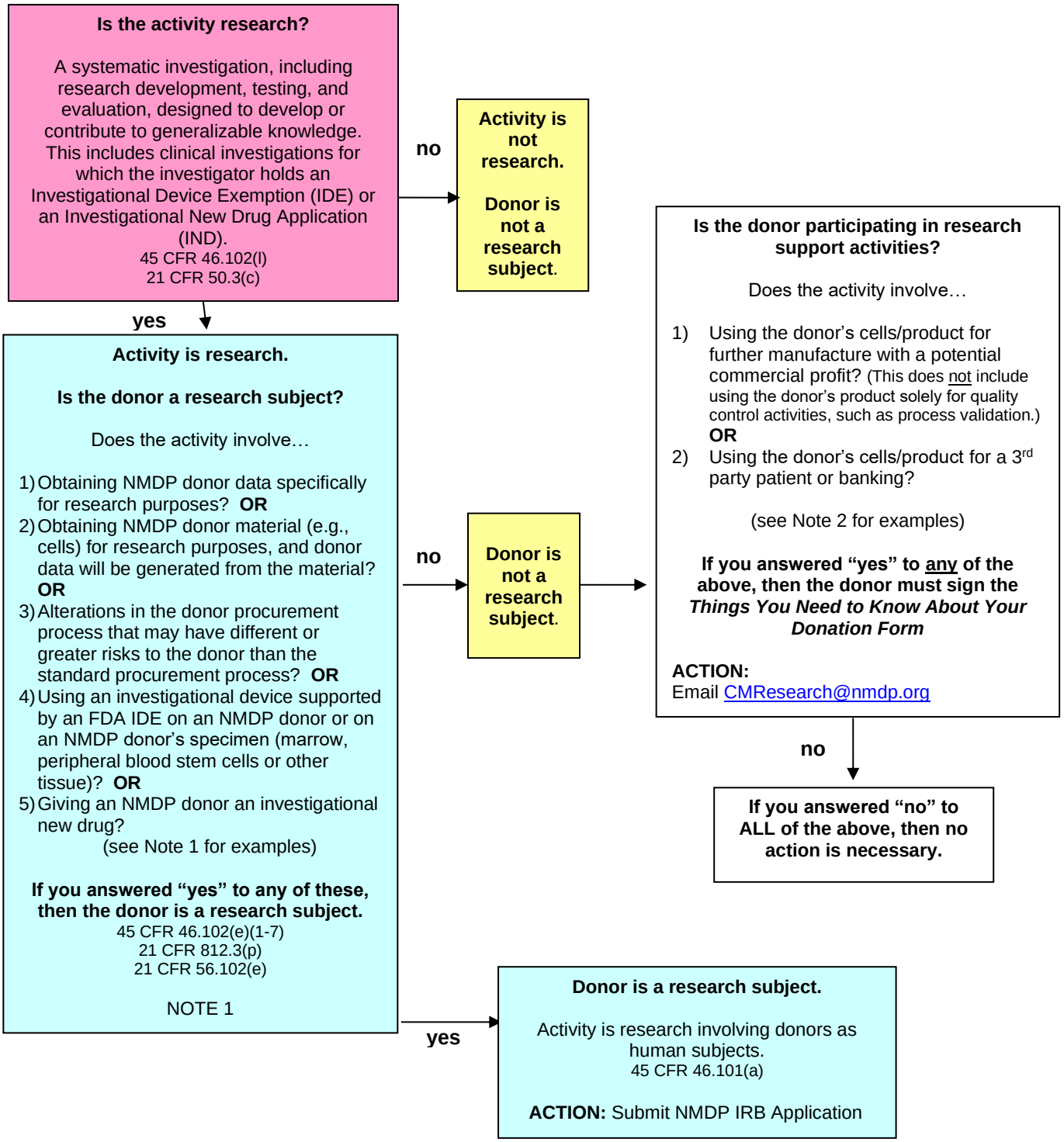
Is the Unrelated Donor a Human Research Subject or Participating in Research Support Activities?

ALGORITHM



Is the Unrelated Donor a Human Research Subject or Participating in Research Support Activities?

ALGORITHM NOTES

Note 1

Examples for which this question would be answered “yes” (donor is a research subject):

1. Individually identifiable donor data (may be coded but link exists at donor center) collected explicitly for research purposes will be included in the research. This does not include standard data provided to all transplant centers as part of the donor selection process (e.g., gender, age, race, weight, HLA typing, standard infectious disease marker, etc.) or results from clinical tests performed at the transplant center, (e.g., chimerism tests). Examples of donor data collected for research purposes are survey or interview questions (e.g., questions regarding donor’s allergy history, etc.) or data obtained from the donor’s donation medical record that are not routinely provided to the center performing the transplant (e.g., donor family history data or lab values for CBC and differential, etc.).

2a. The donor will be asked to provide blood, marrow, PBSC or other tissue samples for laboratory research studies (not for clinical care purposes).

2b. The stem cell collection is specifically altered by the research protocol, and there are research questions that pertain to the donor (e.g., altered method for collecting the product and research questions are about donor safety and recovery).

3. Alterations in the donor procurement process that may have different or greater risks to the donor than the standard procurement process (e.g., multiple bone marrow or apheresis collections for research purposes that are in close proximity to each other).

4. The product will be experimentally manipulated using a device supported by an FDA Investigational Device Exemption (IDE). Investigational device regulations explicitly require donor consent if the donor’s specimen is manipulated with a device under IDE (21 CFR 3(p). If the device is supported by an FDA IND, then donor consent is not required.

Note 2

Examples for which this question would be answered “yes” (donor is <u>not</u> a research subject but <u>is</u> participating in research support activities):

1. The donor’s cells/product will undergo further manufacturing to develop a new drug or therapy for approval by the Food and Drug Administration (FDA). The manufacturer may receive commercial profit from its use.

2. The donor’s cells/product will be banked for possible infusion into a 3rd party recipient but will <u>not</u> be used for future laboratory research.

Human Research Subject

REGULATORY DEFINITIONS

Office of Human Research Protections (OHRP)

OHRP definition of research [45 CFR 46.102(l)]

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.

OHRP definition of human subject [45 CFR 46.102(e)(1-7)]

(1) Human subject means a living individual about whom an investigator (whether professional or student) conducting research:

a. Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
b. Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

(2) Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

(3) *Interaction* includes communication or interpersonal contact between investigator and subject.

(4) *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record). (5) *Identifiable private information* is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

(6) *An identifiable biospecimen* is biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

Food and Drug Administration (FDA)

FDA definition of clinical investigation [21 CFR 50.3(c)]

Clinical investigation means any experiment that involves a test article and one or more human subjects; and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i), 507(d), or 520(g) of the act; or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include experiments that are subject to the provisions of part 58 of this chapter, regarding non-clinical laboratory studies.

FDA definition of human subject [21 CFR 56.102(e)]

Human subject means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient.

FDA definition of human subject from the medical device regulations [21 CFR 812.3(p)]
Subject means a human who participates in an investigation either as an individual on whom or on whose specimen an investigational device is used or as a control. A subject may be in normal health or may have a medical condition or disease.

FDA definition of investigational new drug [21 CFR 312.2(b)]
Investigational new drug means a new drug or biological drug that is used in a clinical investigation. The term also includes a biological product that is used in vitro for diagnostic purposes. The terms "investigational drug" and "investigational new drug" are deemed to be synonymous for purposes of this part.