

- ☐ Document attached to medical record  
☐ For patients

## **Informed Consent Form for PET/CT (FDG) Testing**

**~in the case of non-coverage through Japanese health insurance~**

|                             |                                               |
|-----------------------------|-----------------------------------------------|
| ID No.: _____               | Date of explanation: _____                    |
| Name of patient: _____      | Day/Month/Year                                |
| Date of birth: _____        | Signature of doctor giving explanation: _____ |
| Day/Month/Year              | (Department: _____)                           |
| Gender: _____ Male / Female | (Print): _____                                |
|                             | Signature of staff witness: _____             |
|                             | (Print): _____                                |

### 1. Safety

- ◆ The frequency of allergic reaction against FDG is very rare.
- ◆ It isn't necessary to worry about radiation damages, because there is a small amount of radiation exposure in the whole body.
- ◆ You are requested to stay at the examination area for 2 hours after injecting FDG since the radiation is released out of the whole body, too.
- ◆ Please try hard to avoid having contact with babies and infants, expectant mothers and breast-feeding mothers for several hours after PET/CT(FDG).
- ◆ The amount of radiation exposure of PET/CT(FDA) is 1-4 times as much as that of a gastric barium test.
- ◆ The tension during being given an injection might occur vagal reflex (drop of blood pressure etc.).
- ◆ We provide you with an urgent and adequate medical treatment, in trouble.

## 2. Benefit and Shortcoming

The benefit is to be able to find out many cancers. But granularity, the degree of accuracy is not 100%, because the assessment is difficult, depending on the kind, part and size of lesion and also FDG crowds at the inflammation and normal organs, too. In case the person has severe diabetes, medical imaging is unclear from time to time. PET/CT(FDG) can be postponed if the score of blood sugar on that day is 200mg/dL or over.

## 3. Fee

The fee and the way of payment are explained separately.

## 4. Use of Medical data for education, research, development (Voluntary request)

To improve the quality of medical treatment, there is a case that the data of testing is used with an agreement for education, research, development, etc. In that case, we pay much attention to protecting personal medical data and deal with it not to identify an individual for sure.

## 5. Others

FDG is distributed on that day. Though we completely prepare for checkout of testing equipment and FDG's transportation system, unexpected breakdown of testing equipment or traffic accident during the distribution of FDG, etc. might happen. As a result, PET/CT(FDG) might be drastically delayed or you couldn't receive it. In that case, we would appreciate it if you accept the readjustment.

\*If you wish to receive a second opinion, please tell your doctor-in-charge. He/she will prepare a referral form, your test results, and other necessary materials.

\*You may withdraw the consent at any time if you have submitted the signed informed consent form and have not undergone treatment, procedure, or examination. Please inform the doctor or nurse -in-charge.

To the President of Nippon Medical School Chiba Hokusoh Hospital

I have been given the explanation on the foregoing information and have understood it.

I consent to undergo PET/CT(FDG) Testing and receive an urgent and adequate medical treatment if side effects occur.

|                       |                                                 |
|-----------------------|-------------------------------------------------|
| Date of consent       | Signature of representative giving the consent: |
| _____                 | _____                                           |
| Day/Month/Year        | (Print):_____                                   |
|                       | (Relationship to patient:_____)                 |
| Signature of patient: | Signature of representative giving the consent: |
| _____                 | _____                                           |
| (Print):_____         | (Print):_____                                   |
|                       | (Relationship to patient:_____)                 |

When any difference in interpretation arises because of a nuanced difference in related languages or systems, the Japanese original shall be given priority.

## PET/CT(FDG)検査(自費検査)に関する説明と同意書

ID No. \_\_\_\_\_ 説明日 \_\_\_\_\_ 年 \_\_\_\_\_ 月 \_\_\_\_\_ 日

氏名 \_\_\_\_\_ 説明医師自署または記名押印

生年月日 \_\_\_\_\_

性別 \_\_\_\_\_ 同席スタッフ自署または記名押印

### 1. 安全性

- ◆ FDG に対するアレルギー反応は極めてまれです。
- ◆ 体内の放射線被ばくの量は少ないため、放射線障害を心配する必要はありません。
- ◆ 体外にも放射線を放出するため、注射から 120 分間は検査室から出られません。
- ◆ 終了後数時間は乳幼児・妊婦・授乳中の方との接触をなるべくさけてください。
- ◆ PET/CT の放射線被ばくは胃のバリウム検査の1～4回分程度です。
- ◆ 注射の際の緊張により、迷走神経反射(血圧低下など)が起ることがあります。
- ◆ トラブルが生じた場合には、医療スタッフによる必要な緊急処置を行います。

2. 利点と欠点 利点は多くのがんを発見できることです。しかし、病変の種類・部位・大きさによって評価が難しく、炎症や正常臓器にも FDG が集まることがあり、精度は100%ではありません。重度の糖尿病があると画像が不正確になることが多く、当日の血糖値が200mg/dl 以上ある場合は検査を延期する可能性があります。

3. 検査料金 金額及びお支払いの方法は別途ご説明いたします。

4. 診療データの教育・研究・啓発利用(任意) 医療の質向上のため、検査データを教育・研究・啓発等に使用させていただきます場合があります。その際は、個人情報保護について十分留意し、決して個人を特定できないようにしたデータの取り扱いをします。

5. その他 FDGは当日に輸送されます。検査機器の点検及び FDG の輸送体制には万全を期していますが、万が一の機器の故障や輸送中の事故などの際には、検査が大幅に遅れる・あるいは出来なくなることがあります。その場合には振替の検査日時に関して相談させていただきます。

※セカンドオピニオンをご希望の方はお知らせ下さい。紹介状及び検査結果などを準備いたします。

※ご証明いただいた後でもいつでも同意は撤回できます。その場合は医師・看護師に申し出て下さい。

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日本医科大学千葉北総病院院長 殿

私は、PET/CT 検査を受けるに当たり、上記の説明を理解し、全て了解しました。また、副作用が起った場合には必要な処置を受けることを了承します。

同 意 日                      年                      月                      日      代諾者自署または記名押印 \_\_\_\_\_

(患者との関係 \_\_\_\_\_)

患者本人自署または記名押印

代諾者自署または記名押印 \_\_\_\_\_

\_\_\_\_\_ (患者との関係 \_\_\_\_\_)