_____(*Name of CEO)*_____
CEO & Accountable Officer
NHS _____
Address _____
_____
_____
_____
Post code: _____

Name
Address

Post Code
email:

Date:

Dear _____,

Formal complaint regarding Covid vaccination

1. Personal details

(i) My name is _____

(ii) My date of birth is _____

(iii) My NHS number is _____

(iv) My address is as above.

(v) I received my first dose of the _____ vaccine on _____.

(vi) I received my second dose on _____.

(vii) *(Continue as necessary.)*

(viii) Prior to Covid vaccination I was a *(insert job/career + general health details if appropriate).*

2. Breach of duty of care and medical protocol with regards to informed consent

It has come to my attention that I was not properly informed about the Covid vaccines. I refer you to the exhibited evidence presented herein and enclosed/attached. It shows that NHS _____ failed in their duty of care to follow medical ethics and protocols with regards to obtaining properly informed - and thereby valid - consent, detailed as follows. This evidence is not exhaustive.

Green Book Chapter 2

(i) At the time of my first vaccination, on page 29 of the NHS England document

'COVID-19 vaccination programme Information for healthcare practitioners' (Republished 11 February 2021 Version 3.3)

it states with regards to consent:

> *"Before giving a COVID-19 vaccine, vaccinators must ensure that they have obtained Informed consent from the individual" […] Obtaining consent is discussed in* ***Chapter 2*** *of "Immunisation against infection disease" (the* ***Green Book****)"*

~Exhibit AR01

(ii) At the time of my second vaccination, the advice for consent on page 25 of the document *'COVID-19 vaccination programme Information for healthcare practitioners' (Republished 29 April 2021 Version 3.5)* again refers to the **Green Book Chapter 2**.

~Exhibit AR02

(iii) The **Green Book Chapter 2** refers doctors and healthcare practitioners to both the **GMC** *(page 5 - Professional guidance on consent')* and **BMA** *(page 6 - 'Other key references')* guidelines for consent.

~Exhibit AR03

GMC guidelines on consent

(iv) The General Medical Council guidance on consent confirms that

(a) patients have the right to make informed decisions.

(b) there is an obligation to provide patients with the information they need to make informed decisions.

(c) that information should include potential risks of harm and uncertainties (eg, an experimental, novel gene-therapy product would by definition fall under the categories of "risk" and "uncertainty").

(d) health professionals should not have relied on any assumption that vaccine recipients would not have wanted this information in order to make an informed decision.

(e) health professionals should not have relied on assumptions that vaccine recipients would not have considered such information to be significant in order to make an informed decision.

(f) **health professionals have an obligation to ensure that vaccine recipients understand exactly what they are consenting to**.

(g) otherwise the consent obtained is neither valid nor legal.

~Exhibit AR04

BMA guidelines on consent

(v) The British Medical Association Toolkit on consent for doctors

(a) aligns with, supports and reinforces the GMC guidance on the issues of relevance; sufficiency; risk (an experimental vaccine still within clinical trials with no medium- to long-term data constitutes "risk" by definition); and what an individual patient may attach significance with regards to information provided for informed consent to be valid.

(b) this includes discussing the nature (eg, novel gene technology) and uncertainty (eg, experimental with unknown and incomplete safety profile) of an intervention.

(c) doctors cannot rely on a body of medical opinion for this purpose.

(d) **information should not be withheld**.

(e) failure to do so could be challenged in law.

(f) states that *"**a patient genuinely understanding what is being proposed** is more important than how consent is recorded."* (Page 4)

~Exhibit AR05

Core Knowledge for COVID-19 Vaccinators

(vi) NHS England's vaccinators training slides confirm that, in order for consent to be valid

(a) the person giving consent should receive an explanation of the treatment

(b) the person giving consent must be **appropriately informed**

(c) the person giving consent must have the **necessary information**

(d) the person giving consent must have **adequate information**

(e) the person giving consent must be given **as much information as they need**; and

(f) **informed consent is a legal requirement**

(g) **sufficient evidence-based information must be provided to make balanced and informed decision**

(h) **it is <u>key</u> that the person must understand what they are consenting to**.

~Exhibit AR06 (addendum)

3. Consent NOT informed

When granting my consent for the _____ injections

(i) I was not informed that the vaccine I was injected with was still within Phase III clinical trials.

~Exhibit AR07

(ii) I was not informed that the vaccine I was injected with was

(a) unlicensed **~Exhibit AR08/AR09/AR16**

(b) unproven **~Exhibit AR09**

(c) investigational **~Exhibit AR10/AR09**

(d) experimental **~Exhibit AR11/AR09**

(e) gene therapy **~Exhibit AR12/Ar 13**

(f) genetic modification (whether temporary or otherwise) **~Exhibit AR13**

(iii) I was not informed that by the time of my second dose, the AstraZeneca vaccine had been withdrawn in at the least eighteen countries due to thrombosis and thrombocytopenia (from which I now suffer).

~Exhibit AR14

(iv) I was not informed that by the time of my second dose, the AstraZeneca vaccine had been withdrawn for under-40s in the UK due to thrombosis and thrombocytopenia.

~Exhibit AR15

(v) I was not informed that MHRA's approval was for Conditional Marketing Authorisation only, which is a process required for products that are unlicensed/unproven/experimental/ investigational and/or still within clinical trials, such as the Covid vaccines.

~Exhibit AR16

(vi) The guidance on consent for Covid-19 vaccinations, including

(a) the Green Book chapter on consent

(b) GMC guidance

(c) BMA guidance

(d) Core Knowledge for Covid-19 Vaccinators

(e) Ropewalk Chambers (Barristers regulated by the Bar Standards Board) article *"Informed Consent: Updated GMC Guidance"* (https://ropewalk.co.uk/blog/informed-consent-updated-gmc-guidance/) *"Consent Forms: The guidance is clear that filling in a consent form is not a substitute for a meaningful dialogue tailored to the individual patient's needs."*

~Exhibit AR17

clearly state and confirm that responsibility for informed consent lies with vaccinators, that consent forms are not adequate on their own without "meaningful dialogue", and that sufficient information has to be given for a patient to understand exactly what they are consenting to before their consent can be considered to be informed. No such dialogue took place, and the online facility presented no such information to those booking their vaccination appointments.

~Exhibit AR18

(vii) Supported by the facts and evidence presented in these documents, I state for the record that **I did not understand what I was consenting to: my consent was NOT informed**.

4. Health issues suffered and losses sustained due to the _____ vaccine

As a direct result of accepting Covid vaccination due to NHS _____'s failure of duty of care and failure to adhere to medical standards and protocols (as evidenced)

(i) My health *(complete if/as appropriate)*

(ii) I am disabled and unable to work. *(Adjust/delete as appropriate)*

(iii) I been diagnosed with *(complete/delete as appropriate)*

_____
_____.

(iv) *(Insert any additional notes).*

~Exhibit AR19

(v) I have lost my career as a _____

(vi) I have lost my house _____

(vii) My ongoing health issues are costing me approximately _____ per month on supplements and I have had to pay _____ for private appointments.

(viii) I can no longer support my family.

(ix) My marriage ended due to the pressures of the situation.

(x) I have suffered great emotional and physical pain and distress.

5. My requirements from this complaint

As detailed above, I have suffered demonstrable serious injury and loss from the _____ vaccine. However, this complaint is NOT about my injuries or loss, **this complaint is about NHS _____'s failure to provide the necessary information required prior to injecting me with an experimental substance**.

_____ is Chief Executive of NHS _____ and as Accountable Officer bears ultimate responsibility for all actions and decisions of NHS _____.

I therefore require from NHS _____ a substantive rebuttal to the above points and Exhibits AR01-18, otherwise:

A. an acknowledgement that the evidence provided with this complaint is factual and correct.
B. an acknowledgement that NHS _____ therefore failed in their duty of care to provide sufficient or adequate information prior to vaccination.
C. an acknowledgement that **I did not understand what I was consenting to**.
D. an acknowledgement that **my consent was NOT informed**.

Thank you for your consideration on this matter. I look forward to your response.

Yours sincerely,