Participant Notification

If you have any questions about the information contained within this notification, please feel free to contact the Database Team:
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Telephone: 020 7679 5142; please ask for Dr Gargi Banerjee

Why have I received this notification?

Between 1959 and 1985, nearly 2000 individuals in the UK were treated with human growth hormone extracted from a gland in the brain (the pituitary gland) of people who had died. This treatment was called pituitary-derived growth hormone (also known as cadaveric growth hormone). The treatment was given for severe short stature, particularly if caused by growth hormone deficiency. It was given by several injections per week over months or years.

The UK Health Security Agency (UK HSA), on behalf of the Department of Health and Social Care (DHSC), holds information on people who received treatment with pituitary-derived human growth hormone in the United Kingdom between 1959 and 1985.

We, at the MRC Prion Unit at UCL, would like to use this information for research to better understand the long-term health of people who received this treatment.

We are contacting you because we believe that you received this treatment during this period, and that your information is included in this database.

This document gives you information on what information we wish to collect, and how it will be stored and used. It also gives information on how we will keep your personal information, and your rights.

You can choose not to be included in the research. Choosing to opt out will not impact any NHS care or treatments that you receive currently or in the future.

People who received treatment with this type of human growth hormone were contacted in the early 1990s, and you should therefore know whether you previously received this treatment. If you believe that we have contacted you in error, please contact the database team (details are at the start of this notification document).

This document contains information on the following:

- What information is held already?
- What are we proposing to do?
- Details of the two new databases:
  - "Surveillance Snapshot" Research Database
  - "Permission to contact" Research Database
- How will this information be stored and managed?

What information is held already?

Details of the people who received treatment with pituitary-derived human growth hormone are held in a historical database by the UK Health Security Agency (UK HSA) on behalf of the Department of Health and Social Care (DHSC); UK HSA and DHSC are "Data Controllers" for this historical database. This information was collected at the time when people received treatment. The historical database includes the name, date of birth and hospital (NHS) identifier for each person who received this treatment, as well as details relating to the treatment itself (for example, dates of treatment, type of preparation used and batch number).

UK HSA already legally hold this confidential personal data without consent in the public interest, under Regulation 3 of the Health Service (Control of Patient Information) Regulations 2002 ('Section 251 support'). These data are held for public health reasons because some people who received treatment with pituitary-derived human growth hormone went on to develop a disease called iatrogenic Creutzfeldt-Jakob Disease (CJD).

What are we proposing to do?

We wish to create two new research databases:

1. "Surveillance Snapshot" Research Database; an "opt-out" database, where people are automatically included but can let us know if they choose not to take part
2. "Permission to contact" Research Database; an "opt-in" database, where people need to provide specific consent to be included

UCL will act as Data Controller for these two new databases. Additionally, UK HSA will use the data on our behalf in ways not currently covered by their legal exemption, as will NHS England (previously NHS Digital), who will also process data on our behalf.

Our application to create these two new databases have been approved by the Confidentiality Advisory Group (CAG). This group is an independent body that provides expert advice on the use of confidential personal data without a person's

consent; they provide this advice to the Health Research Authority (HRA), which protects and promotes the interests of patients and the public in health research.

CAG are required to provide approval legally, if using confidential personal data is seen to be in the public interest and there is no practical alternative to use without consent. We applied for CAG approval so that we can legally use confidential personal data, including data on health (which is a type of "special category data") without consent for research purposes. The legal basis for this is Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 ('Section 251 support').

Although these two databases initially use data from the same source (the historical database), they are independent of each other and will handle confidential personal data in different ways. This is described in further detail below.

"Surveillance Snapshot" Research Database; an "opt-out" database

This database will include details of all people who received treatment with pituitary-derived human growth hormone in the United Kingdom between 1959 and 1985. We will use this data to see whether people who received this data are at any increased risk of neurological diseases compared to people who did not receive this treatment. We will do this by reviewing NHS data on hospital attendances for neurological symptoms and diagnoses. For people who have died, we will also review cause of death. Confidential personal data will be used to identify the correct NHS records on our behalf by UK HSA and NHS England (previously NHS Digital). Once this data has been linked, all identifiable information will be removed; this anonymised version will be transferred to us. Information used for research analysis will therefore not contain any identifiable details, so nobody using this data for research purposes will be able to identify an individual from the information that they have access to.

There is no practical alternative to using confidential personal data because in order for our research methods to be robust, we need to include as many people who received this treatment (ideally everyone). We are minimising our use of identifiable data by asking UK HSA (who already have access to the identifiable data) to transfer data to NHS England (previously NHS Digital) for us.

If you do not wish for your health records to be accessible, you can opt out of this database by contacting the database team:

- The proposed work will be advertised via a specific webpage on the MRC Prion Unit at UCL webpage, which will include links to the Participant Information Sheet and UCL Privacy Policy.
- Details will be provided for a named contact (telephone number, email address), so that people who believe they have been treated with pituitary-derived human growth hormone can get in touch to opt out, and a statement will be included on the webpage explaining this.

- If a person gets in touch with the study team to opt out, the study team will ask UK HSA for the anonymised study ID for that person; our copy of their data will then be securely and fully destroyed

"Permission to contact" Research Database; an "opt-in" database

This database will include details of people who received treatment with pituitary-derived human growth hormone in the United Kingdom between 1959 and 1985, and who:

- Are alive and resident in the United Kingdom
- Have provided their consent to be part of the database

The steps by which we will obtain consent are the following:

1) Update of pre-existing historical database described above with NHS data that: (i) confirms the identity of the listed people, and (ii) provides their GP details; UK HSA will provide this update on our behalf and a database containing name, date of birth, sex, NHS number, GP details and growth hormone treatment details will be transferred to us

2) The listed people will be approached via their GP (the rationale for this is provided below):
   - GPs will be sent a consent pack including a participant information sheet, UCL privacy notice and a participant consent form
   - The person's GP will be asked to pass the consent pack to the person
   - The person will then have the opportunity to review consent pack, and make their decision regarding participation

There is no practical alternative to using confidential personal data because in order to contact people for consent, we need to know who they are. We are minimising our use of identifiable data by asking UK HSA (who already have access to the identifiable data) to link the NHS England (previously NHS Digital) data for us, which they can do "in house" (i.e. without transfer of identifiable data) and provide us with the minimum number of details needed for contact.

Approach for contact via GP; rationale and strategy

People who received treatment with this type of human growth hormone were contacted in the early 1990s about the possibility of developing a condition called iatrogenic Creutzfeldt-Jakob Disease (CJD). CJD is a disease caused by an abnormal form of a protein called the prion protein. Iatrogenic CJD means CJD caused by medical treatment, as we believe people who developed this after receiving pituitary-derived growth hormone contaminated with the abnormal form of the prion protein.

We therefore anticipate that the majority of people will be aware that they have received treatment with pituitary-derived human growth hormone. However, in some cases individuals may be unaware that they have received this treatment. Additionally, contact by us might result in unintentional anxiety relating to receipt of this treatment and its potential consequences; these were highlighted as important considerations in our Patient and Public Involvement (PPI) discussion.

In order to mitigate his, we aim to contact individuals via their GP. It is our hope that most people will be known to their GP, and if there are individual reasons why a person should not be contacted (for example, as contact would have a significant negative impact on their mental health), we anticipate the GP would let us know and we would suspend our attempts at contact (following the "unable to contact" pathway, described below). Additionally, we will set up a dedicated telephone line and email address, so that any questions or concerns can be communicated directly with the study team. It is our aim to contact people in small batches, so that our lines of communication are not overwhelmed, and we can address any concerns fully.

Potential outcomes after person receives a consent pack:

(1) Consent given
The person is added to our "Permission to contact" Research Database.
They can choose to opt out at any time by contacting the Database Team.

(2) Consent not given
The person will not be included in our "Permission to contact" Research Database.
Our copy of their data will be securely and fully destroyed.

(3) Person does not respond / unable to contact
In cases where we do not have a response from the person within 1 month of GP contact, we will initially send a written reminder to the relevant GP. Should we receive no response after another two weeks, we will contact the GP directly by telephone in order to ensure that the invitation has been received by them and passed on to the person. We additionally would confirm that it is reasonable to continue to expect a response from the person (i.e. that they are still alive, resident in the UK, there is no other reason why the individual should not be contacted).

For people who are still not contactable, despite these three attempts at contact, we will assume that the person does not wish to be included in our "Permission to contact" Research Database. Our copy of their data will be securely and fully destroyed.

How will this information be stored and managed?

All personal data will be stored in an encrypted online depository called the UCL Data Safe Haven. The UCL Data Safe Haven is encrypted to a high standard to prevent external unauthorised access. Completed paper consent forms will be kept securely in locked cabinets within a locked room at the MRC Prion Unit at UCL; UCL is registered with the Information Commissioner's Office. The room is shared between people who work for the MRC Prion Unit at UCL and NHS National Prion Clinic, and only accessible to authorised research staff who are fully trained on how to confidentially handle personal data. Electronic consent forms are entered directly into the UCL Data Safe Haven and are stored there securely after completion.

Your data will be shared between UK HSA and NHS England (previously NHS Digital) and NHS England and UCL ("Surveillance Snapshot" research database), and between UK HSA and UCL ("Permission to contact" Research Database). UK HSA already hold your data for public health reasons, and they will either transfer your data to NHS England (previously NHS Digital) for data linkage ("Surveillance Snapshot" research database), or link these details with NHS England data "in house" ("Permission to contact" Research Database). The linked data will then be shared with UCL (specifically, the direct research team based at the MRC Prion Unit at UCL); nobody else will have access to your data until you provide consent. Your data will not be shared by UCL with anyone else, except for:

- If you let us know that you do not wish to be in the "Surveillance Snapshot" research database, we will share your details with UK HSA; this is so they can let us know your unique anonymous ID number, so we can delete your record from our system
- For the "Permission to contact" Research Database, we will share your details with your GP in order to contact you

The MRC Prion Unit at UCL works closely with the NHS National Prion Clinic. If someone uses the dedicated helpline, the trained person who answers the call might work for the NHS National Prion Clinic rather than UCL. As an NHS employee, they would not have access to any personal data, and would need permission from the caller to access this, which might be necessary so they can fully address the caller's concerns. Staff who work for the NHS National Prion Clinic are also fully trained on how to confidentially handle personal data.

Data in the "Surveillance Snapshot" research database will be stored until the project ends, in approximately four years (2026). Once the project ends, data will be held in accordance with UCL's Record Retention Schedule, after which all personal data held by UCL will be fully and securely destroyed. Results from the project will continue to be stored, but this will not include personal data at an individual level.

If you consent to being included in the "Permission to contact" Research Database, we will continue to store your details securely in the UCL Data Safe Haven unless you ask us to remove your data from the database, in which case our copy of your personal data will be securely and fully destroyed.