Level 1, 22 Cordelia Street
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16 September 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 and after the winter months. 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.

The safety of our clinical trial participants and staff remains our priority as the COVID-19 affects our normal operations. If Icon's policy affects a clinical trial, sponsors will be contacted as the following changes are being implemented to ensure that enrolled patients are prioritised to receive care in a safe environment. Investigators will work with sponsors to ensure continuity of approved protocols; however expanded patient visit windows, prioritising of clinical trial activities and changes in proposed ways to conduct visits will need to be planned.

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 requirements of the Icon COVIDSafe Workplan.

Keep Well

- Stay at home if you are sick or are a close contact with a confirmed case
- Follow the directions of QLD Public Health for recent attendance at declared locations
- Get tested for COVID-19 if you have symptoms
- Leave work if you become unwell while at work

Keep your space

- Keep 1.5 metres away from others
- Follow our maximum occupancy guide for meeting rooms and breakout areas
- Follow any social distancing markers
- Maximum of 4 people in a lift at any one time

Keep clean

- Clean hands often with soap or hand sanitiser
- Cover coughs and sneezes
- Clean your work surfaces with wipes or cleaner (supplied throughout the site)

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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 visits

On site visits from non-Icon staff have recommenced at limited capacity. Visits need to be pre-approved by the Icon Group CEO in advance and are subject to change at short notice depending on the current government advice. In accordance with Icon Group's COVIDSafe Workplan for the South Brisbane Head Office, only Queensland based visitors are permitted entry into Icon Group premises. Visitors are required to confirm via phone call or email with their Research Data Officer the day prior to the visit that they are well and have not had contact with a confirmed or suspected COVID positive person, are quarantined or advised to be quarantined, or been in a designated hotspot or overseas in last 14 days. The visitor is also required to check the government webpage (QLD Health webpage) for up to date designated hotspots if presenting to site and confirm with the Research Data Officer the day prior to the visit that they have not visited or travelled through a hotspot.

As a minimum external visitors must agree to the site's conditions of entry which include:

- A daily wellness acknowledgement process including a temperature screening check on arrival
- Agree to follow the requirements of Icon Group's COVIDSafe Plan

Also due to the limitations of space in the office and in accordance with our COVIDSafe Workplan, a number of monitoring restrictions have been put in place as follows:

- A maximum of two monitors will be allowed on site at any one time,
- Monitors can only request a maximum of two consecutive monitoring days, &
- Monitors cannot request/book multiple monitoring visits in advance.

Monitoring times are to be between 8:30am and 4:30pm only to allow for time to clean the area. Icon Research staff will be responsible for wiping down the desk, keyboard and mouse before and after the visit.

Icon Research is facilitating a number of alternatives to on-site visits including virtual pre-study meetings, dry site initiation visits, tele-health 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. Use of Microsoft Teams is encouraged to discuss study-related questions while they are at site rather than external visitors sitting with Icon staff which is discouraged under social distancing rules.

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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. Clinical Research Coordinators will continue working in accordance with site specific social distancing requirements and as such 50% of the South Brisbane Research Coordination Team are on site on any given day. 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 Research Data Team at Icon Research has prided 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. Historically this is a result of timely and clear communication between Clinical Research Coordinator staff at Icon Cancer Centre locations and the Data Officers 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 Research Data Team at Icon Research have doubled 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 Research Data Team. Requests for remote off-site review of source data are prioritised according to endpoints of the clinical trial, schedule of data locks, safety concerns and other factors and require at least three weeks' notice for the first appointment in the virtual monitoring room and at least two weeks' notice for subsequent appointments. During this 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 Research Data Officer for the respective clinical trial to request a room.

Icon appreciates the support of our sponsors of our clinical trials ensuring that patients remain on treatment and all safety activities are completed. We ask for patience as we work through the situation, including reducing email traffic, phone communication and expectation of immediate responses from study staff and plans that we cannot predict. 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 Innovation & Operations Manager, Icon Research