

NORTH SHORE MEDICAL CENTER IRB
RESEARCH DETERMINATION WORKSHEET

Submission of this Worksheet is Optional.

- This worksheet is a guide to help the investigator determine if the activity is human subject research and regulated by the Department of Health and Human Services (DHHS) and/ or Food and Drug Administration (FDA).
- Activities that meet the definition of human subject research require submission of an application to the NSMC IRB.
- The worksheet does not have to be submitted to the NSMC IRB, but the IRB will review it upon request.

PI Name:

Title of Activity:

Synopsis:

(Brief description of the research)

I. DHHS Research

Review the following questions to determine whether an activity is human subject research under 45 CFR 46, and requires submission of an **Application** to the NSMC IRB.

A. Does the research meet the DHHS definition of "research?"

Check either 1 or 2 below as the appropriate description of the activity:

1. **A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.**

- Ex:
- pilot studies
 - chart reviews of more than 3 patients
 - comparative studies
 - survey studies
 - medical intervention studies
 - activity to refine research tool in preparation for study

If the activity is a systematic activity as described above, the activity meets the definition of "research" under the DHHS regulations. Exceptions may be considered on a case-by-case basis.

Continue to Question B.

2. **NOT a systematic investigation designed to develop or contribute to generalizable knowledge**

- Ex.:
- Retrospective clinical case reports of 3 or fewer patients
 - QA/QI research developed for a specific unit with no intent to publish and disseminate the results

If the activity is NOT a systematic investigation designed to develop or contribute to generalizable knowledge, the activity does not meet the definition of research under the DHHS regulations. However, it may meet the definition of human subject research under the FDA definition.

If the activity involves an FDA regulated product, proceed to Section II.

- B.** Under the DHHS regulations "human subject" means a living individual about whom an investigator (whether professional or student) conducting research obtains:

- (i) data through intervention or interaction with the individual, or
- (ii) identifiable private information.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. 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 which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

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1. Yes No Does the activity involve a “human subject” under the DHHS definition?

If yes, indicate whether the subjects are living by checking 1 or 2 below.

- a. At least one, if not all, of the subjects are alive.
*If at least one of the subjects is living, the activity involves a “human subject” under the DHHS regulations. **Continue to Question C.***
- b. None of the subjects are living.
*If none of the subjects are living, the activity **does not** involve a human subject under the DHHS or FDA regulations. The activity may require compliance with HIPAA.*

- C. Indicate the type of information the activity will collect about the subjects by checking items 1, 2, and or 3 below:

1. Activity involves obtaining data through interaction or intervention with the subjects. This activity includes interviews (in person or not), surveys, physical procedures, manipulations of the subject’s environment, and any other direct contact or communication with a subject.
2. Activity involves obtaining private identifiable information about the subject. This activity includes chart reviews, lab studies on tissue/specimens, using information from data or tissue repositories.

If you have checked off 1 or 2 above, the activity is collecting human subject research information under the DHHS regulations. An application should be submitted to the IRB.

3. Activity involves use of anonymized tissue or specimens obtained from a data repository and for which the investigator has no access to a code or link to re-identify the source of the tissue or specimen.

*If you have checked off only 3, above, then the research **does not** involve obtaining human subject research information under the DHHS regulations.*

If the research involves an FDA regulated product, proceed to Section II.

- II. If the activity involves an FDA regulated product, other than the use of an FDA approved product in the course of medical practice, the activity must be reviewed under the FDA human subject research regulations.

A. **FDA Regulated Products Used in Human Subject Research.**

Using the following list of definitions, check any and all that apply to your activity.

1. **Drug**

A drug is defined as:

- A substance recognized by an official pharmacopoeia or formulary.
- A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.
- A substance (other than food) intended to affect the structure or any function of the body.
- A substance intended for use as a component of a medicine but not a device or a component, part or accessory of a device.
- A biologic product is any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product applicable to the prevention, treatment, or cure of diseases or injuries. Biologic products are included within this definition and are generally covered by the same laws and regulations, but differences exist regarding their manufacturing processes (chemical process vs. biological process.)

2. **Medical Device**

A medical device is defined as an instrument, apparatus, implement, machine, contrivance, implant, software, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in humans or other animals, or
- intended to affect the structure or any function of the body of humans or other animals, and which does not achieve any of its primary intended purposes through chemical

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action within or on the body of humans or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

3. Dietary Supplement

FDA traditionally considered dietary supplements to be composed only of essential nutrients, such as vitamins, minerals, and proteins. The Nutrition Labeling and Education Act of 1990 added "herbs, or similar nutritional substances," to the term "dietary supplement." Through the DSHEA, Congress expanded the meaning of the term "dietary supplements" beyond essential nutrients to include such substances as ginseng, garlic, fish oils, psyllium, enzymes, glandulars, and mixtures of these.

The DSHEA established a formal definition of "dietary supplement" using several criteria. A dietary supplement:

- is a product (other than tobacco) that is intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by humans to supplement the diet by increasing the total daily intake, or a concentrate, metabolite, constituent, extract, or combinations of these ingredients.
- is intended for ingestion in pill, capsule, tablet, or liquid form.
- is not represented for use as a conventional food or as the sole item of a meal or diet.
- is labeled as a "dietary supplement."
- includes products such as an approved new drug, certified antibiotic, or licensed biologic that was marketed as a dietary supplement or food before approval, certification, or license (unless the Secretary of Health and Human Services waives this provision).

A Dietary supplement:

- for which the activity involves a disease claim. In this case, the dietary supplement will be treated as a drug.
- for which the research activity involves the effect of the product on the structure or function in humans or that characterizes the documented mechanism by which the product acts to maintain such structure or function, provided that such statements are not disease claims - unless the claim is an authorized health claim for which the product qualifies. In this case, the dietary supplement will not be treated as a drug. This activity may be reviewed under DHHS regulations.

B. Answer the following questions to determine if the activity is human research under the FDA regulations and requires submission of an application to the IRB.

1. Is the research activity subject to FDA human subject research regulations?

Check the appropriate description of the research activity.

- a. The activity involves the use of a drug, other than the use of an approved drug in the course of medical practice.
- b. The activity involves the use of a medical device, other than the use of an approved medical device in the course of medical practice.
- c. The results of the activity are to be submitted to the FDA or held for inspection by the FDA.
- d. Tissue specimens are being used to test the effectiveness of a medical device and the information is being submitted to the FDA for FDA approval of the device.

*If you have checked off any one of **a to d** above, the activity may be subject to FDA human subject research regulations. **Proceed to Question 2.***

- e. The activity involves a retrospective chart review of outcomes of patients on a certain drug or device in the course of medical practice.
- f. The activity involves a prospective study of the outcomes of patients who were prescribed a drug or device by their personal physicians, or compares the diagnostic results of scans or tests ordered by their personal physicians.

*If you have checked off only either **e** or **f** above, the activity is **not** FDA regulated and will be reviewed under the DHHS regulations.*

Note: Some activities involving FDA regulated products will not be exempt, even though they seem to fit under the DHHS categories of exempt research. See examples below of

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FDA regulated human subject research activities that are not exempt and for which a full application must be submitted to the IRB for review.

- Ex.:*
- *laboratory studies testing new diagnostic devices using human data/tissue, even if data/tissue is anonymized*
 - *record/image/chart reviews of patients who received FDA regulated products or controls, not in course of medical practice*

2. Does the activity involve a "human subject"?

Check off the description that matches the subjects for this activity.

- a. An individual who is or becomes a participant in research, either as a recipient of an FDA regulated product (approved or experimental) or as a control, as directed by a research protocol and not by medical practice.
- b. An individual who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control.

*If you have checked off **a** or **b** above, the activity involves a human subject under the FDA regulations. The activity requires submission of an application.*

Note: If the research activity is subject to FDA regulations, these requirements apply to the research and must be addressed in the IRB application:

- The consent process must disclose that the FDA may inspect the study records;
- Consent documents must be dated;
- Consent cannot be waived except under the planned emergency research regulations; and
- Consent documentation may only be waived if the activity is minimal risk and documentation of consent is not ordinarily required outside the research context.

If the activity is not subject to DHHS regulations (see section I above) or not subject to FDA regulations (see section II above), the investigator may conduct the activity without submission to the IRB. If you wish to receive written confirmation from the IRB that your activity is not human subject research, submit this form to the NSMC IRB.