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Statistical Highlights

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital Admissions</td>
<td>3,431 discharges</td>
</tr>
<tr>
<td>Patient Days</td>
<td>20,608 days</td>
</tr>
<tr>
<td>Average # of dedicated inpatient beds</td>
<td>61</td>
</tr>
<tr>
<td>VICC Outpatient Visits</td>
<td>158,000</td>
</tr>
<tr>
<td>Total Active Clinical Trials</td>
<td>375</td>
</tr>
<tr>
<td>Total # of staff dedicated to clinical research</td>
<td>167</td>
</tr>
<tr>
<td>Total Faculty Members</td>
<td>200+ physicians and advanced practice nurses; 300+ researchers and physician scientists</td>
</tr>
<tr>
<td>New Cancer Patients</td>
<td>&gt; 6250 each year</td>
</tr>
<tr>
<td>NCI-Designated Comprehensive Cancer Center</td>
<td>Yes, one of 49</td>
</tr>
</tbody>
</table>

General Information

Site Background Information

Vanderbilt-Ingram Cancer Center was established in 1993 and awarded NCI-designation in 1995, then status as a comprehensive cancer center in 2001. Vanderbilt-Ingram has more than 280 members devoted to conducting research and providing care for both adult and pediatric cancers. U.S. News & World Report ranks Vanderbilt-Ingram Cancer Center as #1 in Tennessee for cancer care, recognizing our commitment to innovative therapies and research.

Vanderbilt University Medical Center (VUMC) has been named to the ‘Honor Roll’ of the nation's top hospitals by US News and World Report in their 2018-2019 ranking of ‘America’s Best Hospitals’ and is one of only 20 hospitals nationwide to earn this distinction. Vanderbilt-Ingram Cancer Center is the only adult cancer program in Tennessee to be nationally ranked by U.S. News (among the top 50).

Clinical Trials Shared Resource

The Clinical Trials Shared Resource (CTSR) provides services to assist cancer center investigators in developing, activating and completing scientifically meritorious clinical trials in an efficient, cost-effective and technically sound manner.
CTSR Contact Information

Medical Director:
Name: Vicki L Keedy
Email: vicki.keedy@vumc.org
Phone: 615-322-4967
Fax: 615-343-7602
Title: Clinical Trials Shared Resource Medical Director, Assistant Professor of Medicine
Department: Hematology/Oncology Division
Location: 777 Preston Research Building
Nashville, TN 37203

Initial New Study Contact:
Name: Catherine D. Gregor
Email: catherine.d.gregor@vumc.org
Phone: 615-875-0041
Title: Assistant Director, Operations
Location: 3322 West End Avenue, Suite 1000
Nashville, TN 37203

Research Operations:
Name: Catherine D. Gregor
Email: catherine.d.gregor@vumc.org
Phone: 615-875-0041
Title: Assistant Director, Operations
Location: 3322 West End Avenue, Suite 1000
Nashville, TN 37203

Clinical Operations:
Name: Teresa J. Knoop
Email: teresa.knoop@vumc.org
Phone: 615-936-5848
Fax: 615-936-3026
Title: Assistant Director, Clinical
Location: 1301 Medical Center Drive
Nashville, TN 37203
CTSR Contact Information (cont.)

Compliance Office:
Name: Valerie A. Kordowski
Email: valerie.kordowski@vumc.org
Phone: 615-936-7651
Fax: 615-343-9273
Title: Assistant Director, CTSR Compliance
Location: 525 West End Avenue, Suite 800
Nashville, TN 37203

Pharmacy:
Name: Donna K. Torr
Email: donna.k.torr@vumc.org
Phone: 615-343-2882
Fax: 615-322-3017
Title: IDS Supervisor
Location: 1301 Medical Center Drive
TVC 2906
Nashville, TN 37203

Quality:
Name: Casey H. Braddy
Email: casey.h.braddy@vumc.org
Phone: 615-936-5179
Title: Manager, Quality Assurance
Location: 3322 West End Avenue, Suite 1000
Nashville, TN 37203

Regulatory Affairs:
Name: Rebecca Abel
Email: rebecca.abel@vumc.org
Phone: 615-936-352
Title: Regulatory Manager
Location: 3322 West End Avenue, Suite 1000
Nashville, TN 37203
CTSR Contact Information (cont.)

Data:
  Name: Chelsea R. Henrichs  
  Email: chelsea.henrichs@vumc.org  
  Phone: 615-875-9654  
  Fax: 615-936-5850  
  Title: Manager, Data  
  Location: 3322 West End Avenue, Suite 1000  
  Nashville, TN 37203

Laboratory Processing:
  Name: Heather M. Barnes  
  Email: heather.barnes@vumc.org  
  Phone: 615-936-3428  
  Fax: 615-936-7626  
  Title: Program Manager, Clinical Trials Processing Core  
  Location: 636 Preston Research Building  
  Nashville, TN 37203

Clinical Cancer Center Sites
  "all parking is free"

Preston Research Building/Vanderbilt-Ingram Cancer Center
2220 Pierce Avenue South
Nashville, TN 37232
Parking: Valet. The nearest garage is South Garage, across Pierce Avenue

Medical Center East
1215 21st Ave., S.
Nashville, TN 37232
Parking: Entrance to East Garage and access to valet station is off 21st Avenue on Dixie Place.

The Vanderbilt Clinic
1301 Medical Center Drive
Nashville, TN 37232
Parking: Valet. A skybridge connects to East Garage on the second, third and fourth floors.
The Village at Vanderbilt
1500 21st Ave., S
Nashville, TN 37232
Parking: Behind the building.

Vanderbilt Dayani Center
1500 Medical Center Drive
Nashville, TN 37212

Gateway-Vanderbilt Cancer Treatment Center: Clarksville
375 Alfred Thun Road
Clarksville, TN 37040

Vanderbilt-Ingram Cancer Center Cool Springs: Franklin
324 Cool Springs Blvd.
Franklin, TN 37067

Vanderbilt-Ingram Cancer Center Franklin
2107 Edward Curd Lane
Franklin, TN 37067

Vanderbilt Health One Hundred Oaks: Nashville
719 Thompson Lane
Nashville, TN 37204

Vanderbilt-Ingram Cancer Center at NorthCrest Medical Center: Springfield
500 NorthCrest Drive, Suite 521
Springfield, TN 37132

Vanderbilt-Ingram Cancer Center at Maury Regional Spring Hill
1003 Reserve Boulevard
Radiation Therapy: Suite 120
Medical Oncology: Suite 240
Spring Hill, TN 37174
General Questions

What phases of studies are conducted on site?
First in Human, Phases I-IV

Adult and Pediatric?
Yes

What is the primary location (name and address) to be listed on the 1572?
Henry Joyce Cancer Clinic
1301 Medical Center Drive
Nashville, TN 37232

What additional sites are affiliated with the primary location?
Vanderbilt Breast Center at 100 Oaks
719 Thompson Lane, Ste. 25000
Nashville, TN 37204

What are the therapeutic areas of expertise?
At Vanderbilt, we treat patients with all types of cancer, including rare, complex and advanced cancers that require deep expertise. We treat:

<table>
<thead>
<tr>
<th>Blood cancers</th>
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<tbody>
<tr>
<td>Bone cancers and sarcomas</td>
</tr>
<tr>
<td>Brain tumors</td>
</tr>
<tr>
<td>Breast cancer</td>
</tr>
<tr>
<td>Childhood cancers</td>
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<tr>
<td>Endocrine tumors</td>
</tr>
<tr>
<td>Gastrointestinal cancers</td>
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<tr>
<td>Gynecologic cancers</td>
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<tr>
<td>Head and neck cancers</td>
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<tr>
<td>Lung cancers</td>
</tr>
<tr>
<td>Pancreas cancer</td>
</tr>
<tr>
<td>Prostate cancer</td>
</tr>
<tr>
<td>Skin cancers</td>
</tr>
<tr>
<td>Spine and nervous system cancer</td>
</tr>
<tr>
<td>Testicular cancers</td>
</tr>
<tr>
<td>Urological cancers</td>
</tr>
</tbody>
</table>
What networks / cooperative groups are affiliated with VICC?

National Cancer Institute (NCI)
National Clinical Trials Network (NCTN)
Alliance for Clinical Trials in Oncology (Alliance)
Children’s Oncology Group (COG)
Eastern Cooperative Oncology Group (ECOG)
NRG Oncology Group (NRG)
Southwest Oncology Group (SWOG)
National Comprehensive Cancer Network (NCCN)
Pediatric Blood and Marrow Transplant Consortium (PBMTIC)
The Blood and Marrow Transplant Clinical Trials Network (BMT CTN)
Gynecologic Oncology Group (GOG)
Experimental Therapeutics Clinical Trials Network (ETCTN)
Translational Breast Cancer Research Consortium (TBCRC)

Does your site follow International Conference Harmonization (ICH) and Good Clinical Practice (GCP) guidelines?

Yes

Association for the Accreditation of Human Research Protection Programs (AAHRPP)
Certification:
Yes, since 2004

College of American Pathologists (CAP) Certification:
Yes

Clinical Laboratory Improvement Amendments (CLIA) Certification:
Yes

Fraud, Waste and Abuse (FWA) Certification:
Yes, VUMC FWA#00005756, expires 7/25/2023

Magnet Certification:
Yes, On July 20, 2017, VUMC learned from the American Nurses Credentialing Center (ANCC) that it achieved its third Magnet designation. The first designation was in November 2006 and second designation in April 2012.

Other Institutional Designations and Accreditations:

- Blue Distinction Center for Complex and Rare Cancers (Blue Cross Blue Shield Association/Blue Cross Blue Shield of Tennessee)
- Joint Commission on Accreditation of Healthcare Organization
• American College of Surgeons Commission on Cancer
• American Nurses Credentialing Center Magnet Recognition Program
• National Marrow Donor Program affiliate
• American Association of Cancer Institutes
• Foundation for the Accreditation of Cellular Therapy (blood and bone marrow transplant program)
• Clinical Laboratory Improvement Amendment (blood and bone marrow transplant program)
• Two NCI Specialized Programs of Research Excellence (gastrointestinal and breast cancer)
• Association for the Accreditation of Human Research Protection Programs
• Breast Imaging Center of Excellence (American College of Radiology)
• National Accreditation Program for Breast Centers (American College of Surgeons)

**What resources are available to support the conduct of research at VICC?**
The Clinical Trials Shared Resource (CTSR) provides services to assist cancer center investigators in developing, activating and completing scientifically meritorious clinical trials in an efficient, cost-effective and technically sound manner. The CTSR provides services to assist investigators with:

• Budget and contract negotiation
• Protocol and letter of intent development
• Regulatory compliance
• Study start-up
• Data management
• Research nursing
• Auditing
• Patient referral program
• Eligibility review
• Quality assurance
• Multi-site trial management
Study Teams

**Who are the Physician Team Leads?**
- Thoracic - Leora Horn, MD
- Sarcoma - Vicki Keedy, MD
- GI/Phase I/Multi-Disease - Jordan Berlin, MD
- Bone Marrow Transplant - Madan Jagasia, MD
- Hematology - Michael Savona, MD
- Breast - Ingrid Mayer, MD
- Head and Neck - Michael Gibson, MD
- Neurology - Reid Thompson, MD
- Melanoma - Doug Johnson, MD
- Urology - Nancy Davis, MD
- Gynecology - Marta Crispens, MD
- Plasma Cell Dyscrasias / Lymphoma - Frank Cornell, MD

**How many potential principal investigators?**
> 120

**Will the PI and study coordinator be able to attend an investigator meeting?**
Yes

**Is additional investigator background available on request?**
Yes, more information may be obtained once an investigator has been identified including, but not limited to:
- The patient population to which the investigator has access
- The investigator’s research study experience
- The number of research studies the investigator has conducted and in which specific disease(s)/condition(s)

**Do you have designated personnel to meet the study requirements?**
The CTSR has the following study team members available to support clinical research projects:
- Research Nurses (RNs)
- Clinical Research Coordinators
- Licensed Practical Nurses (LPNs)
- Data Coordinators
- Clinical Trial Managers
- Regulatory Coordinators
Will the PI be available during a monitoring visit to meet with the Clinical Research Associate (CRA)?
Yes, with time and date confirmed in advance.

What is the average # of studies research nurses / coordinators may be assigned at any given time?
The number of studies each research nurse / coordinator works on depends on the requirements and complexity of the studies.

At your site, does the same individual prepare the study medication and administer the drug?
No; VICC has an investigational pharmacy with dedicated research staff utilized for drug preparation. Study drug is administered by appropriately licensed staff.

Can research nurses / coordinators conduct home visits?
Yes, a nurse practitioner home visit program.

Are your lab personnel HAZMAT or IATA certified (equivalent certification is acceptable)?
Yes

Does your staff have radiotherapy credentials?
Yes

Is radiotherapy given as standard fractionation, hyper fractionation, and/or accelerated?
All are available.

What are the requirements for monitor and auditors?
External monitors and auditors must complete an electronic medical records application form, review the site confidentiality form, as well as provide a state issued ID at first visit, prior to obtaining access to study areas.

Do your research study personnel complete HRPP and GCP training?
Yes, HRPP annually and GCP every three years; documentation of training is available upon request.
Participant Population

Demographic statistics about the geographic area and others who come into the site:

Patients come to Vanderbilt-Ingram Cancer Center from the Nashville metropolitan area (36%), State of Tennessee (39%) and United States (25%). VICC’s catchment area is defined as the state of Tennessee, western Kentucky and northern Alabama, and clinical trial participation data are compared with the “cancer patient population” of this area.

The most recent National Cancer Institute Surveillance, Epidemiology, and End Results (SEER) data estimate in 2015, of the 40,537 newly diagnosed cancer cases in the catchment area, 87% occurred among White residents, 12% among African-American and 1% among Hispanic.

Recruitment and Referrals:

Depending on the prioritization flow chart for each disease team and the individual recruitment and retention needs of the study, a participant recruitment plan is customized using various appropriate strategies and tactics. Some of the recruitment and retention tactics are:

- The Vanderbilt-Ingram Service for Timely Access (V-ISTA) program helps prospective patients schedule new patient appointments and helps new patients connect with the appropriate clinical trials
- Public relations activities through Marketing and Communications Department
- Community events such as baby, family and senior expos and health fairs where face to face contact may be made and study materials distributed
- Partnering with community groups (locally and nationally) to disseminate study information through web sites, networks, newsletters, special events/meetings and in-person presentations
- Hospital, outpatient and satellite clinics and community-based practice referrals via the Vanderbilt Health Affiliated Network and academic affiliations
- Internet, radio, television, newspaper (daily and community) advertising, as well as special interest magazines, and others
- Site publications including print and electronic newsletters, magazines and other publications
- CenterWatch (largest clinical trials web site), targeted web advertising and social media
Do you use a referral network of other specialists or General Practitioners for recruiting patients, advertising, or any other support (i.e., patient association, hospital patient database) for recruitment?
   Yes, Vanderbilt Health Affiliated Network (VHAN) / Referral Physician Newsletter (internal/external)

Are there institutional policies that would prevent the collection of the specimens for purposes of this clinical study?
   No

Would participants be able/willing to give archived tissue?
   Yes

IRB/Regulatory

Do you agree to have monitoring visits, sponsor audits and IEC/IRB and regulatory inspections conducted during the course of the clinical trial?
   Yes

Do you have patients whose first language is not English?
   Yes, multiple IRB approved short forms available, as well as certified translators and translator hotline

Do you use off-site storage?
   Yes, for archived studies.
   Iron Mountain
   415 Brick Church Park Drive
   Nashville, TN 37207

Can regulatory documents be collected simultaneously with the contract/budget and IRB review/approval process?
   Yes

Is the use of a central IRB permitted?
   Yes, for federally-funded studies. All industry-sponsored studies must be reviewed and approved by the VUMC IRB.

How often does the local IRB meet?
   Weekly; there are four boards.

What is the submission time prior to an IRB meeting?
   Generally, 10 business days.

What is the turnaround time for written approval documentation from the IRB?
   The total turnaround time from submission to written approval is six to eight weeks.
What is the complete name and address of the IRB?
Vanderbilt University Institutional Review Board
3319 West End Ave, Suite 600
Nashville, TN 37203

Have you been audited by the FDA and if so have you been issued any 483 warnings?
Select studies have been audited by the FDA and there were no 483 warning letters issued.

Is there a need to have informed consent documents translated into other languages?
No, unless required by the sponsor.

Are there any other committees that need to approve the protocol?
The Scientific Review Committee (SRC) ensures that all cancer clinical trials conducted under the auspices of the Vanderbilt-Ingram Cancer Center meet peer-reviewed standards of scientific design, including appropriate scientific rationale, specific aims, study endpoints, biostatistical analysis, and adequate ability to accrue patients. These criteria exist in order to ensure that the study is conducted in accordance with the scientific principles and integrity maintained by the Vanderbilt-Ingram Cancer Center, that the scientific aims of the study can reasonably be met, and that Cancer Center resources used to support clinical investigation are appropriately and wisely used.

How often do these other approval committees meet?
Bi-monthly

Are there informed consent language requirements?
Yes, for subject injury language and HIPAA.

Are original informed consents available for review by the sponsor/monitors?
Yes

What is the turnaround time for written approval documentation for these other approval committees?
SRC approval should be within 5 business days after meeting.

What is the timeframe for query resolution?
VICC CTSR's standard data entry and query resolution timeframe is 10 business days.
Contracts and Budgets

Do you require that the contract and budget are finalized before submitting to the IRB for initial approval?
No, these activities occur in parallel.

Who is responsible for budget negotiations?
Clinical Trial Shared Resources (CTSR) Financial Analyst

Will budget negotiations begin with a draft protocol?
No, we prefer to have a final protocol.

What is your overhead (indirect) rate for industry-sponsored studies?
29%

Do you have standard institutional fees?
Yes, including committee review, study start up and administrative fees.

Do you have a separate department(s) responsible for contracts?
Yes, Office of Contracts Management

Will site accept a unilateral confidentiality disclosure agreement?
Yes

What is the average time for negotiation of clinical research contract at your site?
The target is 90 days.

Payment Information:

<table>
<thead>
<tr>
<th>Tax ID</th>
<th>35-2528741</th>
</tr>
</thead>
<tbody>
<tr>
<td>Industry Sponsored Contracts (ACH Payment):</td>
<td>The Bank of New York Mellon</td>
</tr>
<tr>
<td></td>
<td>Mellon Client Service Center</td>
</tr>
<tr>
<td></td>
<td>500 Ross Street, Room 154-0940</td>
</tr>
<tr>
<td></td>
<td>Pittsburgh, PA 15262-0001</td>
</tr>
<tr>
<td></td>
<td>Ph: 412.369.2825 or 412.234.3347</td>
</tr>
</tbody>
</table>

| Courier, FedEx, UPS or Express Mail: | Vanderbilt University Medical Center |
|                                      | VUMC Finance, Attn: Paula Yarbrough, Director |
|                                      | Box 891236 |
|                                      | 1501 North Plano Road, Suite 100 |
|                                      | Dallas, TX 75081 |

| Wire/routing: | ABA Routing: 043-000-261 |
|               | SWIFT Code: MELNUS3P |
|               | Bank Account Number: 9037889 |
|               | Bank Account Name: Vanderbilt University Medical Center VUMC NON L/C |
|               | Reference: VUMC (or VICC) invoice number |
Facilities

Review of beds and care centers:

<table>
<thead>
<tr>
<th>Outpatient Locations</th>
<th># of Infusion Chairs/Beds</th>
<th>Inpatient Units</th>
<th># of Inpatient beds</th>
</tr>
</thead>
<tbody>
<tr>
<td>Main Campus</td>
<td>64</td>
<td>Stem Cell Transplant/Myelosupression Unit</td>
<td>35</td>
</tr>
<tr>
<td>One Hundred Oaks</td>
<td>19</td>
<td>Vanderbilt University Hospital - Cancer Unit 11N</td>
<td>27</td>
</tr>
<tr>
<td>NorthCrest</td>
<td>8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cool Springs</td>
<td>10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spring Hill</td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TOTAL</td>
<td>104</td>
<td>TOTAL</td>
<td>62</td>
</tr>
</tbody>
</table>

Does your site offer tours of the facilities?
Yes, this can be coordinated through the Clinical Trial Manager for the study portfolio. A virtual tour available upon request.

Laboratory:

Are there on-site laboratory processing facilities?
Yes, the Clinical Trials Processing Core (CTPC) and local clinical laboratory

Are there qualified staff members to draw blood and prepare multiple samples for shipping? Tumor tissue? Frozen samples?
Yes; there is a dedicated Clinical Trials Processing Core to support this work.

Does the research staff have access to dry ice?
Yes

Is a -70/-20 specimen storage freezer available?
Yes

Is there designated research space?
Yes

Please explain the procedure followed in the event of equipment malfunction:
If there is equipment failure, all specimens are immediately transferred to a backup refrigerator/freezer in the Clinical Trials Processing Core. There are additional backup refrigerators/freezers in a separate lab located in close proximity.

Access to a refrigerated centrifuge?
Yes
Is your site capable of compounding Bio-Safety Lab-2 preparations?  
Yes

Does your site perform centrifuge calibrations?  
Yes: annually

Does your site have a BSC and laminar flow hood?  
Yes: We meet the requirements for USP 797 compliance for sterile preparations.

Access to a freezer and liquid nitrogen?  
Yes: liquid nitrogen, -86 C and -20 C

Do you have a cellular lab and/or apheresis lab?  
Yes

Does your site perform freezer calibrations?  
Yes: annually

Are freezers on backup power/monitoring system?  
Yes: all monitored 24/7 and on backup generator

Time restrictions on storage:  
Maximum 6 months of storage

Can you process cells and perform cell count?  
Yes

Pharmacy:

Does your pharmacy have drug destruction policies and procedures?  
Yes, our Standard Operating Procedures are sent to the sponsor at the Site Initiation Visit.

Are there on-site investigational pharmacies with locked storage?  
Yes

Is the drug storage facility temperature-controlled?  
Yes, temperature Standard Operating Procedure is available upon request.

Does your pharmacy have a Good Manufacturing Practice license?  
No

Does someone from pharmacy attend the Site Initiation Visit?  
Yes

Does someone from pharmacy attend the pre-site qualification visit?  
Yes
Does your site have calibration certificates available for the drug storage equipment (i.e. refrigerator, freezer)?
Yes, the equipment is calibrated quarterly and the calibration tool used is calibrated annually. Calibration certificates for the equipment are available upon request.

Is your pharmacy or site staff willing to collect batch numbers of drugs?
We will collect lot numbers and/or kit numbers for investigational products that are provided by the sponsor on the DARF as indicated per the protocol.

How are temperatures recorded for freezers?
Temperatures readings are monitored through radio-frequency identification (RFIDs). All of the Investigational Drug Services Refrigerators/Freezers are connected to a back-up generator. Please refer to Temperature Standard Operating Procedure.

Radiology:

What type(s) of scans will your site be able to perform or have access to?
- MRI
- CT
- PET
- PET/CT
- Ultrasound
- Bone Scan
- 68 Gallium Dotatate Scan

Does your site have the capability to access imaging data (i.e. digital CT/MRI images) from a computer that has an internet connection?
Yes

Is your site able to obtain multiple ECG assessments using equipment provided to you and transmitting the results electronically to a central ECG service provider?
Yes
Computer and Internet

Is there documentation that system users have been trained?
Yes, relevant systems include Epic and OnCore.

Are there written procedures for protection of the electronic records?
Yes

Does the system employ unique IDs and passwords for each user?
Yes, for all institutional systems.

Is there an audit trail / historical electronic log that captures all users’ actions?
For computers, security and system logging is enabled by default. There are additional auditing controls within Epic and OnCore.

Are electronic signatures used in the system?
No, however, original wet signatures are not required; scanned documents are acceptable.

Are sponsors or its designees allowed direct access to electronic systems that contain source data?
Yes, eStar access requires the assignment of a user ID with temporary permission to access Vanderbilt Health Connect for limited panel access. An application for eStar access should be submitted for each individual monitor/study; it can take up to 7 days to process an eStar access request.

Are there multiple access ports for internet use?
Yes

What Windows Operating System (OS) and Service Pack (SP) is used?
Windows 10 Enterprise, Patch level 1709

What is the computer’s processor speed?
Minimum Intel i5, 2.2GHz

What is the computer’s memory (RAM)?
Minimum 8GB

What is the monitor’s display resolution?
Minimum 1600x900

What is the Internet Explorer (IE) version?
Internet Explorer 11

Are there CD-ROM drives?
Yes; in the instance where CD-ROM drives are not installed, external drives are available.
How do the computers connect to the internet?
Stationary computers connect via ethernet. Mobile devices via ethernet when docked, wifi when not.

Is there internet security software installed on the computer?
Windows Defender and/or System Center Endpoint Protection is installed on all Windows computers.

How are data back-ups handled?
No data backups of physical devices. End users utilize shared drives to store business data. Shared drives have 45 day snapshots available and are replicated to an off-site data center.

When changes are made to the system, is there repeat testing and documentation of testing?
Yes.

Is a computer available for EDC data entry at all times throughout the term of the study?
Yes.

Is there an IT/Technical contact available 24/7?
Yes.

Is there a site preference to work with paper source documents or electronic source documents?
Both; a majority of our source is electronic, but some are only paper (ICF, Response assessment, etc.)

Can the CRA connect to the internet while on-site?
Yes, via VUMC guest network.

Does the site prohibit the use of external laptops on the premises?
No.

Does your site have electronic medical records? If yes, is it a validated system compliant with 21 CFR Part 11?
Yes, Epic.

Can the CRA print records from the EHR?
No, copies will be provided as requested for relevant study-related source documentation.

Is there prior site experience with use of an EDC system?
Yes, VICC has experience with many EDC Systems, such as Inform, Medidata Rave, Oracle, Data Track, etc.