

UIC OFFICE OF THE VICE CHANCELLOR FOR RESEARCH

**RESEARCH VS. NON-RESEARCH:
HOW DO I KNOW IF I NEED IRB APPROVAL?**
VERSION 1.2, 03-14-2019

CHARLES HOEHNE, ASSISTANT DIRECTOR, EDUCATIONAL INITIATIVES
OFFICE FOR THE PROTECTION OF RESEARCH SUBJECTS (OPRS)

ORS ADMINISTRATORS MEETING
WEDNESDAY, MARCH 20, 2019, 1:00 PM
AOB 307C

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Handouts:

- PowerPoint Slides
- Policy: Determination Whether Activities Represent Human Subjects Research at UIC (v3.4, dated 01-21-2019)
- Determination application (V2.6, dated 01-21-2019)
- Screen shots: How to Submit a Determination application

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Objectives:

- Examine the 2018 Common Rule definition of Human Subject Research (January 21, 2019)
- Discuss why this definition is problematic
- Discuss strategies for what to do when you aren't sure if you are conducting Human Subjects Research

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Usual Disclaimer

- OVCR, OPRS and the IRB are not required to agree with me.
- To the best of our knowledge, this presentation is consistent with current OVCR, OPRS and IRB policies, procedures and requirements.

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Key Concepts

- In general, oral history projects, journalism, QA/QI, course-related projects and similar activities do NOT represent human subjects research (HSR) as defined by 45 CFR 46.102(f).
- But they may.
- So, you have to understand the Common Rule definition of "human subjects research" to know whether or not you need IRB approval.
- 2018 Common Rule went into effect on January 21, 2019.

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As per HHS

Institutions must make a Human Subjects Research (HSR) determination on a case-by-case basis by asking the following questions:


- 1) Does the activity involve *research* [45 CFR 46.102(d)]?
- 2) Does the research activity involve human subjects [45 CFR 46.102(f)]?

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“Research” defined:

a systematic investigation including research development, testing and evaluation; designed to develop or contribute to generalizable knowledge.



45CFR46.102(d)

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Generalizable Knowledge

The extent to which research findings and conclusions from a study conducted on a sample population can be applied to the population at large (i.e., extending the results beyond a single individual or an internal unit).

The intent to publish or present findings does not factor into the determination of whether a project satisfies the definition of research.

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“Human Subject” defined:

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

- (1) obtains data or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the data or biospecimens, or
- (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

45 CFR 46.102(e)(1)

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Definitions

- **Intervention:** Includes both physical procedures and manipulation of the subject or his environment *for research purposes*.
- **Interaction:** Includes communication or interpersonal contact between investigator and subjects

45CFR46.102(e)(1-2)

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Definitions

- **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).

45 CFR 46.102(e)(4)

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Definitions

- **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. 45 CFR 46.102(e)(5)
- **Identifiable biospecimen:** is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen. 45 CFR 46.102(e)(6)

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So...



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Problems include:

- Misinterpretation of the Common Rule definitions
- Conflict between Common Rule and the ethical standards of other disciplines:
 - Project: Interview individuals with goal of exposing corruption
 - Journalist: Benefit the greater good by getting to the truth
 - Researcher: Minimize risk by safeguarding confidentiality

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Problem Solving Strategies

Again- In general, oral history projects, journalism, QA/QI, course-related projects and similar scholarly activities do NOT represent human subjects research as defined by 45 CFR 46.102(f).

But, when in doubt:

1. Contact OPRS: uicirb@uic.edu or 312-996-1711
2. Submit a "Determination" application.

(Note: If you know your project is HSR, do NOT submit a "Determination" application. If you do not know what type of initial review application to submit for your HSR, contact OPRS)

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Determination of Human Subjects Research Policy (1 of 4)

- Policy: UIC faculty, staff, and students who intend to conduct activities **that may in part** represent research with human subjects **ARE NOT** authorized to decide independently that the project is not subject to the Human Subjects Protection Program
- Policy updated January 21, 2019 to be consistent with the 2018 Common Rule
- Exceptions next slide

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Determination of Human Subjects Research Policy (2 of 4)

OPRS has determined that the following specific activities do not represent human subjects research and, therefore, **do not require the submission of a determination application**:

- Projects limited to accessing and use of de-identified public datasets. (If you are uncertain as to whether or not the dataset meets this criteria, please consult with OPRS.)
- Projects limited to the use of commercial, de-identified non-embryonic human stem cell lines.
- Case reports pertaining to a single individual. Please note this does not include case series of more than one individual or outcomes of a clinical investigation.
- Projects limited to death records, autopsy records, or cadaver specimens provided that the cadaveric tissues/cells are not used for clinical investigations.
- Course-related activities designated specifically for educational or teaching purposes, where data is collected from and/or about individuals as part of a class exercise or assignment but are not intended for research purposes (e.g., quality improvement projects, Capstone projects). (If you are uncertain as to whether or not the activity meets this criteria, please consult with OPRS.)

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Determination of Human Subjects Research Policy (3 of 4)

- **Scholarly and journalistic activities** (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information that focus directly on the specific individuals about whom the information is collected.
- **Public health surveillance activities**, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
- 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.
- Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

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Determination of Human Subjects Research Policy (4 of 4)

How does this work? If possibly HSR and NOT fully one or more of the exceptions:

1. Submit the "Determination" application via OPRS Live.
2. OPRS staff will review the application ASAP.
3. Any communications during the review can be informal.
4. Formal determination sent by OPRS to investigator via email.
5. If NOT HSR, notification will serve as formal documentation of the determination.
6. If HSR, notification will suggest appropriate required level of review based on information provided (exempt, expedited, or convened)

PIs MAY NOT:

- Initiate any activities until a written determination of not human subjects research is obtained from OPRS.

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So, what's the catch?

- Projects conducted as non-research cannot be retroactively approved as research by the IRB.
- Projects conducted as non-research cannot be published or presented as being research.
- Departmental procedures may need to be developed and implemented to screen and track projects.
- Departments will be responsible for oversight of the activity. OPRS/IRB not responsible for the management of adverse events and/or unanticipated problems.

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Questions or comments?

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OPRS Contact Information

1737 West Polk Street, Suite 203

Phone: 312-996-1711

Email: uicirb@uic.edu

Website:

<http://research.uic.edu/compliance/irb>

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Determination Whether Activities Represent Human Subjects Research at UIC

Version: 3.4; Date: 01/21/2019

Approved by: Human Protections Administrator, Director of OPRS

AAHRPP REF #: 114

AAHRPP Elements: I.1.A., III.1.A

POLICY:

- I. UIC faculty, staff, and students who intend to conduct activities that may not represent research with human subjects as outlined in this policy may not independently determine whether the project is subject to or requires regulatory review.
- II. OPRS has determined that the following specific activities do not represent human subjects research and, therefore, do not require the submission of a determination application:
 - A. Projects limited to accessing and use of de-identified public datasets. (If you are uncertain as to whether or not the dataset meets this criteria, please consult with OPRS.)
 - B. Projects limited to the use of commercial, de-identified non-embryonic human stem cell lines.
 - C. **Case reports** pertaining to a single individual. Please note this does not include case series of more than one individual or outcomes of a clinical investigation.
 - D. Projects limited to **death records, autopsy records, or cadaver specimens** provided that the cadaveric tissues/cells are not used for clinical investigations.
 - E. **Course-related activities** designated specifically for educational or teaching purposes, where data is collected from and/or about individuals as part of a class exercise or assignment but are not intended for research purposes (e.g., quality improvement projects, Capstone projects). (If you are uncertain as to whether or not the activity meets this criteria, please consult with OPRS.)
 - F. **Scholarly and journalistic activities** (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information that focus directly on the specific individuals about whom the information is collected.
 - G. **Public health surveillance activities**, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals,



- risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
- H. 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.
 - I. Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.
- III. For research activities that do not engage UIC (refer to the UIC HSPP policy *Engagement of UIC in Human Subjects Research*) please contact OPRS at UICIRB@uic.edu for further instruction regarding submission requirements.

DEFINITIONS:

- I. "Research involving human subjects" means any activity that meets the definition of "research" and involves "human subjects" as defined by DHHS.
 - A. "Research" means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities are deemed not to be research are specified in the Policy section above. (45 CFR 46.102(l))
 - B. "Human Subject" means a living individual about whom an investigator (whether professional or student) conducting research (1) obtains data or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the data or biospecimens, or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. (45 CFR 46.102(e)(1))
 - 1. "Intervention" includes both physical procedures by which data or biospecimens are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. (45 CFR 46.102(e)(2))
 - 2. "Interaction" includes communication or interpersonal contact between investigator and subject. (45 CFR 46.102(e)(3))
 - 3. "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). (45 CFR 46.102(e)(4))
 - 4. "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. (45 CFR 46.102(e)(5))
 - 5. "Identifiable biospecimen" is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen. (45 CFR 46.102(e)(6))



- II. "Systematic investigation" is a project that is planned in advance and that uses data collection and analysis to answer a specific question, testing a specific hypothesis, or developing a theory.
- III. "Generalizable knowledge" is the extent to which research findings and conclusions from a study conducted on a sample population can be applied to the population at large (i.e., extending the results beyond a single individual or an internal unit). *The intent to publish or present findings does not factor into the determination of whether a project satisfies the definition of research.*

PROCEDURE:

- I. UIC faculty, staff, and students must complete and submit the form, *Determination of Whether an Activity Represents Human Subjects Research at UIC*, to UIC OPRS via OPRS Live for any activities that are believed to not involve human subjects research and do not fall within the categories in the Policy section above.
 - A. If a non-UIC site is to be involved in the activity, a letter of support from the site must be uploaded with this application.
- II. The individuals within the OPRS who can provide a determination as to whether an activity constitutes research involving human subjects at UIC are: a) IRB Chairs or designees; b) Director; c) Associate Directors; d) Assistant Directors; and e) coordinators designated by the Director in consultation with the IRB Chairs as being qualified to make this determination.
- III. All individuals who make the determinations use the *Determination of Whether an Activity Represents Human Subjects Research at UIC* review guide when making their determination.
- IV. A letter is generated by OPRS staff that communicates the determination which is sent via email correspondence to the investigator.

REFERENCE:

45 CFR 46.102(e), 45 CFR 46.102(l)

REVISION LOG:

Version (#, date)	Replaces (#, date)	Summary of changes
2.0, 10/01/08	1.0, 4/23/07	Entire policy revised.
2.1, 03/10/09	2.0, 10/01/08	Policy revised to include <i>Determination of Whether an Activity Represents Human Subjects Research</i> form and direction for investigator to submit form.



Determination Whether Activities Represent Human Subjects Research at UIC, Version 3.3

2.2, 09/17/09	2.1, 03/10/09	Policy revised to include Department of Defense sponsored survey research requirements. Created a more detailed "procedures" section that outlined the process.
3.0, 4/17/12	2.2, 09/17/09	Order of policy revised to separate definitions and procedures. Department of Defense and VA definitions of "research" and "human subjects" included. Addition of commercial cell lines as a not human subject research determination. Name of form revised to include "at UIC" for determination of engagement of UIC.
3.1, 07/01/15	3.0, 4/17/12	Limiting the use of ICPRS datasets to secure online (publicly available) datasets. Rephrasing "research" to "projects" when possible. Restructuring "Definitions" for easier readability. Correction of website links. Removal of VA references.
3.2, 11/18/16	3.1, 07/01/15	Removal of instructions to email completed application due to implementation of OPRS Live. Clarification that submissions are logged in administratively as IRB 7, but are not associated with CHAIRb.
3.3, 09/06/18	3.2, 11/18/16	Removed requirement to submit a determination for activities determined by OPRS to not represent human subjects research.
3.4, 01/21/19	3.3, 07/19/18	Updated to incorporate 2018 Common Rule Requirements.



**Determination Whether an Activity Represents
Human Subjects Research at UIC**

Version: 2.6; Date: 01/21/2019

<http://research.uic.edu/compliance/irb>

UIC faculty, staff, and students who intend to conduct activities that may not represent research with human subjects as outlined in the policy **Determination Whether Activities Represent Human Subject Research at UIC** may not independently determine whether the project is subject to or requires regulatory review.

Date Application Completed:

I. Title of Activity:

II. Personnel

A. Principal Investigator

Name (Last, First)	Degree(s)	Net ID (e.g., NetID@uic.edu)
Department	College	University Status <input type="checkbox"/> Student/Fellow/Resident <input type="checkbox"/> Faculty/Staff
Phone Number	UIC E-mail Address (other, only if no UIC E-mail)	

B. Faculty Sponsor – Complete only when PI is a student, fellow, or resident

Name (Last, First)	Degree(s)	Net ID (e.g., NetID@uic.edu)
Department	College	
Phone Number	UIC E-mail Address (other, only if no UIC E-mail)	

C. Primary Contact Other Than PI – Complete only if the primary contact person is different than the PI

Name (Last, First)	Net ID (e.g., NetID@uic.edu)
Phone Number	UIC E-mail Address (other, only if no UIC E-mail)

Principal Investigator grants this personnel access to OPRS Live for this protocol

D. List all co-investigators and key research personnel on Appendix P and upload with this application packet.

III. Activity Funding



- De-Identified (i.e., not linked to individual identifiers)
- Identifiable
- Coded – Will the code will be accessible to the investigators?
 - No
 - Yes: How?

V. UIC Engagement

Note: If OPRS determines UIC is **not** engaged as part of research, UIC IRB approval is **not** required. Adjunct faculty may still refer to their UIC credentials in publications resulting from this research. Please refer to the UIC HSPP policy [Engagement of UIC in Human Subjects Research](#) for additional information.

- A. Will **UIC** receive direct federal funding through a grant, contract, or cooperative agreement for the research?
 - No
 - Yes

- B. Will **UIC** faculty, staff, or students interact or intervene with subjects or identifiable data or specimens for research purposes by performing invasive or noninvasive procedures, including analysis, or manipulating the environment?
 - No
 - Yes

- C. Will **UIC** faculty, staff, or students obtain the informed consent of subjects for the research?
 - No
 - Yes

- D. Will **UIC** faculty, staff, or students obtain for research purposes identifiable private information or identifiable biological specimens **from any source** for the research, even if not directly interacting or intervening with subjects?
 - No
 - Yes

Note: If a non-UIC site is to be involved in the activity, a letter of support from the site must be uploaded with this application. The letter of support must include:

- a) the name and location of the non-UIC site,
- b) a brief description of the activity (e.g., QI/QA project, access to de-identified data, etc.),
- c) the name and contact information of the person who will be overseeing the activity at the non-UIC site, and
- d) confirmation that the proposed activity may be conducted at the site and that local policies will be observed.

How to Submit a Determination Application

Step 1: If you are a First Time OPRS Live User (<https://oprslive.ovcr.uic.edu/>), please register. Otherwise skip to Step 2:

OPRS Live Login

Email
someone@uic.edu

Password
Password

Login

[First Time User](#) [Forgot Password?](#)

Are you submitting a Determination of Whether an Activity Represents Human Subjects Research Read this first!

QUICK Tips:

1. When registering, UIC faculty, staff and students **MUST** use their UIC Email address.
2. If you do not have a UIC email address, please contact OPRS: uicirb@uic.edu or 312-996-1711
3. You do not have to have UIC Investigator Training Record to submit a Determination application via OPRS Live.

Step 2: Read the instructions first!

OPRS Live Login

Email
someone@uic.edu

Password
Password

Login

[First Time User](#) [Forgot Password?](#)

Are you submitting a Determination of Whether an Activity Represents Human Subjects Research Read this first!

QUICK Tip:

1. The primary purpose of this step is to remind investigators of the nine (9) specific activities that do not represent human subjects research and, therefore, do not require the submission of a Determination application.

Step 3: Login

OPRS Live Login

Email

someone@uic.edu

Password

Password

Login






[First Time User](#)

[Forgot Password?](#)






Are you submitting a Determination of Whether an Activity Represents Human Subjects Research Read this first!

Step 4: In the Researcher Dashboard: Click “Start New Determination Application”:

RESEARCHER

-  Start New Submission
-  Start New Determination Application
-  Submissions that need Modifications
-  My Active Protocols
-  My Completed Protocols

-  My Protocols Expired/Expiring in 45 Days
-  My In-progress Full Applications
-  My Rejected Full Applications
-  My Submitted Full Applications
-  Full Submissions Ready for PI Review

-  Accept Amendments as New PI
-  My In-Progress Quick Applications
-  My Rejected Quick Applications
-  My Submitted Quick Applications
-  Quick Submissions Ready for PI Review

QUICK Tips:

1. Please note that there is a dedicated button on the Researcher Dashboard for submitting Determination applications.
2. **IMPORTANT:** To avoid unnecessary delays in the processing and/or review of your submissions, please **DO NOT** submit any other submission types (e.g., Initial Review Applications, Claim of Exemption application) utilizing the “Start New Determination Application” button.

Step 5: Complete Quick Submission (Step One):

Quick Submission (Step One)

What is the Risk Level for this research?

Minimal > Minimal

Your research may qualify for an expedited or exempt review. [Click Here](#) to review [Expedited](#) and [Exempt](#) Categories.

Submission Number*

Auto Generate

Submission Version*

Auto Generate

Submission Version Description*

Version 1.0

Protocol Title*

Insert the Title of Your Project Here

Main Submission Type*

New

Submission Type*

Initial Review

External Review Agency*

Not Applicable

Review Process*

Exempt

Research Type*

Exemption

Save

Next



QUICK Tips:

1. The purpose of Quick Submission (Step One) is to direct your Determination application to the appropriate review panel.

Step 6: Complete Quick Submission (Step Two):

Quick Submission (Step Two)

Protocol Number (unassigned) **Status:** Pending Submission **Expires:** **Protocol Title:** Insert the Title of Your Project Here

Submission Number: 201904850001 **Version:** 1 **SubmissionType:** Initial Application

Enter PI's Email:

Lookup

[Click here](#) to download IRB related forms

Upload your submissions documents

Select document name for uploading your attachments

Determination of Whether an Activity Represents Human Subjects Research at UIC

Comments

Determination Application

Browse...

[Click here to see File Naming Guidelines.](#)

Upload

Following are documents that you have uploaded

File Name	Form Name	Comments	Uploaded By	Uploaded Date	Download	Delete
Determination Application v1 01-01-2016.doc	Determination of Whether an Activity Represents Human Subjects Research at UIC	Determination Application	[REDACTED]	3/13/2019 3:41:31 PM	Original	Delete

Showing 1 to 1 of 1 entries

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Step 7: Complete Quick Submission (Step Four):

Quick Submission (Step Three)

Please check the checkbox of Terms and Conditions and click on Submit to submit your submission to OPRS.

I, Charles Hoehne agree with the Terms and conditions.

Submission Comments

Determination Application

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Submit