NIH Clinical Center
America's Research Hospital

CLINICAL CENTER PROTOCOL RESOURCE IMPACT ASSESSMENT

PROTOCOL TITLE:

PRINCIPAL INVESTIGATOR, INSTITUTE AND BRANCH

This worksheet is to be completed by principal investigators and should be submitted to the CC PRIA Submission email (PRIASubmission@mail.nih.gov) (along with the protocol and informed consent if available) before scientific review. The completed form will be disseminated to applicable CC Department Heads and Institutes to facilitate early interaction with investigators to assess resource requirements while the protocol is in the human subjects review process. The goal of this review is to assure that resource intensive protocols are identified early in the process and that only necessary tests and procedures are built into the protocol design.

If your protocol changes substantially through the protocol planning process in such a way that it changes your resource requirements, please submit a new, updated PRIA for review.

CLINICAL STATUS OF PATIENTS

Protocol Patient Overview (provide information for all items below)

Length of Study (in years):

Total patient enrollment for length of study:

Patient location (check all that apply, and specify locations if known):

- ☐ Outpatient Clinic
- ☐ Day Hospital
- ☐ Inpatient Stay

Total number of inpatient days

Total number of outpatient visits

Anticipated length of inpatient stays (in days)

Interval of visits (e.g. weekly, monthly, annually)

Patient accrual projections (e.g. anticipated patients per week)

New protocol or a revision/modification to an existing protocol ***(select one)***

- ☐ New protocol
- ☐ Revision/modification to an existing protocol

New participants or existing from current protocol ***(select one)***

- ☐ New
- ☐ Existing from a current protocol
  Indicate protocol:

☐ Coordination with Walter Reed National Military Medical Center required

☐ Use of Special Clinical Studies Unit for isolation

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Patient Populations (check all that apply) ***Projected Volume/Year***

- ☐ Adults (> 18 Y.O.) ☐
- ☐ Pediatric (3-18 Y.O.) ☐
- ☐ Pediatric (< 3 Y.O.) ☐
- ☐ Genetic family studies ☐

Functional Status of Patients (Check all that apply)

- ☐ Completely Independent – no physical limitations
- ☐ Some limitations, uses aids for mobility, may require adaptation in hospital environments
- ☐ Requires assistance/supervision
- ☐ Requires service dog
- ☐ Dependent for basic Activities of Daily Living (ADL)
- ☐ Requires complete care
- ☐ Requires oxygen therapy
- ☐ Requires supervision due to cognition or behavioral conditions

Disease Process (Check one)

- ☐ None – healthy volunteers/or remission state
- ☐ Stable, no unstable comorbidities
- ☐ Stable, but may have comorbidities
- ☐ Unstable, advanced or progressed disease which may worsen
- ☐ Critical/multisystem involvement
- ☐ Multiple consultants
- ☐ High probability for infectious disease isolation

DEPARTMENT SPECIFIC RESOURCES

Critical Care Medicine (check all that apply)

- ☐ High risk for medical or surgical ICU admission
- ☐ Predisposition to serious infection (e.g., pneumonia, sepsis, septic shock)
- ☐ Underlying disorder or treatment has risk for the development of major organ dysfunction (e.g. hepatic, renal, or cardiac failure)
- ☐ Expected use for intermediate care (e.g. continuous cardio/pulmonary monitoring)
- ☐ Nuclear cardiology procedures
- ☐ Pediatric ICU admissions
- ☐ Predisposition to infection (e.g. pneumonia, sepsis, septic shock)
- ☐ Underlying disorder or treatment has risk for the development of major organ dysfunction (e.g. hepatic, renal or cardiac failure)
- ☐ Induced sputum specimens
- ☐ Central/Peripheral line insertion mandated

IMAGING

Radiology and Imaging Sciences (check all that apply)

Projected Volume/Year

- ☐ CT scans
- ☐ Cardiac CT scans (includes NHLBI CT scans)
- ☐ MRI/cardiac MRI scans
- ☐ PET/CT scans-Nuclear Medicine (clinical)
  - ☐ PET/CT studies with FDG
  - ☐ PET/CT studies requiring other radiopharmaceuticals
    Indicate radiopharmaceutical(s):
- ☐ MRI-PET scan (consult with Dr. Bluemke)
- ☐ Interventional studies
  Specify procedure type:
- ☐ Ultrasound
- ☐ **Weekend** Radiology Studies needed
- ☐ **Nighttime** Radiology Studies

PET Department (Charged to Institute)

Projected Volume/Year

- ☐ PET Scans (Research scans only)
  Indicate radiopharmaceutical(s):
- ☐ Synthesis of radiopharmaceutical (only needed)
  Indicate radiopharmaceutical (s):

Institute Imaging (Requires Direct Coordination with Institute)

Projected Volume/Year

- ☐ NCI Molecular Imaging Center (Dr. Peter Choyke)
  - ☐ MRI Scans
  - ☐ PET
- ☐ NMR Center (Dr. Lalith Talagala)
  - ☐ MRI Scans
- ☐ NHLBI Echocardiography (Dr. Vandana Sachdev)
  - ☐ Trans-thoracic echocardiogram
  - ☐ Trans-esophageal echocardiogram
- ☐ NHLBI Cardiac MRI (Dr. Andrew Arai)
  - ☐ Cardiac MRI Scan
- ☐ NHLBI Cardiac Catheterization (Dr. Robert Lederman)
  - ☐ Right sided heart catheterization
  - ☐ Left sided heart catheterization

Laboratory Medicine (check all that apply) — ***Projected Volume/Year***

- ☐ Bone marrow testing
- ☐ Chimerism testing (bone marrow transplant program only)
- ☐ Hematology flow cytometry
- ☐ Immunology flow cytometry (other than CD4 and T, B, NK tests)
- ☐ PCR based microbe testing
  - Specify test required: ☐
- ☐ Respiratory pathogen panel
- ☐ Gastrointestinal pathogen panel
- ☐ Fungal antigen testing
- ☐ Specialized contract (off-site) reference laboratory tests
- ☐ Mass spec/HPLC testing
- ☐ Chemistry serial testing panels
- ☐ Malaria testing
- ☐ Testing that requires aliquoting of sample outside of current routing testing
- ☐ Cytogenetic and/or genetic testing of hematologic malignancy
- ☐ Genetic testing of primary immunodeficienes

Nutrition (check all that apply) — ***Projected Volume/Year***

- ☐ Special foods or formulas (specify types)
- ☐ Special diet (research, test or metabolic diets; culture-specify types)
- ☐ Body composition measurements
- ☐ Diet questionnaire or food records (specify)
- ☐ Patients requiring nutritional counseling or education (specify)

Nursing (check all that apply)

- ☐ Telemetry monitoring
- ☐ High level of acuity due to assessments, medications, and/or interventions
- ☐ VAD care
- ☐ Wound care
- ☐ Clinical monitoring requirements (e.g. EEG, 1:1, suicide precautions, and so on)
- ☐ Sleep studies
- ☐ Required nurse accompaniment for imaging (e.g. psych nurse, ratings, infusions, monitoring)

Perioperative Medicine (check all that apply) — ***Projected Volume/Year***

- ☐ Anticipated number of cases that would require anesthesia providers
  - ☐ Onsite
  - ☐ Offsite

Projected Volume/Year

Are pediatric procedures involved (Y/N): ☐

- ☐ Anticipated number of cases requiring operating room support
  - ☐ Operating Room ☐
  - ☐ ICM facility ☐
- ☐ Surgery requiring post-operative hospital admissions ☐
- ☐ Surgery requirement post-operative outpatient recovery ☐
- ☐ Outpatient surgical procedures ☐
- ☐ Special scheduling requirements for study-hours/days ☐
- ☐ Special equipment/supplies/personnel ☐
  - ☐ Storage of equipment (specify): ☐
- ☐ Purchase of new equipment
  - ☐ Increased requirement for specialized surgical supplies or disposables
  - ☐ Training of personnel
    - ☐ Use of new equipment and/or surgical procedures *(specify):* ☐

Pharmacy (check all that apply)

- ☐ Protocol involves the off-label use of marketed drug(s) as the center of the study question
  - ☐ Pharmaceutical company/companies was (were) contacted and will supply the marketed drug(s) at no charge to the CC.
  - ☐ Pharmaceutical company companies was (were) contacted but will NOT supply the marketed drug at no charge.
  - ☐ Pharmaceutical company was not contacted and the Institute will accept the charge.
- ☐ Protocols will involve high medication needs outside of protocol constructs due to comorbidities or disease entity (e.g. CHF, asthma, transplant patients, etc.)
- ☐ All drugs in the study are on the CC formulary.
- ☐ Alternative drug substitutes can be utilized in the protocol (Pharmacy will be consulted).
- ☐ Significant supportive therapy based on protocol treatment (TPN, chemotherapy, etc.)
- ☐ Supportive care and "non-study" medications (e.g. pain medications, antiemetics, antibiotics, growth factors) are selected, dosed and monitored based on current evidence-practice guidelines. Cite guideline: ☐
- ☐ Medications in protocol use CC standard administration times, diluent volumes for IV's and standard clnical doses.

Rehabilitation Medicine (check all that apply)

Projected Volume/Year

- ☐ Mobility/balance, physical impairments or functional activities of daily living deficits with assistive needs ☐
- ☐ Depression/anxiety/social withdrawal/other mental health issues ☐
- ☐ Community integration needs ☐
- ☐ Difficulties with swallowing, speech, vision, language or cognition ☐
- ☐ Significant musculoskeletal or neuropathic pain ☐

Projected Volume/Year

- ☐ Extensive recreation and/or socialization needs
- ☐ Vocational rehabilitation services
- ☐ Skin/wound care or edema/lymphedema issues
- ☐ Pulmonary rehabilitation
- ☐ Administration of functional or quality of life outcome measures for research

Social Work and Language (check all that apply)

- ☐ None
- ☐ Prescreening financial/logistical assistance will be requested
- ☐ Limited English Proficient protocol participants
- ☐ Protocol participants will be recruited/referred from international sources
- ☐ Recruiting from community clinics with uninsured/under resourced populations
- ☐ Need for help accessing health insurance and community health resources
- ☐ Likely need for discharge planning Health Care, Rehab Facility, Hospice)
- ☐ Need to remain in local area for prolonged protocol-related care
- ☐ End of life issues (also notify Nursing, Pain and Palliative Care, Pharmacy)
- ☐ Complex patient education needs
- ☐ Complex psychosocial issues
- ☐ Other:

Transfusion Medicine (check all that apply) ***Projected Volume/Year***

- ☐ Surgical procedures requiring > 6 blood products per case
- ☐ Apheresis for cellular therapy product collections
- ☐ Apheresis for pediatric patients or any patient < 25 kg
- ☐ Cell processing service requirements
- ☐ Transfusion for patient populations with high rate of allo-immunization
- ☐ Therapy requiring modification of standard blood components
- ☐ Therapy with drugs causing coating or destruction of RBC or platelets
- ☐ Therapeutic apheresis: photopheresis, plasma or red cell exchanges
- ☐ Red cell genotyping or red cell phenotypes (reference testing)
- ☐ HLA typing other than low resolution class 1 and class 2
- ☐ HLA typing, low resolution in high volume (> 100 patients per year)
- ☐ HLA typing, conventional sequencing or next generation sequencing
- ☐ HLA antibody testing and antibody profile workup
- ☐ HLA testing to meet a research objective of the protocol
- ☐ HIV, HBV, HCV or HEV (serological testing, RNA or DNA testing)

Consult Services (check all that apply)

Clinical Center

- ☐ Bioethics
- ☐ Internal Medicine
- ☐ Pain and Palliative Care
- ☐ Pediatrics

Non-Clinical Center (Institute providing the service is listed in parentheses)

- ☐ Addiction (NIAAA)
- ☐ Allergic and Immunologic Diseases (NIAID)
  Specify diagnoses and procedures requested:
- ☐ Audiology (NIDCD)
  Indicate if sedated evaluations of auditory function be required (Yes/No):
  Purpose of consult:
- ☐ Bone Marrow Biopsy (NHLBI)
  - ☐ With consult
  - ☐ Without consult
- ☐ Cardiology (NHLBI)
  Specify procedures requested:
- ☐ Dental (NIDCR)
- ☐ Dental Imaging Services
- ☐ Dermatology (NCI)
- ☐ Endocrine Surgery (NCI)
- ☐ Endocrine (NIDDK)
  Specify planned services:
- ☐ Eye (NEI)
  Specify projected number and schedule of visits:
  Specify exam requirements (e.g. comprehensive exam, visual field testing, etc.):
- ☐ Gastroenterology (NIDDK)
  Specify planned services:
- ☐ Genetic Counseling (NHGRI)
- ☐ Hematology (NHLBI)
  Specify procedures requested:
- ☐ Liver (NIDDK)
  Specify planned services:
- ☐ Medical Oncology (NCI)
- ☐ Neurodevelopmental Assessment (NIMH)

☐ Neurology (NINDS)

Specify services (neurology, pediatric neurology, EMG and/or EEG):

☐ Neuropsychology (NIMH)
☐ Oral Surgery (NIDCR)
☐ Orthopedics (NIAMS)
☐ Otolaryngology (NIDCD)
☐ Pediatric Oncology (NCI)
☐ Pathology (NCI)
☐ Pediatric Endocrinology (NICHD)
☐ Psychiatry (NIMH)
☐ Pulmonary (NHLBI)

Specify procedures requested:

☐ Renal (NIDDK)

Specify planned services:

☐ Reproductive Endocrinology and Gynecology (NICHD)
☐ Radiation Oncology (NCI)
☐ Rheumatology (NIAMS)
☐ Sleep study (NIMH)
☐ Surgery (NCI)
☐ Tracheotomy (NIDCD)
☐ Urology (NCI)

Other Non-CC Provided Services

☐ Pulmonary Medicine (NHLBI)

- ☐ Pulmonary Function testing
- ☐ 6 minute walk test
- ☐ Bronchoscopy with lavage (BAL)

Document e-Signed by: Principal Investigator (or designee)

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