1. PURPOSE

The purpose of this guidance is to inform Division of Microbiology and Infectious Diseases (DMID) staff, extramural investigators, site staff, and collaborating institutions on DMID's current thinking on who should be listed as sub-investigators on the Form FDA 1572.

2. GUIDANCE

Section 6 of the 1572 (Names of all Sub-Investigators) should list individuals who, as part of the investigative team, will assist the investigator and make a direct and significant contribution to the data. The site Principal Investigators (PI) should decide who on their team will be making direct and significant contributions to the data.

Sub-investigators are not limited to physicians, research fellows, and residents. Research coordinators or study nurses (for example) who have a role in performing critical study functions and making direct and significant contributions to the data and collection of data should be listed. In general, this is staff that are making subjective decisions about key steps in the protocol, including the following:

	Those performing <u>one or more</u> of these activities should be listed on the 1572	**Those performing <u>only</u> these activities do not need to be listed on the 1572**
Inclusion/exclusion criteria	• Any person that ultimately determines if a participant is eligible for participation in a study. • Any person performing a physical exam or other procedure where a specific finding is used to determine eligibility for a study (e.g. the protocol requires the presence of erythema migrans for a Lyme disease trial).	• A person that decides if a participant does or doesn't qualify for a study based on objective data (such as age or BMI) only. • A person that only collects objective data such as medical history, blood pressure, etc. that are used in determining inclusion/exclusion into the study. • A person performing a physical exam to attest to a general state of health for inclusion in a study.
Primary or secondary endpoints	• Any person that collects data to determine a subjective endpoint, such as "recovery", "improvement", etc., including changes or resolution of physical exam findings. • Any person performing physical exams if the exam is an endpoint, e.g. changes or resolution of physical exam findings. • Any person using/administering surveys as part of an endpoint (e.g. SF-36). • Any person performing any specialized procedure that is used in an endpoint, e.g. skin biopsy, bronchoscopy, bone marrow aspirate, etc.	• Collection of objective data such as oxygenation, hospitalization, date of discharge, etc. • Collection of memory aids or other subject facing IRB approved tools. • Collection or processing of blood samples. • Documenting biospecimens in a data system (e.g. number of aliquots /sample ID). • Collection, processing, or testing of routine clinical samples (NP swab, urethral swab). • Documenting results from routine clinical samples (e.g. entering results into a data system).

Safety assessments	• Any person that is making judgements about Adverse events (AE), including AE grading or relationship. • Any person signing or otherwise taking responsibility for the contents of a SAE form.	• A person that uses objective laboratory data to grade AEs (such as a hemoglobin). • A person that uses a predefined list to identify AEs (i.e. solicited AEs). • A person that completes the SAE form by gathering data from other sources, but not ultimately approving its content. • A person that submits or sends a SAE form only.
Specific Roles	• In the cases where the PI is not a physician, there must be a physician listed as a sub-Investigator.	• Medical technologist taking vital signs. • Phlebotomist taking laboratory specimens. • Laboratory staff processing specimens into samples or shipping samples for storage. • Laboratory staff performing testing (either clinical or research testing). • Clinical/hospital staff collecting clinical data as part of their normal scope of work, e.g. nurses infusing study treatments; respiratory therapist documenting O2 requirements, etc. • Research pharmacists.

<u>Other considerations</u>

All sub-investigators will have additional documentation collected such as a Curriculum Vitae (and/or other documentation of qualifications) and financial disclosure forms, so those listed as sub-investigators should be limited to those meeting the above criteria.

Research Coordinators that make direct and significant contributions to the data, for example recruiting subjects, collection and evaluation of study data and maintenance of study records – however the title alone should not put them in the 1572, and instead the specific activities shoud be considered.

The site PI makes the final decision as to who is listed as sub-investigators on the FDA Form 1572.

- If a sub-investigator is added to the research site, an updated 1572 should be provided to DMID as soon as practicable.
- If a sub-investigator is no longer contributing to the research at a site, the 1572 does not have to be updated, however the additional supporting documents (e.g. delegation or responsibilities log) should be updated and provided to DMID as necessary.
- Staff residents rotating through a service or program (e.g. “a research month”) do not need to be listed on the 1572. Instead names of these individuals and the procedures that they are

expected to perform should be included in the study records and should be provided to the study sponsor.

3. REFERENCES

US FDA Guidance: Frequently Asked Questions – Statement of Investigator (Form FDA 1572). https://www.fda.gov/media/78830/download

4. ADDITIONAL INFORMATION

4.1 Document Lead: ORA Director, DMID

4.2 Posting externally: Yes