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 representative. Translated documents must be IRB approved before use.
***Will you need translated documents or approval of translated documents?**
☐Yes
☒No

***Will the Principal Investigator (PI) or research team be offered recruitment bonuses?** *(extra payments tied to the rate or timing of recruitment or enrollment)*
☐Yes
☒No

Financial Interest Disclosure
Does the Principal Investigator (PI), the PI's immediate family, or any other research personnel or their immediate families, have any of the following financial interests in any entity that is sponsoring the research, or an entity that is manufacturing the product or service being tested, not reported to this IRB in previous submissions for this protocol?

- Any remuneration from the entity in the previous twelve months that exceeds $5,000, when aggregated for the individual and their immediate family
- Any equity interest in the entity
- Any intellectual property rights and interests
- Any governance or executive relationship with the entity

☐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:

☐Copy this person on IRB correspondence
☐Send continuing review forms to this person to be filled out and returned to the IRB

Contacts

Are there any designated contacts for this research (e.g., Sponsor contact, Contract Research Organization (CRO) contact, Site Management Organization (SMO) contact, study coordinator contact)?
☒Yes
☐No

*Contact Type:
Prefix
*First:
Middle:
*Last:
*Email:
*Phone:
Degrees:
*Company/Institution/Organization:
*Address Line 1:
Address Line 2:
*City:

*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

Clinical Pharmacology Unit Services (CPUS)

***Is this a submission to the Clinical Pharmacology Unit Services (CPUS)?**

☐Yes
☒No

IRB Determinations

If the IRB determines that the submission does not represent human research or represents research that is exempt from regulation, do you want the IRB to issue an exempt or not human research determination instead of conducting IRB review? *For research to be exempt from regulation, the research must be limited to:

- *Evaluation of educational methods*
- *Surveys/interviews/focus groups*
- *Benign behavioral interventions*
- *Use/review of specimens/information collected for purposes other than the proposed research*
- *Evaluation of taste and food quality*
- *Creation of a biobank*

● *Use of data and specimens from a biobank*
For more information see 45 CFR §46.104(d)

☒Yes
☐No

***Would you like the IRB to consider whether the research is minimal risk?** *(Research is minimal risk when the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. In general, studies testing drugs or devices are not minimal risk.)*
☒Yes
☐No

Billing Information

***How should we send invoices to the billing contact?**
☐Printed mail
☒Email

Mail stop/cost center *(if applicable):* N/A
Purchase order number (PO#) *(if applicable):* N/A
sIRB code *(if applicable):* N/A

***Is the person to whom we should send invoices listed above as a contact?**
☐Yes
☒No
☐Unsure

Provide contact information for the person to whom we should send invoices:
***First:** Emily
***Last**: Semmel
***Email:** apinvoices@ashrc.org
***Phone:** (202) 552-4902
***Company/Institution/Organization**: ASH Research Collaborative
***Address Line 1**: 2021 L Street NW, Suite 900
***City**: Washington
***State**: DC
***Postal Code**: 20036
***Province**: United States

Vulnerable Populations

***Will the research involve subjects who are adults unable to consent?**
☐Yes

☒No

***Will the research involve subjects who are children?**

☒Yes

☐No

***Will the research involve subjects who are prisoners?**

☐Yes

☒No

***Will the research involve subjects who are pregnant or follow subjects who become pregnant while on study?**

☐Yes

☒No

Other Populations

***Will the research involve subjects with limited English skills?**

☐Yes

☒No

***Will the research involve institutionalized subjects?**

☐Yes

☒No

***Will the research involve subjects who are students or employees of the investigators?**

☐Yes

☒No

Prior IRB Review

***Has another IRB reviewed this research or site and decided to table, defer, disapprove, suspend, terminate, or decline to approve it?**

☐Yes

☒No

IRB Transfer

***Are you transferring IRB oversight from another IRB to this IRB?**

☐Yes

☒No

Consent

***Will subjects or their representatives provide informed consent to take part in this research?**

☒Yes

☐No

HIPAA Waiver of Authorization

***What type of waiver of HIPAA authorization, if any, are you requesting?**

☐Full waiver of authorization

☒Partial waiver of authorization for access to records for subject recruitment or screening

☐Partial waiver of authorization for waiver of signing an authorization form

☐None

Describe or list the identifiers planned to be used or disclosed?

We plan to obtain Duffy typing, absolute neutrophil count (ANC), race, ethnicity, age, sex, medication list, and past medical history.

Explain why access to the protected health information is necessary:

In order to screen the patient population, protected health information is necessary. Sex, age, race, ethnicity, Duffy status, and ANC will be used in a de-identified way in the analysis.

Describe the plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research or justify their retention.

After the site screens the patient to ensure eligibility, a code will be assigned to the patient and only de-identified information will be collected. Identifiers will not be shared outside the site, and will be destroyed after study completion.

Explain why the research could not practicably be conducted without the waiver.

A partial waiver is needed only to screen patients and assess eligibility. Eligibility could not be determined without access to medication lists and past medical history.

Explain why the research could not practicably be conducted without access to and use of the protected health information.

After the screening process, only de-identified information, including age, sex, race, ethnicity, ANC, and Duffy status will be used. This will be de-identified and kept in aggregate.

Subject Payment

Will you pay subjects for participation?

☐Yes

☒No

Confidentiality

Confidentiality refers to the agreements regarding how data will be managed and used.

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

☒Yes

☐No

***Will the research be covered by a Certificate of Confidentiality (COC)?**

☐Yes

☒No

Additional Methods to Maintain Confidentiality

Describe any additional procedures to protect confidentiality *(e.g., confidentiality agreements, coding):*
All data will be stored on site and Data Hub approved servers. Only approved and credentialed study team members will have access to this data.

Institutional Services

Will you conduct this research through an organization that has a contract or Master Services Agreement (MSA) to use WCG IRB (formerly, Western IRB) for IRB Services?

☐Yes

☐No

Principal Investigator (PI) Transfer

Is the Principal Investigator (PI) taking over oversight from another PI?

☐Yes

☐No

Principal Investigator (PI) Specialty

Is the Principal Investigator (PI) a physician?

☐Yes

☐No

Principal Investigator (PI) Licensure

Does the Principal Investigator have a medical license?

☐Yes

☐No

Principal Investigator (PI) Experience

How many clinical trials is the PI currently conducting?
Among the clinical trials that the PI is currently conducting, how many are open to enrollment?

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 the number of investigators and research staff involved with the conduct this research:

Physician Sub/Co-investigators:

Other Sub/Co-investigators:

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 involved in the conduct of this research. For clinical research, the Principal Investigator (PI) must ensure that all investigators and research staff undergo training on Good Clinical Practice (GCP).

Have all investigators and research staff involved with the conduct of this research taken one or more of the following programs and all applicable training programs noted as required?

Collaborative IRB Training Initiative (CITI)

DIA Certified Investigator (CCI)

☐Yes

☐No

Subject Privacy

Privacy refers to persons' interest in controlling the access of others to themselves, such as the ability to control who sees them, hears them, touches them, and has access to their private information. Additional privacy interests include the time and place where individuals provide information, the nature of the information provided by the individuals, the nature of the individual's experiences during the trial, and who receives and can use the information.

Will you or others perform procedures in a private setting?

☒Yes
☐No

Required Submission Materials for Site Only Submission

Submit the following documentation:

- 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)
- 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
Professional sanctions including fines and public reprimands
Professional society membership
Research privileges at any site

- OR -

Is there any action or investigation currently pending before any court of law, federal agency, or state licensing board concerning the professional conduct of the Principal Investigator (PI), or any other

personnel involved in this research in that individual's capacity as a research investigator or as a clinician that has not been reported to this IRB?

☐Yes

☐No

Research Location

Physical address where subjects will be seen or research will take place:
Locations:
Company/Institution/Organization Line 1:
Company/Institution/Organization Line 2:
Country:
Address Line 1:
Address Line 2:
City:
State/Province:
Postal Code:
Which of the following best describes this location's function?
Describe any additional resources available at this location that are relevant to this research:
(optional)

Site number assigned by sponsor (if known): N/A
Daytime phone number for subjects to call for questions or injury:
24-hour phone number for subjects to call for questions or injury:

Do any communities around the above locations(s) have a negative attitude towards the conduct of research?

☐Yes

☐No

Does a local IRB have jurisdiction over research over any of the above locations? (If this site is covered by a Master Services Agreement (MSA) or is a member of our Global Research Network (GRN), you may check "No")

☐Yes

☐No

Are there any state or local laws that impose additional requirements for research?

☐Yes

☐No

Is the distance between any location and the main location greater than 50 miles (80 kilometers)?

☐Yes

☐No

☐There is only one location

Special Instructions

Provide any special instructions or additional relevant information for this submission:

_____
_____
_____
_____

Person Completing This Form

Prefix:
*First:
Middle:
*Last:
Suffix:
*Email:
*Phone:
Company/Institution/Organization *(optional, but preferred):*