

UK Medical Freedom Alliance

Telephone: 0300 061 6161  
[www.cqc.org.uk](http://www.cqc.org.uk)By email: [UKMedicalFreedom@protonmail.com](mailto:UKMedicalFreedom@protonmail.com)

23 November 2021

Dear UK Freedom Medical Alliance,

**Re: Concerns about the COVID-19 Vaccine Consent Form currently being used by Public Health England ('PHE')**

We write further to our email dated 13 July 2021, in which we acknowledged receipt of your letter dated 1 July 2021.

Your letter raised important issues. As such, we considered it necessary to speak with both the General Medical Council ('GMC') and the UK National Health Security Agency ('UKHSA'), which has now replaced Public Health England ('PHE'), hence the delay in responding.

Although UKHSA has now replaced PHE, we will continue to refer to PHE throughout our letter.

**Our regulatory remit**

Before we address the concerns you have raised in relation to the Covid-19 consent form prepared by PHE, it is important to set out the scope of our powers. As you have rightly identified, the Care Quality Commission ('CQC') is the regulator of health and adult social care in England. We monitor, inspect and regulate services to make sure they meet fundamental standards of quality and safety.

In your letter dated 1 July 2021, PHE is referred to as a service provider organisation. However, PHE was an executive agency of the Department of Health with operational autonomy and CQC did not regulate any of its functions. The Health Protection Agency, PHE's predecessor organisation, **was** registered with the CQC. The misunderstanding **may** have arisen from the following paragraphs on CQC's website;

*'PHE brings together a range of functions and responsibilities previously delivered through a number of other organisations, including all functions of the [Health Protection Agency](#) (HPA).*

*HPA was abolished with effect from 1 April 2013 and its functions in respect of regulated activities transferred to PHE. As an executive agency of the department, however, PHE is exempt from registration*

*We have agreed with PHE that we will, on a non-statutory basis, inspect services formerly provided by HPA.'*

<https://www.cqc.org.uk/directory-care/providers/public-health-england>

PHE did not provide regulated activities and in any event, if they did, a general exception was [applicable](#)<sup>1</sup>.

### **Covid-19 consent form**

It is our understanding from our discussions with GMC and PHE, that:

1. The consent form produced by PHE is not mandatory; vaccinations providers can choose to use it or produce their own versions.
2. The consent form is not a standalone document; it is supported by other materials including a letter inviting patients to consent to their vaccination and an information sheet inviting patients to book their vaccination, both of which include a link to information about the side effects. We understand paper copies are also available. This gives patients the opportunity to consider their choice before they book their vaccination.
3. The consent form is only one aspect of the consent process. GMC guidance, '*Decision making and Consent*' makes it clear that dialogue should be an important part of the consent process:

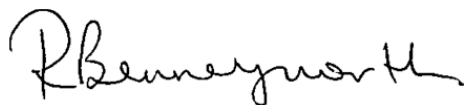
‘54. *Consent forms can be a helpful prompt to share key information, as well as a standard way to record a decision that can make regular review easier. They can also be used to review decisions made at an earlier stage, and the relevant information they were based on.*

55. *But, filling in a consent form isn't a substitute for a meaningful dialogue tailored to the individual patient's needs.'*

The current vaccination programme allows patients to have this dialogue.

We are unable to comment any further of the functions of GMC and PHE and would suggest you liaise with them further directly.

Yours sincerely,



**Dr Rosie Benneyworth BM BS BMedSci MRCP**  
**Chief Inspector of Primary Medical Services and Integrated Care**

---

<sup>1</sup> Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, Schedule 2(5)(b) '*Medical or dental services provided (otherwise than in conjunction with the provision of accommodation in a hospital) only under arrangements made on behalf of service users by a government department.'*