FINAL DRAFT
v1.0
07/12/21

Information for PANORAMIC Hubs

The importance of the PANORAMIC study

The PANORAMIC study is a non-commercial study funded by the NIHR, and supported by the Antivirals Task Force, which will determine the clinical and cost-effectiveness of novel oral antiviral agents used in the community to treat patients with COVID-19. It is a national priority study, endorsed by the CMOs of all four UK nations and will provide the evidence-base for decisions on the deployment of oral antivirals in primary care. With regard to molnupiravir, this would add to the evidence already provided by MSD in their MOVe-OUT study, but conducted in a UK population, who are predominantly vaccinated and where there are different variants circulating.

Hub and Spoke model for PANORAMIC

The model agreed in the PANORAMIC protocol is that "Potential participants can be referred to Hubs by other healthcare facilities for possible inclusion". On advice from the HRA this has been identified as a **clinical referral** i.e. it is primarily for the purpose of clinical care providing an opportunity for the patient to access treatments in the context of a research trial (full details in *Appendix 1*). The model is to have a number of GP practices undertaking clinical referral of potentially eligible patients into the local PANORAMIC Hub, which then functions as a research site.

This document focuses on the activities of Hubs. For Spoke information, please see the equivalent Spoke site document.

Hub Activities

For participants identified at the Hub, or for those referred from Spoke sites to the Hub, a GP, Research Nurse or other healthcare professional from the Hub will complete recruitment procedures, screening, baseline, informed consent and eligibility review. Participants will be provided with a participant pack (containing the antiviral agent, if randomised to this arm), potentially issued by the Hub or sent directly to participants' homes. The Hubs will also allow additional safety monitoring visits where required and as defined in the Intervention Specific Appendix (ISA). A Principal Investigator at each Hub will provide trial oversight for participants recruited via the Hub.

In summary:

***Hub recruitment from own patient lists*:**

1. Hub practices **identify SARS-Cov-2 positive patients** daily in their practice; they can use the PRIDES IT searches available for SystmOne and EMIS. Longer term the NHS Digital Identification Platform, currently being developed, will be used. Patients may also be identified via routine care.

2. **Screen** patient lists to exclude patients known to be pregnant, breastfeeding or currently in hospital.
3. **Contact the patient via phone** (if a patient is unobtainable on the phone, send an agreed text with an invite to call the practice back) and undertake a **full study eligibility check** and **consent the patient** for participation in the study.
4. The Hub can check eligibility online using Spinnaker (site users will be provided with unique log-in details).
5. **Appropriate SNOMED codes are entered** in each patient's clinical record (see *Flowchart 2*) as well as any clinical detail considered to be relevant.

Recruitment of participants referred from Spokes:

1. Hub practices will **receive the referred patient details from the Spoke via NHS email (or similar secure route),** on a patient by patient basis**.**
2. Hubs will conduct eligibility and consent as per steps 3-5 above.
3. If eligible and consented, the Hub site will contact the referring Spoke to confirm that the patient has been consented, by NHS email.

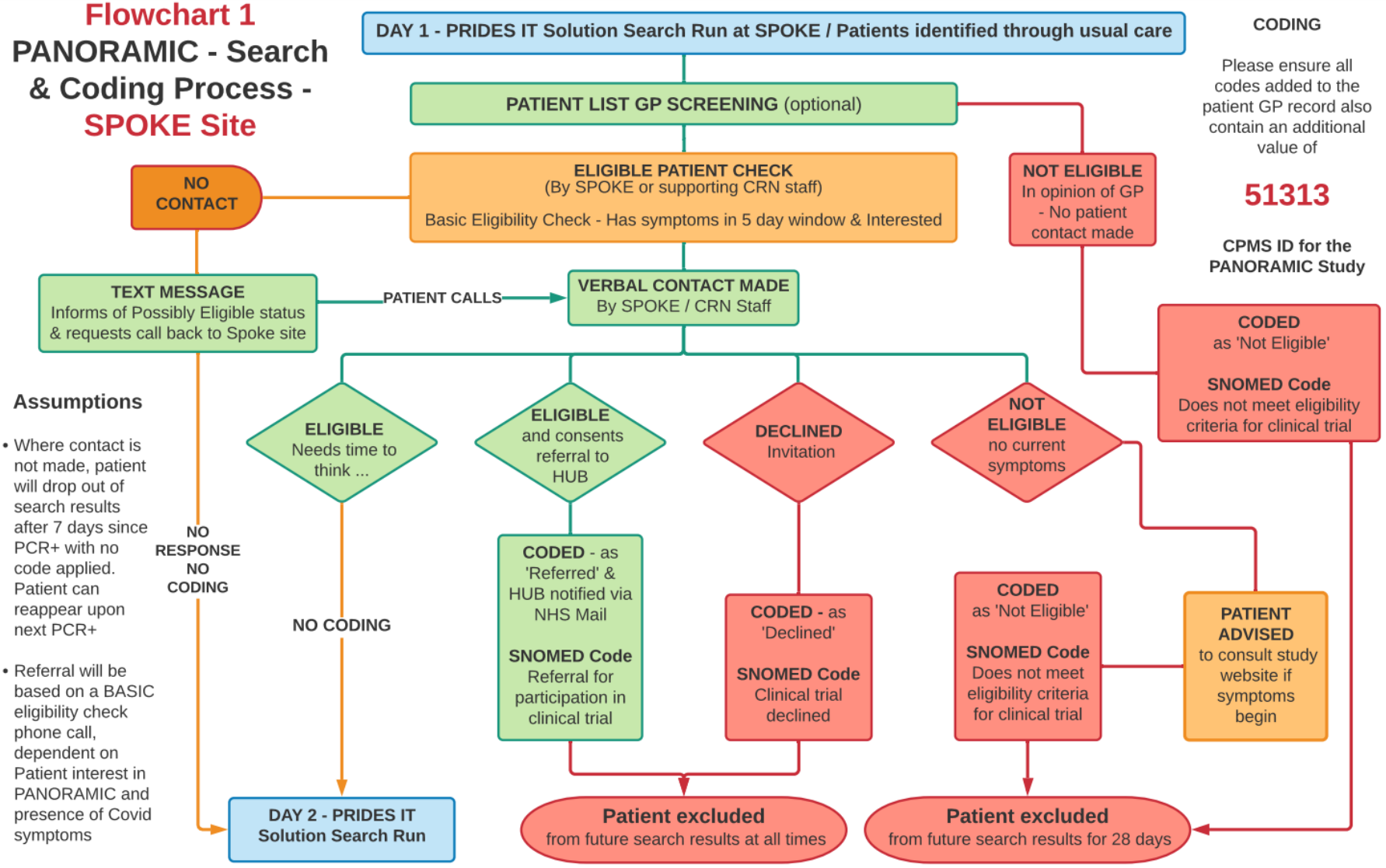
NB: this could be undertaken by **any delegated member** of the practice care team, including CRN support staff, without the need for GCP training.

In addition the **on-going clinical responsibility** for the care of patients recruited from the Hub's own list lies with the Hub practice. This would include continuing care if the patient is randomised to standard of care but also continuing care in the event of worsening COVID-19 symptoms or adverse effects of the IMP.

For patients referred from Spokes, the **on-going clinical responsibility** for their care lies with the Spoke practice, with which the patient is registered, not the Hub.

Funding for Hubs: *Consultation in Use*

Flowchart 1
PANORAMIC - Search & Coding Process - SPOKE Site



CODING

Please ensure all codes added to the patient GP record also contain an additional value of

51313

CPMS ID for the PANORAMIC Study

Assumptions

- Where contact is not made, patient will drop out of search results after 7 days since PCR+ with no code applied. Patient can reappear upon next PCR+
- Referral will be based on a BASIC eligibility check phone call, dependent on Patient interest in PANORAMIC and presence of Covid symptoms

DAY 2 - Search output contains - Patients un-contactable on Day 1 (if PCR+ still recorded in last 7 days) - Patients eligible but need time to consider participation (if PCR+ still recorded in last 7 days) - New patients with PCR+ result in last 7 days & meeting search requirements

DAY 2 - Search output does not contain - Patients contacted on day 1 who have been coded as not eligible, declined or referred

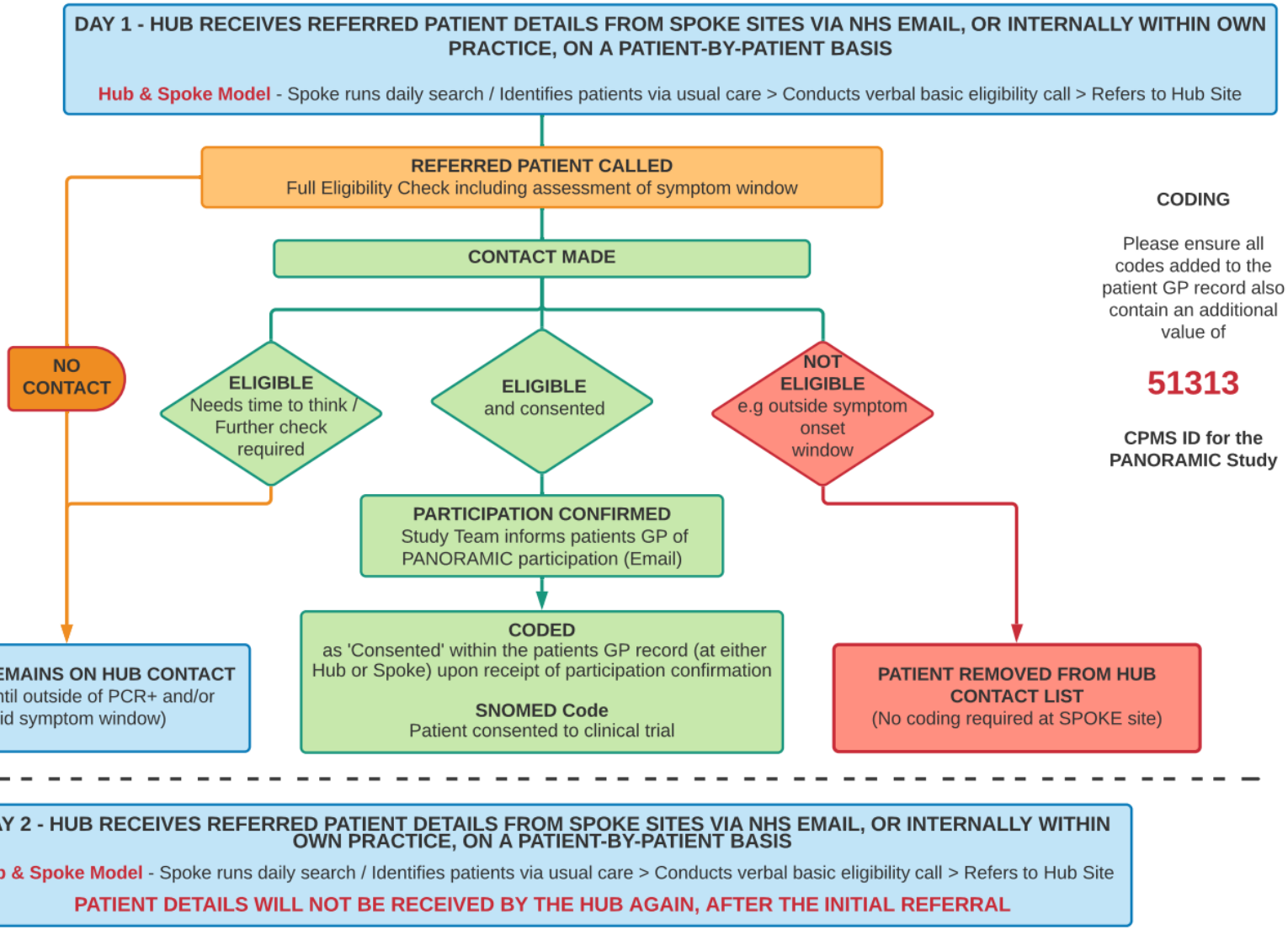
When SPOKE Site receives email notification of consent to participate - SPOKE Site codes patient record to reflect this status (See flow chart 2)

Assumptions

- Where contact is not made, patient will REMAIN on HUB contact list until after 7 days since PCR+ result
- Patients outside of 5 day symptom onset window, or are assessed as Not Eligible for any other reason, will be removed from the HUB contact list
- The HUB will only receive NEW referrals on a daily basis from the SPOKE or from within their own site, once Referral has been made

Flowchart 2 - PANORAMIC - Search & Coding Process

Hub Site processing referrals (from spoke site or own patient list)



CODING

Please ensure all codes added to the patient GP record also contain an additional value of

51313

CPMS ID for the PANORAMIC Study

Appendix 1

HRA clarification regarding clinical referral:

- PANORAMIC will utilise a Hub and Spoke approach to the identification (at Spokes) of patients, potentially eligible to receive the novel intervention, and their referral to Hubs.

- The primary purpose of this referral is not inclusion of an individual within a research study but to offer a patient an intervention that the referring clinician believes may be in the best interest of that patient. The primary purpose is care. That care is being delivered in the context of a real-world trial, as directed by the Secretary of State, but the purpose of the referral is care, not research.

- As such, there is no breach in the duty of confidence arising from the passing of confidential patient information between the Spoke and the Hub. The exchange of information remains within the care team, for the purpose of care. Neither additional consent, nor reliance upon the COPI notice, are necessary to provide an additional common law basis, nor to set aside the common law duty of confidence.

- Additional patient consent is not required, for the exchange of personal data between the Hub and Spoke, under data protection legislation (GDPR or DPA). The usual legal basis and condition for the processing of personal data for care purposes (including special category personal data, i.e. personal data relating to health), apply.

- Whilst consent is not legally required under the common law or data protection legislation, for the exchange of information within the extended care team, it is regarded as good practice for an individual at the Spoke to phone the patient prior to sharing their information. Where contact cannot be made, a text should be sent. In both cases the option for the patient to opt out of the referral should be given and, if taken, respected. This is not consent. It is however an important aspect of processing data transparently and fairly (including as required by the principles of data protection legislation).

- It is not necessary for the individual at the Spoke who contacts the patient to be their registered GP, nor is it necessary for them to hold a substantive or honorary contract with the practice. GPs should carefully select the individuals who will be tasked with performing this care function. In exercising this function, they are part of the care team.

- It is not necessary for Hubs and Spokes to enter into formal data sharing (or data processing) agreements for the purpose of exchanging data for patient care. Data sharing agreements are not legally required. Data processing agreements are legally required (GDPR Article 28(3)) only when a controller/processor relationship exists. Spokes here are not operating as data processors for Hubs. They are operating in their own capacity as care organisations/professionals, making clinical referrals for patient care.