التاريخ : ٢٠١٨/٣/٨ م المرجع : ٣ د ص Ref. :

قرار وزاري رقم (٦٢) لسنة 2018

وزير الصحة :

- بعد الاطلاع على أحكام المرسومين بقانون ونظام الخدمة المدنية وتعديلاتهما .
- وعلي قرار الوزاري رقم 307 لسنة 2015 بشان اعتماد نماذج إقرارات المرضي والسياسات الاسترشادية الخاصة بهم .
- وعلي كتاب رئيس لجنة التحقيقات الطبية العليا بشان اقتراح مجلس اقسام الاشعة باستحداث نموذج لاقرار إعطاء الصبغة الوريدية للمريض عند فحص الاشعة التشخيصية والعلاجية .
- وبناء على مقتضيات مصلحة العمل .

- قـــــــرر -

مادة أولى : يُضاف النموذج المرفق لهذا القرار (نموذج لإقرار إعطاء الصبغة الوريدية للمريض عند فحص الاشعة التشخيصية والعلاجية) للنماذج المرفقة بالقرار الوزاري رقم 307 لسنة 2015 المشار اليه .

مادة ثانية : يبلغ هذا القرار من يلزم لتنفيذه ويعمل به اعتبارا من تاريخه .

الدكتور/ باسل حمود الصباح

وزير الصحة

د. باسل حمود الصباح
وزير الصحة

Organization Name: _____	File NO.
Outpatient clinic: _____	CID NO.
Inpatient : Depart. Unit Ward Room Bed	Name:_____ _____
Date of Admiss.	SEX: M / F DOB: / /
Physician in Charge	

All the items in this form should be completed by the physician / specialist; otherwise it will be illegal.

Patient Consent for use of Intravenous Contrast Media in Diagnostic \ Therapeutic Imaging Procedures

The Ministry of Health, through this form, seeks to obtain a written consent that confirms that the treating physician/specialist has provided the patient with the knowledge about his/her medical and health condition. This will enable the patient to make the appropriate decision regarding your\the patient condition.

Please read the written information carefully before signing the form.

To the patient:

you have been given information about your/ your patient medical condition and the recommended diagnostic examination with the use of intravenous contrast media. The law obliges the treating physician/specialist to inform you about:

1- The nature of your medical condition.
2- The purpose and benefit of the diagnostic imaging procedure with intravenous contrast media.
3- The risks related to use of the intravenous contrast media.
4- Patient preparation and precautions used to avoid the risks of the usage of contrast media.
5- Imaging alternatives and any associated risks.
6- Risk of not using the intravenous contrast media in the diagnostic\ therapeutic procedure.

Medical Condition

The treating physician / specialist has explained to me the following medical condition(s) that exist in my/ my patient case:

.....
.....

I \ legal representative of the patient .....authorize the treating medical team to use

Patient name

intravenous contrast media in the diagnostic\ therapeutic procedure:

.....

It was explained to me the purpose and benefit of the diagnostic imaging procedure with intravenous contrast media which is: .....

The probable risks of using intravenous contrast media

The treating physician / specialist explained to me that, the proposed diagnostic imaging procedure with IV contrast may involve risks and morbidities due to use of contrast media which are as follow:

A- Possible side effects and reactions of Iodinated contrast media (USED IN CT, ANGIOGRAPHY/ INTERVENTION, CESM, IVU, etc.)

I. Acute: occurs within one hour and has three subtypes according to severity

1. Mild: **More common** & the signs and symptoms appear self-limited without evidence of progression, include: Nausea with or without vomiting , Sweating ,Itching, Urticaria , Pallor, Flushing , Swelling: eyes, face , Chills, Shaking , Altered taste , Cough, Nasal stuffiness , Rash, hives ,Headache, Dizziness , Warmth, Coldness and pain ,Anxiety, Paresthesia.

2. Moderate: **less common** and signs and symptoms are more pronounced and need medical intervention, include: Tachycardia/ bradycardia , Mild Laryngeal edema ,Bronchospasm, wheezing, Mild hypotension , Hypertension ,Dyspnea , Generalized or diffuse erythema

3. Severe: **very rare** and the signs and symptoms are often life-threatening and need hospital admission, include: Laryngeal edema (severe or rapidly progressing), Unresponsiveness / Convulsions ,Profound hypotension. , Cardiopulmonary arrest / arrhythmias

II. Delayed: A late adverse reaction to intravascular iodine-based contrast medium is defined as a reaction which occurs 1h to 1 week after contrast medium injection, includes skin reactions similar in type to other drug induced eruptions. Most skin reactions are mild to moderate and self-limiting.

III. Contrast media extravasation: which causes local pain and swelling and can be dealt with it when it happens.

B -Possible side effect and reactions of gadolinium based contrast media (USED IN MRI) :

I. Acute: occurs within one hour and usually mild and self-limited without evidence of progression, include: Nausea with or without vomiting, Sweating ,Itching, Urticaria,Pallor, Flushing ,Swelling: eyes, face, Chills, Shaking , Altered taste , Cough, Nasal stuffiness , Rash, hives , Headache, Dizziness , Warmth, Coldness and pain, Anxiety, Paresthesias

II. Nephrogenic systemic fibrosis: is a rare adverse reaction to MRI IV contrast medium in patient with impaired renal functions, it may occur few weeks to years after the use of IV MRI contrast media. Patient will have symptoms related to fibrosis in body organs more obvious in the skin.

III. Contrast media extravasation: which cause local pain and swelling and can be dealt with it when it happens.

I also understand that the complicating medical condition(s) I / the patient is suffering from, might lead to additional risks. These risks include:

.....
.....

It was explained to me the preparations and precautions that will be used to decrease the risks of the usage of IV contrast media

.....

It was explained to me that the available alternatives to the proposed procedure and its probable associated risks are: .....

The risks of not performing the procedure:

.....

Consent to use intravenous contrast media in diagnostic\ therapeutic procedure

- I have read this consent form in its entirety, I was given a chance to ask questions and all of the questions I have asked have been answered to my satisfaction.

- Refused aspects of care have been signed by me.

- I understand how this procedure is performed and its possible risks and complications.

- I understand that if at any time prior to my/patient procedure I decided that I do not want to go forward with the procedure, I may withdraw my consent.

Having read this form and talked with the treating physician / specialist, my signature below acknowledges that: I give my authorization and consent to the performance of the procedure described above by the treating medical team.

.... / ..... / .... : .....

Patient /legal representative name & signature Da Time

If the consent is signed by somebody other than the patient, please state the reasons and relationship

.....

The procedure has been interpreted to the patient in a language comprehensible to him/her by

.... / ..... / .... : .....

Name & signature Date Time

Physician / Specialist statement:

I have explained to the patient/ legal representative the nature of the diagnostic procedure with the risks, benefits, and alternatives. I have answered all of the patient's/ legal representative questions to the best of my knowledge which I believe led him to be adequately informed. I checked the patient risk factors as in the table below and take the necessary preparations and precautions.

RISK FACTORS CHECK LIST	YES	NO
1-History of allergy (to Iodinated/ Gadolinium based contrast media/food /drugs /asthma etc.)		
2- diabetes mellitus on metformin (Glucophage)		
3- renal disease or renal dysfunction		

Most recent measurement of serum creatinine (mmol/l)/ eGFR (ml/min): ....

Date of result: ..../..../.....

(Results should be within 1 week of the radiologic study for patients with known renal disease, those with risk of renal disease (e.g. Patients on nephrotoxic drugs & Diabetics)

.... / ..... / .... : .....

Physician/specialist name & signature Date Time

The patient/patient legal representative approve the previously given consent to perform diagnostic imaging with IV contrast media that is completed by the referring clinician.

The patient/patient legal representative revoked the previously given consent to perform the diagnostic imaging procedure with intravenous contrast media.

Completed by (Referring physician / specialist
Name .....
stamp & signature): ..... Date: ...../...../.....

Please fill in the "Consent to refuse medical diagnostic/therapeutic procedure" form

All the items in this form should be completed by the physician / specialist; otherwise it will be illegal.

Consent to refuse to use intravenous contrast media in diagnostic \ therapeutic imaging procedure

The Ministry of Health, through this form, seeks to obtain a written consent that confirms that the treating physician/specialist has provided the patient with the knowledge about his/her medical and health condition. This will enable the patient to make the appropriate decision regarding the need to do a diagnostic examination with the use of intravenous contrast media.

Please read the written information carefully before signing the form.

In case of refusal to consent to diagnostic examination with the use of intravenous contrast media please sign below. The patient will continue to receive the appropriate care related to his medical condition despite of this refusal.

I /the legal representative of the patient ..... consent that the treating

Patient name

medical team has explained to me all the risks and complications as consequences of refusal to consent to the diagnostic imaging procedure. I fully understand that the refusal of medical diagnostic/therapeutic procedure may lead to deterioration of my / patient health condition, and my /patient life but this is my wish.

The diagnostic imaging procedure refused is

.....

Risks of refusal to consent to diagnostic imaging procedure include

.....

.....

Benefits of proposed procedure are

.....

Reasons for refusal are .....

I hereby take the responsibility for all consequences happen as a result of refusing the procedure specified for me/the patient.

..../...../..... ...../.....

Patient /legal representative name & signature Date Time

If consent is signed by somebody other than the patient, please state the reasons and relationship

.....

The procedure has been interpreted to the patient in a language comprehensible to him/her by

..../...../..... ...../.....

التاريخ : ١٠/٤/ ٢٠١٨ إشارة : Ref. : ate :

قرار وزاري رقم (١٠٢) لسنة 2018

وزير الصحة

- بعد الاطلاع على أحكام المرسومين بقانون ونظام الخدمة المدنية وتعديلاتهما .
- وعلى القانون رقم 49 لسنة 1960 بشأن المؤسسات العلاجيه .
- والمرسوم بقانون رقم 25 لسنة 1981 بشأن مزاولة مهنة الطب والمهن المعاونه لها.
- وعلى القرار الوزاري رقم (2013/162) بشان إعادة تشكيل لجنة التراخيص الطبية المنصوص عليها بالمادة 17 من المرسوم بقانون رقم 25 لسنة 1981 المشار اليه وتعديلاته .
- وعلى القرار الوزاري رقم 69 لسنة 2018 بشان وقف العمل باللجان . .
- وبناء على مقتضيات مصلحة العمل .

. قـــرر .

مادة أولى : يستمر العمل بالقرار الوزارى رقم (162) لسنة 2013 المشار اليه وتعديلاته .

مادة ثانية : يبلغ هذا القرار من يلزم لتنفيذه ، ويعمل به من تاريخه .

الدكتور/ باسل حمود الصباح

وزير الصحـة

د. باسل حمود الصباح
وزير الصحة