IRB Reliance Request/ Registration Form
Application for an External Institution to serve as IRB of Record

Instructions for use: To be completed when a USA investigator is submitting an initial request to rely on an IRB outside of USA for multi-centered research study.

Register project in IRBNet and include the following:

- This completed form
- USA IRB Part A Application (Smart Form)
- A copy of the protocol
- Consent/Assent forms approved by the External IRB
- IRB approval letter(s) from the External IRB

1. USA Site Information

USA Principal Investigator (PI):	
PI Department:	Contact person:
PI telephone #:	Contact person telephone #:
PI email address:	Contact person email address:
Sponsor Name:	www.ClinicalTrials.Gov Number:
Study Title:	

List of Research Team Members *NIH human subjects training, ACRP and HIPPA in research training, if applicable, must be completed*	**Individual's Role** (e.g., PI, Co-PI, coordinator)	**Duties** (see table below for code #)

PLEASE NOTE: If more space is needed to list research team members, please attach an additional sheet of paper.

Assigned Study Duties
(In Column 3 in above table, enter as many numbers as appropriate to describe study duties. For clarification, you may further describe duties within the IRB protocol as needed.)

1. Recruitment	**2.** Obtains consent	**3.** Determine Subject Eligibility for Accrual
4. **a**) Subject Physical Examinations or **b**) Follow-up Visits including physical assessments	**5.** Perform study procedures or Specimen Collection	**6.** **a**) Administer or Dispense Study Drugs, Biologics or Devices (must be licensed) or **b**) Receive, Store, Manipulate or Account for Study Drugs, Biologics or Devices
7. Subject Randomization or Registry	**8.** Collection of Subject Data	**9.** Report Data (CRFs, e-CRFs, Spreadsheets)
10. Data Analysis	**11.** **a)** Review Adverse Events **b)** Treat and Classify Adverse Events	**12.** Other (Please insert explanation in column 3 after the number. You may further describe within the protocol)

2. External IRB Information *please provide the following information about the IRB you wish to rely upon:*

Institution/ IRB Name:	FWA Number**(if applicable):**
IRB Registration Number**(if known):**	Point of Contact for IRB:

Provide External PI Information:
Name:
Email:
Institution Name:

Is the use of the external IRB required for site participation? ☐ YES ☐ NO

3. HIPAA and Use of Protected Health Information

USA cannot rely on an external IRB for HIPAA. Only USA's IRB can issue a HIPAA waiver for USA Protected Health Information (PHI). To access and/or collect (PHI) held by USA you must use:

- USA HIPAA Authorization
- USA Application for Waiver of HIPAA Authorization form.

NOTE: The authorization form originates from the covered entity that owns the data.

3a. Data Security

Do you plan to maintain electronic identifiable health information specific to this study within USA facilities utilizing USA security? (i.e., research databases, spreadsheets, or computing applications)

☐ Yes (complete sections A, B, and C) ☐ No (if so, skip to next section)

A. Please indicate how study data will be kept secure (Check all that apply):

☐ Data is coded; data key is destroyed at end of study
☐ Data is coded; data key is kept separately and securely
☐ Data kept in locked file cabinet
☐ Data kept in locked office/suite
☐ Electronic data protected with password
☐ Data stored on a secure network
☐ Portable storage (i.e. laptop, flash drive)
☐ Other

B. Describe how data will be protected for any portable device:

C. Complete and submit a separate application for the establishment of a research database registration with the IRB new project application. The form is located in IRBNet Forms and Templates

4. Other Regulatory Committees:

Please indicate if your study requires approval from any of the following regulatory committee, or involved the use of regulated materials *(check all that apply)*:

☐ Institutional Biosafety Committee
☐ Institutional Animal Care and Use Committee
☐ Human Gene Transfer/Recombinant DNA Research
☐ Radiation Safety Committee

5. Hospital: Staff/Resources/Facilities:

a. Will this protocol use hospital staff, resources, or facilities? ☐ NO ☐ YES (if yes, complete below)

☐ Infusion Center
☐ Cyberknife
☐ Laboratory
☐ Radiology
☐ Pharmacy
☐ Respiratory
☐ Cardiology (ECG, ECHO) GI Lab
☐ Neurology (EMG, ABER, SSER)
☐ Other (specify):

b. Who will financially be responsible for hospital charges incurred as part of the study? Is there separate funding or is the patient's insurance responsible?

c. Who will provide staff education regarding the pharmaceutical drugs and / or hospital procedures? *(Include the information that will be covered)*

d. List the Hospital resources that will be utilized that are research related; and how often the tests and procedures will occur or be performed:

e. Please explain the reason for this request**:**

6. Primary Awardee:

☐ USA
☐ Institution being requested to act as IRB of record
☐ Other (specify):

7. Recruitment Methods: Specify who will be responsible for obtaining informed consent from subjects. Check all boxes that apply to the research study

☐ Study Team from the reviewing institution will be responsible subject recruitment
☐ USA Study Team Members will be responsible for subject recruitment
☐ Other (specify):

Recruitment Materials:
Check all boxes that apply to the research study.

☐ Recruitment Materials approved by the Reviewing IRB will be used. **NOTE*:*** A copy of all Applicable IRB approved Recruitment Materials must be submitted to the USA IRB for review.
☐ Recruitment Materials approved by the Reviewing IRB and modified for USA will be used. ***NOTE:*** A copy of all applicable USA specific Recruitment Materials must be submitted to the USA IRB for review.
☐ There are no Recruitment Materials.

8. Principal Investigator's Commitment:

By electronically signing the IRBNet package, the PI certifies that the information provided in this application is complete and accurate, and that this study meets the USA IRB criteria for review by a central IRB. I also understand that the Institution reserves the right to disapprove any study approved by a central IRB.

The PI has ultimate responsibility for the conduct of the research study, its ethical performance, and the protection of the rights and welfare of human subjects. PI agrees to conduct this research study in accordance with all applicable federal and state regulations and USA IRB policies and practices governing human subject research.

PI understands that no research involving human subjects will convene until central IRB approval and all necessary USA approvals are in place. The PI will ensure that if members of the USA research team access protected health information from a USA covered entity in order to seek consent/authorization for research, such access is necessary for the research, is solely for that purpose, and the information will not be removed from the covered entity without authorization or an approved waiver.