

## 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](mailto: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

***Patient Populations (check all that apply)***

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

**Projected Volume/Year**

***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**

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

**PET Department (Charged to Institute)**

**Projected Volume/Year**

<input type="checkbox"/> PET Scans (Research scans only)	<input type="text"/>
Indicate radiopharmaceutical(s): <input type="text"/>	
<input type="checkbox"/> Synthesis of radiopharmaceutical (only needed)	<input type="text"/>
Indicate radiopharmaceutical (s): <input type="text"/>	

**Institute Imaging (Requires Direct Coordination with Institute)**

**Projected Volume/Year**

<input type="checkbox"/> NCI Molecular Imaging Center (Dr. Peter Choyke)	<input type="text"/>
<input type="checkbox"/> MRI Scans	
<input type="checkbox"/> PET	
<input type="checkbox"/> NMR Center (Dr. Lalith Talagala)	<input type="text"/>
<input type="checkbox"/> MRI Scans	
<input type="checkbox"/> NHLBI Echocardiography (Dr. Vandana Sachdev)	<input type="text"/>
<input type="checkbox"/> Trans-thoracic echocardiogram	
<input type="checkbox"/> Trans-esophageal echocardiogram	
<input type="checkbox"/> NHLBI Cardiac MRI (Dr. Andrew Arai)	<input type="text"/>
<input type="checkbox"/> Cardiac MRI Scan	
<input type="checkbox"/> NHLBI Cardiac Catheterization (Dr. Robert Lederman)	<input type="text"/>
<input type="checkbox"/> Right sided heart cauterization	
<input type="checkbox"/> 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 immunodeficiencies

**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 clinical 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)***

***NOTE: Please save your file as a new document so you can make changes to the original PDF without invalidating the signature, and click "Save".***