FLORIDA ATLANTIC UNIVERSITY

FORM 106: HUMAN SUBJECTS RESEARCH (HSR) DETERMINATION FORM

Instructions: Complete this form to help determine if your project qualifies as research that involves the use of human participants or qualifies as not-human subjects research (NHSR).

If the project is **secondary use research, secondary research, or funded**, or you need an official letter, please submit the form into the Novelution system at https://fau.novelution.com/login. If you do not have an account, you can create one by clicking into the Novelution page and logging in with your FAU credentials.

The PI must electronically certify the submission in Novelution. All projects submitted through Novelution will receive an official determination from the FAU IRB.

> **Note: If using a de-identified data set or specimen samples, a letter of collaboration from the cooperating institution stating this must be included. A data use agreement (DUA) or Material Transfer Agreement (MTA) may be required. Further guidance is available on the following web pages:*
> https://www.fau.edu/research-admin/sponsored-programs/files/fau-dua-guidance-02-10-2017.pdf
> https://www.fau.edu/research-admin/research-integrity/files/guidance-secondary-data-analyses-v3.pdf

---

SECTION I: Project Details

Title of Project:

PI Name: College/Dept.:

Phone: Email:

Funding Agency: Novelution Sponsored programs #:

Contract/Grant Title:

1. Project Summary: *(Briefly summarize your study, how you will obtain the information, and how you will use the information gathered)*

2. What is the nature of your project? (Check all that apply):

- ☐ Literature Review limited to peer-reviewed and grey literature
- ☐ Systematic review
- ☐ Meta-analysis (study that combines data from other studies)
- ☐ Secondary research using publicly available dataset(s) with individual level-data that REQUIRES a password of special access
- ☐ Secondary research using publicly available dataset(s) with aggregate data (e.g., from public health reports)
- ☐ Secondary research using non-publicly available dataset(s) (e.g., dataset provided by an investigator/organization)
- ☐ Synthesis of existing aggregate reports (no individual-level data)
- ☐ Work involving surveys, interviews, or focus groups
- ☐ Monitoring/evaluation
- ☐ Quality assurance/ quality improvement (QA/QI) or evaluation of program limited
- ☐ None of the above (continue to next section)

FLORIDA ATLANTIC UNIVERSITY

FORM 106: HUMAN SUBJECTS RESEARCH (HSR) DETERMINATION FORM

3. Is the proposed activity covered by new or existing IRB approval/determination?

☐ Yes ☐ No

If yes, please provide the following information. If no, proceed to next section.

Name of Principal Investigator on project:

Date of IRB approval/ determination:

Name of IRB providing approval/ determination, if not FAU:

If FAU IRB, study number as listed on IRB approval/ determination:

If FAU IRB, study title as listed on IRB approval/ determination:

SECTION II: Project Determination

1. Is the proposed activity a ***systematic investigation including research development, testing, and evaluation***? [Systematic investigation means carried out using step-by-step procedures organized according to a set of interrelated ideas or principles.] ☐ Yes ☐ No

2. Is the proposed activity designed to develop or contribute to ***generalizable knowledge***? (see guidance below; If you are unsure, please contact the Research Integrity office.) ☐ Yes ☐ No

Generalizable knowledge	**"Not generalizable knowledge" (examples)**
• Benefits extend beyond the immediate population of study to society, other researchers, scholars, or practitioners in field. • Drawing conclusions, testing or generating a hypothesis. • Publication or presentation to inform the field of study. • Contributing to a theoretical framework or body of knowledge. • Test a new device, product, drug or biologic material	• Program evaluation or quality improvement intended **only** for an institution's internal assessment and management. • Biography or medical case history that is not generalizable beyond that individual. • Journalism, Oral History • Political poll • Classroom or training activities where the only objective is to teach students proficiency on a topic. • Disease outbreak investigations and Public Health Surveillance activities conducted, supported, requested, ordered, required, or authorized by a public health authority • Innovative medical therapy to improve the health of an individual patient. • Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes

If you answered 'No' to one question, STOP the proposed activity is **not** research under DHHS regulations.
If you answered 'Yes' to both questions the proposed activity is research under DHHS regulations.
Continue to the next section to determine whether the research involves human participants.

FORM 106: HUMAN SUBJECTS RESEARCH (HSR) DETERMINATION FORM

3. Does the research involve obtaining information **about** living individuals (e.g., personal opinions, thoughts, feelings, etc) ☐ Yes ☐ No

If you answered 'No',  The research is **not** human subjects research under DHHS regulations.
If you answered 'Yes', continue to next question.

4. Does the research involve intervention or interaction with the individuals? ☐ Yes ☐ No
If you answered 'No', continue to next question.
If you answered 'Yes', the research is human subjects research under DHHS regulations. *Submit an application to the IRB for review and approval.*

5. Is the information individually identifiable? ☐ Yes ☐ No

Consider whether the identity of the participant will or may readily be ascertained or associated with the information.

- The research involves access to identifiable private information through access to private records (medical, school, employment, other individual-level data)
- The investigator will be obtaining data/specimens with identifiable private information
- The data/specimens will be coded and the code could allow them to be re-identified, either directly or indirectly via deductive disclosure
- The research involves access to any of the following identifiable private information:

1. Names
2. Account Numbers
3. Certificate/License numbers
4. Social Security Numbers
5. Device Identifiers and serial numbers
6. Health plan beneficiary numbers
7. Full-face photographic or comparable images
8. Vehicle identifiers and serial; numbers, including license plate numbers
9. All elements of dates related to and individual, except year (of birth, admission to facility, etc)
10. Fax Numbers
11. Telephone numbers
12. Electronic email address
13. Medical record numbers
14. Web universal resource locators (URLs)
15. Biometric Identifiers, including fingerprints and voiceprints
16. Internet Protocol (IP) addresses
17. Any geographic subdivisions smaller than a state, except for the initial three digits of a ZIP code
18. Any other unique identifying number, characteristic or code.
19. FAU Z- Number

If you answered 'No',  The research is **not** human subjects research under DHHS regulations.
If you answered 'Yes', the research is human subjects research under DHHS regulations. *Submit an application to the IRB for review and approval.*

SECTION III: FDA Determination for research involving drugs, devices, biologics, tobacco, foods, or other FDA regulated products.
Answer the questions below to determine if your human subjects research is subject to FDA regulations.

FLORIDA ATLANTIC UNIVERSITY

FORM 106: HUMAN SUBJECTS RESEARCH (HSR) DETERMINATION FORM

1. A) Is the clinical investigation an experiment that involves one or more human participants (as defined in IRB Policy 2010-5), and B) Will the investigation involve one or more of the following test articles?

- Foods or dietary supplements that include a nutrient content claim or a health claim
- Infant Formulas
- Food and color additives
- Drugs (including dietary supplements) for human use
- Medical devices for human use
- Biological products for human use
- Electronic products

☐ Yes ☐ No

AND

Are the results of the investigation intended to be submitted to the FDA to support an application for research or marketing permit? ☐ Yes ☐ No

OR

Are the results of the investigation intended to be held for inspection by the FDA as part of an application for a research marketing permit? ☐ Yes ☐ No

If you answered 'Yes', to any of the above, the proposed activity **is** human research under FDA regulations. Your project requires IRB review.
If you answered 'No', to no to any of the above, the proposed activity is **not** research under FDA regulations.