Statement of Facts

Claimant: MJ Sutherland

Document Reference No: NE013712676GB

16th September 2022

CLAIMANT: Michael J Sutherland, [redacted]

RESPONDENT: Jeffrey Ace, Chief Executive Officer Dumfries & Galloway NHS Board, Ground Floor North, Mountainhall Treatment Centre, Bankend Road, Dumfries, DG1 4AP

Despite on multiple occasions being provided with information and evidence regarding fraudulent Covid testing, the experimental vaccines and informed consent, Jeff Ace failed to raise any investigation or any concern at all about these issues, instead failing to obtain informed consent whilst denying that the Covid vaccinations were still within clinical trials, with Mr. Ace even stating that a positive Covid test was somehow a valid diagnosis simply because it was government policy.

In this Statement of Facts, evidenced by the Exhibits included with this document,

I, Michael J Sutherland, along with the supporting signatories, do hereby claim:-

PRINCIPLES OF PUBLIC LIFE IN SCOTLAND

(1) THAT/

(i) In his role as Chief Executive Officer of Dumfries & Galloway Health Board, Respondent is bound by the Principles of Public Life in Scotland (**Exhibit MJS01**).

(ii) Under the section entitled "Duty" within **Exhibit MJS01** there is "*a duty to act [...] in accordance with the core tasks of that body*", the core tasks of NHS Dumfries & Galloway Health Board being the health, wellbeing and interests of the people of Dumfries & Galloway.

(iii) In the section entitled "Selflessness" within **Exhibit MJS01** it is stipulated that there is "*a duty to take decisions solely in terms of public interest*" and that consequently Respondent must act *solely in terms of the public interest* at all times, regardless of instructions received from any other organisation, any other corporate entity, or any other source.

(iv) In the section entitled "Integrity" within **Exhibit MJS01**, it states: "*You must not place yourself under any [...] obligation to any individual or organisation that might reasonably be thought to influence you in the performance of your duties.*" meaning that, regardless of and despite any instructions received that contravene the Principles of Public Life in Scotland and/or professional and/or medical ethics, Respondent has a duty to act *solely in terms of the public interest* and remain strictly within those Principles.

(v) As 'Accountable Officer' and by his own admission, Respondent is responsible for *all actions and decisions* of NHS Dumfries & Galloway.

COVID VACCINES

(2) THAT/

(i) All Covid vaccines administered to date by NHS Dumfries & Galloway are within ongoing Phase III clinical trials, as evidenced in **Exhibit MJS02**.

(ii) The MHRA's algorithm confirms that each vaccine is "A CLINICAL TRIAL OF A MEDICINAL PRODUCT", as evidenced in **Exhibit MJS03**.

(iii) The MHRA's Conditional Approval for Emergency Use confirms that the Pfizer vaccine is an unlicensed product that does not have full marketing authorisation as evidenced in **Exhibit MJS04**.

(iv) In review of FOI 21-159 (**Exhibit MJS17**) Respondent stated that the vaccines were not a 'clinical trial' as they had been approved for use by the MHRA and JCVI. However, the

MHRA's Conditional Approval for Emergency Use does NOT mean that a product is no longer classified as a clinical trial; on the contrary, the reason the Covid vaccines required such emergency use approval in the first place *is precisely because they have not been given full authorisation as they are still within clinical trials*.

(v) Medicinal products within clinical trials are classed as Unproven Interventions, as evidenced in **Exhibit MJS05**.

(vi) Medicinal products within clinical trials are classed as Investigational Medicinal Products, as evidenced in **Exhibit MJS06**.

(vii) Medicinal products within clinical trials are classed as **experimental** products, as evidenced in **Exhibit MJS07**.

(viii) mRNA/viral vector vaccines are classed as gene therapy, as evidenced in **Exhibit MJS08**.

(ix) Each Covid vaccine is a gene therapy product which, according to the manufacturers, operate at genetic level to recode the recipients' genes in order to instruct the host cells to manufacture the Sars-CoV-2 spike protein. This is also classed as **genetic modification**, as evidenced in **Exhibit MJS09**.

(ix) Despite the MHRA's Conditional Approval for Emergency Use, the fact is that the Covid-19 vaccines are still within Phase III clinical trials as evidenced, and are therefore:

a. Unlicensed (**Exhibit MJS04**)
b. Unproven (**Exhibit MJS05**)
c. Investigational (**Exhibit MJS06**)
d. Experimental (**Exhibit MJS07**)
e. Gene therapy (**Exhibit MJS08**)
f. Genetic modification (**Exhibit MJS09**)
g. Unlicensed, unproven, investigational genetic experimentation.

REGULATIONS / DECLARATION OF HELSINKI

(3) THAT/

(i) NHS Dumfries & Galloway, including but not limited to its Health Board, doctors and vaccinators are bound by UK Regulations including the Medicines for Human Use (Clinical Trials) Regulations 2004 (**Exhibit MJS10**).

(ii) The Medicines for Human Use (Clinical Trials) Regulations 2004 Schedule 1 Part 2 (CONDITIONS AND PRINCIPLES WHICH APPLY TO ALL CLINICAL TRIALS) states that *"Clinical trials shall be conducted in accordance with the principles of the Declaration of Helsinki."* (**Exhibit MJS11**).

(iii) NHS Dumfries & Galloway, including but not limited to its Health Board, Respondent, doctors and vaccinators are thereby bound by the Declaration of Helsinki.

BREACH OF REGULATIONS / DECLARATION OF HELSINKI

(4) THAT/

(i) Schedule 1 PART 1 Paragraph 3(1) of the Medicines for Human Use (Clinical Trials) Regulations 2004 (**Exhibit MJS10**) states "[…] *a person gives informed consent to take part* […] *in a clinical trial only if his decision […] is given freely <u>after that person is informed</u> of the <u>nature</u>, significance, <u>implications</u> and <u>risks</u> of the trial"*

Regulations therefore stipulate that consent cannot be deemed to be informed, or thereby valid or legal, unless Covid vaccine recipients were informed of

a. The <u>*nature*</u> of the treatment (ie, that it is a gene therapy/modification technique that recodes the recipients genes in order to produce the Sars-CoV-2 spike protein).
b. The <u>*implications*</u> and <u>*risks*</u>; ie, that the vaccines are unlicensed, unproven, investigational, experimental gene therapy products still within Phase III clinical trials and with no data on medium- to long-term adverse health effects.)

Neither (a) nor (b) occurred and therefore NHS Dumfries & Galloway, including but not limited to its Health Board, Respondent, doctors and vaccinators, are in breach of the Medicines for Human Use (Clinical Trials) Regulations 2004.

(ii) Article 37 of the Declaration of Helsinki "Unproven Interventions" states

"In the treatment of an individual patient, where proven interventions do not exist or other known interventions have been ineffective, ***the physician****, after seeking expert advice,* ***with informed consent from the patient*** *or a legally authorised representative,* ***may use an unproven intervention*** *if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering.* ***This intervention should subsequently be made the object of research,*** *designed to evaluate its safety and efficacy. In all cases, new information must be recorded and, where appropriate, made publicly available."* (**Exhibit MJS11**)

To conform to the established medical ethics of informed consent, the Declaration of Helsinki and thereby the Medicines for Human Use (Clinical Trials) Regulations 2004, vaccine recipients should therefore have been

(a) Informed that the product was an Unproven Intervention still within clinical trials
(b) Made the object of research

Neither (a) nor (b) occurred and therefore NHS Dumfries & Galloway Health Board including but not limited to Respondent, doctors and vaccinators are in breach of the Declaration of Helsinki.

GENERAL MEDICAL COUNCIL

(5) THAT/

(i) The *"Covid-19 vaccination guidance to NHS Boards"* (**Exhibit MJS12**) refers NHS Boards to *"the Green Book Chapter on Consent"* (**Exhibit MJS13**)

(ii) In the Green Book Chapter on Consent, the section entitled *"Professional guidance on consent"* refers doctors to *"The General Medical Council guidance for doctors on decision making and consent (2020)"* (**Exhibit MJS14**)

(iii) The section "About our Decision making and consent guidance" within **Exhibit MJS14** states:

"*Consent is a* ***fundamental legal and ethical principle****.* ***All patients have the right*** *to be involved in decisions about their treatment and care and* ***to make informed decisions*** *if they can. The* ***exchange of information*** *[…]* ***is essential*** *to good decision making. Serious harm can result […] if they are not* ***given the information they need*** *[…] so they can make* ***informed decisions*** *about their care.*"

(iii) Article 10(e) of **Exhibit MJS14** "The information you give patients" states

10. ***You must give patients the information they want or need to make a decision****.*

This will usually include:

e. the ***potential*** *benefits,* ***risks of harm****,* ***uncertainties*** *about and likelihood of success for each option,* ***including the option to take no action****.*

(iv) Article 12 of **Exhibit MJS14** "The information you give patients" states

12. You ***should not rely on assumptions*** *about:*

f. the ***information a patient might want or need***
g. the ***factors a patient might consider significant***
h. the importance a patient might attach to different outcomes.

(v) Article 26 of **Exhibit MJS14** "The information you give patients" states

"26. If you are ***uncertain*** *about the diagnosis, or the* ***clinical effect*** *a particular treatment might have,* ***or if the available evidence of*** *benefits and* ***harms*** *of an option* ***is unclear, you should explain this to the patient****."*

(vi) Article 31 of **Exhibit MJS14** "The information you give patients" states

31. You must be clear about the scope of decisions so that ***patients understand exactly what they are consenting to****.*

(vii) The Ropewalk Chambers (Barristers regulated by the Bar Standards Board) article entitled *"Informed Consent: Updated GMC Guidance"* (**Exhibit MJS15**) states

"*Discussing the benefits and harms:*

- *Clear and up-to-date* ***information****, based on the best available evidence,* ***about the potential*** *benefits and* ***risks*** *of each option* ***must be provided****. This must include the option to take no action.*
- ***Risks of harm*** *and potential benefits* ***that the patient would consider significant for any reason****.*
- ***Level of risk or degree of uncertainty*** *associated with any of them* ***to make sure the patient has the opportunity to consider relevant information that might influence their choice*** *between the available options*

"*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****.*

(viii) IN SUMMARY/

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 (with an unproven, unlicensed, experimental, investigational and novel gene therapy product falling under the categories of "risk" and "uncertainty" by definition)
d. Health professionals should not have relied on any assumption that vaccine recipients would not have wanted this information (ie, that the vaccine was gene-based therapy and still within ongoing Phase III clinical trials) 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*** (ie, that the Covid vaccines are unproven, unlicensed, experimental, investigational, novel gene therapy products)
g. Meaningful dialogue taking the above GMC guidance into account should have occurred prior to vaccination, but did not, therefore vaccine recipients **did not understand exactly what they were consenting to**;
h. NHS Dumfries & Galloway, including but not limited to its Health Board, Respondent, doctors and vaccinators, failed to conform to the GMC Guidance on consent stipulated via the *Covid-19 vaccination guidance to NHS Boards*; all consent obtained was therefore NOT informed, and therefore NOT VALID nor LEGAL.

BRITISH MEDICAL ASSOCIATION

(6) THAT/

(i) As previously stated in item (5)(i)above, the *"Covid-19 vaccination guidance to NHS Boards"* (**Exhibit MJS12**) the section entitled *"Consent forms"* refers NHS Boards to *"the Green Book Chapter on Consent"* (**Exhibit MJS13**)

- In **Exhibit MJS13** the section entitled *"Other key references"* refers to *"British Medical Association (2019). Consent and refusal by adults with decision-making capacity – A toolkit for doctors"* (**Exhibit MJS16**), which states
    - **In order for consent to be valid** the patient must have been offered **relevant information**.
    - Patients must have been offered **sufficient information** to make an **informed decision**.

- Patients require **sufficient clear and accurate information**, in a way they can understand, **before providing consent**.
- Information should be tailored according to the **nature**, complexity **and level of risk of the proposed treatment**, and the individual concerns, wishes and values of each patient.
- This includes information about **risks** and potential side-effects
- Doctors can **no longer rely on the support of a responsible body of medical opinion** ('the Bolam test') **in deciding what information they should provide** to patients. Instead, they **must provide information** about **any risk** to which the **individual patient would attach significance**.
- **Should I withhold any information? No. You should not withhold any information the patient needs to make a decision**, including when a relative or carer asks you to. **Failure to provide sufficient relevant information could be challenged in law**.
- This includes **discussing the nature** and **extent of any uncertainty** regarding the clinical effect of a particular intervention.

(ii) IN SUMMARY/

a. the BMA Toolkit for doctors aligns with, supports and reinforces the GMC guidance on the issues of **relevance**, **sufficiency**, **risk** (ie, experimental vaccines are within clinical trials and as such there are no medium- to long-term data) 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** and **uncertainty** 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**.

SCOTTISH GOVERNMENT & PUBLIC HEALTH SCOTLAND GUIDANCE

(7) THAT/

(i) In his Review of FOI 21-159 (**Exhibit MJS17**), Respondent stated that *"… the Scottish Government provides guidance to all Scottish Health Boards. This guidance is available on their website, with the following as a link* (**Exhibit MJS18**) *to the Exhibits and letters issued"*

a. On the link **Exhibit MJS18** the section entitled "*Guidance - Support for health and social care professionals*" links to "*Coronavirus (COVID-19): vaccination guidance for health and social care professionals*" (**Exhibit MJS19**)

- On **Exhibit MJS19** there is nothing to suggest that health professionals should break from Regulations or medical ethics protocols, and nothing to suggest that vaccine recipients should not be informed of the experimental gene modification nature of the vaccines, nor that the product is still within clinical trials.

b. In the same section "Guidance *- Support for health and social care professionals"* there is a link to *"Coronavirus (COVID-19): guidance for use of Pfizer BioNTech vaccine in care homes"* (**Exhibit MJS20**)

- In **Exhibit MJS20** it is stated: *"The following has been written under the assumption that **informed consent** has been provided by residents or staff."*

c. On **Exhibit MJS18** the section entitled "Correspondence" provides a link to *"Coronavirus (COVID-19): vaccination of children and young people - letter from Chief Medical Officer Directorate"* (**Exhibit MJS21**) containing a paragraph entitled "Informed consent", which states

> *"In all instances, the offer of vaccination to children and young people **must be accompanied by appropriate information** to enable them, and those with parental responsibility, to be **adequately apprised** of the **potential harms** and benefits of vaccination **as part of the informed consent process prior to vaccination**."*

(ii) The "*Covid-19 vaccination guidance to NHS Boards*" document (**Exhibit MJS12**) states

a. *"Before administering the Covid-19 vaccine,* ***it is the responsibility of immunisers to ensure that informed consent has been obtained*** *from the patient by a Registered Practitioner"*
b. *"NHS Boards and Care Homes should* ***utilise existing mechanisms and processes for obtaining consent****, using Public Health Scotland information materials* ***to support this****"*
c. *"in order* ***to further support existing consent processes*** *and mechanisms, a template Covid-19 consent form is made available in Appendix A of this guidance. The use of this template is not mandatory.* ***NHS Boards have established processes in place for producing consent forms and these should be utilised****."*

(iii) In point 5 of the response to FOI Ref.: 20-500 (**Exhibit MJS33**) a D&G Health Board FOI Officer made a false statement: *"****The rules on informed consent are decided nationally by the Scottish Government*** *and included published information leaflet for the person before consent to vaccination. NHS Dumfries and Galloway are fully compliant with ensuring that informed consent as required by the Scottish Government is obtained."*

The above evidence refutes that statement, as it is clearly stated on the links provided by Respondent that Health Boards and immunisers must **use existing processes** to ensure that informed consent is obtained, only using the government guidance *in support* of this.

(iv) IN SUMMARY/

Scottish Government and Public Health Scotland guidance

- Does not instruct Health Boards to withhold information that the vaccines are still within ongoing clinical trials.
- Does not instruct Health Boards to withhold information that the vaccines function via genetic modification.
- Makes it clear that informed consent must be obtained by immunisers.
- Makes it clear that that informed consent must be accompanied by appropriate information.
- Makes it clear that the guidance provided to Health Boards was *to support* existing NHS Boards consent processes, rather than acting as a replacement for them.
- Even had the guidance instructed a, b, or both, it is *in terms of the public interest* for Respondent to adhere to the Principles of Public Life in Scotland, Regulations and established medical ethics including GMC/BMA guidance and the Declaration of Helsinki, regardless of *any individual or organisation that might reasonably be thought to influence Respondent in the performance of his duties*.
- NHS Dumfries & Galloway including Respondent, Health Board, doctors and vaccinators have failed the people of Dumfries & Galloway with regards to established **medical ethics** on informed consent.
- NHS Dumfries & Galloway including Respondent, Health Board, doctors and vaccinators failed the people of Dumfries & Galloway with regards to **Regulations** on informed consent.
- NHS Dumfries & Galloway including Respondent, Health Board, doctors and vaccinators failed the people of Dumfries & Galloway with regards to **legal requirements** on informed consent.
- As Accountable Officer and *"responsible for all of the actions and decisions of our local NHS",* Respondent bears ultimate responsibility for those actions, decisions and omissions.
- Respondent has shown a Wilful Neglect of Duty to the people of Dumfries & Galloway, has failed to act *in terms of the public interest* and thereby the Principles of Public Life in Scotland, has failed with regards to Regulations, medical ethics and legal requirements for informed consent, and as such is not a Fit and Proper Person for the role of Health Board CEO.

FRAUDULENT USE OF PCR/LATERAL FLOW TESTS

(8) THAT/

(i) A government or any other entity stating a falsehood does not turn that falsehood into fact.

(ii)/

a. The information provided in **Exhibit MJS22** serves as irrefutable evidence that PCR tests are not capable of diagnosing any disease, nor of determining infection status.

b. The information provided in **Exhibit MJS23** serves as irrefutable evidence that lateral flow tests are not capable of diagnosing any disease, nor determining infection status.

c. To reinforce these facts, in November 2020 a Judgment of the Lisbon Court of Appeal ruled PCR tests to be unreliable for forcing people into self-isolation, providing further evidence that PCR tests are not capable of diagnosis (**Exhibit MJS24**).

d. To reinforce these facts, in March 2021 an Austrian court ruling determined that PCR tests are not suitable for diagnostics (**Exhibit MJS25**).

e. To reinforce these facts, in April 2021 a court in Weimar, Germany, also ruled PCR tests unsuitable for diagnostics: *"Also the expert Prof. Dr. rer. biol. hum. Kämmerer also confirms in her expert opinion on molecular biology that **a PCR test** – even if it is performed correctly – **cannot provide any information on whether a person is infected with an active pathogen or not**."* (**Exhibit MJS26**).

f. Unless Respondent can provide substantive evidence that, contrary to item (8)(i) above, a government or any other entity stating a falsehood DOES turn that falsehood into fact, the truth of the matter is that neither PCR nor lateral flow tests are capable of diagnosing disease or determining infection status.

g. In addition to points (8)a-f, in response to FOI Ref 11/10/21/ar/1478 (**Exhibit MJS34**) Public Health England confirmed that it held no information on any scientific studies, articles, or other data conclusively proving that a positive PCR test following a following a positive lateral flow test is sufficient to confirm diagnosis of infection with Covid-19.

(iii) According to the Fraud Advisory Panel document entitled *"Fraud in Scotland"* (**Exhibit MJS27**), *"Fraud is committed when someone achieves a practical result by the means of an **intentional false pretence** or **dishonest misrepresentation**. In other words, where a **deliberate deception** is used to **cause someone to do something they would not otherwise have done**. There must be a causal connection between the deception and the practical result. The range [...] is incredibly wide, from **outright lies to implied representations or suggestions of something which was untrue, including silence as to the truth** in certain circumstances. **An omission can be sufficient if the accused is under a duty to make a representation**. The false pretence must have a 'practical result'. Any practical result will suffice. There is no minimum requirement of loss for the offence, nor is there any need for the perpetrator to have gained as a consequence."*

(iv) Determination of infection status or complicity in allowing such diagnoses to be made in full knowledge that a test that is not capable of doing so constitutes *"intentional false pretence"*, *"dishonest misrepresentation"* and *"deliberate deception"*, and would achieve the *'practical result'* of causing someone *"to do something they would not otherwise have done"* (e.g., self-isolation).

(v) NHS Dumfries & Galloway, its Health Board including but not limited to Respondent and one Dr. Regina McDevitt, who has been complicit in the closure of schools and self-isolation of a multitude of children on the basis of PCR/lateral flow testing, have previously been provided with evidence that PCR and lateral flow tests are incapable of diagnosis.

(vi) Despite being provided with that evidence and therefore being in full knowledge that Covid tests are incapable of determining infection status, NHS Dumfries & Galloway, its Health Board including but not limited to Respondent and Dr. Regina McDevitt, were complicit in multiple counts of fraudulent diagnoses with PCR and lateral flow tests.

(vii) NHS Dumfries & Galloway, its Health Board including but not limited to Respondent and Dr. Regina McDevitt are therefore complicit in criminal conduct, including but not limited to one, more or all of

a. Common Law Fraud as defined by the Fraud Advisory Panel (**Exhibit MJS27**).

b. Civil Fraud as defined by the Fraud Advisory Panel (**Exhibit MJS27**).
c. Misfeasance in Public Office (**Exhibit MJS28**).
d. Wilful Neglect of Duty by a Public Official (**Exhibit MJS29**).
e. Medical Malpractice (**Exhibit MJS30**).
f. In the case of minors, Child Maltreatment, aka Child Abuse (**Exhibit MJS31**).

(viii) Respondent is advised of Point 56 of *Wilkinson, R (on the application of) v Broadmoor Hospital, Responsible Medical Officer & Ors [2001] EWCA Civ 1545 (22 October 2001)* (**Exhibit MJS32**), which states: *"**The fact that they are performing statutory functions** which may sometimes be susceptible to judicial review **does not relieve them of responsibility** in tort **for wrongful acts**."*

(9) OVERALL SUMMARY/

(i) The failure of NHS Dumfries & Galloway health professionals to obtain fully informed consent for a novel gene-therapy product within clinical trials is a violation of medical ethics, including but not limited to:
   a. Hippocratic Oath
   b. Nuremberg Code
   c. Declaration of Helsinki
   d. GMC Guidelines on Consent
   e. BMA "Consent and refusal by adults with decision-making capacity - A toolkit for doctors"
   f. The Universal Declaration on Bioethics and Human Rights Article 6

(ii) The failure of NHS Dumfries & Galloway health professionals to obtain fully informed consent for a novel gene-therapy product within clinical trials is a gross breach of Regulations and codes of conduct, including but not limited to:
   a. Medicines for Human Use (Clinical Trials) Regulations 2004
   b. Declaration of Helsinki
   c. The Principles of Public Life in Scotland

(iii) The complicity of NHS Dumfries & Galloway heath professionals in the fraudulent misuse of Covid testing is a violation of criminal, ethical, civil and professional codes of conduct as evidenced, and as
   a. Respondent was informed of all of the above information.
   b. Respondent has failed to act *in terms of the public interest* and multiple violations of the Principles of Public Life in Scotland
   c. Respondent is complicit in the failure to obtain properly informed or thereby valid or legal consent from vaccine recipients, including parents of vaccinated children and pregnant women, in direct violation of Regulations and medical ethics.
   d. Respondent is complicit in fraudulent diagnoses with the misuse of Covid testing as evidenced.
   e. Members and employees of NHS Dumfries & Galloway, including but not limited to Respondent, doctors and vaccinators, are complicit in one, more or all of the crimes and violations evidenced herein.
   f. Accountable Officer for NHS Dumfries & Galloway, Respondent bears ultimate responsibility for those violations, transgressions and crimes.

Claimant invites Respondent to attest to the contrary.

I, Michael J Sutherland (Claimant), state on penalty of perjury that I believe the facts stated in this document (Ref: NE013712676GB) to be accurate and truthful. I understand that proceedings may be brought against anyone who makes, or causes to be made, a false statement without an honest belief in its truth.

Signed _____ Date _____