Leicester Cardiovascular Biomedical Research Unit

# Work Instruction:

**WI/LCB/026 – caTissue Data Entry (BRICCS)**

Log onto caTissue

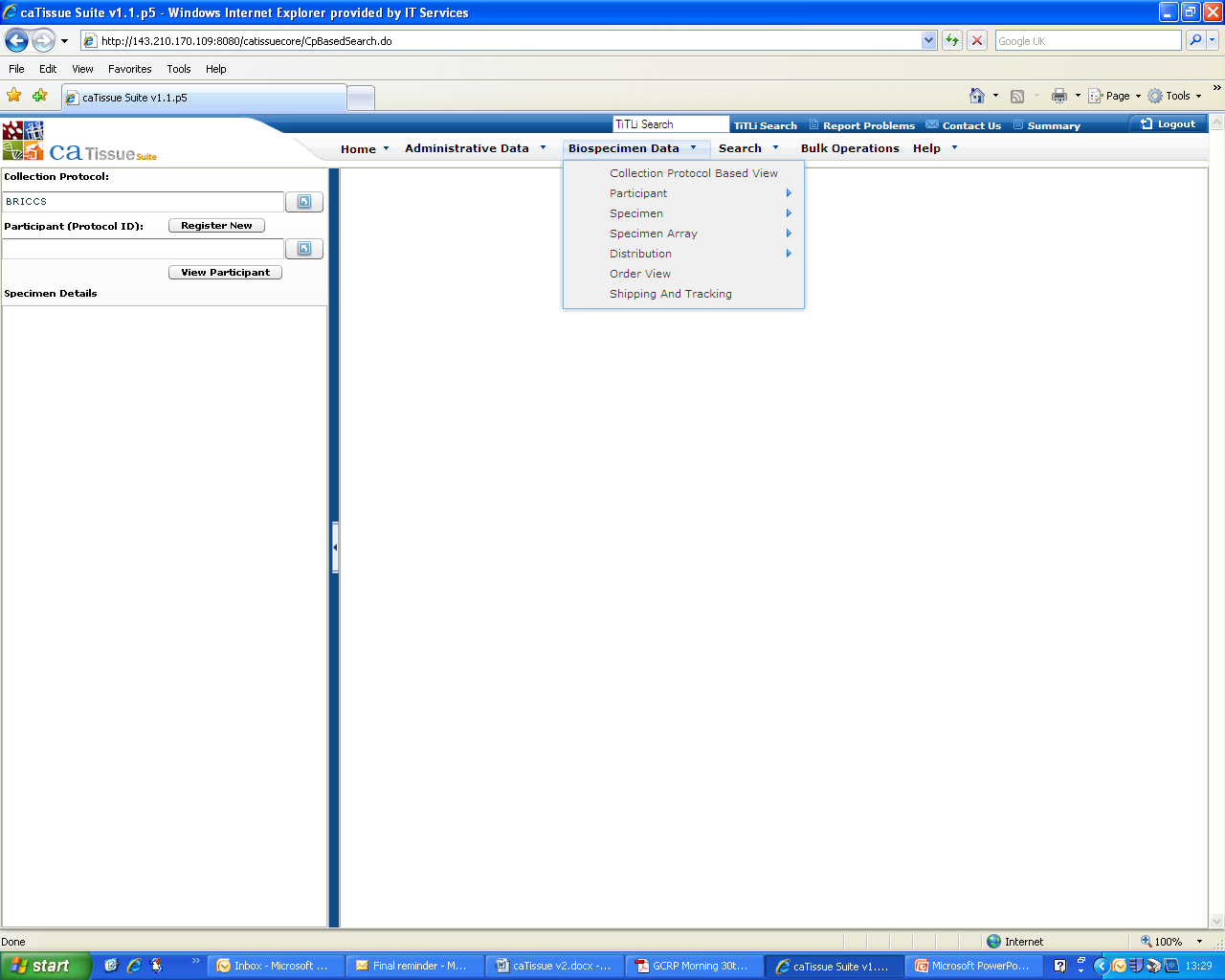
To enable 2D barcode scanning of the aliquot storage tubes, VisionMate needs to be setup as follows:

1. Open VisionMate software.
2. Select single tube mode.
3. Turn keyboard wedge on by selecting “show single tube” under “config”.
4. Set keyboard wedge to TRUE on option list (RHS)

**Registering a new participant on caTissue:**

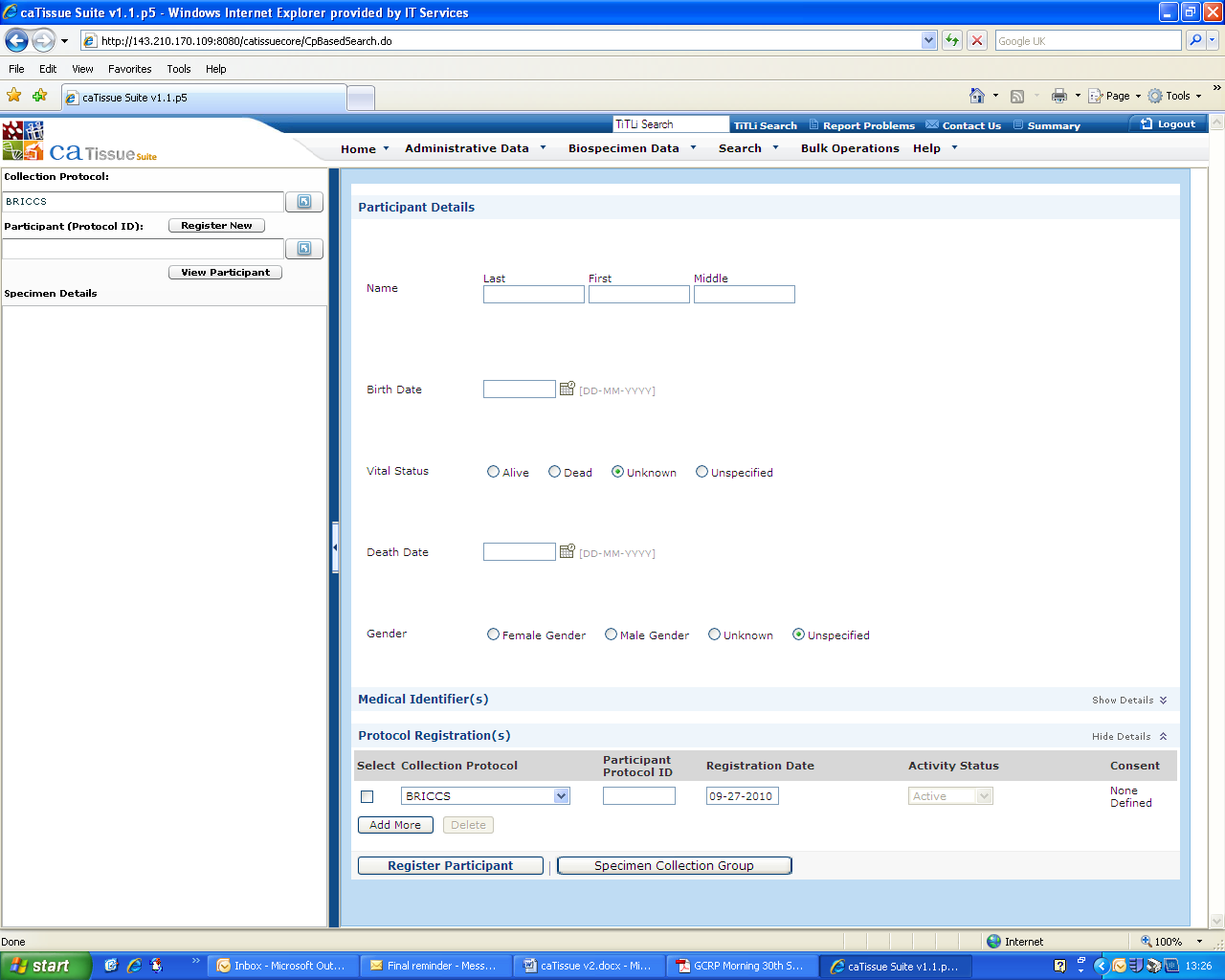
1) Under “Biospecimen Data” drop-down list select “Collection Protocol Based View”

* Select “BRICCS” from the “Collection Protocol” drop-down list on the LHS
* Click “Register New”



2) Within the “Participant Details” section, complete the following:

* **Last name** = BPt number (scan from serum bag)
* **Participant Protocol ID** = Lab processing number (5 digit number e.g. 00171)
* **Registration Date** = Date first specimen collected n.b. date format is mm-dd-yyyy. By default, Today’s date is shown
* Click “**Register Participant**”



3) Click on “Blood Collection” listed under “Specimen Details” on the LHS. Under “Specimen Collection” complete the following:

* **Collection site** = Glenfield Hospital
* Select **Collector** from the drop down list. This will be the person that delivered the samples. Enter the **Date** and **Time** collected (as recorded on the sample bags). n.b. Date format is currently mm-dd-yyyy. Use the calendar to avoid errors. By default, Today’s date is entered.
* Select the **Receiver** from the drop down list. This will be the person in the lab. that checks the samples before they are processed. Enter the **Date** and **Time** received. n.b. Date format is mm-dd-yyyy. Use the calendar to avoid errors. By default, Today’s date is entered.
* Record any issues identified upon receipt of the bloods (e.g. missing samples or low volumes) within the **Comments** field (located below the “Activity Status” field). Aim to use standardised statements explaining the issue(s) - refer to the Protocol Deviations section of this work instruction for examples.
* Issues relating to the delivery and receipt of samples (e.g. late receipt or not delivered on ice) to be entered in **Comments** within the “Received” section under Events
* If the bloods are not all collected at the same time point, this should be noted in the **Comments** field within the “Collected” section under Events.
* Make sure that the box relating to “Specimen entry based on collection protocol” is ticked (located within the “Add Multiple Specimens” section) *even if the set of blood samples is incomplete??*
* Set the **Collection Status** to “Complete” if all blood samples are received (even if some are subsequently discarded due to low volume or poor quality). If samples were delivered late (i.e. after 1.5 hours??) select to “Complete-late”? If some samples were missing from the collection (and are not to be collected at a later date) then select “Incomplete”. If some bloods are missing from the collection and are to be collected at a later date, select “Pending-partially complete”. *n.b. If no blood samples are received (i.e. only Urine is collected from the participant and it is confirmed that bloods will not be taken), what do we do? Enter collection status as “Not Collected”??? but this requires other fields to be collected e.g. collector and receiver??*
* Click **Submit** and agree to propagate times etc across all samples. n.b. if some blood specimens are collected at a different time point then the collection and delivery events for those specimens will need amendment. Make sure these amendments are made before the derivative or aliquot information is entered for those samples otherwise their collection and delivery times will also need amendment to match the parent sample (See Protocol Deviations).

4) Enter all the specimen information for the parent samples in the top section, which is listed in the order Serum, Citrate plasma, EDTA plasma and Whole Blood. Complete the following fields:

* **Barcode** = prefix (s, c, e or b) + lab processing number (5 digits). Prefixes:

s = Serum (brown tube)  
c = Citrate plasma (green tube)  
e = EDTA plasma (red tube)  
b = Whole blood (purple tube)

* **Label** = BSa Number on sample tube. Scan from tube or enter manually
  + Ensure format is BSa not BSA and include all lead 0s
  + For the EDTA plasmas, concatenate the two BSa numbers i.e. BSaxxxxxxxxBSaxxxxxxxxxx
* Tick the “**coll**” boxes for every parent sample entered. \*\*This is critical\*\*

5) Work through each derivative for each parent blood specimen. Use the radio buttons beside each parent blood specimen to navigate. Enter the following:

* Derivative **Label** = prefix + lab processing number (i.e. same entry as in parent barcode field)
  + Two derivative samples are needed to produce the EDTA plasma aliquots because the aliquots have two different volumes (0.5ml and 1ml). These two derivative samples should be labelled as a and b. i.e. e00181a and e00181b
  + For the buffy coat, the 2D barcode from the final storage tube is entered into the derivative label. No further aliquots are produced. The storage location needs to be entered at this level. The default setting for the buffy volume (Qty field) is a cell count of 1000 to represent a 1ml volume. *Should we estimate the volume of buffy stored rather than set the default to 1000?*
* Tick the “**coll**” box for every derivative that exists \*\*This is critical\*\*
* The EDTA plasma, citrate plasma and serum derivatives are recorded as being stored virtually as multiple aliquots are subsequently produced and kept.
  + The Whole blood tube is not processed any further so no derivatives are produced. The storage position needs to be entered for the whole blood tube at the parent level as this sample goes straight into the -80oC freezer after analysis on the haematology analyser.

1. For each aliquot enter the following:
   * **Label** = Enter the 2D barcode in the label field (scan tube using VisionMate or type manually)
   * **Storage Position**: Enter the storage location
   * Tick the “**coll**” box for every aliquot created \*\* This is critical\*\*
2. Once all data has been entered for the blood collection, click **Submit**. All icons on LHS should go purple for the specimens/aliquots that have been entered as collected.

* Click on Urine Collection on the LHS. Enter the following:
  + As for blood collection, enter **collection site** as Glenfield Hospital, select the **collector** & **recipient** and enter the **date** and **time**. Select the appropriate **collection status** and enter any **comments** relating to the collection, as appropriate. Click on **submit**
  + **Barcode** = prefix + lab processing number (e.g. u00181)
  + **Label** = BSa number scanned from urine tube
  + For each aliquot, enter the 2D barcode for aliquot **label**. Click the “**coll**” box and enter the **storage position**

n.b. there is no derivative level for the urine, just parent and aliquots

To find the records for a particular participant, type the BPt or Lab processing number (i.e. protocol participant ID) in the “Participant” box on the LHS. Then click “view participant”. The number entered can be partial.

**Data amendments:**

If data in caTissue requires amending, a reason for making the amendment should be logged somewhere (e.g. in a comments fields) as the audit trail only records who made the change and when.

If the location of a sample needs amending this should be done as a transfer event. Do not edit the location already entered. The reason for the transfer event can be logged in the comments section relating to that event.

Initials needed in comment explaining data amendment??

**Creating new racks and storage boxes:**

**Deleting records:**

**Withdrawal of consent:**

**Protocol deviations – data entry suggestions**

**n.b. Whenever entering data, remember to click Submit before exiting the data entry screen otherwise no changes will be saved**

**A) Specimen not collected:**

1. *At the Specimen Collection Group level:*
   1. Record in the **Comments** field. *e.g. “Serum specimen not collected”*
   2. Set **Collection status** to “Incomplete” (if no further specimens are to be collected)

**B) Specimen collected but discarded before processing (e.g. volume too low):**

1. *At the Specimen Collection Group level:*
   1. Record in the **Comments** field at the “Specimen Collection Group” level.   
      e.g. *“One EDTA plasma specimen (BSa0000xxxxx) was destroyed due to having insufficient volume”* or “Citrate specimen (BSa0000xxxxx) was destroyed due to having insufficient volume” or *“Whole blood specimen destroyed due to leakage after running on Haematology Analyser”*
   2. Enter the **Label** = BSa number. Do not do this if only one of the EDTA plasma specimens is being discarded (see Protocol Deviation C)
   3. Enter the **Barcode** = prefix + lab processing number (e.g. u00181).
   4. Document that the specimen was discarded by logging a disposal event via the events tab as follows:
      1. Select “disposal” from the event list
      2. Enter name of person that disposed of the sample and time disposed
      3. Set **Activity status** to “closed”
      4. Enter reason for disposal in the **Comments** field: e.g. “*Whole blood specimen destroyed due to leakage after running on Haematology Analyser”*

**C) Only one EDTA plasma tube collected or processed instead of two:**

1. *At the Specimen Collection Group level:*
   1. Record in the **Comments** field. e.g. *“One EDTA plasma specimen (BSa0000xxxxx) was destroyed due to having insufficient volume”* or *“Only one EDTA plasma specimen collected”*
2. *At the parent specimen level:*
   1. Enter the **Label** = BSa number and the **Barcode** = prefix + lab processing number (e.g. e00181) of the one specimen processed
   2. Amend Initial and Available volumes from 15ml to 7.5ml
   3. Record in the **Comments** field and state action taken. e.g. *“Only one EDTA plasma specimen collected. Sufficient EDTA plasma was obtained from single specimen”*
3. *At the derivative level:*
   1. Enter both a and b derivative labels as normal (unless not all aliquots were created)
   2. Change the buffy coat volume from 1000 to a 500 cell count.
4. *At the aliquot level:*
   1. Amend aliquot volumes to match those obtained

**D) EDTA plasma volumes too low for plasma storage, but ok for buffy**

1. *At the parent specimen level:*
   1. Enter the **Label** = Concatenated BSa numbers and the **Barcode** = prefix + lab processing number (e.g. e00181) as normal
   2. Record in the **Comments** field and state action taken. e.g. *“Only one EDTA plasma specimen collected but volume insufficient for obtaining plasma. Only buffy obtained”*
2. *At the derivative level:*
   1. Enter the buffy coat information and amend the cell count to match the volume of buffy obtained
   2. Do not enter the a and b derivatives

**E) Sample quality issues e.g. haemolysed, lipaemic:**

1. *At the parent specimen level:*
   1. Record in the **Comments** field and state action taken. *e.g. “One EDTA specimen (BSa0000xxxx) was haemolysed. All EDTA plasma aliquots derived from other specimen. Buffy obtained from both”* Or *“Serum specimen was lipaemic. Five aliquots still created as per protocol”*
2. *At the aliquot level:*
   1. Open the Received event (via the events tab) and select the appropriate option from the **Quality** drop-down list for each aliquot
   2. Amend the aliquot volume as necessary

*Q. Should we record the quality issue at the derivative level too?*

*Q. If aliquots/derivatives are not created, what do we do with the placemarkers? Can we record that they were “not collected” for status but cannot do this without entering a label that doesn’t exist.*

*Q If all bloods appear to be lipaemic or haemolysed should we assume that the whole blood is too and record that in the Comments field at the parent specimen level e.g.“Presumed to be lipaemic/haemolysed as for all other blood specimens. Does this matter for the buffy sample? What does cloudy or coloured urine indicate?*

**F) Sample delivered late (after 1.5 hours):**

1. *At the Specimen Collection Group level:*
   1. Record the delay in the **Comments** field within the “Received” section

**G) Low volume specimen resulting in reduced volumes aliquoted and stored:**

1. *At the parent specimen level:*
   1. Record in the **Comments** field and state action taken. e.g. Only 2mls of urine collected. Aliquots of 0.5mls stored instead of 1ml
2. *At the aliquot level:*
   1. Amend the volume collected as necessary

**H) Blood samples collected over two or more time points:**

1. *At the Parent specimen level:*
   1. Click on the Events tab
   2. Open the collection event. Amend collection event time and date. State in the **Comments** field that specimen was collected at a later time point *e.g. “EDTA plasma specimen collected at 14:30”*
   3. Open the received event. Amend received event and time. State in the **Comments** field that specimen was received at a later time point *e.g. “EDTA plasma specimen received at 14:45”*

*If the parent specimens delivered at a later time point are entered into caTissue at a later time point to the initial collection, then the revised collection and delivery times should be propagated to all derivatives and aliquots. If this does not happen, then each of the derivatives and aliquots will need their times amending via the events tab. n.b. Submitting changes to the specimen collection group data will lead to propagation of the initial collection and delivery time points entered on that screen, thereby overriding amended time points for specimens collected at a different time. Need to avoid this happening.*

**I) Decision made during processing to dispose of sample after entering details on caTissue (e.g. barcode in label field and intended storage location):**

1. *At the aliquot level:*
   1. *Record that the specimen was discarded by logging a disposal event via the events tab as follows:*
      1. Select “disposal” from the event list
      2. Enter name of person that disposed of the sample and time disposed
      3. Set **Activity status** to “closed”
      4. Enter reason for disposal in the **Comments** field: e.g. “*Whole blood specimen destroyed due to leakage after running on Haematology Analyser”*

*Presumably the 2D barcodes cannot be reused but the storage locations in the freezer become available again after a disposal event*

**J) Storage location incorrectly entered into caTissue:**

1. *At the aliquot level:*
   1. Click on the Events tab
   2. Select “Transfer” from event list
   3. Enter new storage location manually
   4. Enter Comment in field to explain the transfer e.g.

**QC checks:**

Cross-check barcodes in scanned box with caTissue box map

**Searches:**

1. Enter 2D barcode – system shows you who patient is (with full list of specimens)
2. Identify collections with a pending status.
3. Select samples based on quality, volume, dates etc…
4. Pull-out Bpt and lab. processing number based on BSa or other criteria (e.g. date collected)
5. Identify missing urines or bloods (select on pending status?)
6. Summary data. Number of participants, number of urine samples, number of blood collections etc..)

**Basic checks:**

Format of 2D barcodes (10 digits)

Format of BSa number

Correct concatenation of prefix and lab. processing number (i.e. urines are u).

Check that receipt is after collection (check may already exist in database)

Check that collector is a collector and receiver is a receiver

Lab processing number consistent for all parents and derivatives (e.g. all have 181)

No “pending” samples (eventually all should have status other than pending)??

**Questions**

Q. If parent sample not received, do we delete the placemarks (i.e. black dots). We can’t log that they are not collected as there is no BSa number for the label field. Do we enter something in the label field so that we can create a record – but this has to be unique?

Q. Where do we log lab processing issues (e.g. centrifuge wrong temperature or spin speed). Time limits exceeded. Which level? Parent, derivative or aliquot

Q. Initial volumes – should these not match what is stored (according to the protocol)or should the leftovers by “disposed of” otherwise the remainder appears available. Should available volume be set to 0 for parents and derivatives that are aliquoted? How is the available field updated?

**Advanced searches**

**Location of data entry fields:**

|  |  |  |
| --- | --- | --- |
| **Field** | **Field name (back end)** | **Data field location** |
| Blood or Urine collection | CollectionPointLabel | Collection Protocol Event |
| BPt number | Last Name | Participant |
| Lab processing number (Participant Protocol ID) | Protocol Participant Identifier | Collection Protocol Registration |
| Registration date onto protocol | Registration Date | Collection Protocol Registration |
| Collection status of blood or urine collection (e.g. Complete, incomplete, pending etc) | Collection Status | Specimen Collection Group |
| Label (parent = BSa, derived = prefix + lab processing or aliquot = barcode) | Label | Specimen |
| Barcode (parent, derived or aliquot n.b. only used for parent e.g. s00299) | Barcode | Specimen |