Asterisked (*) fields are required.
Highlighted text = site to provide

Setup

Who are you requesting this new research submission to be reviewed by?
*Select all regions where you need board review.

- US Review
- Canadian Review
- Other (International)

*What type of submission are you making? Please select an option below.

- A New Site for Initial Review
- Clinical Use of Humanitarian Use Device (HUD)

Find the study to which you're adding a new site or PI.
Study Name: Validating and Developing Duffy Null Specific Absolute Neutrophil Count Reference Ranges for Adults and Pediatrics
Sponsor Protocol ID: None
IRB Tracking ID: ***
*Submission Name

Documents for subjects must be in language understandable by the subject or the subject's

• Yes
No

Principal Investigator (PI) Information

Prefix:
*First:
Middle:
*Last:
*Email:
*Phone:
Degrees:
*Company/Institution/Organization:
*Address Line 1:
Address Line 2:
*City:
*State:
*Postal Code:
*Province:
State or Province:
*Country:

• Copy2:

*State:
*Phone:

Multi-site Studies Central IRB

For multi-site studies – has the sponsor/CRO designated this IRB as the central IRB for most sites or the single IRB for this study?

- Yes
- No
- I don't know

Contract Research Organization (CRO) Information

*Is a Contract Research Organization (CRO) involved in the research?

- Yes
- No

Federal Funding

*Is this research funded, supported, or conducted by a United States federal department or agency?

Yes
No

*Select the federal department or agency funding the research:
Doris Duke Charitable Foundation

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• Yes
• No

*Would you like the IRB to consider whether the research is minimal risk?

No

[redacted]n?

Yes

• No

*Will the research involve subjects who are prisoners?

• Yes

• No

[redacted]

*Will you be subject to and in compliance with HIPAA?

Site Management Organization (SMO) Information

Is a Site Management Organization (SMO) involved with this research site?

- Yes
- No

Site Enrollment Estimate

The IRB will not consider this estimate to be an enrollment limit for the site.
What is the planned number of subjects to be enrolled locally?

Research Team Information

Indicate thenumber of investigators and research staff involved with the conduct this research:
Physician Sub/Co-investigators
Other Sub/Coinvestigators
Research Coordinators
Other research staff

Research Team Training

The Principal Investigator (PI) must ensure that all investigators and research staff undergo training on the ethics and regulations of human subject protections before being involveth.4 (o)-981 (v)2.4 (o)-9.6 (l)7.6 (v)

Yes
• No

Required Submission Materials for Site Only Submission

Submit the following documentation:

x Advertisements and recruitment scripts specific to your site (Advertisements and recruitment materials and changes to advertisements and recruitment materials must be IRB approved before their use)
x Curriculum vitae for the Principal Investigator (PI), if a current one is not already on file with the IRB

Administrative Actions

Has the Principal Investigator (PI) or any other personnel involved in this research had any of the following that has not been reported to this IRB:

FDA Warning Letter
NIDPOE (Noticed of Initiation of Disqualification Proceedings and Opportunity to Explain)
Suspension or termination by an IRB
Suspension by a federal or governmental agency (such as FDA, HHS, or Health Canada)
OHRP Determination Letter, Health Canada Inspection Letter with observations, or similar
Form FDA 483 in the past 5 years

- OR-

Has the Principal Investigator (PI) or any other personnel involved in this research had any of the following denied, revoked, suspended, reduced, limited, placed on probation, not renewed, relinquished, sanctioned, fined, or subject to disciplinary action that has not been reported to this IRB?

Clinical privileges at any site
DEA licensure
Fellowship/board certification
Medical licensure in any state, nation, or province
Membership on any hospital staff
Prescribing privileges

Special Instructions