

新型インフルエンザ予防接種予診票
Questionnaire for the New Influenza A-H1N1 Vaccination

(高校生に相当する年齢以上の者対象)
High School students or people within the equivalent age range and older people

Form with fields for Address, Name of the person who will receive the vaccine, Sex (Male/Female), Date of birth, and Age (満歳ヵ月). Includes a field for Body temperature before the consultation.

Table with 3 columns: 質問事項 Questions, 解答欄 Answers (はい/いいえ/Yes/No), and 医師記入欄. Contains 20 rows of questions regarding vaccine information, health status, and previous reactions.

医師の記入欄 Space to be filled by the physician. Includes a decision box for whether the vaccine can be administered and a space for the physician's signature or stamp.

保護者の記入欄 Space to be filled out by parents / guardians. Includes a list of vaccine options, a checkbox for consent, and a date/signature line.

Bottom section for vaccine details: ワクチンメーカー名, ロット番号, 接種量 (ml), 実施場所, 医師名, 接種年月日.

### 新型インフルエンザ予防接種予診票 Questionnaire for the New Influenza A-H1N1 Vaccination

(小学校 6 年生以下の者)

Children below 12 years old (6<sup>th</sup> grade of Elementary School and lower grades or children within the equivalent age range)

		診察前の体温 Body temperature before the consultation		.....°C
住所 Address				
受ける人の氏名 Name of the person who will receive the vaccine	男 Male 女 Female	生年月日 Date of birth	(year) (month) (day)	年 月 日
保護者の氏名 Parent / guardian's name		Age (満 歳 カ月)		

質問事項 Questions	解答欄 Answers		医師記入欄
あなたのお子さんの発育歴についておたずねします About your child's development: 出生体重 Weight at birth ( ) g			
分娩時に異常がありましたか Was there any problem during childbirth delivery ?	はい Yes	いいえ No	
出生後に異常がありましたか Was there any problem after the delivery (childbirth)?	Yes	No	
乳幼児検診で異常があるとされたことがありますか Have you ever been told about any problem or abnormality during your baby's consultations or periodical exams?	Yes	No	
生まれてから今までに先天性異常、心臓、腎臓、肝臓、脳神経、免疫不全症、その他の病気にかかり、医師の治療（投薬など）を受けていますか Since birth up to the present moment, has your child ever had any congenital abnormality; cardiac, kidney, hepatic, cerebral neural diseases, immunodeficiency disorder, etc, and due to this problem, is s/he under medical treatment or taking any medicine? 病名 If yes, please write down the name of the disease. ( )	Yes	No	
その病気の主治医には、今日の予防接種を受けてよいといわれましたか Has the physician in charge of the treatment authorized the child to receive today's vaccine?	Yes	No	
今日体に具合の悪いところがありますか Today, does your child feel indisposed or have any health problem? 具体的な症状を書いてください If yes, please describe the symptoms.	Yes	No	
最近 1 ヶ月以内に、家族や遊び仲間に、インフルエンザ、麻疹、風しん、水痘、おたふくかぜなどの病気の方がいましたか Over the last 30 days, did any family member or friend get influenza, measles, rubella, chicken pox, mumps, etc.? 病名 If yes, please write down the name of the disease. ( )	Yes	No	
最近 1 ヶ月以内に予防接種を受けましたか Has the child received any preventive vaccine over the last 30 days? 予防接種の種類 If yes, which vaccine? ( )	Yes	No	
新型インフルエンザ又は季節性インフルエンザの予防接種を受けたことがありますか Has the child ever taken the vaccine against the new influenza A (H1N1) or the seasonal influenza? その際に具合が悪くなったことはありますか On this occasion, did the child feel indisposed after taking the vaccine?	Yes	No	
これまでにインフルエンザ以外の予防接種を受けて具合が悪くなったことはありますか Has the child ever felt indisposed after taking any preventive vaccine (excluding the vaccine against influenza A-H1N1)? 予防接種の種類 If yes, which vaccine? ( )	Yes	No	
ニワトリの肉や卵などにアレルギーがありますか Is the child allergic to poultry meat (chicken), eggs, etc?	Yes	No	
薬や食品で皮膚に発疹やじんましんが出たり、体の具合が悪くなったことがありますか Has your child ever had any skin allergy (such as skin rash, nettle rash) or felt indisposed due to any medication or food intake?	Yes	No	
ひきつけ (けいれん) をおこしたことがありますか Has your child ever had convulsions? At what age? ( ) 歳頃 years old.	Yes	No	
そのとき熱が出ましたか On that occasion, did your child have fever?	Yes	No	
近親者に予防接種を受けて具合が悪くなった方はいますか Has anyone in your family felt indisposed after receiving any vaccine?	Yes	No	
近親者に先天性免疫不全と診断されている方はいますか Does any family member have congenital immunodeficiency problems?	Yes	No	
今日の予防接種について質問がありますか Do you have any question regarding today's vaccination? (女性のみ) 現在妊娠している、又は妊娠している可能性はありますか (For women) Is she pregnant or is there any suspicion of pregnancy?	Yes	No	

#### 医師の記入欄 Space to be filled by the physician

以上の問診及び診察の結果、今日の予防接種は  可能  見合わせる  
 The vaccine can be administered. The vaccine cannot be administered.

保護者に対して、予防接種の効果・目的、接種するワクチンの有益性及び副反応並びに予防接種健康被害救済制度について説明をした。

医師署名又は記名押印

#### 保護者の記入欄 Space to be filled out by parents / guardians

医師の診察・説明を受け、予防接種の効果・目的、接種するワクチンの有益性、重篤な副反応の可能性などについて理解した上で、以下のワクチンの接種を

- インフルエンザHAワクチン (3価ワクチン) [国内産ワクチン] HA Trivalent Influenza Vaccine [domestic production]
- A型インフルエンザHAワクチン (H1N1株) [国内産ワクチン] HA vaccine against Influenza A (H1N1 strains) <domestic production>
- アレパンリック (H1N1) 筋注 (グラクソ・スミスクライン株式会社) Arepanrix™ (H1N1) <Glaxo SmithKline Corp.>

※接種するワクチンにチェック☑してください。

After receiving the doctor's diagnosis and listening to the explanation about the vaccinations' objectives, effects and after fully understanding the possibility of serious side reactions, do you want your child to receive one of the vaccines above? (Check which of the vaccines above you want ☑ and also circle one of the options below about your wish to administer the vaccine).

( 希望します Yes, I want my child to receive the vaccine ・ 希望しません No, I don't want my child to receive the vaccine )

Date: Year/年 Month/月 Day/日 保護者自署 Parent/Guardian's name

ワクチンメーカー名、ロット番号	接種量	実施場所・医師名・接種年月日		
メーカー名		実施場所		
Lot No.		医師名		
		接種年月日	平成	年 月 日

# 新型インフルエンザ予防接種予診票 Questionnaire for the New Influenza A-H1N1 Vaccination

(中学生に相当する年齢の対象：保護者が同伴する場合)

Children from 13 to 15 years old (1<sup>st</sup> to 3<sup>rd</sup> grade of Junior High School and children within the equivalent age range), when accompanied by the parent / guardian.

住所 Address		診察前の体温 Body temperature before the consultation		.....:..... °C
受ける人の氏名 Name of the person who will receive the vaccine	男 Male	生年月日 Date of birth	(Year) (Month) (Day)	年 月 日
保護者の氏名 Parent / Guardian's name	女 Female	Age (満 歳 カ月)		

質問事項 Questions	解答欄 Answers		医師 記入欄
接種を受ける方の発育歴についておたずねします About your child's development: 生まれたときの体重が少なかったり、出産時、出生後、乳幼児検診などで異常があるといわれたことがありましたか When the child was born, did s/he have low weight or during / after the child's birth and /or during health check-ups, have you ever been told about any problem or abnormality?	あった Yes	なかった No	
生まれてから今までに先天性異常、心臓、腎臓、肝臓、脳神経、免疫不全症、その他の病気にかかり、医師の治療（投薬など）を受けていますか Since birth up to the present moment, has your child ever had any congenital abnormality; cardiac, kidney, hepatic, cerebral neural diseases, immunodeficiency disorder, etc, and due to this problem, is s/he under medical treatment or taking any medicine? 病名 If yes, please write down the name of the disease. ( )	はい Yes	いいえ No	
その病気の主治医には、今日の予防接種を受けてよいといわれましたか Did the doctor in charge of the treatment authorize the child to receive the vaccine today?	Yes	No	
今日体に具合の悪いところがありますか Is the child feeling indisposed today? 具体的な症状を書いてください If yes, describe the symptoms.( )	Yes	No	
最近1ヶ月以内に、家族や遊び仲間に、インフルエンザ、麻疹、風しん、水痘、おたふくかぜなどの病気の方がいましたか Over the last 30 days, did any family member or friend get influenza, measles, rubella, chicken pox, mumps, etc.? 病名 If yes, please write down the name of the disease. ( )	Yes	No	
最近1ヶ月以内に予防接種を受けましたか Did your child receive any preventive vaccine over the last 30 days? 予防接種の種類 If yes, which vaccine? ( )	Yes	No	
新型インフルエンザ又は季節性インフルエンザの予防接種を受けたことがありますか Has the child ever taken the vaccine against the new influenza A (H1N1) or the seasonal influenza? その際に具合が悪くなったことはありますか	Yes	No	
On this occasion, did the child feel indisposed after taking the vaccine?	Yes	No	
これまでにインフルエンザ以外の予防接種を受けて具合が悪くなったことはありますか Has the child ever felt indisposed after taking any preventive vaccine (excluding the vaccine against influenza A-H1N1)? 予防接種の種類 If yes, which vaccine? ( )	Yes	No	
ニワトリの肉や卵などにアレルギーがありますか Is the child allergic to poultry meat (chicken), eggs, etc. ?	Yes	No	
薬や食品で皮膚に発疹やじんましんが出たり、体の具合が悪くなったことがありますか Has your child ever had any skin allergy (such as skin rash, nettle rash) or felt indisposed due to any medication or food intake?	Yes	No	
ひきつけ(けいれん)をおこしたことがありますか Has your child ever had convulsions? At what age? ( )歳頃 years old	Yes	No	
そのとき熱が出ましたか On that occasion, did your child have fever?	Yes	No	
近親者に予防接種を受けて具合が悪くなった方はいますか Has anyone in your family felt indisposed after receiving any vaccine?	Yes	No	
近親者に先天性免疫不全と診断されている方はいますか Does any family member have congenital immunodeficiency problems?	Yes	No	
今日の予防接種について質問がありますか Do you have any question regarding today's vaccination? (女性のみ) 現在妊娠している、又は妊娠している可能性はありますか (For women) Is she pregnant or is there any suspicion of pregnancy?	Yes	No	

### 医師の記入欄 Space to be filled by the physician

以上の問診及び診察の結果、今日の予防接種は  可能  見合わせる

The vaccine can be administered. The vaccine cannot be administered.

保護者に対して、予防接種の効果・目的、接種するワクチンの有益性及び副反応並びに予防接種健康被害救済制度について説明をした。

医師署名又は記名押印

### 保護者の記入欄 Space to be filled out by parents / guardians

医師の診察・説明を受け、予防接種の効果・目的、接種するワクチンの有益性、重篤な副反応の可能性などについて理解した上で、以下のワクチンの接種を

- インフルエンザHAワクチン (3価ワクチン) [国内産ワクチン] HA Trivalent Influenza Vaccine [domestic production]
- A型インフルエンザHAワクチン (H1N1株) [国内産ワクチン] HA vaccine against Influenza A (H1N1 strains) <domestic production>
- アレパンリック (H1N1) 筋注 (グラクソ・スミスクライン株式会社) Arepanrix™ (H1N1) <Glaxo SmithKline Corp.>

※接種するワクチンにチェック☑してください。After receiving the doctor's diagnosis and listening to the explanation about the vaccinations' objectives, effects and after fully understanding the possibility of serious side reactions, do you want your child to get immunized? (Check which of the vaccines above you want ☑ and also circle one of the options below about your wish to administer the vaccine).

( 希望します Yes, I want my child to receive the vaccine ・ 希望しません No, I don't want my child to receive the vaccine )

Date: 年 月 日 保護者自署 Parent / Guardian's signature

ワクチンメーカー名、ロット番号	接種量	実施場所・医師名・接種年月日		
メーカー名		実施場所	医師名	
Lot No.		接種年月日	平成 年 月 日	

新型インフルエンザ予防接種予診票
Questionnaire for the New Influenza A-H1N1 Vaccination

(中学生に相当する年齢の対象：保護者が同伴しない場合)

Children from 13 to 15 years old (1st to 3rd grade of Junior High School and children within the equivalent age range), when not accompanied by the parent / guardian.

Form with fields for Address, Name of the person who will receive the vaccine, Sex (Male/Female), Date of birth, and Age (満歳ヶ月).

Table with 3 columns: 質問事項 (Questions), 解答欄 (Answers), and 医師記入欄 (Physician's entry). Contains 15 rows of questions about development, medical history, and vaccination status.

保護者の記入欄 Space to be filled out by parents / guardians. Includes instructions, a list of vaccine options, and a section for the parent/guardian's signature and date.

医師の記入欄 Space to be filled by the physician. Includes a section for the physician's signature and a table for recording vaccine details.

Table with 3 columns: ワクチンメーカー名、ロット番号 (Vaccine manufacturer name, Lot No.), 接種量 (Dose), and 実施場所・医師名・接種年月日 (Implementation location, Physician name, Vaccination date).

## New Influenza Vaccine

<Eligible Junior High School students: not accompanied by parents / guardians>

[Domestically produced vaccine / imported vaccine]

**To parents / guardians raising Junior High School children that are within the eligible age to receive the vaccine**

In case of administration of the new influenza vaccine, children should be accompanied by parents/guardians. However, in case of eligible Junior High School students (from 13 to 15 years old), it is possible to administer the vaccine as far as parents/guardians read carefully the explanatory letter, fully understand it and sign the “letter of agreement & authorization” (that can be found in the end of this document) and the questionnaire. The responsibility lies on parents/guardians and they should carefully give explanations to the child about the vaccine. After signing the “letter of agreement & authorization” and the questionnaire, parents/guardians should give these documents to their children and they must present them on the day of vaccination along with the Maternal and Child Health Handbook (for those who have it). If parents/guardians do not understand the contents of this explanatory letter or if the child refuses to receive the vaccine alone, parents/guardians must accompany their children to the vaccination venue. In case of doubts, parents/guardians should consult a physician or the division in charge at the municipal office.

In addition, even if parents/guardians decide that the vaccine should be administered but on the vaccination venue the child refuses to receive it or if the physician in charge judges that the child is not in good health condition and the application of the vaccine is not adequate, eventually it will not be administered. The vaccine will not be administered if the “letter of agreement & authorization” and questionnaire are not signed by parents/guardians.

### 1. Purpose of the vaccine

Most of people infected by the new influenza (A-H1N1) virus present mild symptoms and recover quickly. However, there are cases in which the symptoms become severe (see table 1). This vaccine aims at reducing the symptoms caused by the disease even if the child gets infected. However, have in mind that the administration of the vaccine does assure that the child will not be infected or it will prevent the child from having severe symptoms.

(Table 1) Number of new influenza patients that presented severe symptoms.

(approximate values)	Total	10 to 14 years old	15 to 19 years old
Total number of patients	20, 770,000	4,760,000	2,800,000
Severe cases (%)	1,561 (0.008%)	181 (0.004%)	49 (0.002%)

\* Total number of patients: the data is from July 6, 2009 to August 15, 2010.

The number of severe cases were taken based on patients that were hospitalized on July 28, 2009 or people hospitalized from 29th and presented for a period of time acute encephalopathy, acute pneumonia, who were on a artificial respirator or were treated in a intensive care unit.

### 2. Information on the imported vaccine

The imported vaccine aims at meeting the demand for vaccines in case the national production is not enough to provide vaccines to everyone. This imported vaccine has been authorized by foreign national agencies and in order to be introduced in Japan, it went through an special approval process. The imported vaccine is produced by the company Glaxo SmithKline Corp. (mentioned below as GSK) and commercialized as Arepanrix™ (H1N1). Read carefully the following information on the efficiency and safety of this vaccine.

(英語)

- **Use of adjuvant (immunological agent) that have not been used in Japan**

Domestically produced vaccines do not include this agent. Adjuvants are used to increase the efficacy of vaccines and contribute to the reduction of the quantity of antigenic agent (antigen) in each dose of the vaccine. It has been observed that in case of vaccines that contain adjuvants, such as the imported ones, the frequency of occurring side effects is higher.

In the case of the imported vaccines, it was also observed that the probability of having pain on the vaccination site are higher. In case of the vaccine produced by GSK, it has been observed a high incidence of headache and general reactions in the body.

- **Occasional presence of agglutinated particles**

Occasional presence of agglutinated particles has been observed in the vaccine produced by GSK. Up to the present moment, there has been no reports on the effect of these agglutinated particles on the efficiency or security of the vaccine. In addition, there has been no evidence of the causal-relationship between these agglutinations and the side reactions.

- **Utilization of bovine-derived material in the manufacturing process**

The vaccine uses bovine-derived materials that do not meet the Japanese standards. It is impossible to disconsider completely the risk of occurring “spongiform encephalopathy”, a kind of neurological illness affecting the brain issue. However, the risks are considered very low due to strict manufacturing standards.

- **Cases of allergic reaction (anaphylactic reaction)**

In Canada, it has been reported that a lot of vaccines presented cases of anaphylactic reaction compared to other lots. As a response, the authorities in Canada decided to put on hold one lot of the vaccine (this lot was not imported by Japan) and continued the utilization of other lots. In Canada, the frequency of severe allergic reactions following immunization did not exceed the rates typically reported for other vaccines (1 event per 100,000 doses).

### **3. Safety of the vaccine**

The vaccine against the new influenza meets the required safety standards. However, there has been observed redness and pain on the vaccination spot (redness, tumefaction, pain, etc.). Temporarily the person may also have fever, bout of vomiting and headache (attack of fever, chill, headache, fatigue, vomiting, etc.). On rare occasions, persons may develop a rash with itching in the whole body (exanthema, nettle rash, rubefaction, itching paraesthesia, etc.). In case these symptoms become severe, it is recommended to consult a physician and receive proper medical care.

In case of the seasonal influenza vaccine, it can be observed swelling and pain on the vaccination spot in 10 to 20% of vaccinee people. These reactions, however, disappear within 2 to 3 days. In 5 to 10% of the cases, the person may also have fever, bout of vomiting and headache. These symptoms disappear within 2 to 3 days.

Although there is no strong evidence with the administration of the vaccine, there have been reports of some severe cases of difficulties in movements of the hands and feet, unconsciousness (Guillain-Barre syndrome, acute encephalopathy, acute disseminated encephalomyelitis – ADE, convulsions, hepatic function disorder, noisy inspiration, purple spot, etc.).

In most cases, if these symptoms are treated properly and quickly, the person can recover. In rare cases, these symptoms may leave subsequent complications.

In addition, in case the person presents any unusual reaction, changes in the body condition, fever, convulsions, etc, please consult a physician immediately.

### **4. Vaccination Adverse Reaction Relief System**

According to the Preventive Vaccination Law, a person is considered to be facing health hazard when, after receiving a vaccine, s/he presents severe side reactions to the same. In this case, the person may claim for compensations. However, compensations can only be claimed for cases in which the causal relationship between the vaccine and the side reaction has been proved and recognized by the Minister of Health, Labor and Welfare.

## 5. Important points to be observed when administering the vaccine

The vaccine can only be administered if the person is in good health condition. If the child is under medical treatment or is not in good health condition, please consult the physician in charge and the decision on the administration of the vaccine should be based on his/her judgement. In addition, the following people should take the vaccine taking into consideration his/her health condition:

1. People having underlying illness such as cardiac problems, respiratory disease (including bronchial asthma), kidney problems, liver disease, blood disease, developmental disorders, etc.
2. People who within 2 days after taking the vaccine present access of fever, exanthema, nettle rash or any suspicion of allergic reaction.
3. People who had convulsions previously.
4. People, including family members, who had any immunological problem.
5. People who are allergic to the components of the vaccine, eggs, poultry meat and other poultry-derived product and have risk of having allergic reactions such as skin rash.

If you plan to administer the imported vaccine on your child, please consult your doctor before making your decision.

People with the following conditions cannot take the vaccine:

1. People with fever (37.5 °C or higher).
2. People who have a severe acute disease.
3. People who had any severe allergic reaction (anaphylactic shock) caused by any component contained in the vaccine against influenza.
4. People who were not authorized by their physician to receive the vaccine.

More detailed information can be obtained at the Ministry of Health, Labour and Welfare:

Website: <http://www.mhlw.go.jp/bunya/kenkou/kekaku-kansenshou04/>

Information Center: 03-3234-3479

After reading this document and understanding completely its content, and based upon your child's full awareness about this vaccine, please sign the "letter of agreement & authorization" below if you agree to administer the vaccine (it is not possible to administer the vaccine without parents/guardians' agreement and signature).

### Letter of agreement & authorization

私は、新型インフルエンザの予防接種を受けさせるに当たっての説明文書を読み、予防接種の目的、効果、安全性について理解しました。この文書を持参する本人の保護者として、新型インフルエンザのワクチンを接種することに同意します。

I declare that I read the informative pamphlete and fully understood the information on Influenza H1N1 vaccine, its objective, effects and safety. I also declare that, as the child's parent/legal guardian, I authorize the administration of the vaccine.

保護者ご氏名（フルネーム） Parent / guardian's name

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保護者自署（フルネーム） Parent / guardian's signature

-----  
住所 Address

-----  
緊急の連絡先 Telephone number for emergency (mobile, workplace, etc.)  
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Apart from the "Letter of agreement & authorization" above, it is also necessary to fill out and sign the questionnaire. It is necessary to present one (1) "Letter of agreement & authorization" and also filled out one (1) questionnaire for each child that will receive the vaccine. If any item is missing or if one of the documents is not signed by the parent / legal guardian, the child cannot receive the vaccine.

(英語)