What is a human subject? 45 CFR 46.102 (f)

(f) Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains
(1) Data through intervention or interaction with the individual, or
(2) Identifiable private information.
**Decedents**

“A human subject is … a living individual … ”

Decedents are not human subjects.

HIPAA still applies, so
1) request a determination and
2) complete a HIPAA form for decedents.
(f) *Human subject* means a living individual about whom an investigator conducting research obtains
(1) Data through **intervention** or interaction with the individual, or
(2) Identifiable private information.
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(f) *Human subject* means a living individual about whom an investigator conducting research obtains
(1) Data through intervention or interaction with the individual, or
(2) *Identifiable* private information.
... or obtains **identifiable private information**

Data or samples are identifiable when the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
EXEMPT FROM IRB OVERSIGHT

FULL IRB REVIEW

NOT HUMAN SUBJECTS
NOT HUMAN SUBJECTS

- Data or samples cannot be linked by the investigator to the specific individual, either directly or indirectly through coding systems.
- If non-OHSU and coded, OHSU investigator agrees to never receive the “key to the code.”
- Truly, really, thoroughly anonymous.
EXEMPT FROM IRB OVERSIGHT

Our investigator might or does know the identity of subjects but records only de-identified data.
FULL IRB REVIEW

Identifiable private information is studied.

Our investigator might know the subjects or Identifiers are associated with the data/samples
IRB OVERSIGHT

EXEMPT FROM IRB OVERSIGHT

After initial review, continuing review is conducted every 3 years. Only a few questions are asked.

FULL IRB REVIEW

Annual continuing review with full questionnaire required.

NOT HUMAN SUBJECTS

Memo is generated; study is terminated from eIRB.
EXEMPT FROM IRB OVERSIGHT

- Stays in eIRB so if study changes, it can be easily modified
- Continuing review every 3 years

FULL IRB REVIEW

- More robust research, more variables
- Allows longitudinal data collection
- Allows check-ups on outliers
- Allows re-contact
- Yearly CRQ update

NOT HUMAN SUBJECTS

- Fewer documents required by IRB
- No continuing review required
- No personnel changes to report
- No termination request when study is complete
CONS

EXEMPT FROM IRB OVERSIGHT

- More documents required at initial review
- Termination required
- PI and personnel changes required

FULL IRB REVIEW

- More documents required at initial review
- Full continuing review questionnaire (CRQ) required each year
- Privacy and security protections must be rigorous.

NOT HUMAN SUBJECTS

- Terminated, so if study changes a new study must be created.
- HIPAA forms still required
Identifiers – some are relatively obvious ... 

email@email.com

503-867-5309

MRN PT1000

SS# 123-45-6780

Health Plan #TAKECARE-10-500
Identifiers – some are not obvious.
Identifiers – some really are not obvious.
HIPAA
Level of IRB Oversight is Not Determined by HIPAA.

But ...

WE MUST

COMPLY

WITH

HIPAA
Maybe there’s no “HI” in your “PHI” ...

HIPAA only covers protected health information. If your data aren’t related to health, you will have no HIPAA requirements.
HIPAA’s 16 Direct Identifiers

- Name
- Street address
- Telephone number
- Fax number
- Email address
- Social security number
- Medical record number
- Health plan beneficiary number
- Account number
- Certificate/license number
- Vehicle identifiers and serial number, including license plate number
- Device identifier and serial number
- Web Universal Resource Locator (URL)
- Internet Protocol (IP) address number
- Biometric identifier, including finger and voice print
- Full face photographic image and any comparable image
### Spot the direct identifier ....

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<th>Married</th>
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*Codes derived from identifiers are identifiers.*
HIPAA’s Indirect Identifiers

- Dates
- Age over 89
- City, County, State, or Zip Code

If OHSU releases data that include only these identifiers, a Data Use Agreement must be in place.
### Spot the indirect identifier ....

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Quiz Time

Let’s put our new knowledge to the test...
Scenario 1

Survey being mailed to families in a few Oregon counties related to a recent clinic visit. Initial questions relate to the reason for the visit, several question are rating scales related to satisfaction with the physician, clinic, etc., and one question on the survey asks for one of 3 counties (Benton, Deschutes or Union) to be selected.
Scenario 1 - HIPAA

Q: Does HIPAA apply?
A: Yes – reason for visit will likely elicit health information.

Q: Are any HIPAA identifiers collected?
A: Yes – geographic subdivision smaller than state

Q: Direct or indirect identifier?
A: Indirect
Scenario 1 – IRB

Q: What level of IRB oversight?

Non-human subjects?

Exempt?

Expedited?
**Scenario 1 - Conclusion**

Answer:
This particular submission was ultimately determined to be QI due to the nature of the survey but if the survey were for research the determination on this would have been exempt.

Why:
Survey means interacting/intervening with humans, but identities are not readily ascertainable due to the population of the counties.
Scenario 2

Research on existing data collected by an outside group. Data will be shared with OHSU investigators for research purposes as coded and OHSU investigators will not have access to the "code-break." The data OHSU investigators will receive includes health information and 2 dates (date of last contact and date of death). The N for this particular data set is 5,000.
Scenario 2 - HIPAA

Q: Does HIPAA apply?
A: Yes – data set will include health information

Q: Are any HIPAA identifiers collected?
A: Yes – dates

Q: Direct or indirect identifier?
A: Indirect
Scenario 2 - IRB

Q: What level of IRB oversight?

Non-human subjects?

Exempt?

 Expedited?
Scenario 2 - Conclusion

Answer:
This submission was determined to be non-human subjects research.

Why:
NHS vs. exempt because not only was the identity of subjects considered not readily ascertainable but also there is not interacting/intervening with human subjects in order to obtain the data.
Mark your calendars!

Introduction to IRB Review
5/1/2014
11:30 AM – 12:30 PM
CHH 3178

Lost & Stolen Devices
5/22/2014
11:30 AM – 12:30 PM
UHS 8B60

Education:
http://www.ohsu.edu/xd/about/services/integrity/training/irb-education.cfm

Visit our website for more information:
http://www.ohsu.edu/xd/research/about/integrity/irb/index.cfm