatment achieved.**
Ramping protocol	**First 250 shocks at 25% (See 1.8.1 Power level reference chart for kV** (EDAP TMS, 2012)**)** **Second 250 shocks at 50%** **Third 250 shocks at 75%** **Following the first 750 Shocks, aim to reach 100% power as tolerated before 1000 shocks** **Average treatment power will therefore be around 80%.**
Energy levels	**Maximum 1000J to renal stone** **Maximum 1400J to ureteric stone**
Shockwaves	**Maximum of 3000 shockwaves delivered per treatment session**
Frequency	**1.2Hz**
Treatment session	1 hour
Interval between treatments	4 weeks (EDAP TMS 2012)
Discharge letter	Radiographer to populate template and copy for ECR, Patient notes and GP.

Time between treatments

There is little evidence on the time between ESWL treatments; there is evidence to show that a patient can be retreated after 24 hours. A safe regime would leave the **interval between elective treatments as 4 weeks** (EDAP TMS, 2012).

European Urology 2017 Guidelines for ESWL Treatment

3.4.2.1.3.2 Best clinical practice

Summary of evidence - Number of shock waves, energy setting and repeat treatment sessions	LE
Stepwise power ramping prevents renal injury.	1b
Clinical experience has shown that repeat sessions are feasible (within one day for ureteral stones).	4
Optimal shock wave frequency is 1.0 to 1.5Hz.	1a

(European Association of Urology , 2017)

e. REVENUE BUSINESS CASE PROFORMA COVER

(To be submitted with every business case)

To be tabled at SMT Meeting TBC

Name of Organisation	Southern Health & Social Care Trust
Project Title	Extra Corporeal Shockwave Lithotripsy (ESWL) & Generalised Stone Services at Southern Health & Social Care Trust Draft V.03
Total Cost	**£TBC**
Start Date	**£TBC**
Completion Date	**Recurrent funding requested from 2018/19 onwards £TBC**

Complete this section if bid is for new funding

BID FOR NEW FUNDING	
Is this bid for new funding (Y/N)	**Yes**
How much total funding required?	**£TBC**
How much funding required per year?	**£TBC**
Is this funding to be made recurrent?	**Yes**

Complete this section if funding available within existing allocation

Funding available within existing allocation (Y/N)	**No**
Total cost of proposal	**N/A**
Cost of proposal per year	**N/A**
Is this cost within recurrent allocation?	**N/A**

Is this business case	***Y/N***
(a) Standard	***Yes***
(b) Novel	**-**
© Contentious	**-**
(d) Setting a precedent	**-**
If yes to (b) or (c) or (d) , requires Departmental & DFP approval Is Departmental / DFP approval required	

Approvals & submissions

Prepared by:		
Name Printed	**NICKY HAYES**	**(signed)**
Grade/Title	**Planning Officer Band 5**	
Date	**APRIL 2018**	

Approved by:		
Name printed	**ESTHER GISHKORI**	**(signed)**
Grade /Title	**Director of Acute Services**	
Date	**APRIL 2018**	

Approved by:		
Name printed	**HELEN O'NEILL**	**(signed)**
Grade /Title	**Director of Finance**	
Date	**APRIL 2018**	

Approved by:		
Name printed	**SHANE DEVLIN**	**(signed)**
Grade /Title	**Chief Executive**	
Date	**APRIL 2018**	

Complete this section if Department / DFP approval required

Date submitted to Department
Department/ DFP approval (y/n)
Date approved

BUSINESS CASE TEMPLATE	REVENUE FUNDING £50k - £250k

SECTION 1: PROJECT BACKGROUND, STRATEGIC CONTEXT & NEED

Introduction
This paper outlines a proposal associated with enhancing the Extra Corporeal Shockwave Lithotripsy & Generalised Stone Service within the Southern Health & Social Care Trust.

Associated costs of **£TBC** have been identified from **TBC** funding stream and approval is now being sought from Senior Management Team for the progression of this proposal.

The Trust's Senior Management Team confirmed at its meeting on 24 January 2018 that it was supportive of a proposal being developed.

Background
The Southern Health & Social Care Trust (SHSCT) was established on 1st April 2007 following the amalgamation of Craigavon Area Hospital Group, Craigavon & Banbridge Community, Newry & Mourne and Armagh & Dungannon Health and Social Services Trusts. It is one of six organisations that provide a wide range of health and social care services in Northern Ireland.

The Trust provides acute hospital and community services to council areas of Armagh, Banbridge and Craigavon; Newry, Mourne and Down; and Mid Ulster – a population of some 369,000. The acute hospital services provided by the Trust are also used by people from outside the Southern area including Fermanagh, Down and Lisburn, Antrim, Cookstown, Magherafelt and the Republic of Ireland.

The Trust's hospital network comprises two acute hospitals (Craigavon Area Hospital and Daisy Hill Hospital) with a range of local services provided at South Tyrone Hospital. The hospitals work together to co-ordinate and deliver a broad range of services to the community.

Both acute hospitals provide inpatient, out-patient and day case services across a range of specialties. These include a 24-hour Emergency Department and unscheduled medical and surgical services.

The Trust is responsible for the delivery of high quality health and social care to its resident population and employs 13,000 staff.

Extra Corporeal Shockwave Lithotripsy (ESWL)
This is a non-invasive procedure which is used in the treatment of kidney stones that are too large to pass through the urinary tract. The procedure is carried out by Consultant Urologists who have experience in urinary tract stone disease. In the first instance, kidney stones will be detected via the use of x-rays/scans which will determine their presence and location.

Patients within the Southern Trust area suitable for this specific treatment regime may attend on an

elective basis or in the case of patients referred for urgent admission, ESWL may be carried out during the inpatient stay. The procedure entails breaking down the stones in the kidney, bladder or ureter (tube that carries urine from the kidneys to the bladder) by sending high-frequency ultrasound shock waves directly to the stone once located with fluoroscopy (a type of x-ray) or ultrasound. The shock waves cause large stones to be broken down into smaller pieces to enable these to pass through the urinary system. Treatment sessions last for approximately an hour.

Strategic Context
Guidelines for the management of renal colic/renal and ureteric stones are documented in:-

- British Association of Urological Surgeons "**Standards for the Management of Acute Ureteric Colic" September 2017**
- National Institute for Health & Care Excellence guideline **"Renal & Ureteric Stones: Assessment and Management (consultation 20 January to 17 February 2017)"**

"Stone removal is recommended in the instance of persistent obstruction, failure of stone progression or increasing or unremitting colic. The choice of treatment to remove a stone depends on the size, site and shape of the stone. Options include extra corporeal shockwave lithotripsy (ESWL) ureteroscopy with laser, percutaneous nephrolithotomy or open surgery".

"Where suitable, ESWL offers a non-invasive treatment with lower complication rates and a shorter hospital stay".

In addition, the current standards associated with care for acute stone pain and use of ESWL (British Association of Urological Surgeons "***Standards for the Management of Acute Ureteric Colic" September 2017)*** states that "for symptomatic ureteric stones, primary treatment of the stone should be the goal and should be undertaken within 48 hours of the decision to intervene" – is this the text to be referred to???

Local Context
"Improving Together" the Trust's Corporate Plan 2017/18 – 2020/21 sets out the strategic direction for the next four year period and includes challenges and opportunities to create better health outcomes for the population within the Southern area.

The Corporate Plan recognises the need for service reform as a result of the changing needs of our local population, new ways of delivering care and treatment in line with the financial and workforce resources available to us.

The key objectives which the Trust will strive to achieve are:-
- Promoting safe, high quality care
- Supporting people to live long, healthy active lives
- Improving our services
- Making the best use of our resources
- Being a great place to work, supporting developing and valuing our staff
- Working in partnership

Demographic Growth:
- The Trust has the second largest population in NI 369,000. The Trust population is projected to increase by over 20% between 2016 and 2039 (compared to the NI projected growth of 8.5%) including more significant growth in our ageing population

Current Service Provision
At the present time, there are a total of two Lithotripsy machines across Northern Ireland, a mobile machine sited in Belfast and a machine located within the Stone Treatment Centre (STC) at Craigavon Area Hospital.

Lithotripsy treatments are delivered to the Southern Trust's resident population in addition to patients residing outside of the Trust's catchment area (from January 2017 South Eastern Trust patients have undergone stone treatment procedures at CAH).

Current Capacity
The STC facilitates a total of three weekly ESWL sessions which take place on Monday, Wednesday and Friday mornings. The first treatment commences at 9.00 am with the session ending at 1.00 pm. A total of **9** patients undergo ESWL treatments every week.

Patients' referrals for stone treatment regimes are received via a number of channels including:-

1. Emergency Departments at Craigavon Area, Daisy Hill and South West Acute (Enniskillen) Hospitals
2. General Practitioners within the Southern Trust region and the South West Acute Hospital's local population
3. Wards in Craigavon Area Hospital, Daisy Hill Hospital and South West Acute Hospital
4. Consultant Urologists from Southern and South-Eastern Health & Social Care Trusts
5. Letterkenny Hospital, Republic of Ireland
6. Altnagelvin Hospital

Although emergency ESWL treatments can be made available if there is a cancellation, predominantly emergency treatments are performed on Mondays, Wednesdays and Fridays - TBC

The current staffing establishment per session consists of:-

- 0.30 wte Consultant
- 0.30 wte Radiographer
- 0.30 wte Band 5 Nurse
- 0.30 Band 3 Healthcare Assistant

Key Issues/Assessment of Need
The growing demands being placed upon the Trust's ESWL & Generalised Stone Service understandably proves challenging when taking into consideration the number of issues in terms of:-

1. Demand & Capacity
Since the introduction of the Extra Corporal Shockwave Lithotripsy (ESWL) service on 11 September 1998, there has been a steady increase in the number of patients being offered this treatment regime.

In January 2017, there were a total of 108 adult patients awaiting treatment, however by January 2018 the figure has dramatically increased to a total of 233 adult patients showing a staggering 116% rise.

This figure equates to an average of 31 patients being added to the waiting list per month.

The waiting time for treatment (as of January 2018) is presently 8 months.

2. Emergency ESWL Provision for Upper & Distal Ureteric Stones

In addition to the number of adult patients awaiting outpatient (elective) ESWL treatment, on average approximately 10 patients will have a ureteroscopy performed each week at Craigavon Area Hospital.

Some of these patients could be suitable to undergo "emergency ESWL" treatment, however due to the restricted use of the Lithotripser machine at the present time, this cohort of patients have to undergo their treatment within Main Theatres at Craigavon Area Hospital as there are only ESWL sessions 3 days per week.

Understandably, this practice is counter-productive as it hinders the Trust's ability to adhere with the respective guidelines associated with the assessment and treatment of ureteric stones[1] which states that "primary treatment of the stone should be the goal and should be undertaken within 48 hours of the decision to intervene" – is this the relevant text to use TBC. More non-invasive procedures and extended availability across the week would support the Trust to comply with guidelines.

3. Service Model

The Lithotripser machine has been in operational use since the late 1990s (circa 20 years). At that time, the working practices put in place adequately met the needs of the service. Inevitably changes in medical practice have evolved in recent years however no modifications or adaptions to the working practices within the STC have been implemented. As a consequence, it has not been possible to optimise the potential to develop the Southern Trust's ESWL & Generalised Stone Service.

Given the existing service model, provision of a service which represents value for money whilst making best use of the facilities available is not achievable. The insufficiencies are particularly prevalent within the following areas:-

- Increased number of patients being **referred** into the Service
- As the majority of patients initially opt for treatment to be given without the need for a general anaesthetic, the number of patients awaiting elective ESWL treatment inevitably causes a rise in **waiting times**
- As a consequence of current waiting lists, patients' **x-ray/scan images** become out-of-date often emanating in the loss of a treatment 'slot' as the patient cannot undergo their planned ESWL procedure if there is a possibility that their renal stones have become dislodged
- A significant amount of nursing **administration** associated with patient documentation which is undertaken on the day of treatment impinges on the allocated treatment time

4. "Time & Motion" Study

In an effort to address the inefficiencies with the current service model, a "Time & Motion" study was conducted in December 2017. This involved a group of multi-disciplinary staff reviewing and 'process mapping' the "Renal & Ureteric Stone" pathway in order to streamline the processes, improve treatments/safety and patient follow-up reviews.

On conclusion of the "Time & Motion" study, a number of recommendations were identified which included:-

- The need for a Stone Multi-Disciplinary Team (MDT) to be established
- With the introduction of an MDT this would facilitate:-
  - a platform for discussion of complex patients

- referrals received from Emergency Departments, Wards and GPs to be reviewed giving due consideration to each individual patient's condition
- a review of patients' imaging
- an informed decision to be made in relation to the most appropriate treatment pathway for each patient for example ESWL, Ureteroscopy etc which would be in line with guidelines (eg British Association of Urologists, NICE etc)

- New documentation to be developed such as:-
  - Ureteric & Renal Stone Referral
  - Patient Information Pack

5. Staffing Resources

In view of the recommendations emanating from the "Time & Motion" study, a change in practice was introduced in December 2017 which enabled a Stone Multi-Disciplinary Team to be established together with an agreed Referral Pathway to be developed.

At that time, the potential to increase capacity was identified if changes associated with the nursing administration process could be introduced.

It highlighted that if the requisite administration could be performed prior to a patient attending for their treatment, this could permit an additional patient per session to be treated (eg a total of 4 patients would undergo an ESWL procedure per session).

However, with insufficient staffing resources presently available, the delivery of an efficient and effective ESWL & Generalised Stone Service is compromised.

- **Administrative & Clerical**

With the weekly MDT meeting taking the form of a "virtual clinic" there is a significant amount of administration to be progressed in advance of the weekly meetings which encompasses:-

- ensuring all the requisite paperwork is available for the meeting (eg referral forms, prescription sheets, diagnostic results etc) which require populating during the MDT meeting when outcomes are discussed/agreed
- preparation of MDT lists
- population of worklist on NIECR for ease of access during the MDT meeting
- taking notes of the MDT meetings, completing the electronic MDT outcome form, populating patient templates with agreed outcomes from MDT in order to send to patients
- ensuring follow-up arrangements are made
- tracking follow-up arrangements/results

In addition to the duties associated with the weekly MDT meetings, there are a number of administrative tasks in respect of the elective ESWL process which are detailed below:-

- Population of appointments and preparation of lists
- Ensuring all ESWL related treatment paperwork is available (eg prescriptions, nursing checklist, post-treatment advice)
- Creating and printing of booklets and distribution of patient documentation (to negate the need for this to be undertaken on the day of treatment TBC)
- Sending for list and confirming patients' attendances
- Ordering notes for ESWL treatment day
- Arrangement/tracking of follow-up

A patient letter template was created on Patient Centre to enable Consultant Urologists' secretaries to type up the weekly patient letters. However, the increased workload is unsustainable given the

other duties assigned to Consultant secretaries. As a consequence, delays associated with the typing up of the MDT letters are regularly experienced TBC

- **Medical, Nursing & Radiology**

In view of the volume of administrative tasks associated with both the MDT meetings in conjunction with the ESWL processes, this can often result with the Specialty Doctor in Urology providing a degree of administrative support to the Stone Treatment Centre.

In terms of ESWL Sonographer training, there is a detailed protocol which must be adhered to in order for Sonographers to become competent in ESWL. This involves a period of supervised targeting and treatment of renal calculi in both adults and paediatrics which must encompass both ultrasound and fluoroscopic control. In addition, a minimum of 50 treatments must be achieved and in the event of a trainee being absent for a prolonged period of time (eg maternity leave), there may be a requirement for part of the process to be repeated. On completion of the requisite training and to allow progression, it will necessitate a Sonographer participating in ultrasound audit programmes and undertaking future training updates to ensure continuing professional development and assessment of accuracy.

Reference 1 *– British Association of Urological Surgeons Standards for the Management of Acute Ureteric Colic September 2017*

SECTION 2 (a): OBJECTIVES

Project Objectives	Measurable Targets
1. Improve access to ESWL Service by 31 March 2019	• Increase access across the week ➢ Baseline – 3 sessions per week (as of April 2018) ➢ Target – 7 sessions per week
2. To improve compliance with Commissioning Plan Objective 4.12 ➢ No patient waits longer than 13 weeks for inpatient/daycase ESWL treatment by September 2019	• Facilitation of appropriate ESWL provision which meets the demand for elective treatment:- ➢ Baseline – as of January 2018, a total of 148 patients are awaiting more than 13 weeks for elective ESWL treatment ➢ Target – minimum of 30% reduction in *reduce routine waiting times in the first instance*
3. Improve the efficiency of the current ESWL Service by 31 March 2019	• Increase number of patients treated per session:- ➢ Baseline – a total of 3 patients per session (as of April 2018) ➢ Target – a total of 4 patients per session (on appointment of additional staffing resources)

SECTION 2 (b): CONSTRAINTS

Constraints	Measures to address constraints
1. Availability to appoint additional staffing resources	The Trust will ensure that robust recruitment processes are in place, maintaining close

	links with BSO and Human Resources to ensure that any issues which may arise are promptly addressed
2. Recurrent revenue funding not secured	The Trust will maintain close links with the HSCB in order to proactively seek financial support for the service

SECTION 3: IDENTIFY AND DESCRIBE OPTIONS

OPTION NO	BRIEF DESCRIPTION OF OPTION
1	**Do Nothing/Status Quo - continue with existing arrangements** This option will entail the continuation of the existing service model of 3 ESWL sessions per week permitting a total of 9 patients to be treated. Although this option will not meet the project objectives, it has been shortlisted as a base case comparator.
2	**Increase ESWL Sessions from 3 to 7 Sessions per week within Stone Treatment Centre at Craigavon Area Hospital** This option will entail the appointment of additional staffing resources and permit the current 3 ESWL weekly sessions to be extended to 7 ESWL sessions per week. It will accommodate a total of 4 patients per session to be treated, emanating in additional capacity to facilitate a further 19 patients per week (eg 4 patients per session x 7 sessions equates to 28 patients TBC) in comparison to the 9 patients that are presently seen each week.
3	**Provision of a Dedicated Team for Stone Treatment Centre at Craigavon Area Hospital** Similar to Option 2, this option will consist of a significant number of staffing appointments being made enabling the number of weekly ESWL sessions to be extended from 3 to 7 sessions. It will permit a total of 4 patients per session to be treated, facilitating an additional 19 patients to be seen per week (eg 4 patients per session x 7 sessions equates to 28 patients TBC). With provision of a dedicated team of multi-disciplinary staff aligned to the Stone Treatment Centre at Craigavon Area Hospital it will enable all ESWL treatments, weekly MDT meetings, the complete outpatient journey (from investigation to review) to be effectively managed. Provision of a dedicated ESWL session for patients residing within South Eastern Trust area will also be deliverable. Is there any additional information as to what this option will deliver that needs incorporated?

SECTION 4: PROJECT COSTS

Option	Year 1 (£'000)	Year 2 (£'000)	Year 3 (£'000)	Total (£'000)
1				
2				
3				

COST ASSUMPTIONS:

Option 2
There will be a requirement for the following additional **posts to be appointed**
Can you please confirm exact staffing requirements please

- XX wte Band 5 Staff Nurse
- XX Band 3 Health Care Assistant
- XX wte Radiographer
- Xx wte Band 4 Admin & Clerical

Option 3
There will be a requirement for the following additional **posts to be appointed**

Can you please confirm exact staffing requirements please

- XX wte Band 5 Staff Nurse
- XX wte Band 3 Health Care Assistant
- XX wte Band Radiographer
- XX wte Consultant Urologist
- XX wte Registrar
- XX wte Band 4 Admin & Clerical

Goods & Services
- Are there any additional consumables that would be required for the no of sessions proposed TBC
- The anticipated life span of Lithotripter equipment is 10 years however it is not dependent upon the number of shocks/treatments/patients
- The current equipment has been in operational use since 1998 and is on the capital equipment list for Acute Directorate for replacement

SECTION 5: NON-MONETARY BENEFITS

The non-monetary benefits associated with the project are detailed below:-

Non-Monetary Benefit	Option 1 Status Quo/Do Nothing	Option 2 Increase Sessions within the Stone	Option 3 Provision of a Dedicated Team for

		Treatment Centre	Stone Treatment Centre
Provision of additional sessions per week	• With no improved access to the service, enhanced utilisation of Hospital facilities will be untenable	• Facilitation of an additional 4 weekly sessions will enable higher volumes of patients to undergo their treatment resulting in a total of 28 patients being seen on a weekly basis.	• Similar to Option 2, this option will facilitate a further 4 weekly sessions to take place thus enabling a higher percentage of patients to undergo treatment each week (circa 28 patients).
Reduced Waiting Times for Treatment	• As the number of patients being referred into the Service will continue to grow, it will result in a rise in waiting times. Therefore, patients will continue to experience lengthy waiting times for their treatment	• The patients' experience will be greatly enhanced as they will receive treatment for their conditions within an appropriate timeframe	• Similar to Option 2, the patients' experience will be significantly enhanced as the patient journey (from investigation to review) will be managed within an appropriate timeframe by a dedicated service team
Improved efficiency	• With the volume of administrative tasks associated with both MDT meetings and the ESWL processes, the degree of administrative support from the Specialty Doctor will still be prevalent (understandably, a situation which does not make best use of skills). • With no improved service provision, the use of Main Theatres at CAH for some patients' procedures will continue.	• As administrative tasks will be progressed prior to the day of treatment, a reduction in nurse administration on the day of treatment will be deliverable. This will increase capacity for treatment of an additional patient per session (total of 4 patients as opposed to 3 patients per session). • The potential loss/delay of treatment sessions will significantly reduce as x-ray scans will be up-to-date. • As more non-invasive treatment will be deliverable, fewer patients will require treatment within Main Theatres	• As with Option 2, there will be a reduction of nurse administration on the day of treatment as administrative tasks will be progressed prior to the day of treatment. This will increase capacity for treatment of an additional patient per session (total of 4 patients). • The potential loss/delay of treatment sessions will significantly reduce as x-ray scans will be up-to-date. • This option will provide dedicated ESWL sessions for South Eastern

		at CAH. Therefore, permitting patients to be managed within an appropriate environment. • Delivery of a more streamlined service will be achievable.	patients • With dedicated staffing within the Stone Treatment Centre this will optimise the facilities available within the Stone Treatment Centre at CAH and enhance the patient's journey.

SECTION 6: PROJECT RISKS & UNCERTAINITIES

The project risks associated with this scheme are detailed in the table below:-

Risk Description	Likely impact of Risk H/M/L			State how the options compare and identify relevant risk management/mitigation measures
	Opt 1	Opt 2	Opt 3	
1. Inability to Appoint Staff	**N/A**	**L**	**L**	**Option 1** – N/A **Options 2&3** - there is the potential that no applicants may apply for the new posts, however this is deemed to be a 'low' risk. • **Mitigation Measure** - the Trust will ensure that robust recruitment processes are in place and any issues raised by BSO are promptly addressed
2. Recurrent revenue funding not secured	**N/A**	**M**	**M**	**Option 1** – N/A **Options 2&3** – this is a possibility that recurrent funding may not be secured and therefore this is considered a 'medium' risk • **Mitigation Measure** – the Trust will maintain close links with the HSCB/continue to seek financial support from the HSCB
Overall Risk (H/M/L):	**N/A**	**L/M**	**L/M**	

SECTION 7: PREFERRED OPTION AND EXPLANATION FOR SELECTION

Option 1 - Status Quo/Do Nothing

- With no modifications being made to existing service model, there will be no enhanced utilisation of Hospital facilities
- The waiting times associated with ESWL treatment will continue to grow, therefore patients will continue to experience lengthy delays for treatment
- There will still be a requirement for the Specialty Doctor to provide a degree of administrative support which does not make best use of medical staffing resources
- The number of ureteroscopies will steadily increase as no additional capacity for elective ESWL treatments will be attainable
- No improvements to the efficiency of the ESWL & Generalised Stone Service within the Southern

Trust will be achievable

Option 2 - Increase ESWL Sessions from 3 to 7 Sessions per week within Stone Treatment Centre at Craigavon Area Hospital

- This option will enable the weekly Extra Corporeal Shockwave Lithotripsy (ESWL) sessions to be extended from 3 to 7 sessions per week
- It will provide increased capacity as a total of 4 patients per session will be treated, equating to a total of 28 patients receiving treatment per week (in comparison to 9 patients treated at the present time).
- The patient's experience will be greatly enhanced as waiting times for treatment will reduce therefore patients will receive treatment for their conditions within an appropriate timeframe
- The potential loss/delay of treatment sessions will significantly reduce as x-rays/imaging scans will be up-to-date
- As some patients may no longer require invasive treatment, fewer patients will require treatment within Main Theatres at CAH
- With more non-invasive procedures and extended availability being attainable, this will support the Trust to improve compliance with the requisite guidelines/recommendations (British Association of Urologist, National Institute for Clinical Excellence) as delivery of an enhanced ESWL Service to patients requiring treatment of renal stones will be achievable.
- An improved skill mix of staff will be attainable

Option 3 - Provision of a Dedicated Team for Stone Treatment Centre at Craigavon Area Hospital

- Similar to Option 2 above, this option will enable the weekly Extra Corporeal Shockwave Lithotripsy (ESWL) sessions to be extended from 3 to 7 sessions per week.
- It will provide increased capacity as a total of 4 patients per session will be treated, equating to a total of 28 patients receiving treatment per week (in comparison to 9 patients treated at the present time).
- The patient's experience will be significantly enhanced as the patient journey (from investigation to review) will be effectively managed within an appropriate timeframe
- As some patients may no longer require invasive treatment, fewer patients will require treatment within Main Theatres at CAH

- With more non-invasive procedures and extended availability being attainable, this will support the Trust to improve compliance with the requisite guidelines/recommendations (British Association of Urologist, National Institute for Clinical Excellence) as delivery of an enhanced ESWL Service to patients requiring treatment of renal stones will be achievable.
- This option will make provision for a dedicated team of staffing to be aligned to the Stone Treatment Centre at Craigavon Area Hospital which will enable all ESWL treatments, weekly MDT meetings and the complete patient journey (from investigation to review) to be efficiently and effectively managed.
- An improved skill mix of staff will be achievable.

Is there any additional information that needs to be incorporated?

The preferred option is Option 2 – Increase ESWL Sessions from 3 to 7 Sessions per week within the Stone Treatment Centre at Craigavon Area Hospital as this will enable a further 4 weekly sessions to be delivered giving the Trust additional capacity to treat a total of 28 patients per week. Therefore, the patient's experience will be greatly enhanced as the current waiting times for treatment will reduce.

As more non-invasive treatment regimes will be achievable this will improve the Trust's compliance with British Association of Urologists and NICE guidelines/recommendations whilst permitting patients to be managed within an appropriate environment.

Any potential loss or delay of treatment sessions due to x-rays/imaging scans being out-of-date will reduce.

With an increase in capacity, the Trust will be able to deliver a more streamlined and efficient ESWL & Generalised Stone Service to its resident population.

SECTION 8: AFFORDABILITY AND FUNDING REQUIREMENTS

AFFORDABILITY STATEMENT	Yr 0 £000's	Yr 1 £000's	Yr 2 £000's	Yr 3 £000's	Totals £000's
Required					
Capital required					
Revenue required					
Existing budget :					
Capital					
Revenue					
Additional Allocation Required:					
Capital					
Revenue					

AFFORDABILITY ASSUMPTIONS

SECTION 9: MANAGEMENT ARRANGEMENTS

The following project management roles have been agreed:-

- Project Owner – Mrs Esther Gishkori (Director of Acute Services)
- Project Director – Mrs Heather Trouton (Interim Executive of Nursing & Allied Health Professionals (with responsibility for Cancer & Clinical Services)
- Project Manager – Mrs Martina Corrigan, Head of ENT & Urology

The project timescales associated with this proposal are detailed in the table below:-

Project Timescales	
Business Case Approval	May/June 2018
Submission of Business Case to HSCB	May/June 2018
Confirmation of Funding	June/July 2018
Recruitment Process Commenced	July/August 2018
Staff in Post	October 2018

SECTION 10: MONITORING AND EVALUATION

Who will manage the implementation?	Mrs Martina Corrigan - TBC Head of Service – ENT & Urology
Who will monitor and evaluate the outcomes?	A Head of Service independent to the project - TBC
What other factors will be monitored and evaluated?	
When will this take place?	April 2019

SECTION 11: ACTIVITY OUTCOMES (TRUSTS ONLY)

	Specifiy activity, e.g. IP, DC OPN, OPR, Contacts etc					
	IP	**DC**	**OPN**	**OPR**		
Baseline						
Additional activity						
New Baseline Activity						

SECTION 12: BENCHMARKING EVIDENCE TO SUPPORT PREFERRED OPTION

HSC TRUST RESEARCH & DEVELOPMENT FUND

APPLICATION FORM 2018 – 2019

N.B. Applications should only be submitted for research which can be completed by 31 March 2019 as funding cannot be carried forward to the next Financial Year

Name of Applicant:	Mr Michael Young	
Job Title:	Urology Consultant	
Work Address:	Craigavon Stone Treatment Centre, Craigavon Hospital	
Contact Details:	Tel:	Mobile: Personal Information redacted by the USI
	Email: Personal Information redacted by the USI	
Project Title:	Kidney and Ureteric Stones Treated With Extracorporeal Shockwave Lithotripsy Using the EDAP i-sys Sonolith Lithotripter: Successful stone clearance and complications	
Project Outline:	**<u>Context/Background – why it is important to do the research,</u>** Kidney Stones have afflicted the human population for thousands of years, having been identified in Egyptian mummies, and even make up part of the classical Hippocratic Oath from the 4th century BC (Tefekil A, 2013). Kidney Stones can be identified in 8% of the population (BAUS). In the United Kingdom renal colic (pain from kidney stone) is common, with 12% of men and 6% of women having at least one episode of renal colic in their lifetime, with the incidence peaking at 40-60 years of age for men and late 20's for women (Bultitude M, 2012), (NZ, 2014). The difference between male and female risk in decreasing, this is likely due to the increase in obesity and western diet in women (NICE, 2015). **The overall incidence of kidney stones is rising.** In America the 1994 incidence rate of 1 in 20 has almost doubled to 1 in 11 when compared to year 2007-2010 data (Hitt, 2012). The risk of further stones	

	development is high, with 30% to 40% chance of recurring at 5 years (NICE, 2015). The Craigavon Urological Stone Treatment Centre (CAH STC) looks after an area greater than the geographical Southern Trust boundaries, caring for a population of 420000. In addition the CAH STC receives regular referrals from the other trusts, namely the South Eastern Trust. How the Urologist treats a kidney stone is dependent on location and size of the stone, as well as patient comorbidities. The majority of stone can be treated by Extracorporeal Shockwave Lithotripsy (ESWL), available onsite at Craigavon Area Hospital, and is the only fixed site ESWL in Northern Ireland, or in fact the North of the Ireland! In order to fulfil the demand of ESWL stone treatments, the CAH STC must provide 1100 treatment per year. ESWL is a well-recognised treatment modality for Kidney stones, and is recommended by the European Association of Urology guidelines (C Turk 2017) and NICE (NICE 2015). Since the invention of ESWL in 1980 we are now on the 4th Generations of Lithotripter. The Southern Trust invested around £430000 in a new EDAP TMS i-sys lithotripter to replace an older model. It has its own dedicated centre, with the treatment sessions run by a radiographer and nursing staff. The patients are awake for their treatments, with oral pain relief. ESWL has less risk of complication and is safer when compared to more invasive Urological stone procedure of Ureteroscopy and Percutaneous Nephrolithotomy. A PubMed search using various combinations of search terms of 'ESWL', 'SWL', 'EDAP TMS', i-sys sonolith did not generate any clinical papers on the success outcomes of the i-sys sonolith lithotripter. As technology progresses, evidence is required to demonstrate that the Lithotripter in use is still providing effective kidney stone clearance rates, at a low complication rate. **Aim – broad statement about what the research will entail** To assess the outcomes of stone clearance rates for kidney and ureteric stones using the i-sys sonolith lithotripter. To

	provide complication rates and patient satisfaction with receiving the treatment modality for their stones. **Objectives – the actions required to meet the aim of the research** 1. **Patient demographics** (age, sex, BMI) 2. **Kidney stone factors pre-treatment** (Size, location, Hounsfield units, stone to skin distance) 3. **ESWL treatment parameters** (Ramping protocol, average power delivered, total energy delivered, type of pain relief) 4. **Patient satisfaction** with treatment, including pain score) 5. **Outcome of treatment**: (stone clearance, fragmentation, no change, other procedures needed) **Sample/Participants – the people/data who will be the focus of the research and how you will gain access** All patients undergoing ESWL for treatment of kidney or ureteric stones. The above data required in objectives is already recorded in the patient's clinical notes. **Data Collection Method – Qualitative/Quantitative/Mixed Methods e.g. interviews, questionnaires, focus groups – provide some information about the proposed method(s)** Prospective study for the outcome of ESWL using the i-sys sonolith. A data collection excel spreadsheet would be created to record the objective setting data. The data (objectives 1-4) would be best inputted at time of treatment, and outcome data (objective 5) at the Stone Multidisciplinary Meeting (MDT). The Stone MDT is the platform where patients are currently listed for ESWL and also their follow-up imaging discussed at 4-6 weeks following treatment to assess treatment success. Objective 4, patient satisfaction would be assessed via a questionnaire, the same day of treatment completion. **Ethical Considerations – ethical issues relating to the research e.g. Consent** ESWL is already a recognised and recommended treatment

	for kidney and ureteric stones by EAU and NICE. Consideration to alternate treatment modalities or change in treatment parameters if data was to demonstrate unsatisfactory stone clearance rates or complications from the use of the i-sys sonolith lithotripter. **Potential outputs – what will be the impact on patient care** Provide data to support the on-going funding of the ESWL service. Provide data to patients on the percentage success for stone clearance using the i-sys sonolith and complication rate. This will aid patients to make a fully informed choice on their treatment options. Provides data to the wider clinical and scientific community on use of the i-sys sonolith lithotripter and treatment of kidney and ureteric stones. **Data Analysis method – dependent on whether data is numerical or text based e.g. SPSS, thematic analysis** There will be a mixed data analysis method. Stone clearance rates will be numerical, and could be statistically compared against older lithotripter data sets of clearance, as well as statistical comparison against the more invasive surgical treatment of ureteroscopy for stone clearance. Patient satisfaction and complication rates can also be numerically processed, analysed and compared against similar studies for other lithotripters or surgical modalities. **Proposed start date** October 2018 **Proposed end date** October 2019 (although it would be of benefit for data collection to continue for a 4 or 5 year period to potential give around 5000 treatments, and so provide robust data and one of the largest ESWL evidence bases, future funding could be discussed with the Trust) **Specify how the time required to undertake the Study will be incorporated into your work and other personal**

	commitments Study data will be collected by the proposed funding for a research radiographer or nurse, they will be aided in their write up and analysis of the data. Time to oversee and support the project will be dedicated on a weekly bases by Mr Young Urology Consultant, including time following the weekly Thursday morning MDT **References** BAUS. (n.d.). *Kidney Stones*. Retrieved Febuary 02, 2018, from British Association of Urology: https://www.baus.org.uk/patients/conditions/6/kidney_stones Bultitude M, R. J. (2012). Management of renal colic. *BMJ*, 345. C. Türk, A. N. (2017). *Urolithiasis*. Retrieved Febuary 08, 2018, from European Association of Urology Guidelines : http://uroweb.org/guideline/urolithiasis/#3 Hitt, E. (2012, May 24). *Incidence of Stone Disease Has Doubled Since 1994*. Retrieved November 2016, from Medscape : http://www.medscape.com/viewarticle/764518 NICE. (2015). *Renal or ureteric colic - acute*. Retrieved Febuary 08, 2018, from https://cks.nice.org.uk/renal-or-ureteric-colic-acute#!backgroundsub:2 NZ, B. (2014). Managing patients with renal colic in primary care: know when to hold them. *Best Practice Journal New Zealand*. Tefekil A, C. F. (2013). The History of Urinary Stones: In Parallel with Civilization. *Scientific World Journal* .
Outline how the Project relates to the Trust's Corporate Objectives:	The project aims to deliver evidence behind the use of the i-sys sonolith lithotripter in the treatment of kidney and ureteric stones. And…. • Provides safe, high quality care • Maximize independence and choice for our patients and clients • Support people and communities to live healthy lives and improve their health and wellbeing • Make the best use of resources • Be a great place to work, with staff being actively involved in providing evidence based medicine in the form of ESWL

	• Learning opportunity for a member of staff to enhance a service, share the learning, benefit patients.
Outline the potential to develop into a larger research Project:	The data could be continued to be collected every year to provide one of the largest data sets and evidence for ESWL using the i-sys sonolith. The data collected would aid the development of regional, national (NICE and BAUS) and international guidelines (e.g EAU) for the use of ESWL in treatment of kidney and ureteric stone using the i-sys sonolith lithotripter.
Financial Support Required:	**Please provide a full breakdown of the costs required**: • Salary costs – The costs should support either a radiographer or nurse (band 5). • Goods and Services costs – The cost wold be for the time of radiographer or nurse to collect the data, data analysis, presentation of data. • Cost Centre to which any funding awarded should be credited (To be provided by your Line Manager) • Outline how you would take forward the proposal if only a percentage of the funding requested is awarded to your application: a) We would scale the project down if funding did not allow for complete collection and analysis of every patient. b) The project is achievable with a day a week, although 2 or more days a week would produce more robust data collection, evidence and impact to any potential publication and information for patients.
Line Manager Support:	**Please provide the name and job title of your Line Manager whose agreement you have sought to submit this application:**

	Martina Corrigan
Line Manager	**Line Manager to provide a short statement to confirm support of this application**
Line Manager's Signature and Date	

Completed Forms should be returned by email to Irene Knox, Research Manager (Personal Information redacted by the USI no later than Friday, 13 July 2018

Urology Departmental Meeting
18 June 2015

AGENDA

1. New OP
2. Review OP
3. Dashboard
4. Elective – IN's/Days – Urgents
5. Urodynamics
6. Cancer performance paper
7. Peer Review
8. Red Flag capacity over July (escalation email from Mandeville)
9. Workshop on 26 June 2015
10. Future dates for workshops
11. AOB

Urology PERFORMANCE – June 2022

Urology Priority 2 update as at 14/06/2022:

	16/03/2022	14/06/2022
P2A	0	1
P2B	18	21
P2C	48	49
P2D	215	208
TOTAL	**281**	**279**

The priority 2 caseload includes a mixture of proven cancers, clinically suspected cancers, and benign disease. Within the proven cancer patients a small number are undergoing multimodality treatment and have narrow treatment windows.

In order for our decision making to be objective and transparent as we assign our limited capacity to patients requiring surgery, it is agreed that we approach this activity along the following priorities, using waiting time (days on surgical waiting list) as the additional metric.

Priority A = proven cancer with short treatment window post chemotherapy / radiotherapy
Priority B = proven cancer
Priority C = suspected cancer
Priority D = benign disease

New Out Patient Waiting List (with no dates) report 1				
	16/03/2022		14/06/2022	
Urgency	**No on WL**	**Longest Wait**	**No on WL**	**Longest Wait**
Red Flags	229	19 weeks	270	2-4 weeks
Urgent	340	310 weeks	181	198 weeks
New Urgents with 352	1015	313 weeks	239	210 weeks
Routine	3632		3397	332 weeks
Total	**5216**		**4087**	

New URGENT/ROUTINE Outpatients waiting with no dates. ***As at 14/06/2022***

- Removing the patients transferred to IS the total number of New Urgents is 181.
- Due to patients, returning to trust for reasons such as not being suitable for IS or refusing IS our Trust longest waiter is **210 weeks**. If we do not count the patients, who have been offered IS but returned to trust our Longest would have been **198 weeks (Due to upgrade from Urgent).**
- The average longest waits for patients who have not be transferred to IS is 16 Weeks.
- All upgrades and new add ons will be transferred to 352 in Quarter 2

Total activity to date with 352 as at 14/06/2022

352 Activity
14.06.22

	Complete					Booked			TOTALS
	February	March	April	May	June	July	Aug	Sept	
Consultation	421	419	228	474	193	21	1	0	1757
Investigation	342	413	244	549	330	35	0	0	1913
Procedure	12	105	107	143	102	28	1	0	498
Post Op Review	0	0	11	7	11	2	0	1	32
Review	0	10	84	72	98	72	1	1	338
TOTALS	775	947	674	1245	734	158	3	2	**4538**

NOP WL breakdown as at 14/06/2022

	Urgent	Routine	Urgent	Routine
	Mar-22	Mar-22	June-22	June-22
Weeks waiting	Total with no dates	Total with no dates	Total with no dates	Total with no dates
0-10	206	176	444	146
11-20	143	149	86	93
21-30	84	99	14	102
31-40	84	116	8	99
41-50	106	125	18	94
51-60	101	123	20	135
61-70	52	70	15	112
71-80	76	80	10	86
81-90	84	66	7	78
91-100	58	66	10	69
101-110	103	123	5	69
111-120	147	136	10	86
121-130	95	168	15	122
131-140	10	155	19	141
141-150	3	164	1	178
151-160	1	134	3	122
161-170	1	131	0	135
171-180	1	161	1	130
181-190	0	164	2	124
191-200	3	134	1	152
201-210	2	99	1	113

211-220	1	98	0	101
221-230	0	100	0	86
231-240	0	108	0	90
241-250	2	109	0	91
251-260	0	119	0	91
261-270	0	116	0	94
271-280	0	97	0	104
281-290	1	89	0	90
291-300	1	69	0	88
301-310	3	100	0	69
311-320	0	0	0	68
321-332	0	0	0	39
Total	**1368**	**3644**	**690**	**3397**

Urology Referrals per year (year is April-March)

Year	**Total	Average per month
2017-2018	6208	517
2018-2019	6622	551
2019- 2020	6338	528
2020-2021	4589	382
2021-2022	5747	479
2022-2023 (to May 2022)	421	211

Review outpatient backlog update (as at for 14th June 2022)

	May 22		June 22	
	Total	**Longest Date**	**Total**	**Longest Date**
Glackin	30	Nov-20	35	Nov- 20
O' Donoghue	336	Mar-17	375	Mar- 17
Young	480	Dec-16	499	Dec- 16
Haynes	93	Feb-19	103	Feb- 19
Omer	41	Feb- 21	43	Feb- 21
Khan	34	Dec- 21	65	Dec- 21
O' Brien	159	Jul- 13	160	Jul- 13
Tyson	24	Nov-19	35	Oct- 19
Jacob	34	Jul- 17	34	Jul- 17
Total	**1231**		**1349**	

Adult Inpatient and Day case waiting lists – position as at 14/06/2022

Consultant	Urgent Ins	Weeks Waiting	Routine Ins	Weeks waiting	Urgent D/C	Weeks waiting	Routine DC	Weeks waiting
Glackin	46	181	66	273	48	191	55	199
O'Donoghue	137	329	58	368	41	271	66	376
Young	162	404	74	409	132	381	174	409
Haynes	67	351	54	385	38	267	44	310
Khan	14	77	22	83	36	140	31	73
O'Brien	94	410	33	391	11	408	13	372
Tyson	31	182	21	221	13	160	21	166
Total	**405**		**328**		**319**		**404**	

Summary Adults – total = 1948 pts
Urgent Inpatients = 405 patients; longest wait 404 Weeks
Routine Inpatients = 328 patients; longest wait 409 weeks
Urgent days = 319 patients; longest wait 408 weeks
Routine days = 404 patients, longest wait 409 weeks

Urology Departmental Meeting
23 July 2015

AGENDA

1. Introduction of New Medical Director and discussion of the issues and challenges in Urology.
2. Infection Control issues – 4th Floor
3. RQIA Visit to 3 South
4. Regional Review Paper for discussion along with nominations for sub-groups
5. Peer Review – Serious Concerns (update)
6. New Clinics – Stocktake
7. Any Other Business

Urology Departmental Meeting
8 October 2015

AGENDA

1. Apologies
2. Administration of Mitomycin
3. Infection control
4. FY1 duties on the wards
5. Saline TURP System (agree a date that suits for Susan England at meeting)
6. Antibiotic Stewardship (do we need to invite Melanie Pathiraja – Consultant microbiologist to a future meeting?)
7. Paediatrics – Daisy Hill Hospital
8. Emergency Theatre utilisation
9. Urology oncall Registrar rota
10. Working Group updates (SBA/CCG referral for advice and banner guidance)
11. Triage
12. Greenlight laser – Rep Mark Devoy would like to attend a future meeting to provide information on this.
13. Hospital at night
14. TROC pathway (Kate and Jenny to attend)
15. FPSA or not FPSA?? (Derek McKillop attending the meeting on 22 October at 12:30)
16. Any other Business

DEPARTMENTAL MEETING 22nd SEPTEMBER 2016

Chair: Mr Young

Present: Mr Glackin, Mr O'Brien, Mr Suresh, Mr O'Donoghue, Pamela Johnston, Theatre Manager & Sr. England

Apologies: Mr Haynes , Mrs Corrigan

TOPIC: SALINE RESECTION

The specifications for the saline resectoscope system were presented. Mr Young outlined the history behind the move to the saline resection, also explaining that the last year had been spent trialling the various resectoscopes. Mr Young asked the forum if they had regarded enough time had been given to each of the resectoscope providing companies so that an adequate assessment could be made for each of the scopes. The unanimous decision was that the trial period for each of the resectoscopes was adequate to make an opinion.

We all agreed that the appraisal form used was of a good standard and certainly adequate to make a surgeons' assessment of each scope. The overall assessment looked at scope quality, ease of use, product design and effectiveness of the core principal of diathermy and resection of tissue. Second component to be evaluated were costs of generators and disposables. Thirdly was the topic of CSSD and backup. Scoring was undertaken from the feedback forms with the result that the WOLF system was the poorest and was not fit for purchase. In third place was the TONTARRA system which was described as having a variable performance with regards to the resection loop activity. The STORZ and the OLYMPUS system scored virtually equally on the various points with an overall equal score. It was recorded that there was no cystoscope present on the OLYMPUS resectoscope tray for evaluation but we generally felt that this was not an issue to take into account. There was general record of a fairly good ease of use and that the vaporisation module component was good. Several negative points related to the working element of inflow/outflow not being ideal; there were some comments on excessive bubble formation on the resectoscope loop as well as some other comments relating to slow resection. Overall however this was a system that could be purchased. With regards to the STORZS system, it was felt that the cutting modality of the resectoscope loop was excellent. Overall the scope components were easily constructed and there was a generalised good ease of use. Comments with regards to consistency and haemostasis had been positive. One of the major points in its favour was that the STORZ system could be easily changed if required on an urgent basis to the use of glycine. This in the current climate of change from one system to another in association with the range of urologists within the unit was a more suitable system for the team in Craigavon Area Hospital. The STORZ system certainly was a system that could be purchased.

Purely on the ease of use principal, excluding other criteria (i.e. cost and CSSD), the option came down to either STORZ or the OLYMPUS system, the other two being excluded. Four surgeons voted for the STORZ, one electing for the OLYMPUS. Mr Haynes was not present for this vote but on subsequent conversation later in the day, Mr Young put the same question to Mr Haynes asking for his comments on ease of use and again he had no particular preference and was happy to run with the global opinion.

On reviewing the various costs, it was noted that the disposables did have a variable range. It was accepted that loop quality did vary and that loops could be purchased from different sources. We all felt that this was not a particularly focused point for making a decision (namely cost of loop).

The price of the individual resectoscope systems was recorded noting that the OLYMPUS system was significantly more expensive in totality. The OLYMPUS system would have to be purchased completely whereas the STORZ system could be involve both new scopes and modification of current sets. (The costs set out for this meeting were significantly in favour of the STORZ system but it was appreciated that if a STORZ completely new systems was to be included that this information was to be presented to the forum before a final decision was made).

A further significant contributor to decision making was the generator needed for the electrical input. Although the OLYMPUS company was going to offer a free £40,000 generator, we did record that we may need up to three generators in view of the amount of urology sessions occurring at the same time. (The forum did not know if the company would supply three free generators. They felt it unlikely but enquiries would be made). The current generator system available within the Trust is multifunctional and therefore would already suit the STORZ system more appropriately. Even with the OLYMPUS generator system, this would result in increased machinery parking within the theatre environment. Overall this was regarded as a fairly substantive pointer in favour of the STORZ system.

CONCLUSION

In concluding, the vote on several aspects namely ease of use, cost, generator type were all in favour of the STORZ system. All the urologists have backed this decision with a unanimous vote.

This decision was based on the information supplied with a final decision pending the outstanding enquiries, namely the cost of a completely new STORZ resectoscope system and the cost of the OLYMPUS cystoscope. This would give a truly like for like comparison. The additional enquiry related to the OLYMPUS generator issue.

Mr Young will add an addendum to this document when the above information becomes available before final sign off.

The paperwork with regards to this has been forwarded to the Service Administrator, Martina Corrigan and to Pamela Johnston, Theatre Manager.

M Young
22nd September 2016
Chair of Session

ADDENDUDEM to outstanding information in relation to Saline resection Systems

1/ Full cost specification for STORZ and OLYMPUS resectoscope systems (excluding generator) have now been supplied and presented by the Theatre management. This is included on the updated evaluation sheet. (see enclose document)

(*The conclusion of the forum group remains the same – namely that STORZ is less expensive*)

2/ OLYMPUS will only supply one free generator

This information is to be presented at the next Departmental meeting for ratification

M Young

12th October 2016

Urology Performance – 19 February 2019

Referrals received

2016-2017 - 5463
2017-2018 - 4594
2018-2019 – 3807 (up to end of January 2019)

Red Flag referrals (Total for one year = 3430)

62 DAY REFERRALS	Dec 17	Jan 18	Feb 18	Mar-18	April18	May 18	Jun 18	July 18	Aug 18	Sep 18	Oct 18	Nov 18	Dec 18	Jan 19
Urological Cancer	118	138	161	182	157	160	183	147	193	175	197	193	180	173
31 DAY REFERRALS	Jan 18	Feb 18	Mar-18	April18	May 18	Jun 18	July 18	Aug 18	Sep 18	Oct 18	Nov 18	Dec 18	Dec 18	Jan 19
Urological Cancer	99	86	76	64	82	77	75	101	56	104	66	57	57	73
Total	**217**	**224**	**237**	**246**	**239**	**237**	**258**	**248**	**249**	**279**	**263**	**250**	**237**	**246**

CAPACITY = 4 per consultant per clinic and if a registrar available then this increases to 6, therefore should have 6 consultants x 6 slots = 36 per week

New Outpatient waiting lists

Total on waiting list = 3687

Total URGENT waiting a date is 669 (longest = 24 weeks) (note that there are 6 others waiting longer but are in the PB cycle (1 x 147 weeks, 1 x 133 weeks, 1 x 87 weeks, 1 x 63 weeks, 1 x 58 weeks and 1 x 40 weeks)

Total ROUTINE waiting a date is 3018 (longest is waiting 161 weeks)

RED FLAGS waiting with no dates:

Referral	No waiting	Time Waiting
Urology (Prostate)	**44 patients**	**67 days**
Urology (Haematuria)	**57 patients**	**61 days**
Urology (Other)	**14 patients**	**26 days**

Dr Paul Hughes clinic in DHH has been cancelled for the first 2 weeks of March currently have 11 patients to be booked.

Review outpatient backlog (taken from Business objects) – should have been seen by 31 March 2019

Consultant		
	total	**Longest date**
Mr Young (general)	284	July 2015
Mr Young (stones)	618	March 2015
Mr O'Brien	675	March 2015
Mr Glackin	80	February 2017
Mr Haynes	59	October 2018
Mr O'Donoghue	549	September 2015
Mr Jacob	634	February 2017
Enniskillen	157	March 2016
Total	**3056**	

Total per year

2015	**77**
2016	**198**
2017	**661**
2018	**1485**
2019	**635**

Adult Inpatient and Daycase waiting lists – position 19 February 2019 (1805 patients)

Consultant	Urgent Ins	Weeks Waiting	Routine Ins	Weeks waiting	Urgent D/C	Weeks waiting	Routine DC	Weeks waiting
Mr Young	161	231	66	264	114	208	208	251
Mr O'Brien	216	237	57	237	36	212	23	235
Mr Glackin	53	110	34	119	48	56	38	51
Mr Haynes	91	178	47	225	22	94	50	216
Mr O'Donoghue	119	156	34	195	88	102	26	203
Mr Jacob	37	150	18	161	102	130	117	167
Total	**677**		**256**		**410**		**462**	

Paediatrics Inpatient and Daycase waiting lists – position 19 February 2019 (27 patients)

Consultant	Urgent Ins	Weeks Waiting	Routine Ins	Weeks waiting	Urgent D/C	Weeks waiting	Routine DC	Weeks waiting
Mr Young	0	0	0	0	2	4	1	81
Mr O'Brien	7	55	4	182	1	35	2	134
Mr Glackin	0	0	0	0	0	0	1	11
Mr Haynes	0	0	0	0	1	61	0	0
Mr O'Donoghue	1	9	1	128	0	0	2	105
Mr Jacob	2	70	0	0	2	115	0	0
Total	**10**		**5**		**6**		**6**	

Planned patients that should have been seen

Consultant	
Mr Young	57
Mr O'Brien	42
Mr Glackin	20
Mr Haynes	40
Mr O'Donoghue	41
Mr Jacob	23
Total	**223**

Martina Corrigan

SHSCT Adverse Incident Reporting (IR2) Form -December 2020

The new Regional CCS2 codes which will replace 'Type', 'Category', 'Subcategory', and 'Detail' have been updated.

A full list of these codes can be found here for review.

Incident Details
ID & Status

Incident Reference ID	Personal information
Submitted time (hh:mm)	20:25

Incident IR1 details

Notification email ID number	W Personal information
Incident date (dd/MM/yyyy)	20/11/2014
Time (hh:mm)	17:00
Does this incident involve a patient under the age of 16 within a Hospital setting (inpatient or ED)	
Does this incident involve a Staff Member?	
Description Enter facts, not opinions. Do not enter names of people	Patient discussed at Urology MDM on 20th November 2014. Recorded outcome Patient 102 s Re-staging MRI scan has shown organ confined prostate cancer for direct referral to Dr H for Radical Radiotherapy. For OP Review with Mr O'B.' Was reviewed by Mr O'B in OP on 28th November 2014. No correspondance created from this appointment. Referral letter from GP received 16th October 2015 stating that Patient 102 had not received any appointments from oncology.
Action taken Enter action taken at the time of the incident	Patient 102 has now been referred to Oncology. This has been done by email and letter. Investigation with MDM team, direct referral was generated at CAH but no record of being received in Belfast.
Learning Initial	
Reported (dd/MM/yyyy)	21/10/2015
Reporter's full name	Mark Haynes
Reporter's SHSCT Email Address	
Opened date (dd/MM/yyyy)	18/11/2015
Last updated	David Cardwell 06/17/2016 09:17:40
Were restrictive practices used?	
Name This will auto-populate with the patient/client's name if the person-affected details have been entered for this incident.	Patient 102

Location of Incident

Site	Craigavon Area Hospital
Loc (Type)	Outpatient Clinic
Loc (Exact)	Urology Clinic
Directorate	Acute Services
Division	Surgery and Elective Care
Service Area	General Surgery

Speciality / Team Urology Surgery

Staff initially notified upon submission

Recipient Name	Recipient E-mail	Date/Time	Contact ID	Telephone Number	Job title	Originated from
No details found for the contact with ID [redacted]	sharon.kennedy[redacted]	21/10/2015 20:26:07	[redacted]			Level 1 Form
No details found for the contact with ID [redacted]	Eamon.Mackle([redacted]	21/10/2015 20:26:07				Level 1 Form
Connolly, Connie	[redacted]	21/10/2015 20:26:06			Acting Acute Governance Co-Ordinator	Level 1 Form
Mackin, Dawn	[redacted]	21/10/2015 20:26:06			Nursing Governance CoOrdinator	Level 1 Form
Young, Michael	[redacted]	21/10/2015 20:26:05			Consultant	Level 1 Form
Smyth, Paul	[redacted]	21/10/2015 20:26:05			Head of Unscheduled Care	Level 1 Form
Trouton, Heather	[redacted]	21/10/2015 20:26:05			Assistant Director of Acute Services	Level 1 Form
Glenny, Sharon	[redacted]	21/10/2015 20:26:04			Operational Support Lead	Level 1 Form
Nelson, Amie	[redacted]	21/10/2015 20:26:04			Head of Service	Level 1 Form
Corrigan, Martina	[redacted]	21/10/2015 20:26:03			Head of ENT and Urology	Level 1 Form

Management of Incident

Handler Enter the manager who is handling the review of the incident	Martina Corrigan
Additional/dual handler If it is practice within your team for two managers to review incidents together use this field to record the second handler	
Escalate You can use this field to note the incident has been escalated to a more senior manager within your Service/Division- select the manager from this list and send an email via the Communication section to notify the manager the	

incident has been escalated to them.	
Date of final approval (closed date) (dd/MM/yyyy)	17/06/2016

Linked records

No Linked Records.

Coding

Datix Common Classification System (CCS)

Category	
Sub Category	
Detail	

Datix CCS2

Type	
Category	
Sub-Category	
Detail	
Is this a Haemovigilance /Blood Transfusion or Labs-related Incident?	No
Is this an incident relating to confidentiality? This may include inappropriate access / disclosure, loss or theft of records etc	No

SAI / RIDDOR / NIAIC?
Click here To Help you determine whether or not an incident constitutes an SAI please refer to the Regional SAI reporting criteria by clicking here.

SAI? Click To help you determine whether or not an incident constitutes an SAI please refer to the Regional SAI reporting criteria by clicking here.	
Is this incident RIDDOR reportable? Below are the 5 categories which qualify a RIDDOR Reportable incident (click on blue links for further definition): 1. Employee or self-employed person working on Trust premises is killed or suffers a major injury 2. A member of the public on Trust premises is killed or taken to hospital 3. An incident connected with the Trust where an employee, or self-employed person working on Trust premises, suffers an "over 3 day injury (being incapacitated to do their normal duties for more than three consecutive	

days (not counting the day of the accident but including weekends and rest days). Incapacitation means that the member of staff is absent or unable to do their normal work e.g. placed on lighter duties which are not part of their normal work)

4. Dangerous Occurence attributable to the work of the Trust

5. A doctor has notified you in writing that a Trust employee suffers from a reportable work-related disease

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Is this a NIAIC Incident
NIAIC (Northern Ireland Adverse Incident Centre) incidents relate to medical devices. If a medical device is involved in an incident consider the list below to identify if the incident is NIAIC reportable;

- design or manufacturing problems

- inadequate servicing and maintenance

- inappropriate local modifications

- unsuitable storage and use conditions

- selection of the incorrect device for the purpose

- inappropriate management procedures

- poor user instructions or training (which may result in incorrect user practice

---

Investigation

Investigator	Andrea Cunningham
Date started (dd/MM/yyyy)	18/11/2015
Actual Impact/Harm This has been populated by the reporter. To be quality assured by the investigating manager.	Major

---

Risk grading
Click here

When the incident has a Severity (actualimpact/harm, grading of insignificant to moderate, you need to plot on the matrix oppositethe Potential impact/harm. Deciding what are the chances of the incident happening again under similar circumstances. (Likelihood) and multiply that by the potential

	Consequence				
Likelihood of recurrence	**Insignificant**	**Minor**	**Moderate**	**Major**	**Catastrophic**
Almost certain (Expected to occur daily)	○	○	○	○	○
Likely (Expected to occur weekly)	○	○	○	○	○
Possible	○	○	○	○	○

impact if it were to reoccur (consequence) The overall risk grading for the event will be determined by plotting: consequence multiplied by likelihood = risk grading. Refer to impact table here:	**(Expected to occur monthly)**					
	Unlikely (Expected to occur annually)	○	○	○	○	○
	Rare (NOT expected to occur for years)	○	○	○	○	○
		Grade:				

Action taken on review Enter here any actions you have taken as a result of the incident occurring; e.g. communicating with staff / update care plan / review risk assessment (corrective and preventative action)	181115cc- preliminary review by FSS established that there was no dictation done on this patient. Incident returned to SEC and will be escalated to HOS and AMD
Action Plan Required? A formal action plan is required for all Moderate to Catstrophic incidents. If you tick yes an "Action plan" section will appear below. Use this to create your action plan.	

Action Plan

No actions

Lessons learned

Lessons learned If you think there are any lessons from an incident which could be shared with other teams please record here. If not please type "none".	
Date investigation completed (dd/MM/yyyy)	
Was any person involved in the incident?	No
Was any equipment involved in the incident?	No

Notepad

Notes Use this section to record any efforts you have made as part of your investigation e.g. phonecalls / requested patient / client's chart / awaiting staff to return from sick leave. This will inform Governance staff who will be monitoring timescales for the completion of investigations etc, and reduce the amount of phone calls/emails to you requesting same information	

Communication

Recipients

Message

Message history

Date/Time	Sender	Recipient	Body of Message	Attachments
22/03/2016 12:08:10	Kerr, Vivienne	martina.corrigan@ Personal Information redacted by USI	This is a feedback message from Vivienne Kerr. Incident form reference is Personal The feedback is: Please see Datix which is now coded under urology. Please go to Personal Information redacted by USI Personal Information redacted by USI	
11/12/2015 14:55:26	Cardwell, David	martina.corrigan@ Personal Information redacted by USI	This is a feedback message from David Cardwell. Incident form reference is Personal information The feedback is: Hi Martina, Helen Forde has asked me to send this to you with the following message: Personal information redacted by Personal information - I think it should go to Martina Corrigan as it says there was no correspondence for the appointment – so it wasn't that the secretary didn't type it – I think it was that it wasn't dictated so that would need to go to Head of Service for urology to discuss with consultant. Regards David Cardwell Please go to Personal Information redacted by USI Personal Information redacted by USI	
18/11/2015 14:29:44	Connolly, Connie	Carroll, Anita	This is a feedback message from Connie Connolly. Incident form reference is Personal information The feedback is: Martina- i have taken this back to SEC as it appears no dictatation was done. Will need review by yourself and governance will support if needed. Connie Please go to Personal Information redacted by USI Personal Information redacted by USI	
18/11/2015 14:29:44	Connolly, Connie	Personal Information redacted by USI	This is a feedback message from Connie Connolly. Incident form reference is Personal information The feedback is: Martina- i have taken this back to SEC as it appears no dictatation was done. Will need review by yourself and governance will support if needed. Connie Please go to Personal Information redacted by USI Personal Information redacted by USI	
18/11/2015 14:29:43	Connolly, Connie	Corrigan, Martina	This is a feedback message from Connie Connolly. Incident form reference is Personal Information redacted by USI The feedback is: Martina- i have taken this back to SEC as it appears no dictatation was done. Will need review by yourself and governance will support if needed. Connie Please go to Personal Information redacted by USI Personal Information redacted by USI	
18/11/2015 14:29:43	Connolly, Connie	Robinson, Katherine	This is a feedback message from Connie Connolly. Incident form reference is Personal information redacted by USI The feedback is: Martina- i have taken this back to SEC as it appears no dictatation was done. Will need review by yourself and governance will support if needed. Connie Please go to Personal Information redacted by USI Personal Information redacted by USI	
18/11/2015 11:41:44	Connolly, Connie	Mark.Haynes@ Personal information redacted by USI Personal information	This is a feedback message from Connie Connolly. Incident form reference is Personal Information The feedback is: Hi all- i have moved this to FSS for investigation and close. There may be 2 teams which cross over in relation to this issue. I wasnt sure so i gave access to all. Moved to review Connie Please go to Personal Information redacted by USI Personal Information redacted by USI	
18/11/2015 11:41:43	Connolly, Connie	Robinson, Katherine	This is a feedback message from Connie Connolly. Incident form reference is Personal information The feedback is: Hi all- i have moved this to FSS for investigation and close. There may be 2 teams which cross over in relation to this issue. I wasnt sure so i gave access to all. Moved to review Connie Please go to http: Personal Information redacted by USI Personal Information redacted by USI	
18/11/2015 11:41:43	Connolly, Connie	Forde, Helen	This is a feedback message from Connie Connolly. Incident form reference is Personal information redacted by USI The feedback is: Hi all- i have moved this to FSS for investigation and close. There may be 2 teams which cross over in relation to this issue. I wasnt sure so i gave access to all. Moved to review Connie Please go to http Personal Information redacted by USI	

			[redacted] to view the incident	
18/11/2015 11:41:42	Connolly, Connie	Carroll, Anita	This is a feedback message from Connie Connolly. Incident form reference is [redacted] The feedback is: Hi all- i have moved this to FSS for investigation and close. There may be 2 teams which cross over in relation to this issue. I wasnt sure so i gave access to all. Moved to review Connie Please go to http: [redacted] to view the incident	

Medication details

Stage
Prescriber Name
Medication error
Medication involved If multiple medications involved enter the primary medication affecting the incident, and record the others in the description
Correct medication
Form administered
Correct form
Dose and strength involved
Correct dose
Route involved
Correct route

Falls Information
Please Quality Assure all information as part of your investigation

Did the fall occur in Hospital or Community Setting?
Specific Location of Fall
Exact location of Fall Please describe in free-text exactly where the fall occurred
Injury Suspected?
Harm?
Buzzer / bell available within reach before fall?
Floor surface
Footwear suitable?
Walking aid in use / reach?
Mental State
First fall this admission or repeat?
Days since admission
Was the patient receiving medication which may affect the risk of falling?
Family informed of fall?
Outcome of Bedrails Assessment

Result

Pressure Ulcers

Was this incident in respect of a Pressure Ulcer?

Equipment details

Product type

Brand name

Serial no

Description of device

Current location

CE marking?

Description of defect

Model/size

Documents added

No documents.

People Affected

	ID	Title	Forenames	Surname	Type	Approval status
▶	Personal Information redacted by the		Patient 102		Patient/Client/Service User	Approved

Employees

	ID	Title	Forenames	Surname	Type	Approval status
▶	Personal Information redacted by the USI	Mr	Mark	Haynes	Staff - Medical and Dental	Approved
▶			Marie	Dabbous	Staff - Administrative and Clerical	Approved
▶			Shauna	McVeigh	Staff - Administrative and Clerical	Approved
▶		Mr	Aidan	O Brien	EMPL	Approved

Other Contacts

No Other Contacts

Stinson, Emma M

From: Haynes, Mark [redacted]
Sent: 11 January 2017 12:45
To: Boyce, Tracey
Subject: FW: [redacted]

As discussed below is correspondence between [redacted], Martina Corrigan and me regarding a patient who had no letters from previous consultations. The letter [redacted] refers to stating that the patient was to have her non functioning kidney removed was an e-discharge from [redacted]. She had been seen in [redacted].

I first saw her when admitted [redacted] she had her surgery later that month.

Mark

-----Original Message-----
From: Haynes, Mark
Sent: 12 April 2016 13:28
To: Corrigan, Martina
Cc: [redacted]
Subject: RE: [redacted]

I saw this lady this morning on my ward round.

I have not been involved in her care to date, I have not received a referral, there are no letters on ECR and her notes detailing previous consultations were not available to me on the ward..

I have discussed a plan going forward that will depend upon how her current pain settles. If it does not settle she will get a nephrostomy, either way I will be looking to arrange an urgent lap nephrectomy. I cannot at present be certain of the date but would hope that it'll be before the end of May.

Mark

-----Original Message-----
From: Corrigan, Martina
Sent: 12 April 2016 08:08
To: [redacted]
Cc: Haynes, Mark
Subject: RE: [redacted]
Importance: High

Good morning,

This patient was admitted this morning via A&E under Mark Haynes. I have copied Mark into this email.

Thanks

Martina

Martina Corrigan
Head of ENT, Urology and Outpatients
Southern Health and Social Care Trust
Craigavon Area Hospital

Telephone: Personal Information redacted by the USI
Mobile: Personal Information redacted by the USI
Email: Personal Information redacted by the USI

-----Original Message-----
From: Personal information redacted by USI Personal Information redacted by the USI
Sent: 11 April 2016 12:19
To: Corrigan, Martina
Subject: FW: Patient 103

Martina,
Just to update this girl was at ED in DHH and with me this AM.There was some suggestion of a further uss but I have defererd organising that until I hear what the IUROLOGISTS ARE DOING.

Thanks,
PB

_____
From: Personal information redacted by USI
Sent: 08 April 2016 10:19
To: Corrigan, Martina Personal Information redacted by the USI
Subject: FW: Patient 103

_____
From: Personal information redacted by USI
Sent: 08 April 2016 10:01
To: martina.cottigan Personal Information redacted by the USI
Subject: Patient 103

Martine
Sorry to ask you qabout this patient.I have a letter stating she is to have a Personal information redacted by USI removed.However i am not sure if she is under the care on Mr Haynes or O'Brien and ECR does not help.Could you direct me twhoever might know if she is on a waiting list and if so which one and how long is the wait.
many thanks
PB

Corrigan, Martina

From: Haynes, Mark <[redacted]>
Sent: 14 June 2018 08:33
To: Corrigan, Martina
Subject: Litigation
Attachments: Confidential - Medical Negligence Claim - [redacted] (30.0 MB); Confidential - Medical Negligence Claim - [redacted] (4.94 MB)

Morning again

I have received these emails from the litigation team regarding difficulty getting responses from Mr O'Brien.

Have these been raised with him before?

Mark

CT

Surname

Patient 108

[redacted]

Southern Health and Social Care Trust

Craigavon Area Hospital

CONFIDENTIAL

First Name(s)

Patient 108

[redacted]

Patient 108

[redacted]

Retention Details	Clinical Trial Label (if required)		Alert Label (if required)	HCN Number	Hospital Number
			Personal Information redacted by the USI [redacted]	Personal Information redacted by the USI [redacted]	Personal Information redacted by the USI [redacted]

Personal Information redaction by the USI

[redacted]

29063 03/13

ICU

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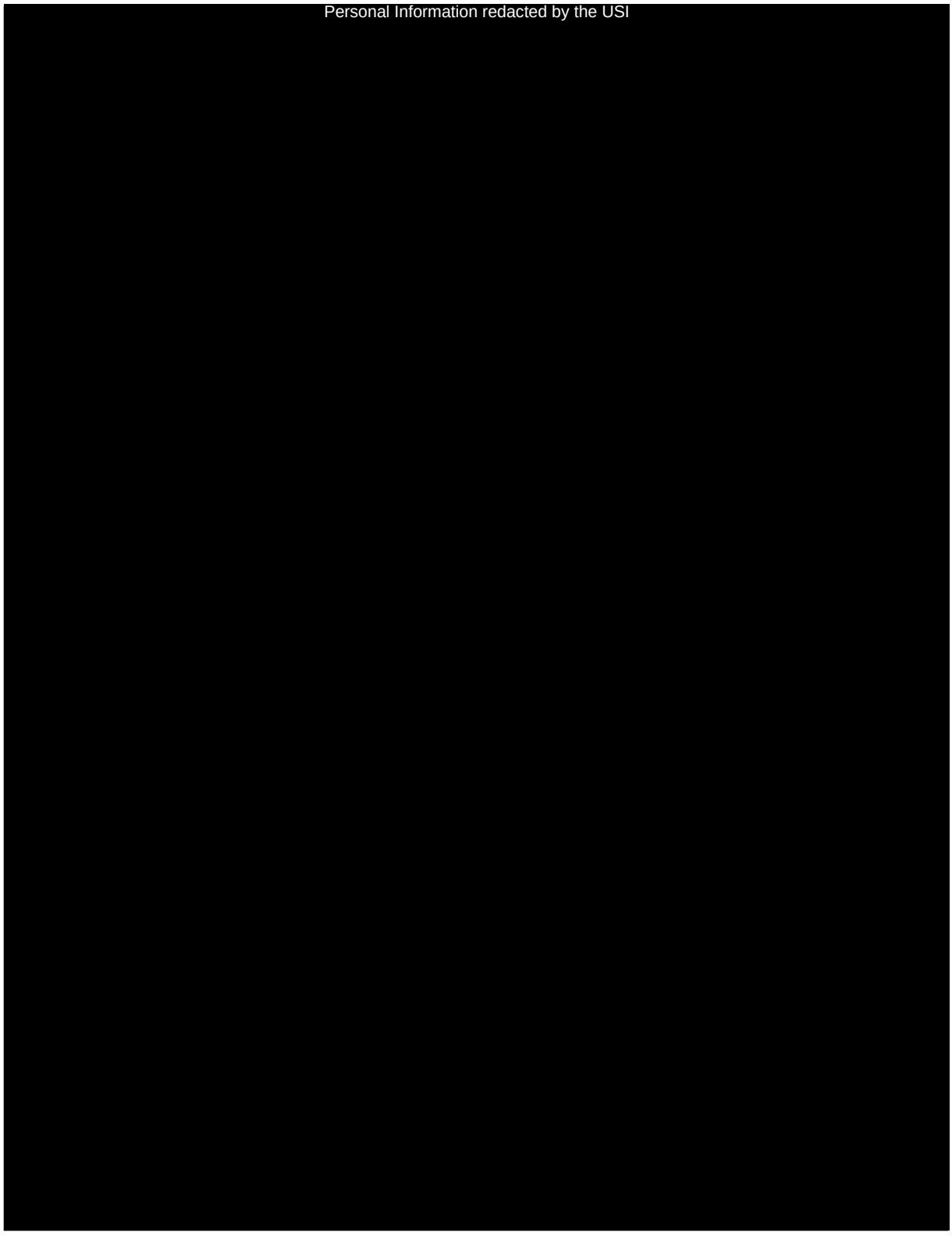

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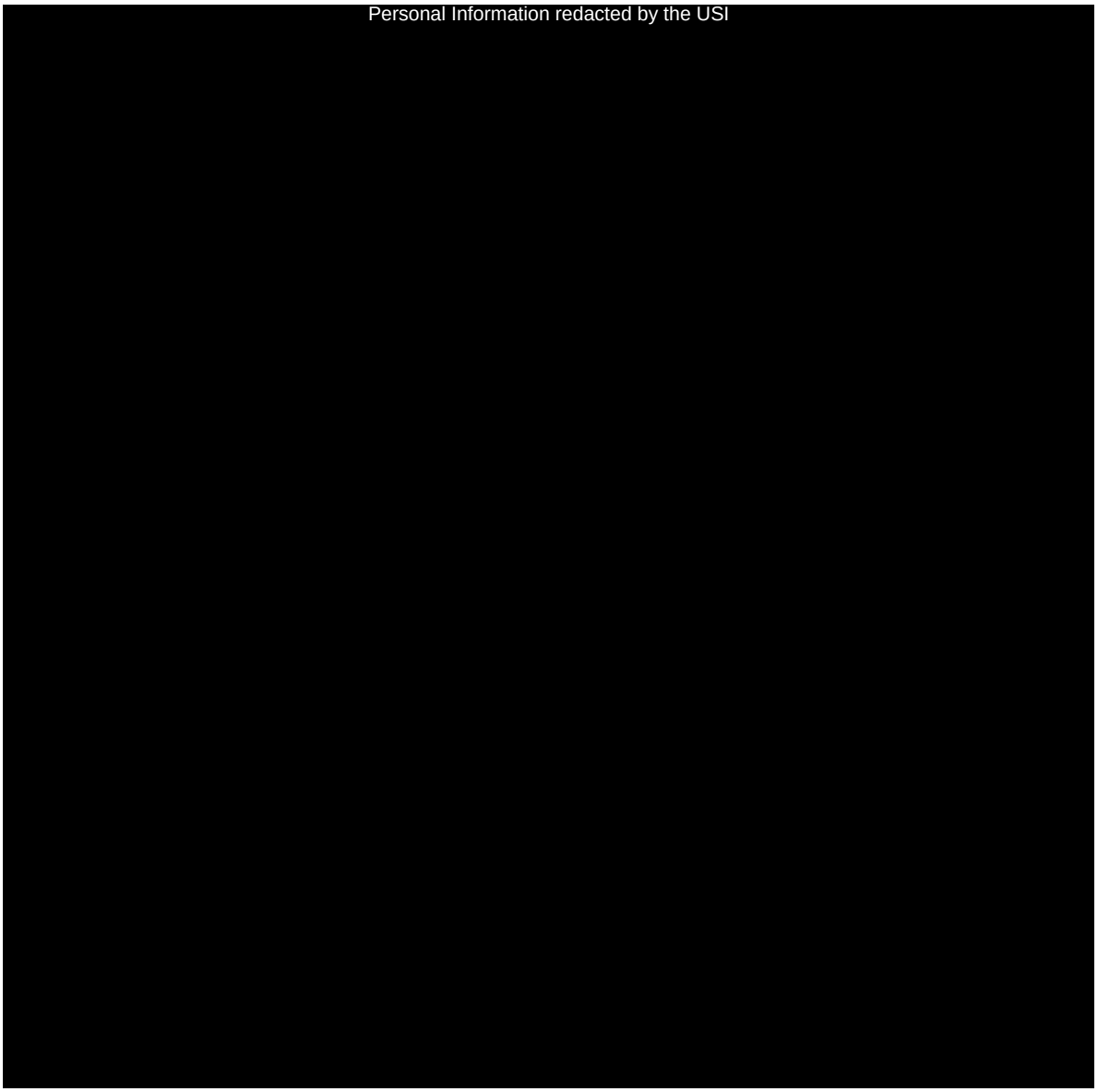

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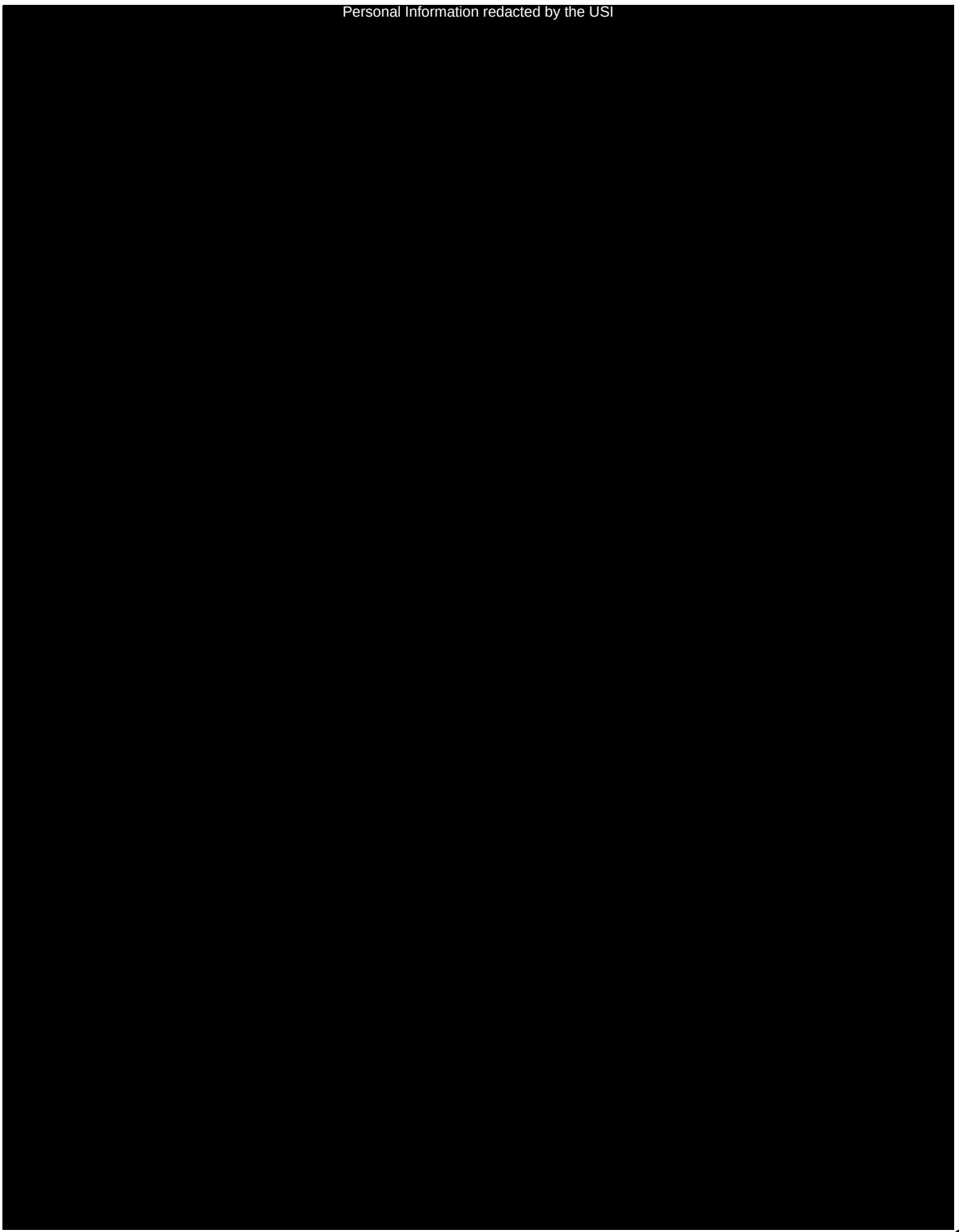

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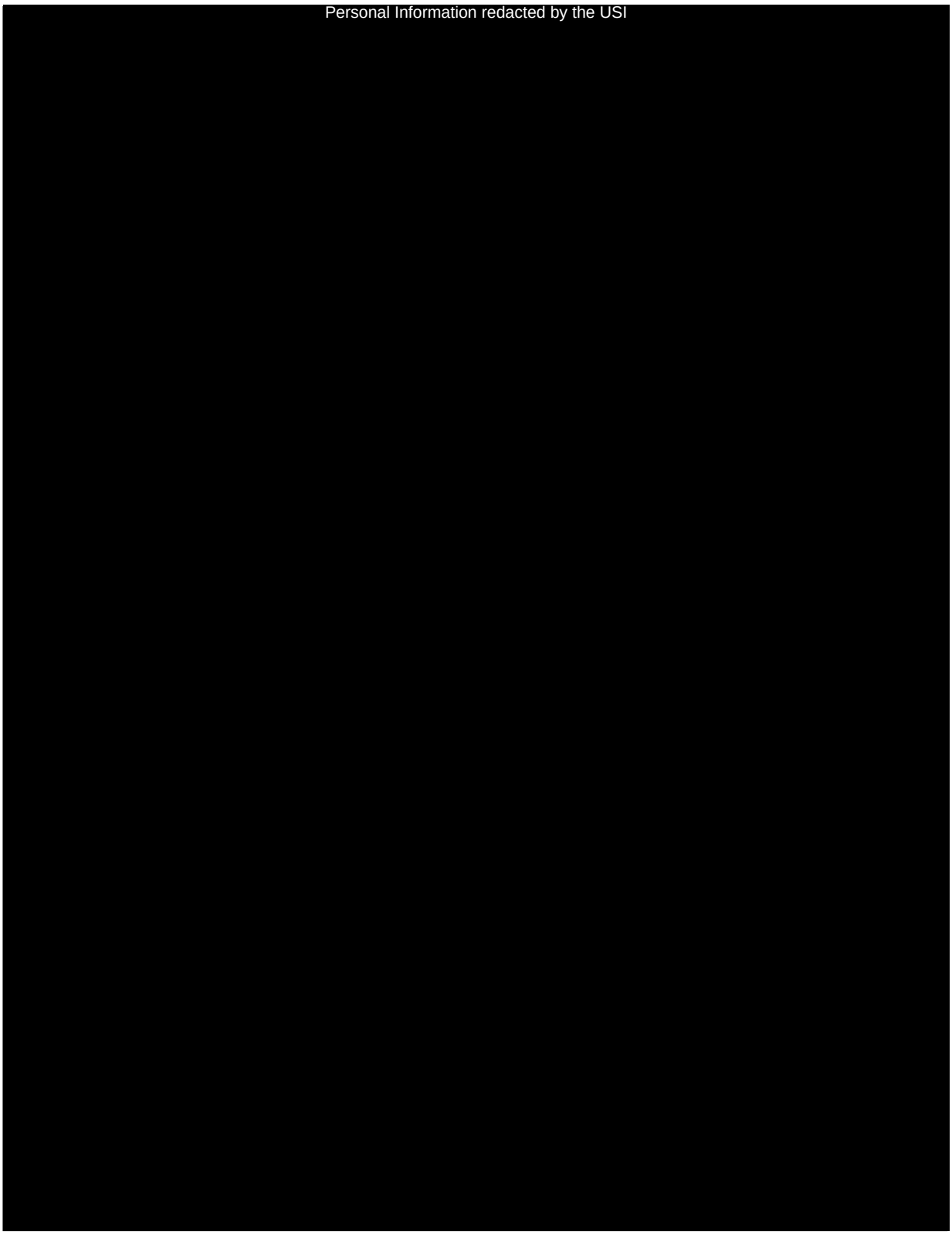

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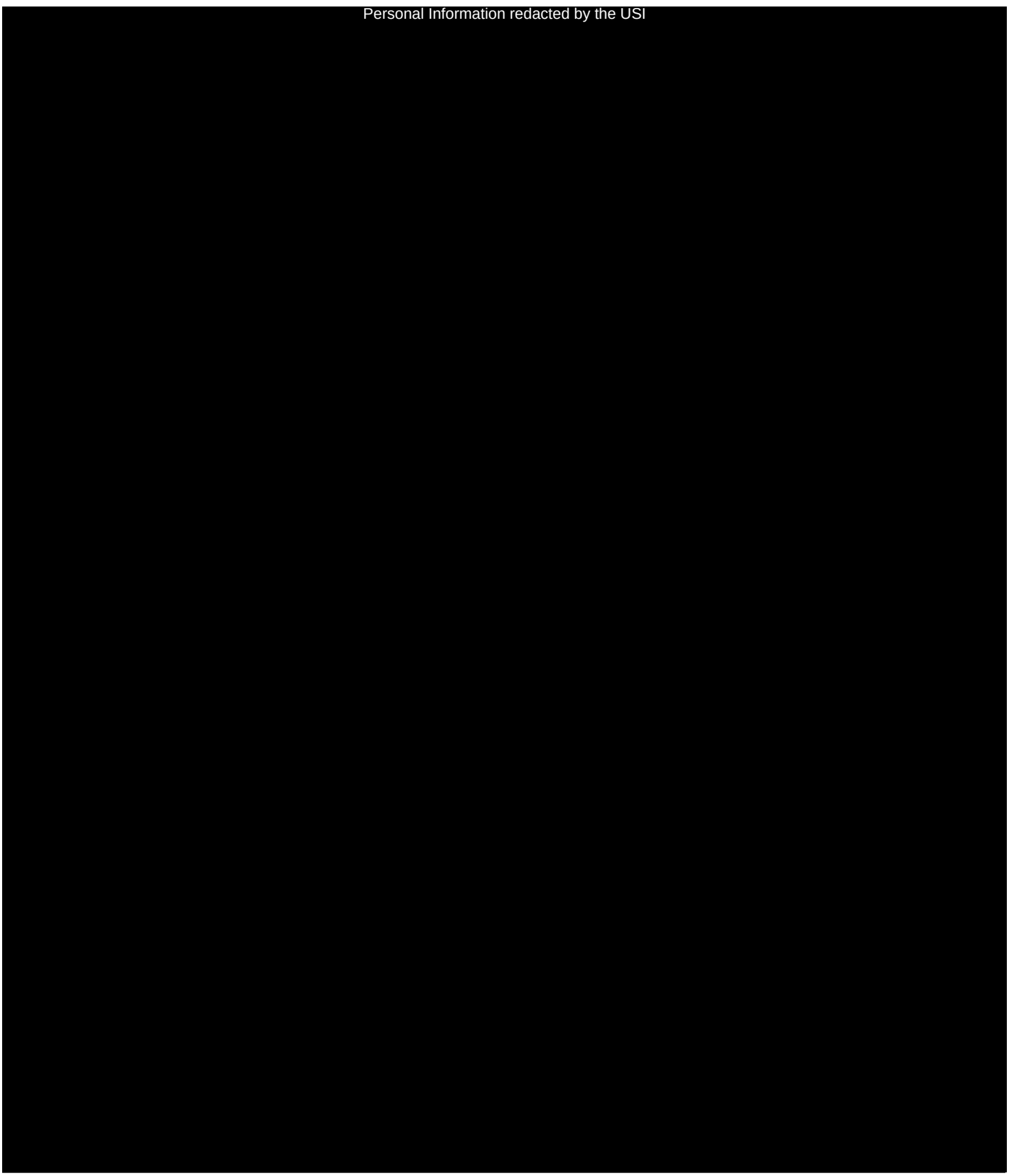
[redacted]

Urology MDM @ The Southern Trust



Personal Information redaction by the USI

[redacted]

29033

UROLOGY

Southern Health and Social Care Trust

CRAIGAVON AREA HOSPITAL
68 LURGAN ROAD
PORTADOWN, BT63 5QQ

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[redacted]

Southern Health and Social Care Trust

CRAIGAVON AREA HOSPITAL
68 LURGAN ROAD
PORTADOWN BT63 5QQ

Personal Information redacted by the USI

[redacted]

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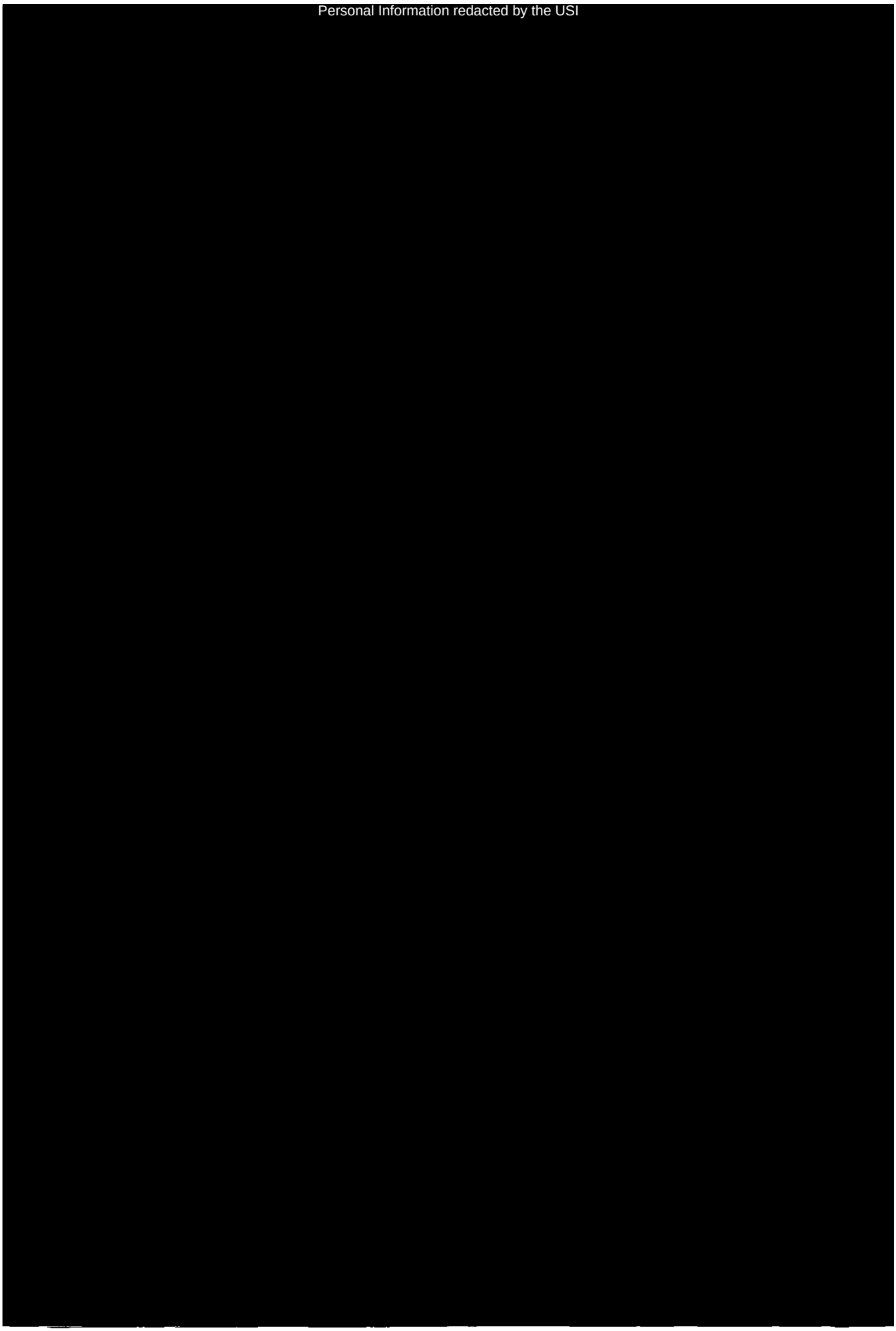

Southern Health and Social Care Trust

Craigavon Area Hospital, Lurgan Road, Portadown, Craigavon, County Armagh, BT63 5QQ
Tel: 028 3861 3674/2952

Ward Tel:

Notes Copy

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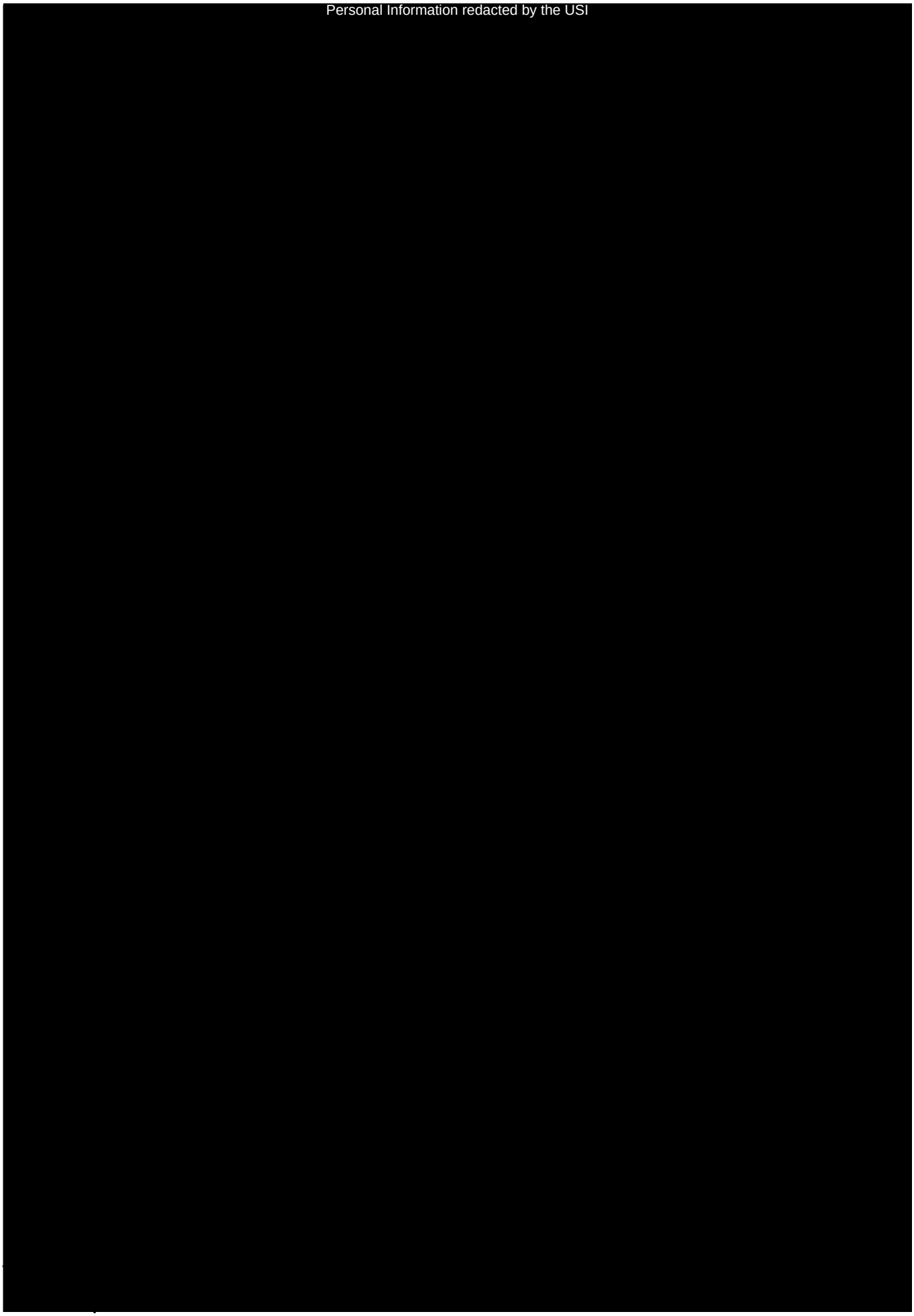
3

Personal Information redacted by the USI

[redacted]



Northern Ireland Ambulance Service Patient Report Form

Form No:

WIT-54912

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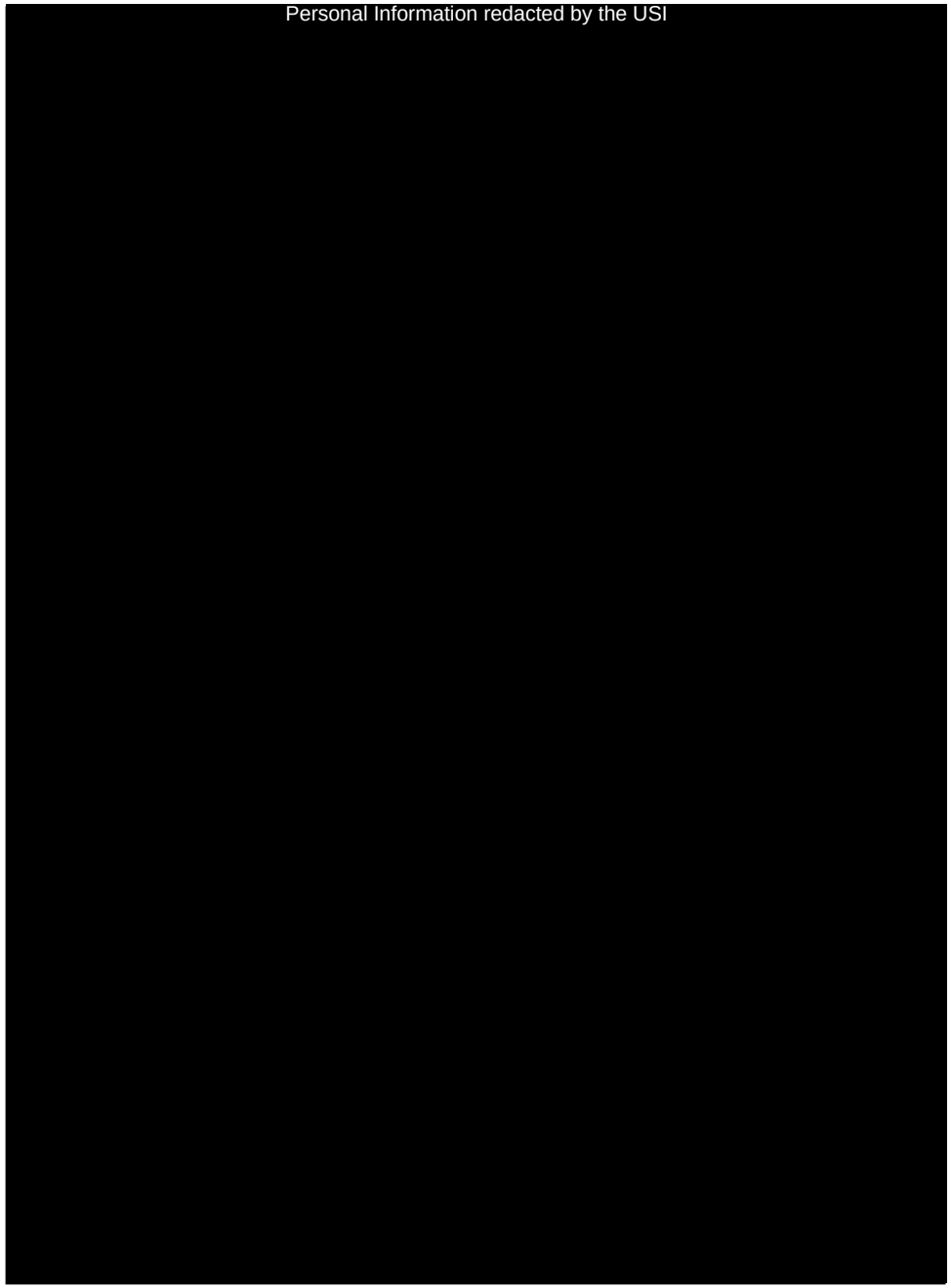
CONFIDENTIAL

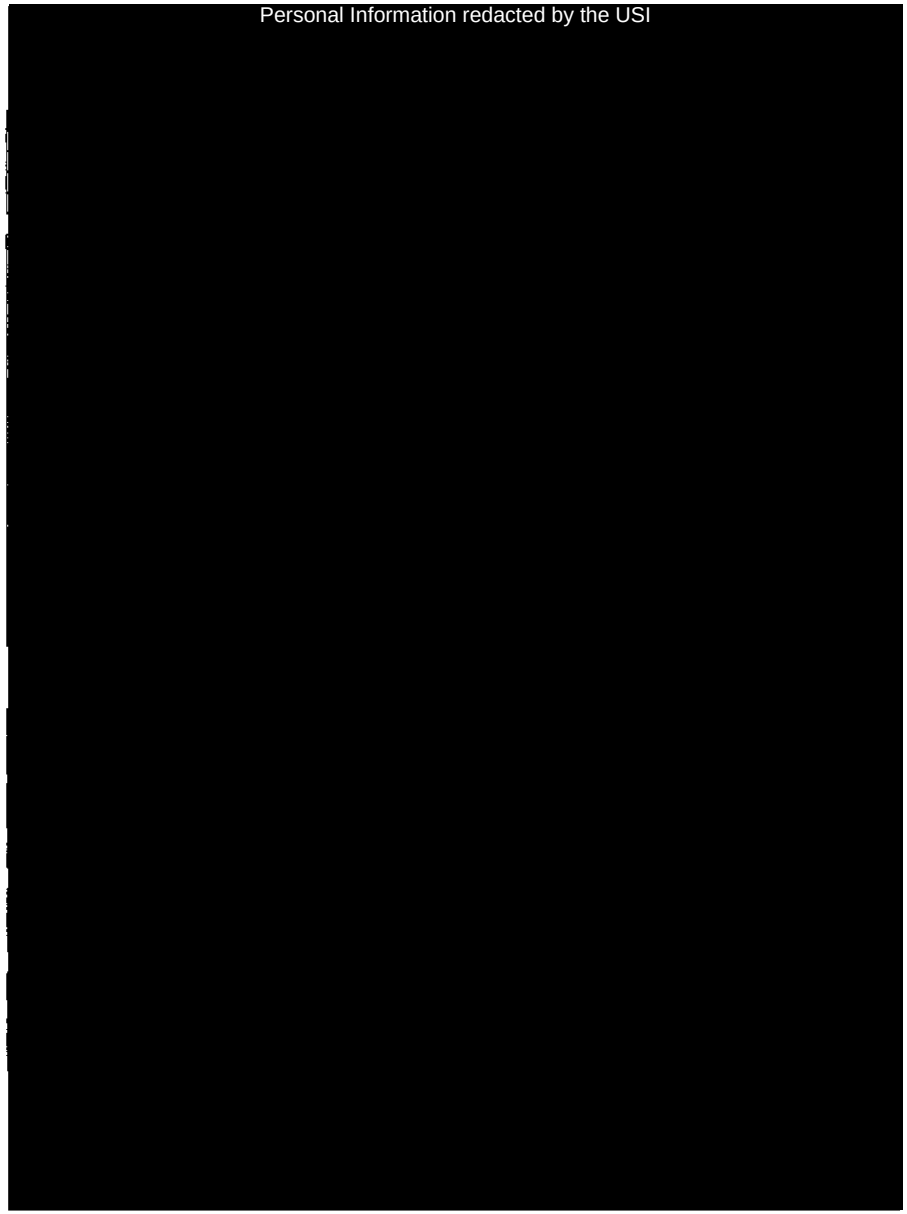
CONFIDENTIAL

Arm Weakness

above in the patients best interests

Received from Mr Mark Haynes on 20/09/22. Annotated by the Urology Servic





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[redacted]

Medicine Prescription and

Rewritten on (date)

Personal Information redacted by the USI

[redacted]

Personal Information redacted by the USI

As required medication

Patient Name: WIT-54916

Personal Information redacted by the USI

As required medication

Patient Name: _____

Personal Information redacted by the USI

Regular injectable medication

Patient Name: _____

Personal Information redacted by the USI

Personal Information redacted by the USI

Oxygen section

Patient Name: WIT-54918

Personal Information redacted by the USI

Personal Information redacted by the USI

[redacted]

Non Injectable antimicrobial medication

Patient Name: WIT-54919

Personal Information redacted by the USI

[redacted]

Regular non-injectable medication

Patient Name: _____

Personal Information redacted by the USI

Regular non-injectable medication

Patient Name: _____ WIT-54920

Check allergies/medicine sensitivities and patient identity

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Southern Health and Social Care Trust

Craigavon Area Hospital, Lurgan Road, Portadown, Craigavon, County Armagh, BT63 5QQ
Tel: 028 3861 3674/2952

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[redacted]

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Received from Mr Mark Haynes on 20/09/22. Annotated by the Urology Servic

OPERATION NOTES

Affix Label

[redacted]

Personal Information redacted by the USI

[redacted]

Signature of Surgeon: .....

Personal Information redacted by the USI

[redacted]

Personal Information redacted by the USI

POSTOPERATIVE INSTRUCTIONS/ MONITORING

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Personal Information redacted by the USI

[redacted]

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[redacted]

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[redacted]

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Patient Protection	Procedure	Monitoring	Vascular Access		Airway Management	Ventilation/Positio

[redacted]

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SHSCT Blood Component Prescription and Transfusion Record. Version 4.

Southern Health and Social Care Trust

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Received from Mr Mark Haynes on 20/09/22. Annotated by the Urology Servic

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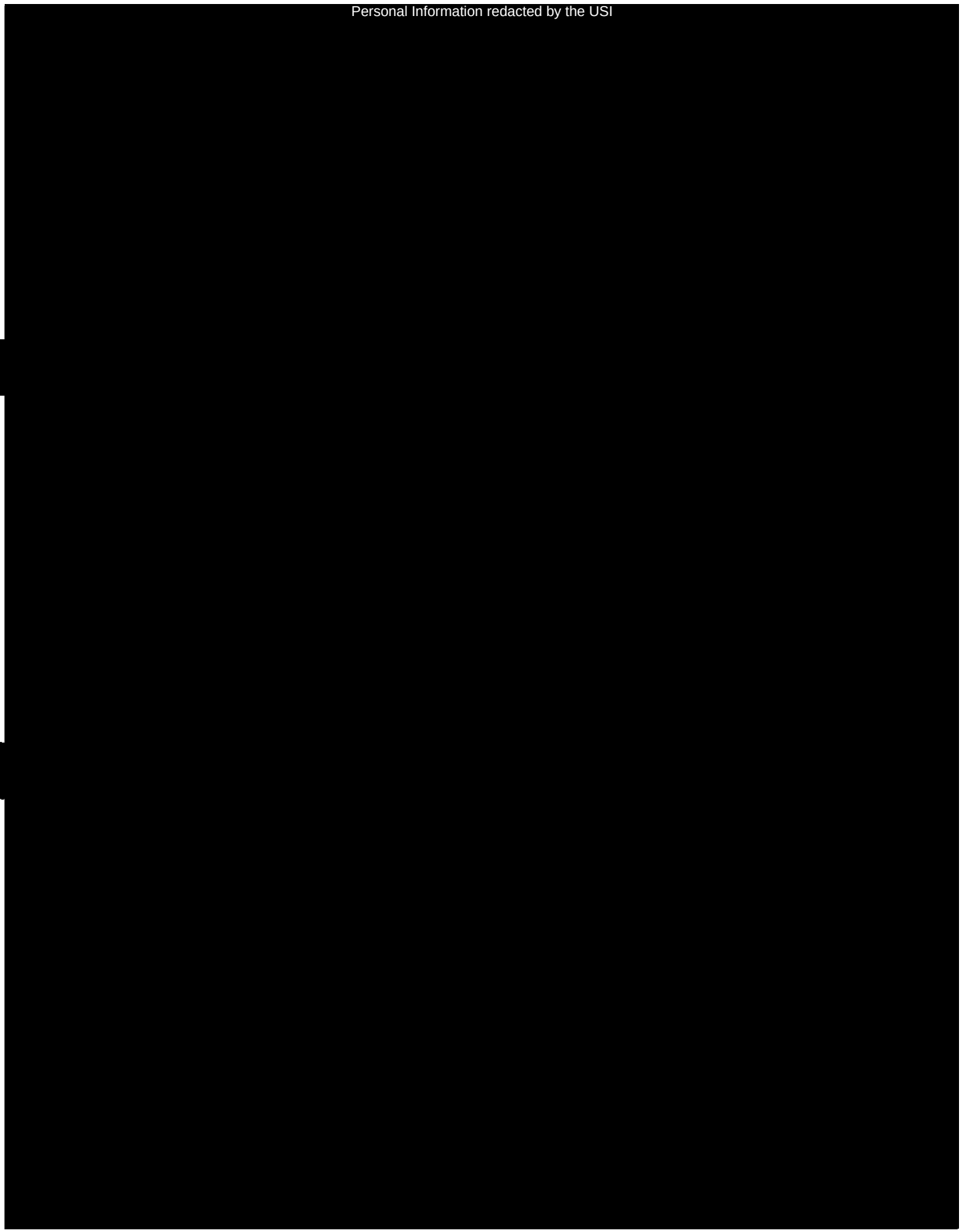

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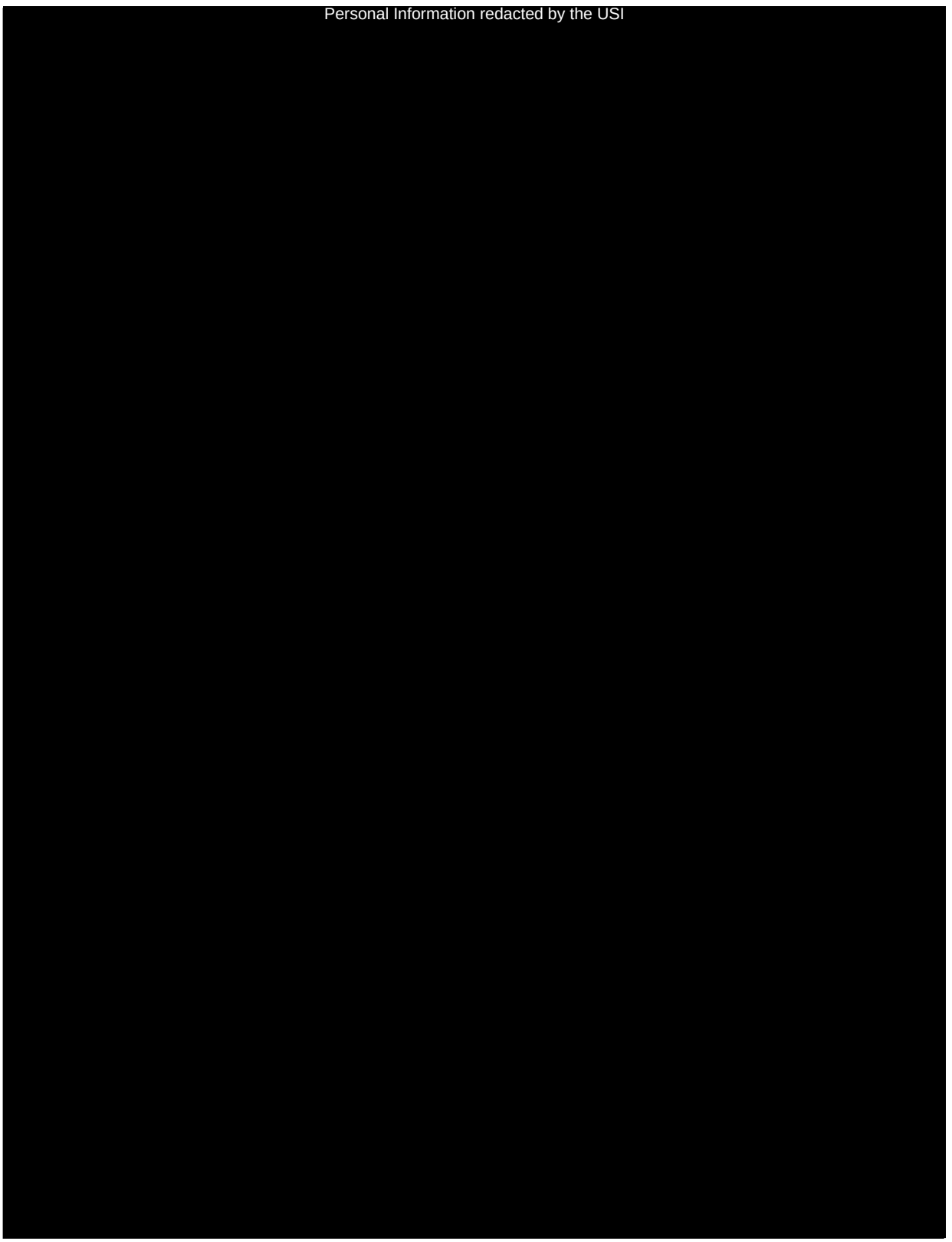

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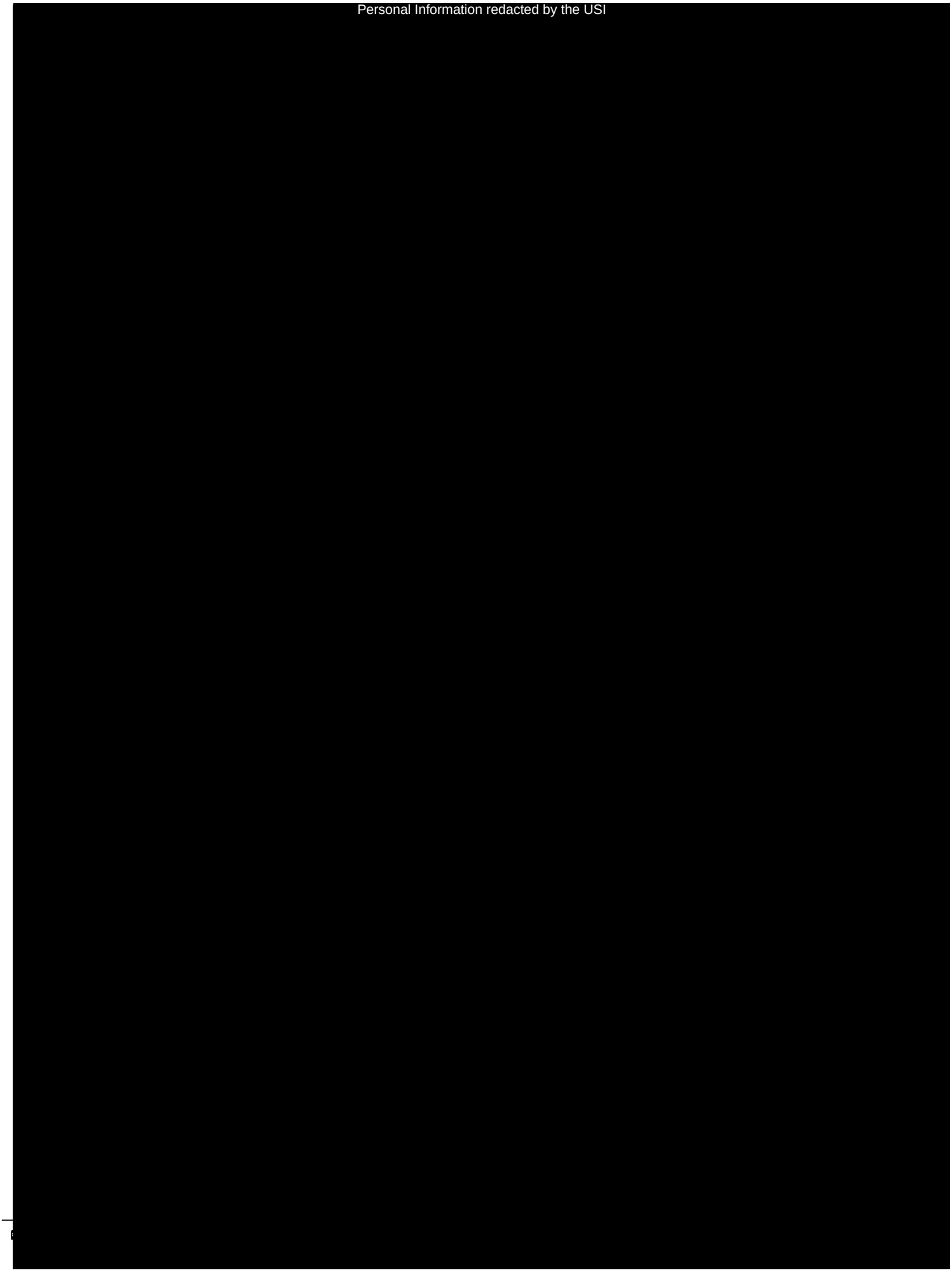

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[redacted]

[redacted]

Signature of Surgeon: .....

Personal Information redacted by the USI

Personal Information redacted by the USI

Patient Protection	Procedure	Monitoring	Vascular Access		Airway Management	Ventilation/Positioning
AAGBI Equipment Check	Date:	Machine ID	Peripheral	Arterial	By Op:	

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ANAESTHESIA RECORD

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ANAESTHESIA RECORD

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ANAESTHESIA RECORD

Personal Information redacted by the USI

[redacted]

[redacted]

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[redacted]

As required medication

Patient Name: WIT-54994

Personal Information redacted by the USI

[redacted]

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Personal Information redacted by the USI

Patient 108

DOB:

WIT-54995

Personal Information redacted by the USI

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Personal Information redacted by the USI

Oxygen section

Patient Name: _____ WIT-54996

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8

Personal Information redacted by the USI

[redacted]

Print Bleep 22[00]

5

Non Injectable antimicrobial medication

Patient Name: WIT-54997

Personal Information redacted by the USI

[redacted]

Monitoring information

Personal Information redacted by the USI

Regular non-injectable medication

Patient Name: WIT-54998

Personal Information redacted by the USI

Print Bleep 22⁰⁰

Print Bleep

Personal Information redacted by the USI

[redacted]

Personal Information redacted by the USI

Rewritten on (date)

[redacted]

Personal Information redacted by the USI

[redacted]

As required medication

Patient Name: WIT-55000

Personal Information redacted by the USI

[redacted]

Personal Information redacted by the USI

[redacted]

Regular injectable medication

Patient Name: WIT-55001

Personal Information redacted by the USI

[redacted]

Personal Information redacted by the USI

[redacted]

Oxygen section

Patient Name: WIT-55002

Personal Information redacted by the USI

[redacted]

Personal Information redacted by the USI

Non Injectable antimicrobial medication Patient Name: **WIT-55003**

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Regular non-injectable medication

Patient Name: WIT-55004

Check allergies/medicine sensitivities and patient identity

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[redacted]

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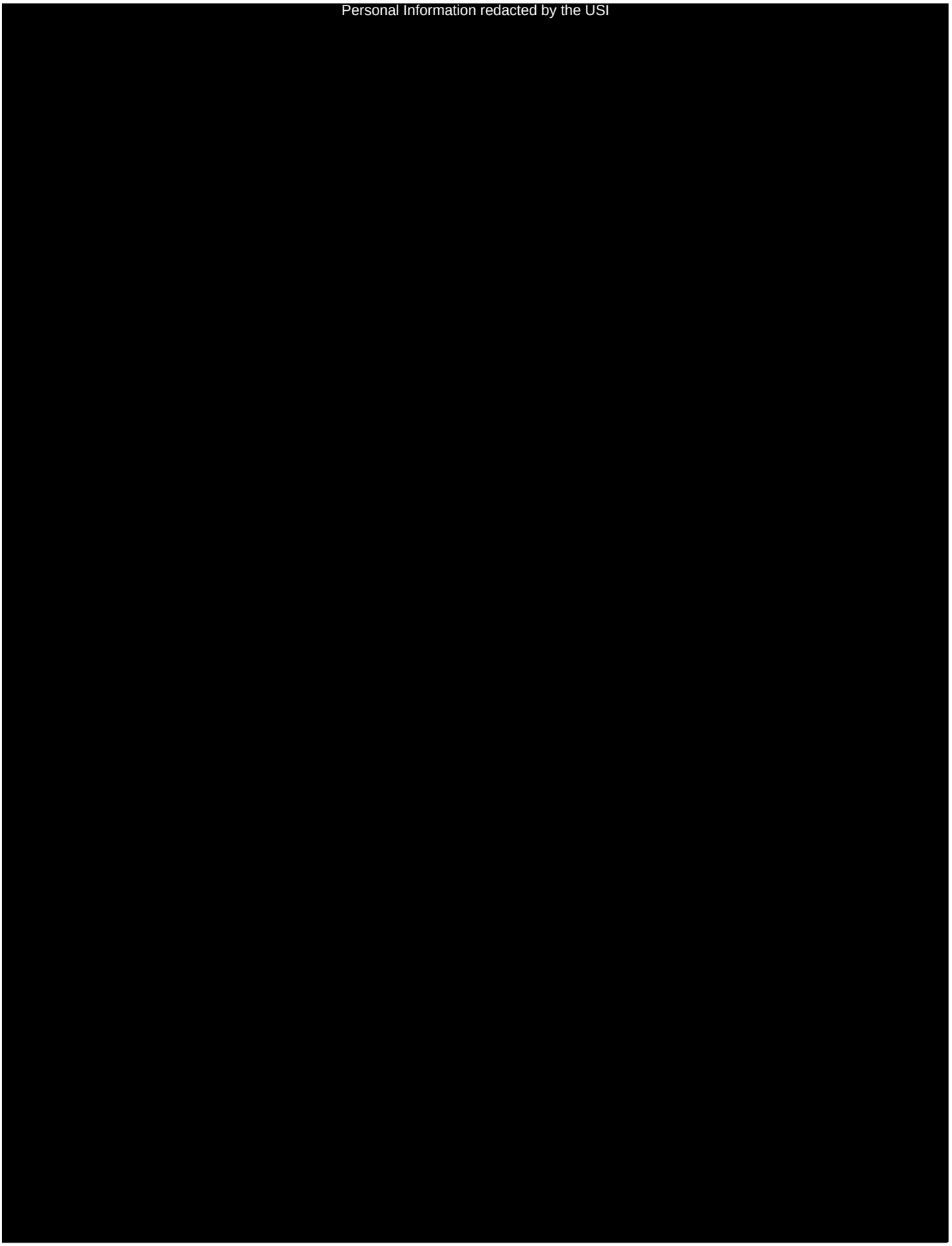

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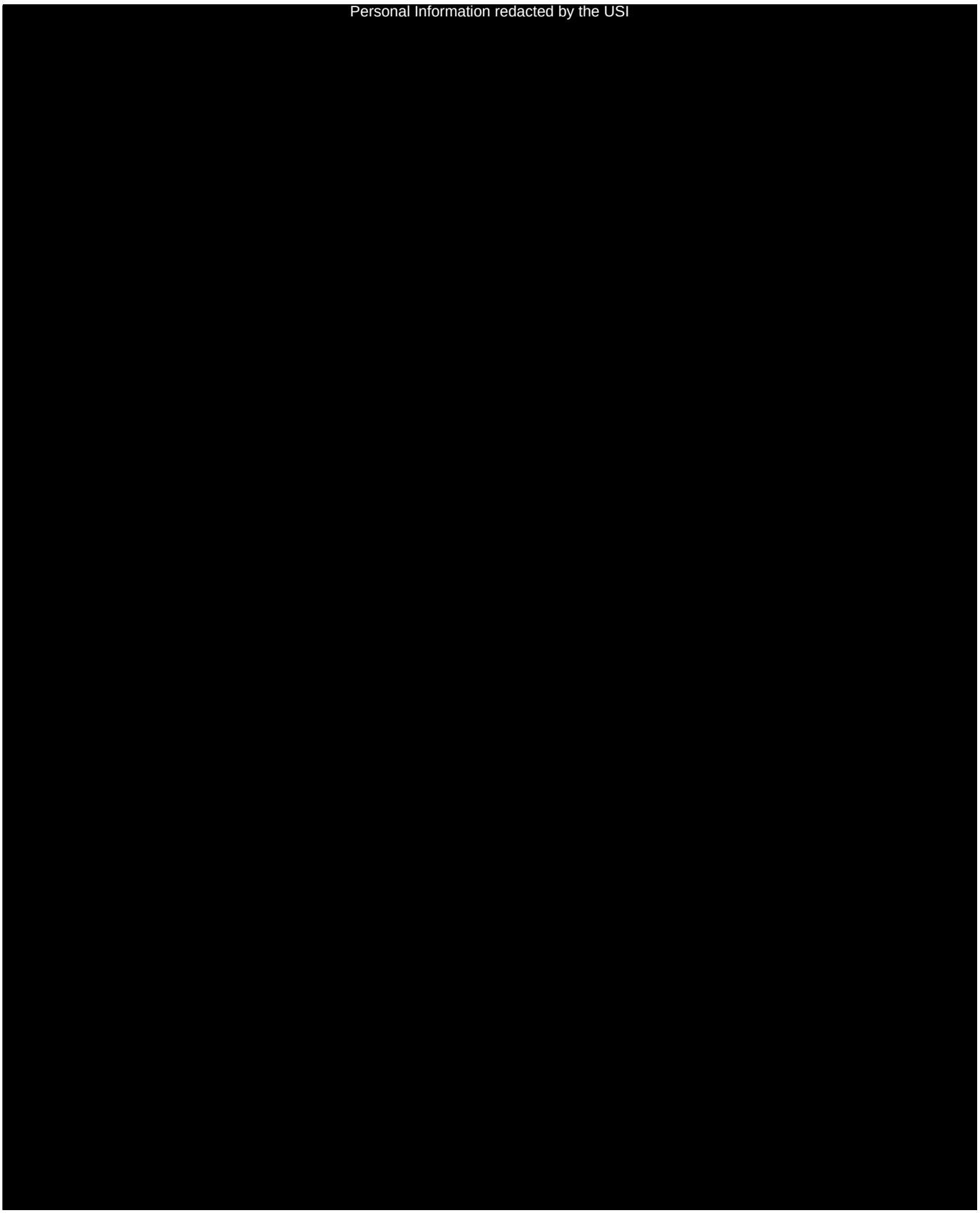

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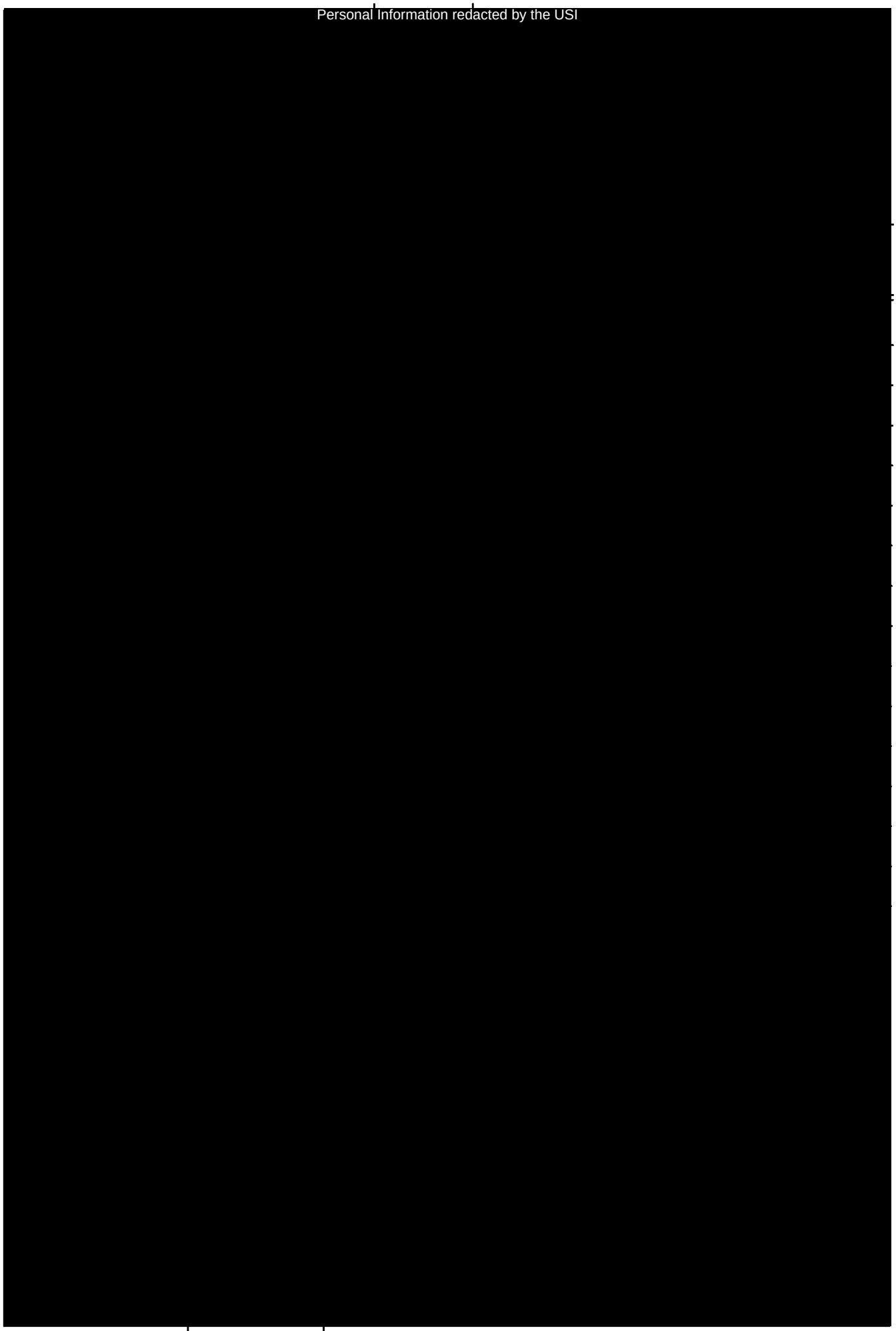

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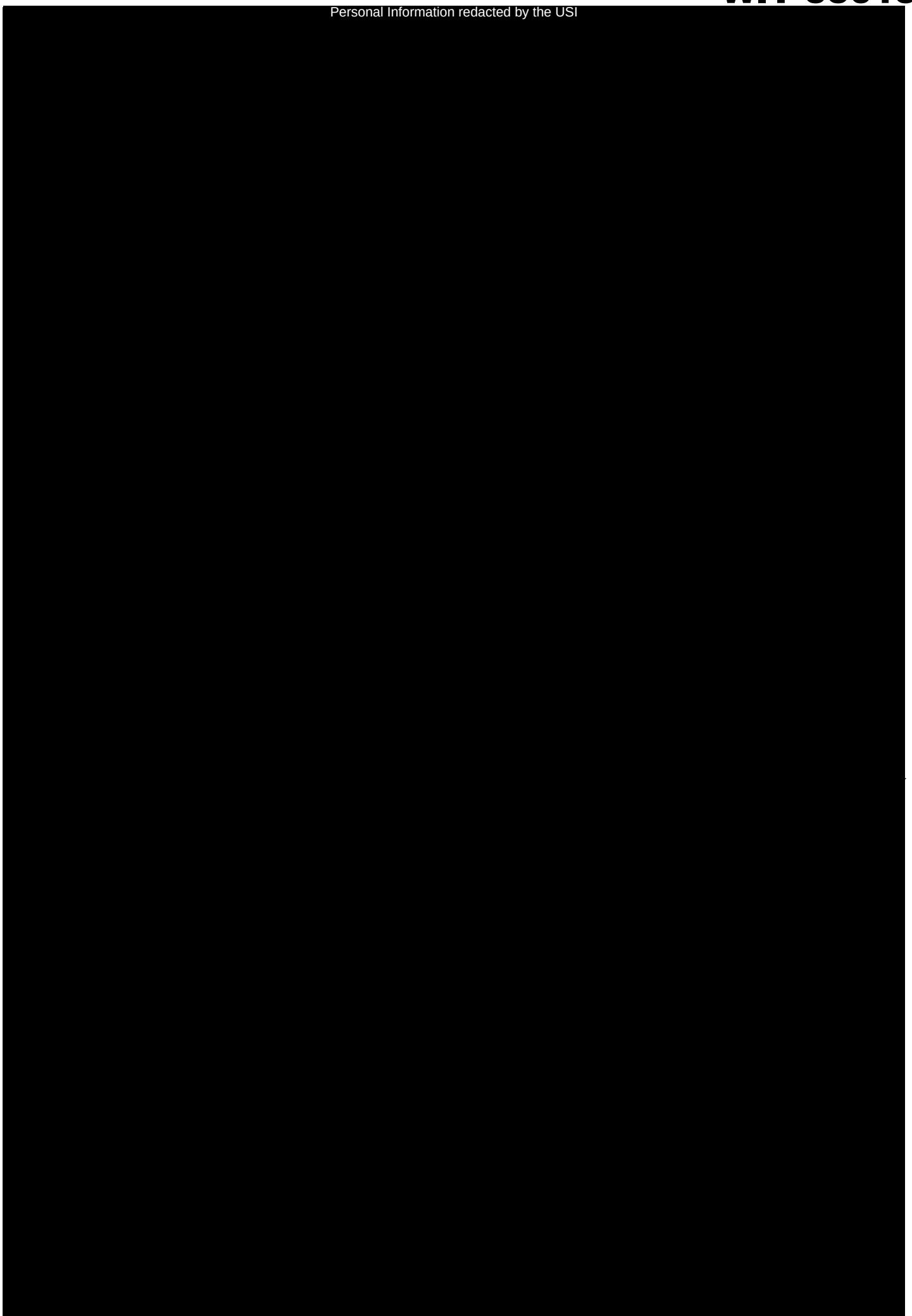

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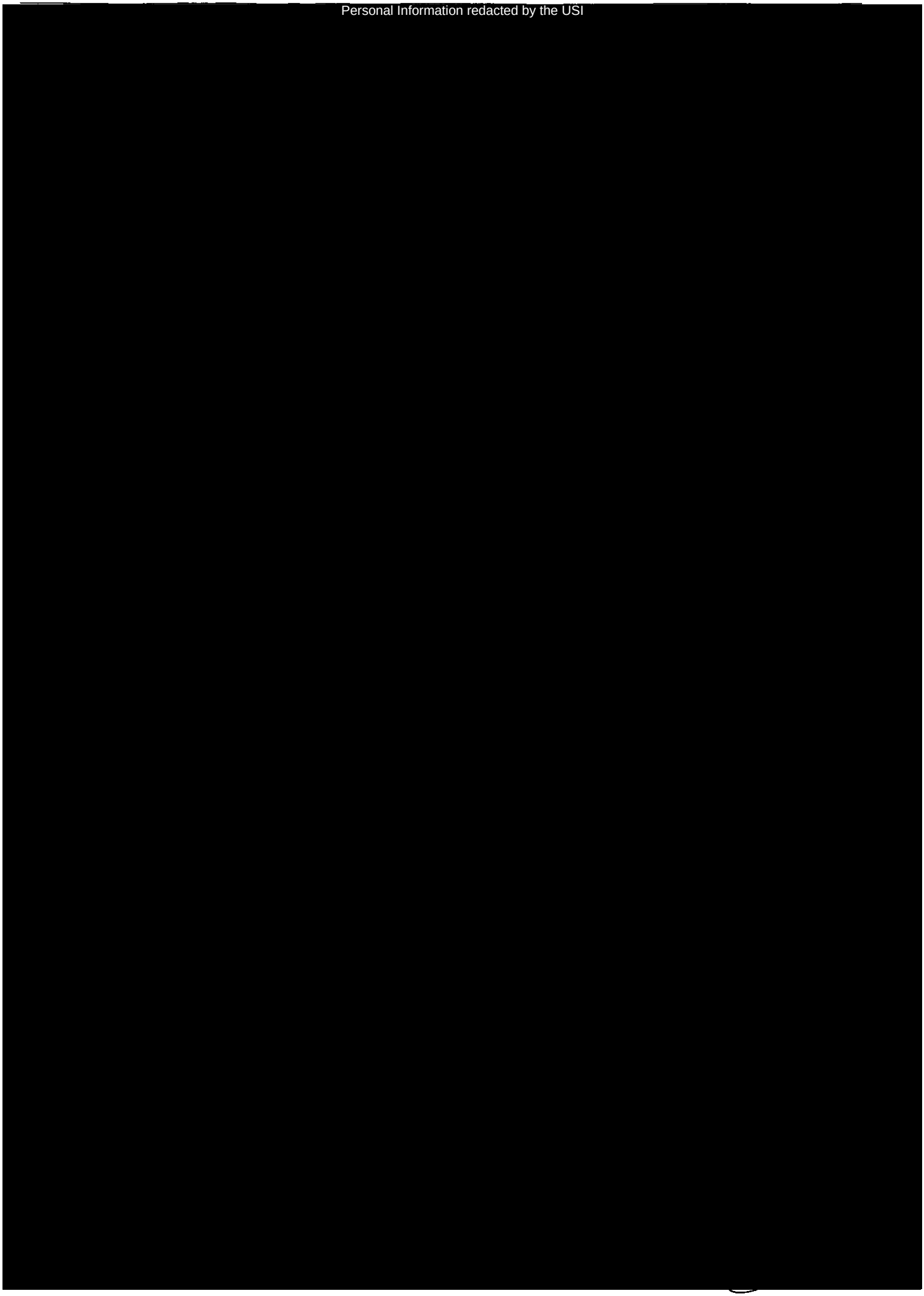

[redacted]

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R

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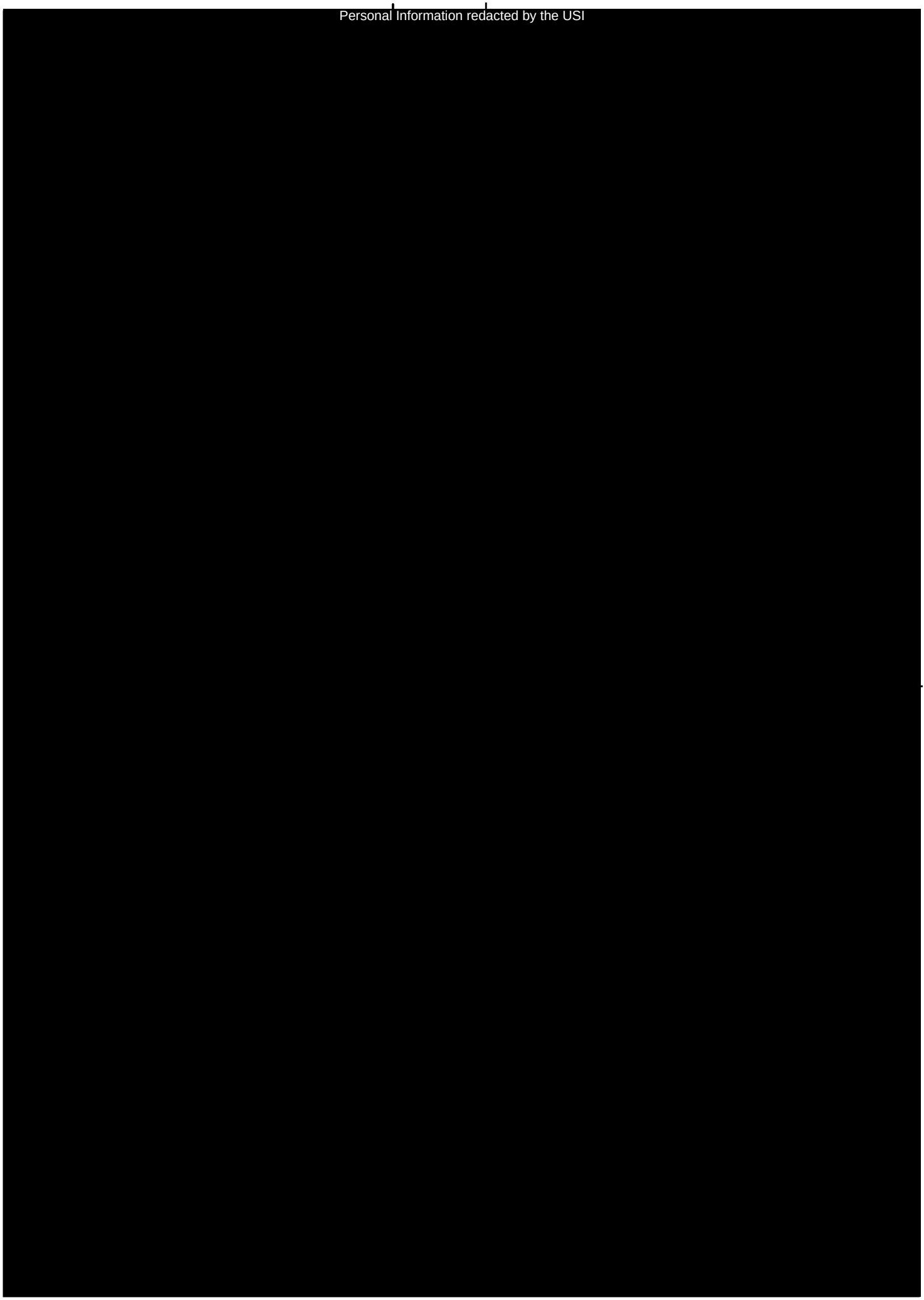

Personal Information redacted by the USI

[redacted]

R

[redacted]

R

[redacted]

Personal Information redacted by the USI

[redacted]

R

[redacted]

78/CA 2/I

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[redacted]

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[redacted]

[redacted]

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78/CA.2/1

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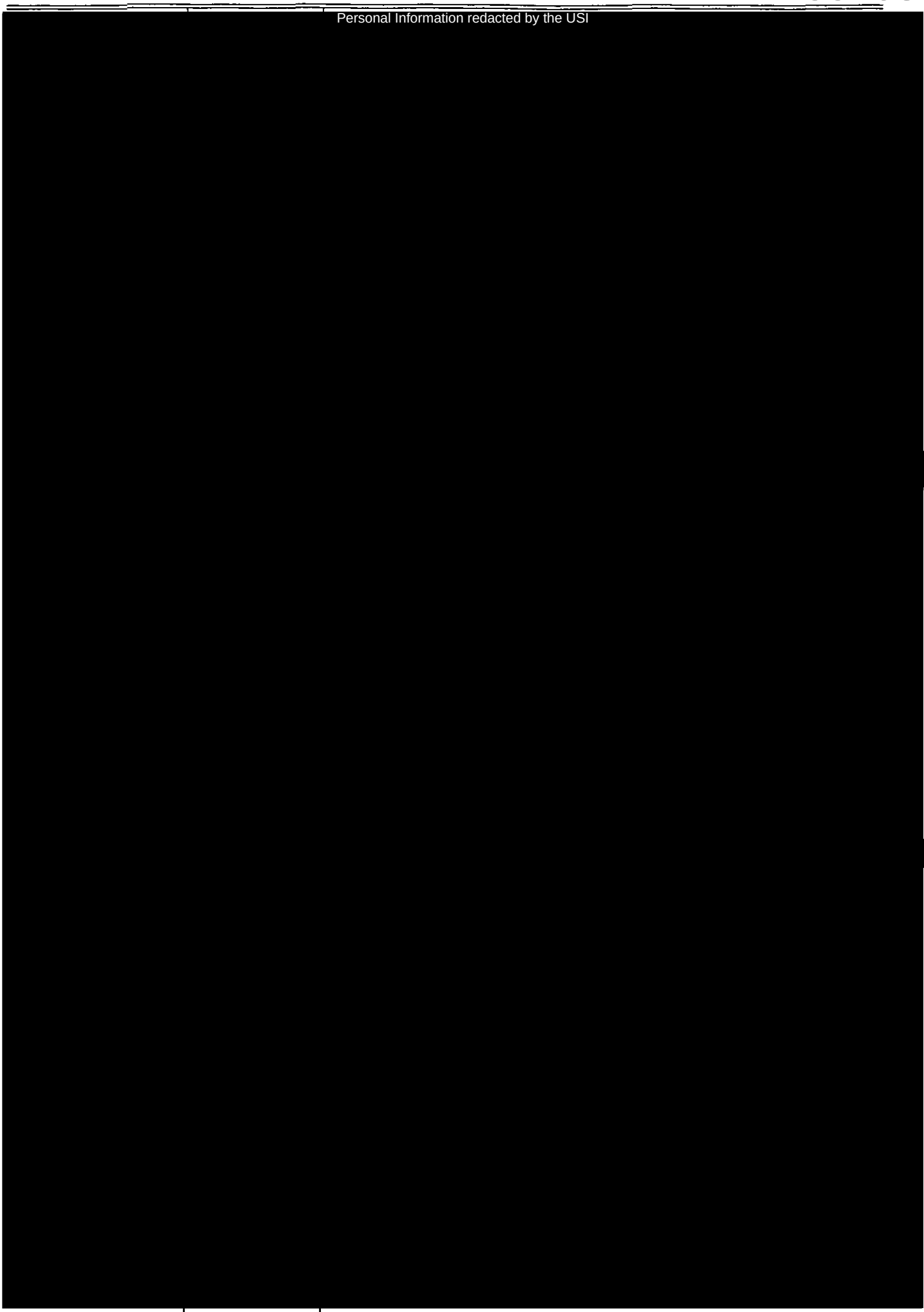

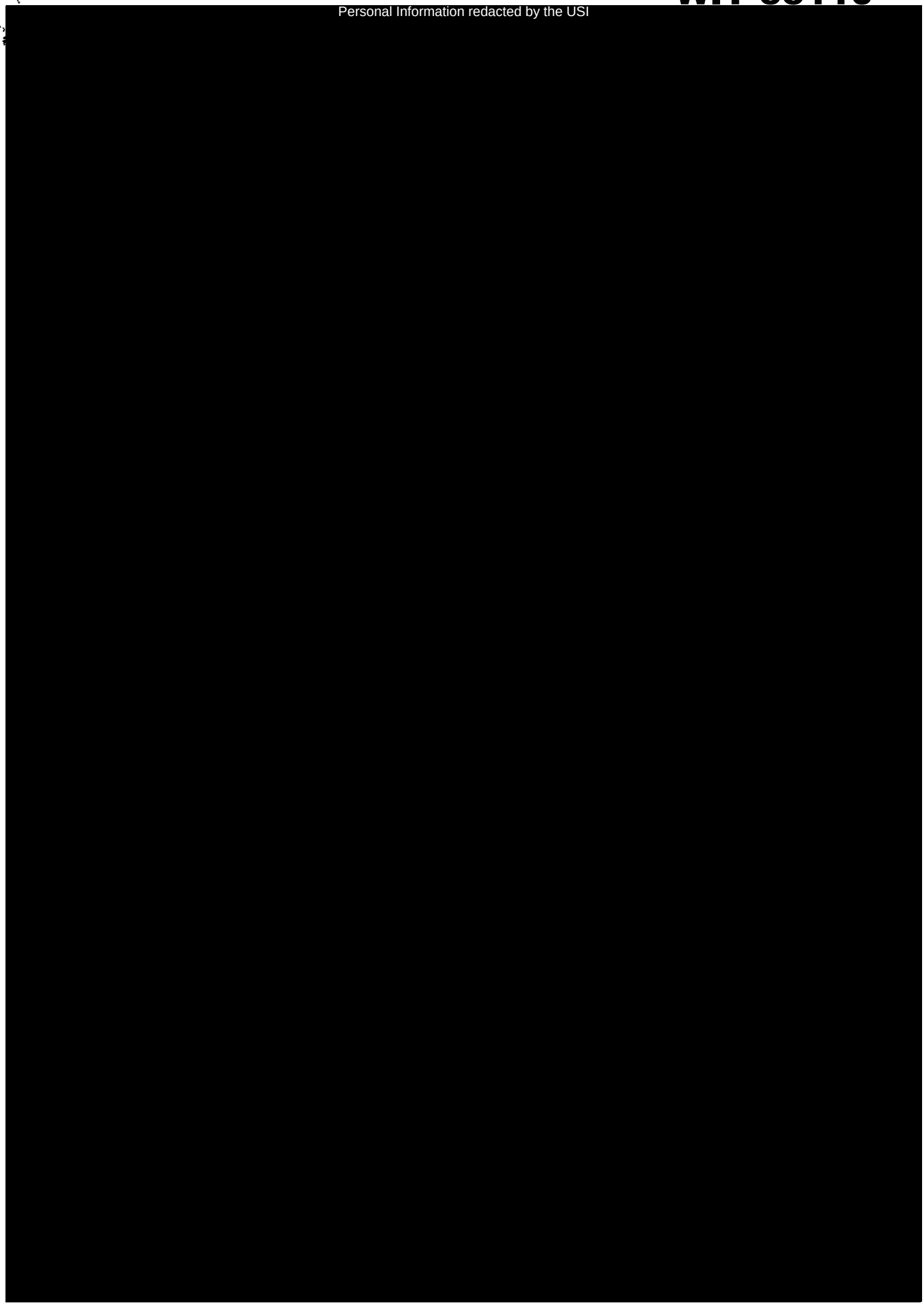

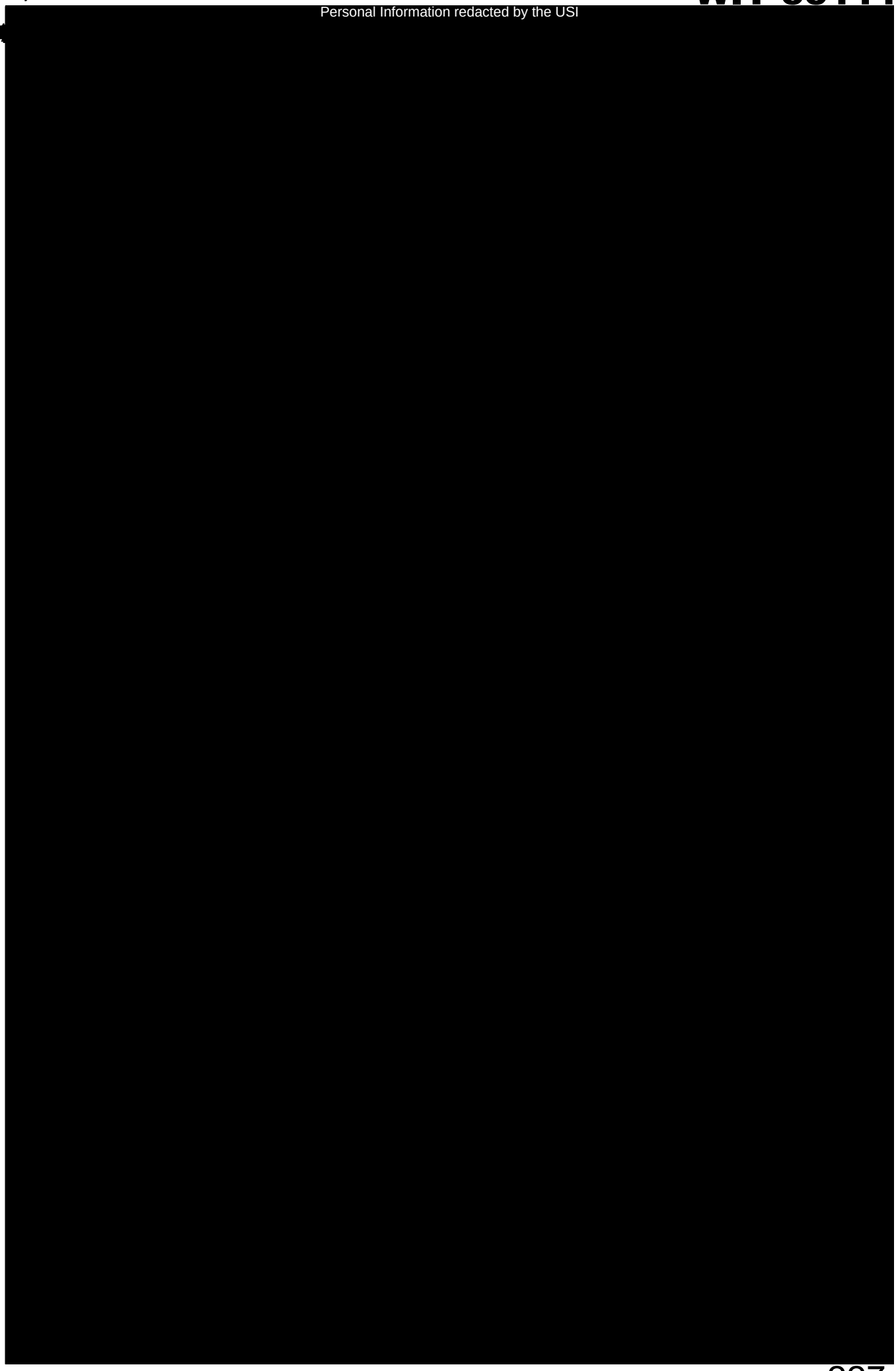

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Patient's Medications

WIT-55136

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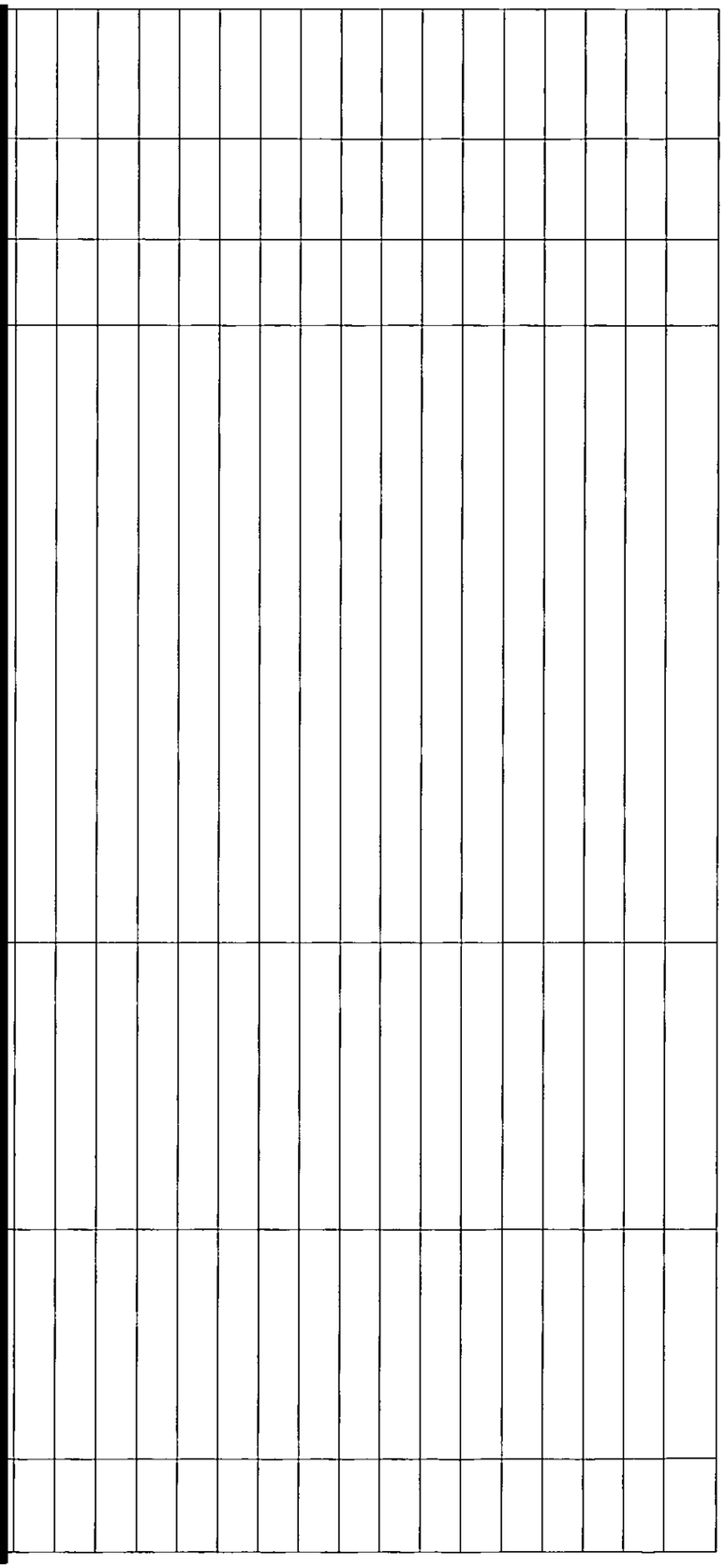

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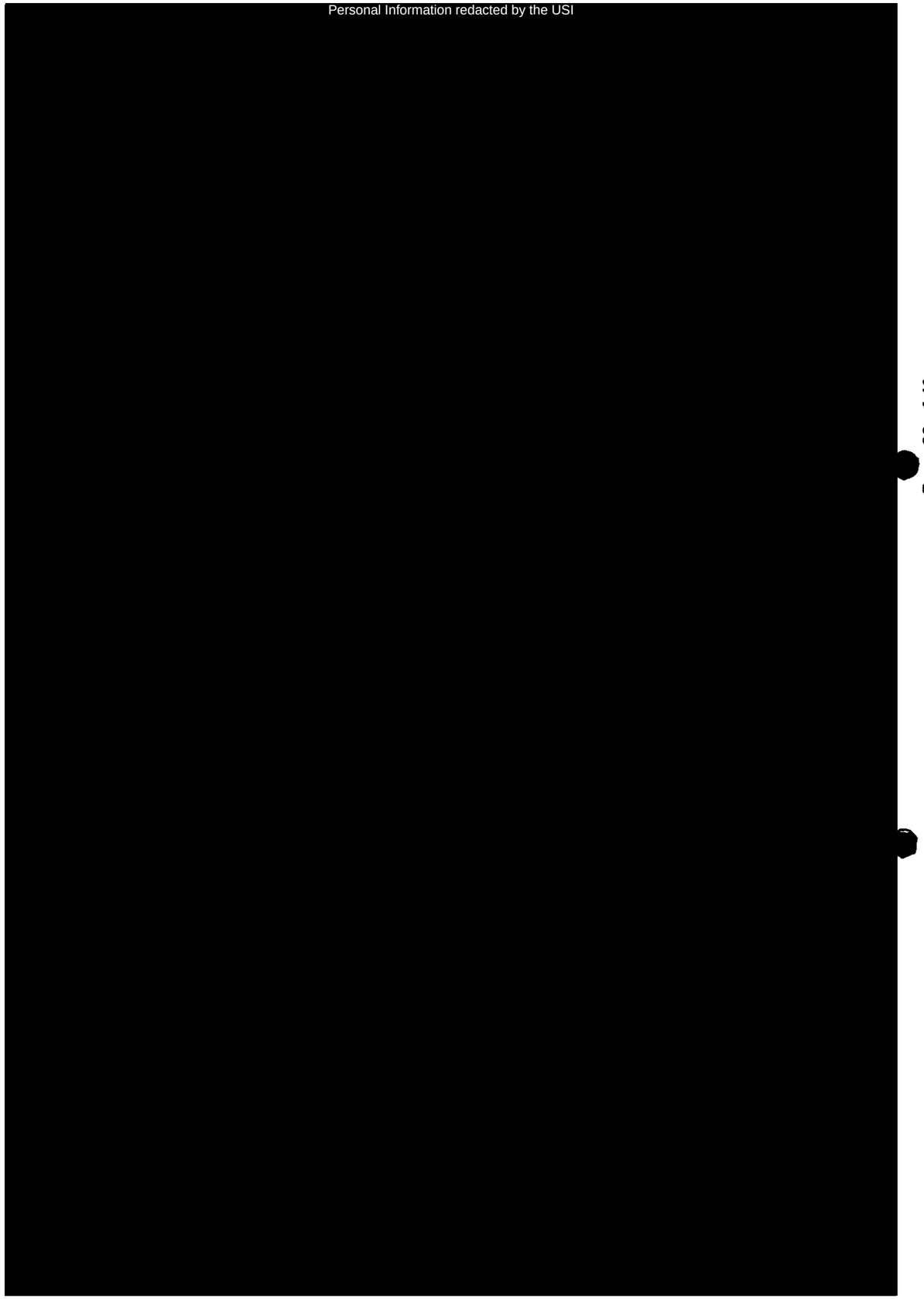

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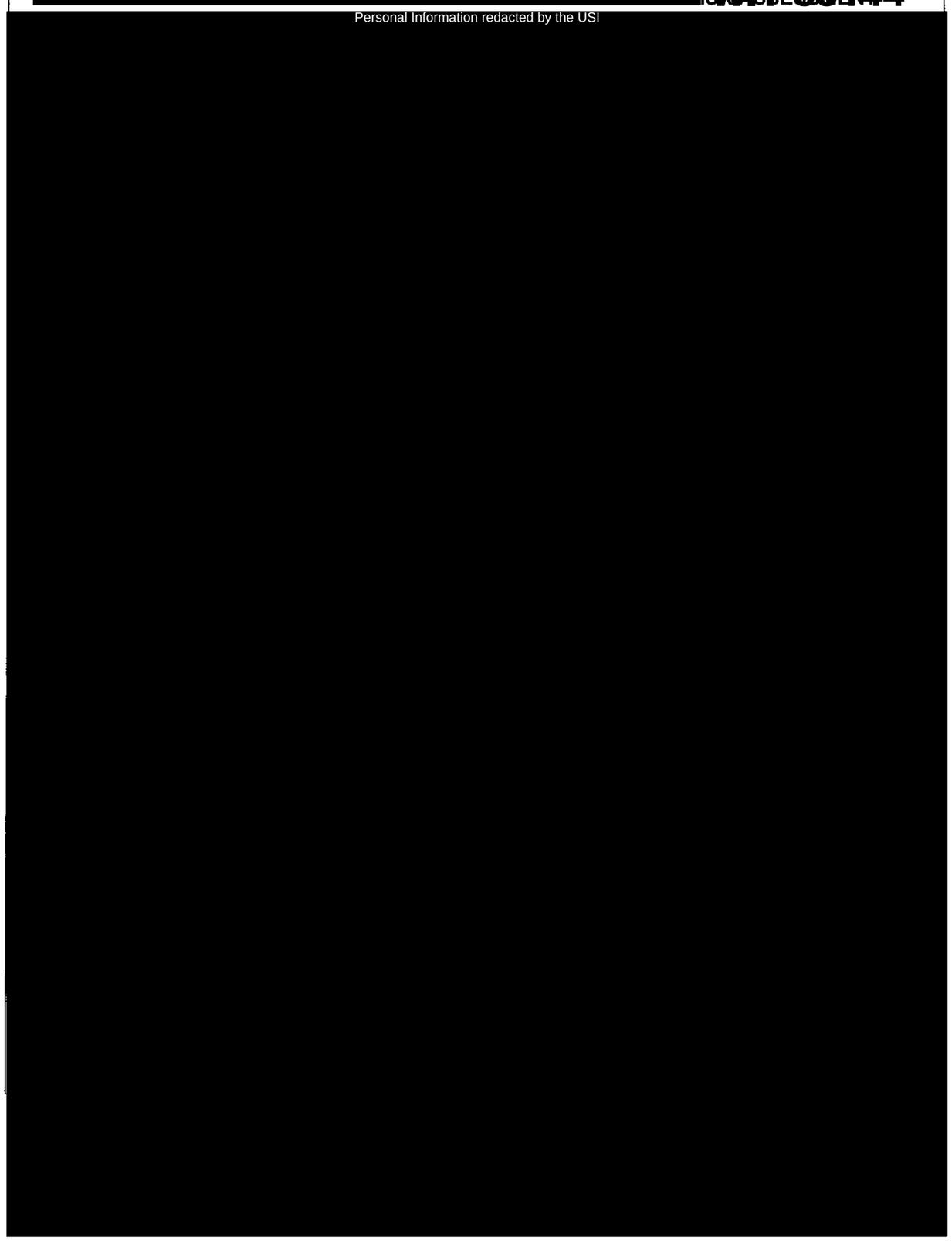

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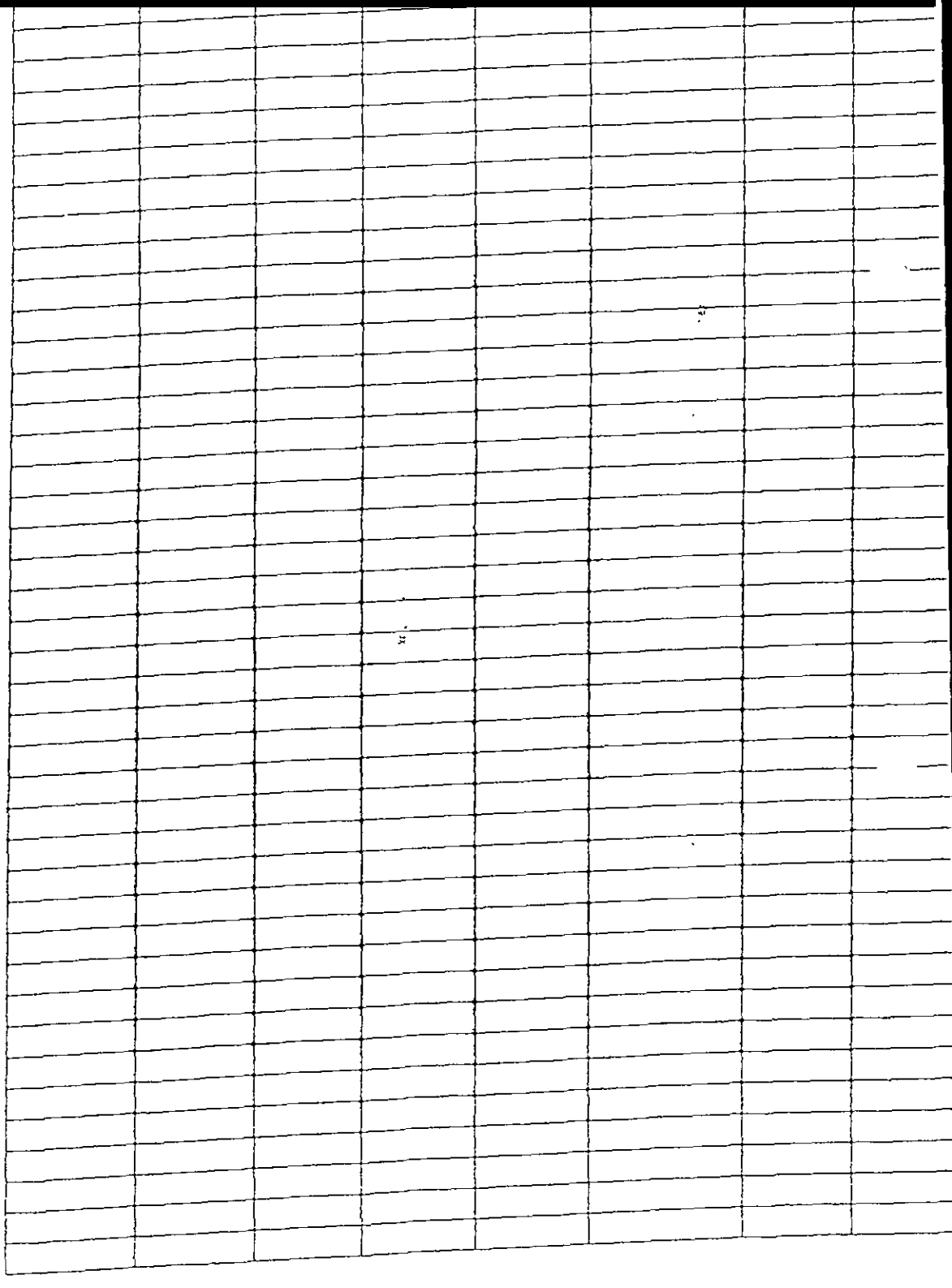

Southern Health and Social Care Trust

DEPARTMENT OF NUTRITION A) DIETETICS
HOSPITAL ENTERAL FEEDING REGIMEN

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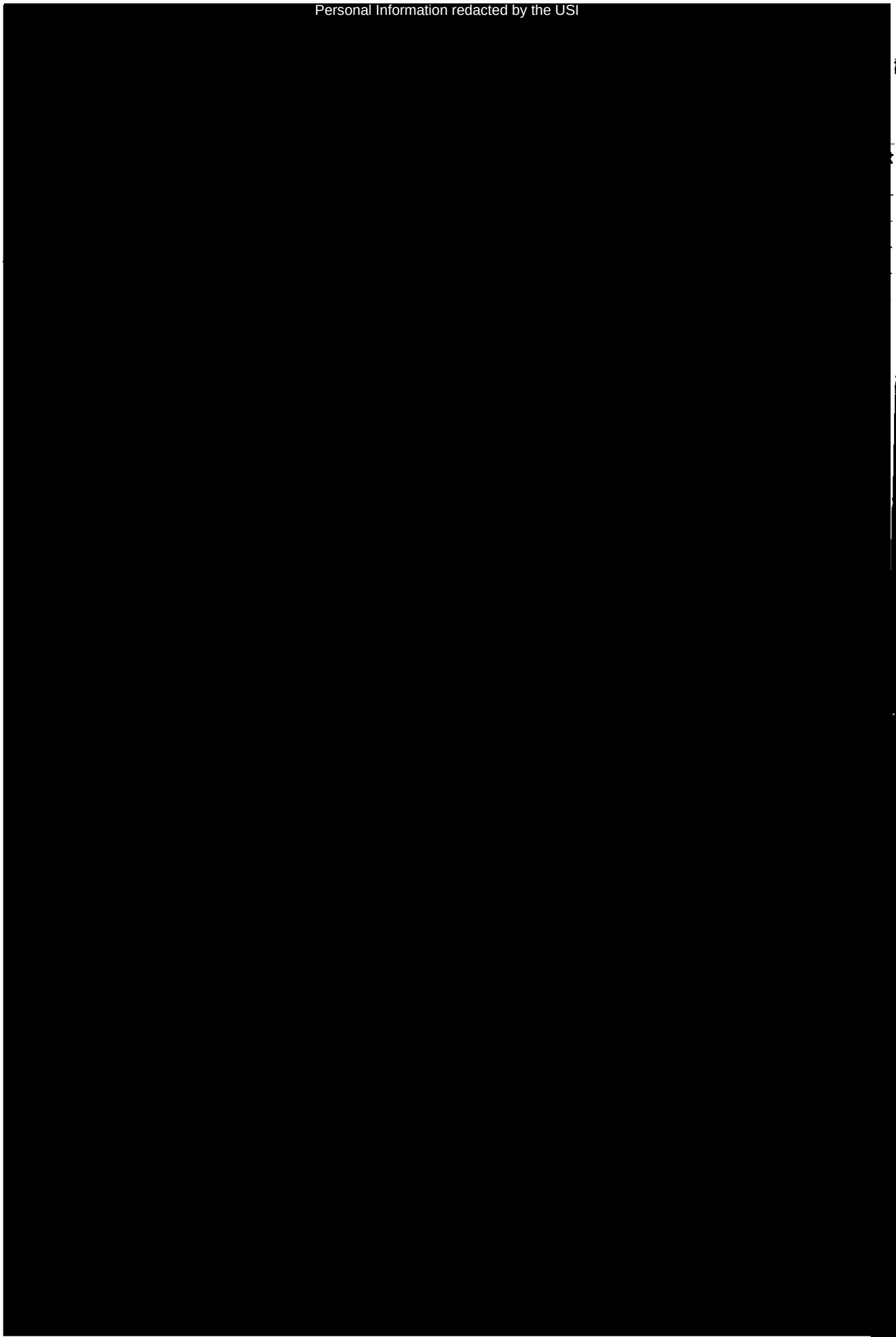

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Daily Fluid Balance & Prescription Chart

WIT-55189

Adult

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24hrs 7.30 AM – 7.30 AM **Daily Evaluation of Nursing Care** (Date)

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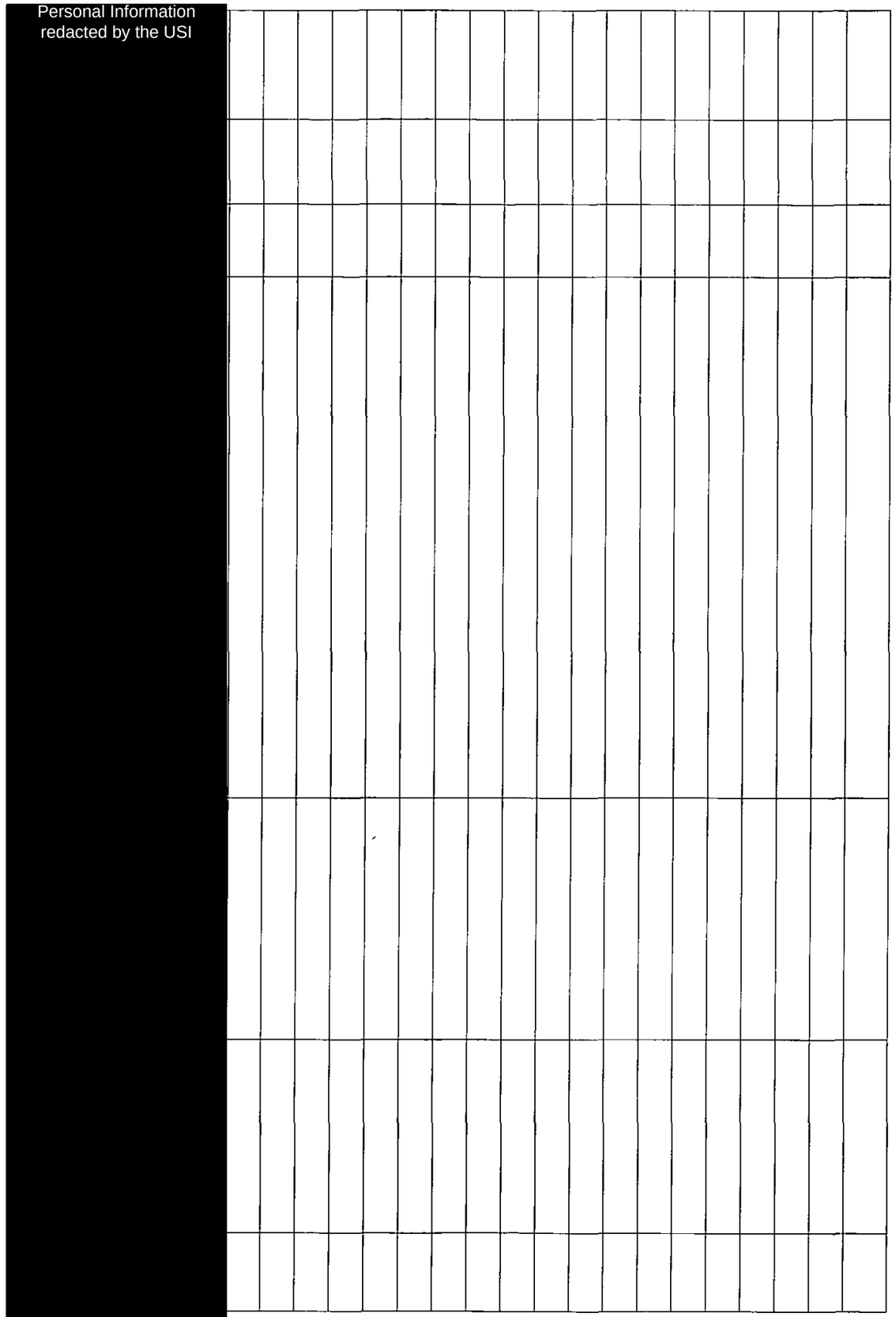

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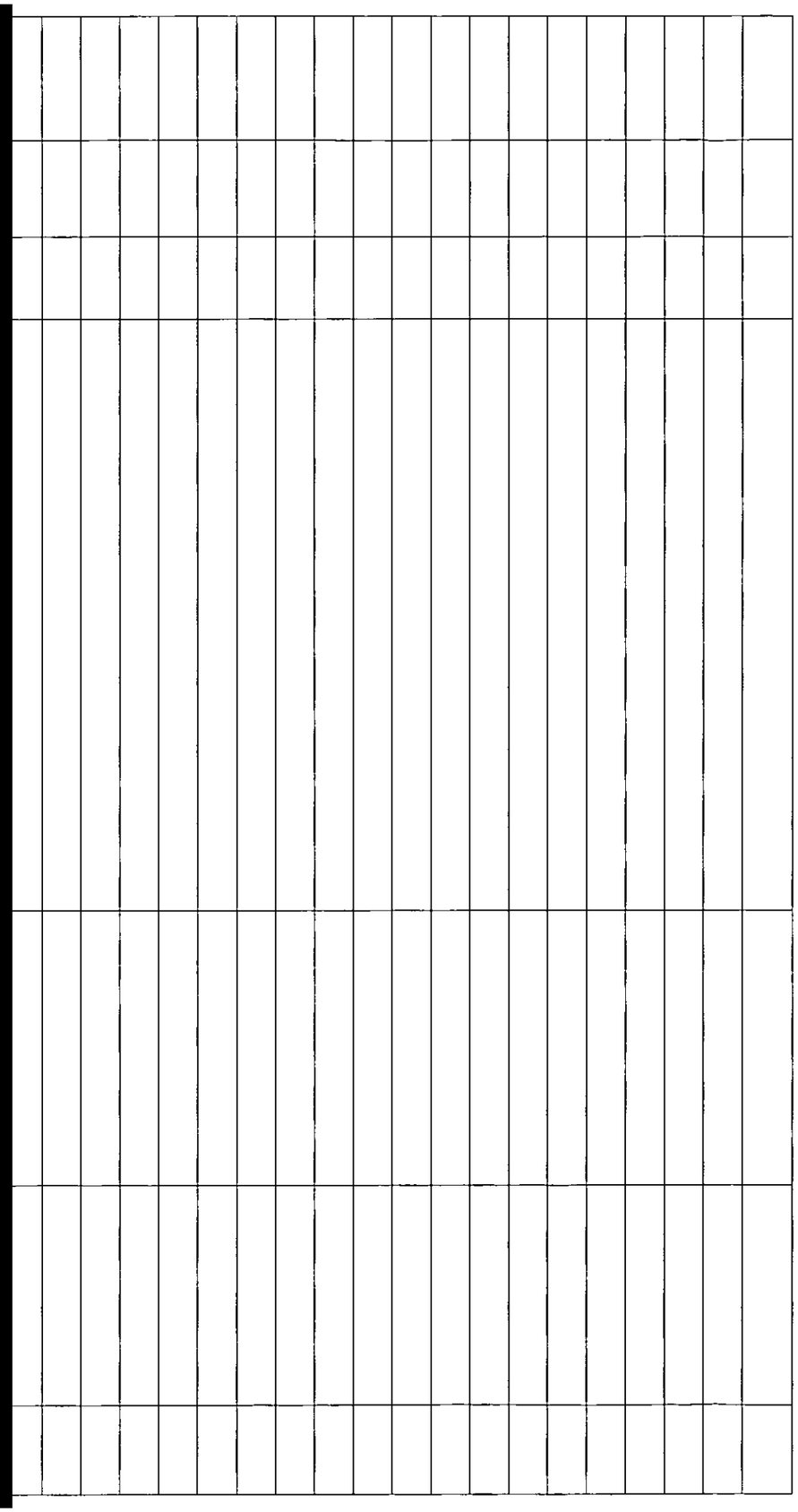

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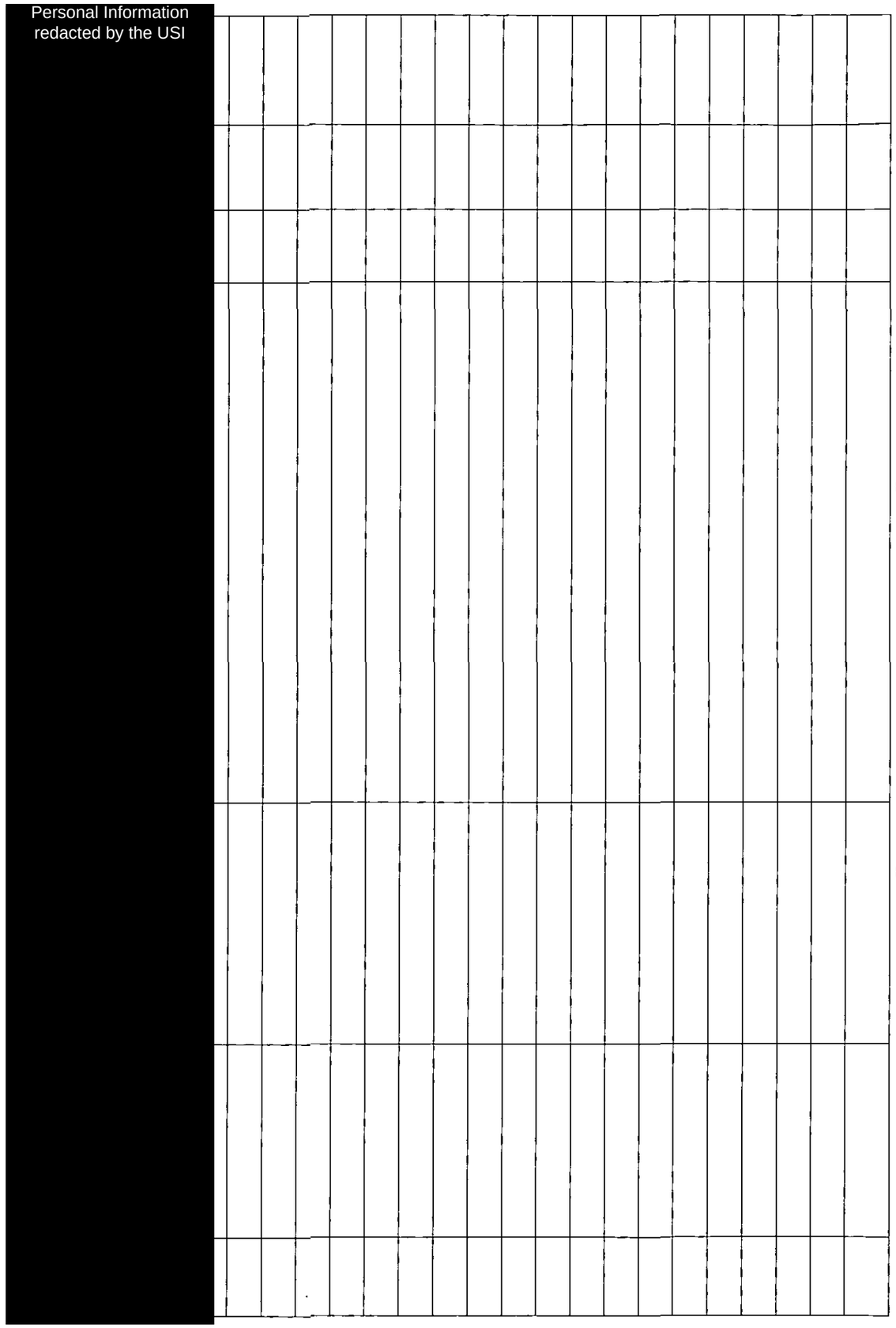

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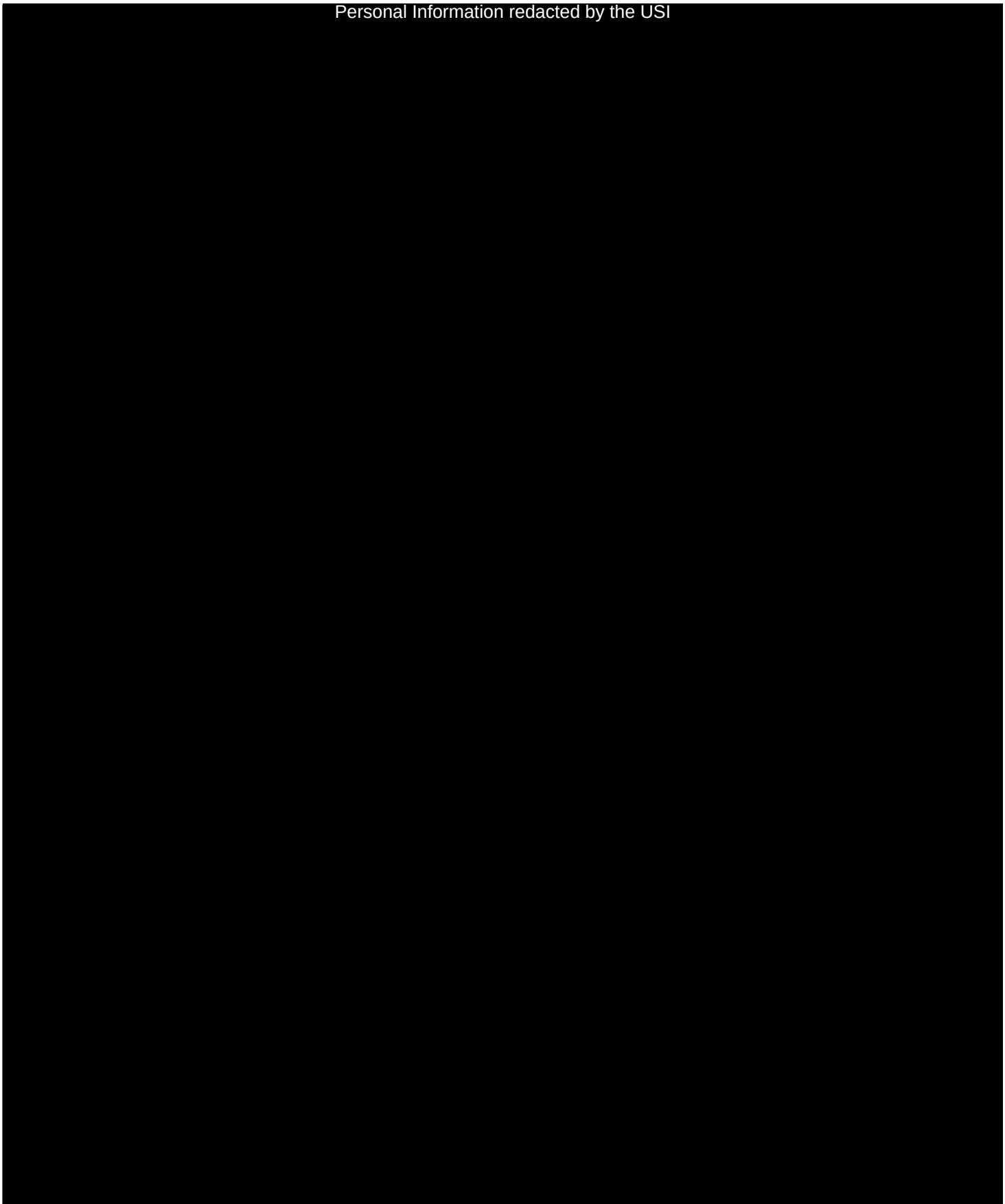

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