Dear Margaret

Please find attached the protocol requested by the Committee today.

With kind regards

Ray Mitchell
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PROTOCOL FOR RELEASE OF PATIENT SLIDES

1. On receipt of a request from a patient (or their representative) seeking access to patient slides relating to their participation in the national cervical cancer screening programme, the HSE/NSS will first take reasonable steps to verify the identity of the requester. Where a request is made by a legal representative on behalf of a client, the signed authority of the patient (or in the case of a deceased patient, of a family member) will be sufficient evidence of same.

2. The HSE/NSS will ask the requesting patient (or their representative) to nominate:
   a. the pathologist and laboratory to which they wish their slide(s) to be released, together with a shipping address for that laboratory; and,
   b. the secure courier who will effect the safe transfer of the slides to that pathologist and laboratory. (Alternatively, the contracted laboratory may arrange for a secure courier to send the slide(s) to the patient’s nominated pathologist/laboratory).

3. Unless otherwise agreed in advance with the HSE/NSS, slides will only be released to an accredited laboratory certified as complying with international standard ISO 15189 (or equivalent).

4. The requesting patient (or legal representative of the patient/deceased patient) will also be asked to confirm their agreement that:
   a. neither they nor their nominated pathologist will remove any existing or apply any new markings to the slide(s) unless permitted to do so by order of a court;
   b. they will notify their nominated pathologist that any existing markings are not to be removed or any new markings applied to the slide(s) without the prior approval of the court;
   c. where the removal of markings is technically feasible and is permitted by order of the court upon application by the requesting patient, the requesting patient agrees that such markings will be removed solely by the relevant laboratory contracted to the HSE/NSS;
   d. the slides will be returned by the requesting patient to the HSE/NSS or contracted laboratory in a secure fashion within a period of not more than 20 working days (or 10 working days in the context of legal proceedings that are being fast-tracked through case-management);
   e. it shall be the responsibility of all parties, including couriers, laboratories and experts instructed by the parties, to take all appropriate care of the slides whilst in their possession or control in accordance with best practice for the carriage, handling, examination and care of cytology materials and to ensure that slides at all times remain in the same condition they were in at the point of their release;
   f. upon the return of the slides, and subject to such order as may be made by the Court upon application by the HSE/NSS or the contracted laboratory, post-cancer diagnosis markings may be removed by the
HSE/NSS or the contracted laboratory for the purpose of such forms of review as the HSE/NSS or the contracted laboratory may wish to commission; and,

g. slides may be released in due course (in anonymised or pseudonymised format) to the International Clinical Expert Review Panel established by Government to review issues relating to the cervical screening programme generally.

5. Upon confirmation of the matters set out above, the HSE/NSS and/or contracted laboratory (depending on where the slide is held) will:

   a. before releasing any slide, take a range of high resolution digital images of the slides, showing all markings presently appearing on them, which will be made available to the requesting patient or their representative on request as soon as practicable; and,

   b. send the slide(s) to the patient’s nominated pathologist/laboratory by secure courier (whether nominated by the patient or otherwise arranged by the contracted laboratory).

6. The NSS or contracted laboratory will take and make available to the patient or their representative the high resolution digital images referred to at point 5a on request and as soon as practicable save that they shall not be required to make them available within a period of less than 5 working days (in the context of legal proceedings that are being fast-tracked through case-management) or 10 working days in all other cases.