Level 1, 22 Cordelia Street
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22 June 2020

Dear Sponsor or CRO,

Despite the pandemic affecting everyone's lives and business operations globally, at Icon we find ourselves in a strong position with Australia and New Zealand moving into a state of preparedness. This sees Icon Cancer Centre and Icon Research inching closer to 'business as usual', with our focus on increased vigilance via screening and distancing measures to contain community transmission during the winter months. As stated before, staff have had to learn freshly developed protocols for treating patients at various levels of COVID risk and many people have had to work from home and find new ways to share information, have robust debate and make decisions without the normal non-verbal communication to assist.

Icon continues to evaluate Icon Cancer Centre and other site of business operations to segregate the teams on site and to implement working arrangements that limit cross infection. This transition will be assessed to ensure that they are equipped and ready to manage this new way of working before further changes are made and include enforcing the minimum distance of 1.5m between workstations or 1 staff member in a $4m^2$ space.

Icon Research have implemented specific actions and changes to policy that to ensure trial participant safety, compliance with Icon's values and Icon's social distancing and infection control measures are followed. In addition to the changes documented on previous correspondence to Sponsors and CROs at https://iconcancercentre.com.au/research/#covid-19 , Icon Research have further updates to policies and work practices relating to the restriction to on-site monitoring visits, impact of reduction in staff and remote data review by external monitors.

1. Restriction to on-site monitoring visits

On site monitoring visits continue to be postponed until the 1st of July 2020 in accordance with Icon's operational model of Preparedness under the Icon Group COVIDSAFE Workplan. For all interstate visitors, including monitors, they need to apply for a border pass at the following website: https://www.qld.gov.au/border-pass/non-resident-travelling-to-queensland .

For external visitors, such as monitors, based in Queensland and not requiring a border pass, will need to comply with the resection to external closure until July 2020. This restriction applies not only to Icon Head office but also research offices at Icon Cancer Centre clinics and Rivercity Pharmacy.

Icon Research is facilitating a number of alternatives to on-site visits including virtual pre-study meetings, dry site initiation visits, telehealth appointments for study participants, delivery of oral investigational drug to patients, video or phone calls to resolve queries, virtual secure data rooms for remote source data verification and use of digital signatures instead of hard copy wet-ink authorisations.

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2. Staffing at Icon and Icon Research

Currently all Queensland Icon Research teams are able to work at either at Icon Cancer Centre locations or the Icon Research Cordelia Street office as normal provided that adherence to infection control and social distancing policies are followed. The Victorian Icon Research team will continue on a working from home model with attendance at Icon Cancer Centre Richmond on a limited basis and only when required to ensure compliance with clinical research protocols.

3. Data entry and query resolution timelines

The Data Management Team at Icon Research prides itself on the ability to have all clinical trial data entered into electronic data capture (EDC) systems within a 5 day post protocol visit window or other contractually agreed time lines. This is a result of timely and clear communication between Clinical Trial Coordinator staff at Icon Cancer Centre locations and the Data Managers at Cordelia Street. As a result of the COVID-19 pandemic and interruptions to visit management including telehealth consultations, incomplete visit requirements, reduced staffing at both Icon Cancer Centre and Cordelia Street, the management team at Icon Research have increased the acceptable time lines for EDC completion to 10 days post protocol visit window.

4. Remote data review by external monitors

Icon Research uses SiteDocs Portal, a product of TrialDocs, as an electronic investigator site file (eISF) and facility for off-site monitoring of all relevant site-specific, trial-specific and patient-specific data via secure data rooms. This application is managed by the Data Manager Team Lead and the Research Operations Manager and permission would only be granted by them after receiving a request from the Data Manager for the trial. Requests are prioritised according to endpoints of the clinical trial, schedule of data locks and other factors and would require at least two weeks' notice for an appointment in the virtual motoring room. During this two week period CRAs and monitors are required to complete training from TrialDocs, authorisation of a visitor and trial specific Confidentiality Deed and provision of a list of trial participant visits to be reviewed. Please approach your primary Data Manager for the respective clinical trial to request a room.

I would like to thank you for your flexibility, compassion and patience as we adhere to Icon policy, protocol compliance and care for patients and staff concurrently. Please contact me on (07) 3737 4558 or adam.stoneley@icon.team if you have any additional questions or concerns, or refer to updated Letters to Sponsors at https://iconcancercentre.com.au/research/#covid-19 .

Kind regards,

Adam Stoneley

Research Operations Manager, Icon Research