Secondary Analysis of Data and Biospecimens

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Objectives

- Review definitions as they apply to regulatory requirements
- Explore the considerations and process used for secondary research review
- Discuss case examples of determinations
- Review exempt and IRB pathways for secondary research projects
- Examine Total Cancer Care biorepository
- Explore possible secondary use arrangements
How do we determine review requirements?
Federal Regulations

Department of Health and Human Services (DHHS)

- 45 CFR 46 (Common Rule)
- Subpart B: Pregnant women, fetuses, neonates
- Subpart C: Prisoners
- Subpart D: Children

Food and Drug Administration

- 21 CFR 50 (Informed Consent)
- 21 CFR 56 (IRBs)
There are three main questions*:

<table>
<thead>
<tr>
<th>Definitions</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the project <em>research</em> according to the applicable regulations (DHHS, FDA, etc.)?</td>
<td>continue</td>
<td>stop</td>
</tr>
<tr>
<td>Does the project involve <em>human subjects</em> according to the applicable regulations (DHHS, FDA, etc.)?</td>
<td>continue</td>
<td>stop</td>
</tr>
<tr>
<td>Is our institution <em>engaged</em> in the research involving human subjects?</td>
<td>continue</td>
<td>stop</td>
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*the order of the questions matters!
1. Is the project research?

Is the project research according to DHHS regulations?

A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.
Is the project *research* according to FDA regulations?

The FDA has defined “clinical investigation” to be synonymous with “research.”

*Clinical investigation* means any experiment that involves a test article and one or more human subjects that either

1. Meets the requirements for prior submission to FDA under sections 505(i) or 520(g) of the Food, Drug, and Cosmetic Act; or

2. Need not meet the requirements for prior submission to FDA under the sections noted above, but the results of which are intended to be later submitted to or held for inspection by FDA as part of an application for a research or marketing permit.
Questions to ask:

• Is it systematic?
• What is the purpose of the project? Are there multiple purposes (quality improvement, teaching, clinical, research, etc.)?
• Are drugs or devices involved in a way that triggers FDA requirements?
• Is the project designed to develop or contribute to generalizable knowledge?
• How will the data and/or specimens be used?
Systematic Investigation:

A planned scientific or scholarly activity involving qualitative or quantitative data collection and/or data analysis that sets forth an objective(s) and a set of procedures intended to reach the objective(s), i.e., to acquire knowledge, develop a theory, or answer a question.
Generalizable Knowledge:

Information from which one may infer a general conclusion; knowledge brought into general use or that can be applied to a wider or different range of circumstances

- For example, publication and presentation are typical methods used to disseminate research findings, thereby contributing to “generalizable knowledge.” However, not all information that is published or presented represents generalizable knowledge.
- Generalizable knowledge is also interpreted to include data intended for general use, regardless of its eventual distribution or acceptance.
Examples of activities involving secondary analysis that do not meet the definition of research:

• Data collection solely for internal departmental, school, or other university administrative purposes

• Data collection/analysis purely for internal quality improvement/assessment purposes

• Independent contract, commercial, or consultant activities conducted as a service or as work for hire without professional recognition as a collaborator (e.g., no authorship credit, no additional intended research use by Ohio State personnel)
Please Note:

Other processes and requirements may still apply even if the project does not constitute regulated human subjects research

- HIPAA
- FERPA
- Biosafety (IBC)
- Internal quality improvement and/or assessment review processes
2. Does the project involve *human subjects* according to DHHS regulations?

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
Does the project involve *human subjects* according to FDA regulations?

An individual who is or becomes a participant in research, either as a recipient of a test article or as a control. A subject may be either a healthy human or a patient. For research that involves medical devices, a human subject also includes an individual on whose specimen an investigational device is used.
Questions to ask:

• Is information about individuals collected?
• Is information about living individuals collected?
• Exactly what data points are being collected? From where/who? How?
• Are the sources public or private?
• Do the sources contain individually identifiable information?
• Is the development or testing of a device involved?
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 in order for accessing or obtaining the information to constitute research involving human subjects under DHHS rules.
Individually Identifiable

Materials are considered individually identifiable when the identity of the participant is or may readily be ascertained by the investigator or the investigator’s staff, or associated with the information.

Note: Individually identifiable for the purposes of HRPP policy may be similar to, but is not the same as, individually identifiable health information or protected health information as defined by the HIPAA Privacy Rule at 45 CFR Part 160. Limited data sets released from data repositories with IRB approval to release such data sets are not considered to be individually identifiable.
Protected Health Information (PHI)

Health information that is individually identifiable (contains at least one of the 18 HIPAA identifiers) and created or held by a covered entity

- HIPAA authorization is required when the data to be stored for future research include protected health information
HIPAA Identifiers

1. Names
2. All geographical subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code in certain circumstances
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older
4. Phone numbers
5. Fax numbers
6. Electronic mail addresses
HIPAA Identifiers (cont.)

7. Social Security numbers
8. Medical record numbers
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers, including license plate numbers
13. Device identifiers and serial numbers
14. Web Universal Resource Locators (URLs)
15. Internet Protocol (IP) address numbers
16. Biometric identifiers, including finger and voice prints
17. Full face photographic images and any comparable images
18. Any other unique identifying number, characteristic, or code
3. Is Ohio State engaged in human subjects research activities?

Engaged: Involved in human subjects research in such a way (or to the extent) that the ethical and regulatory requirements for human subjects protection are applicable.

An individual (or organization) generally becomes engaged in human subjects research when for the purposes of non-exempt research the individual (or organization’s employee or agent) obtains any of the following:

- Data about research participants through intervention or interaction, identifiable private information about research participants, and/or informed consent of research participants.
Note: An organization is also engaged in human subjects research whenever it receives a direct federal award to support non-exempt human subjects research.

- The fact that Ohio State receives a federal award for work that involves non-exempt human subjects research automatically engages us in human subjects research requiring review (DHHS definitions), even if no activities are taking place at Ohio State or conducted by Ohio State researchers.

- In general, Ohio State IRB review is required. In limited circumstances, we may cede IRB review to one of the other participating institutions, but this is done through a formal process facilitated by ORRP staff.
When are individuals providing existing materials considered engaged in the research?

The Office of Human Research Protections (OHRP) does not consider the act of solely providing identifiable or coded materials (for example, by a tissue repository) to constitute involvement in the research conduct. However, if the individuals who provide the materials cooperate on other activities related to the project with the investigators who receive such information or specimens, then OHRP would consider such additional activities to constitute engagement in the conduct of the research.

Examples of such additional activities include, but are not limited to: (1) the study, interpretation, or analysis of the data resulting from the coded information or specimens; and (2) authorship of presentations or manuscripts related to the research.
Questions to ask:

• What activities will Ohio State personnel perform?
• What materials will Ohio State access or receive?
• What are the roles of any external institutions/investigators?
• What agreements are in place?
• Is Ohio State the direct awardee on a federal grant?
After asking the three questions, there are four possible determinations:

1. The proposed project/activity is not regulated human subjects research (HSR) and may be conducted without requesting exemption or IRB review (no formal application needed); or

2. The proposed project/activity is regulated HSR, but Ohio State is not engaged in the research and the project may be conducted without requesting exemption or IRB review (no formal application needed); or
Possible Review Determinations (cont.)

3. The proposed project/activity is regulated HSR, Ohio State is engaged, and the project appears to meet the criteria for exemption from IRB review (an exempt application should be submitted); or

4. The proposed project/activity is regulated HSR, Ohio State is engaged, and the project requires IRB review (an IRB application should be submitted for Expedited or Full-Board review)

Mailbox: ORRPDeterminations@osu.edu
Examples of Human Subjects Research Determinations
Case 1

A faculty member from Nursing wants to collect and analyze student demographics, student grades, and student assignments, as well as instructor demographics and instructor feedback for the past 5 years in all sections of two introductory level courses generally taught by new faculty.

Does he need review?
Is it research according to DHHS regulations?

Questions to ask-
- Is it systematic?
- Is it designed to develop or contribute to generalizable knowledge?
- What is the purpose of the project?
- How will the data be used?
Additional information

• The faculty member will analyze the data to compare the courses taught both before and after the implementation of a new instructor training program.
• The information he gathers will be used internally to evaluate and improve the training program
• The data will not be used for any other purposes
Not Research

At Ohio State, we would determine that this project is not *research* (and therefore no human subjects review is required), as the purpose of the project is internal, programmatic development.

The project is *not* intended to create, develop, or contribute to generalizable knowledge.
But what if…

the faculty member also knew that in addition to using the data for internal purposes, he wanted to design the project and data collection to make claims applicable beyond Ohio State?

• Now this activity meets the federal definition of research
• Remember that when there is research intent (i.e., a project is designed to develop or contribute to generalizable knowledge) then review is still required even if the project is also intended for non-research purposes, such as quality improvement
Case 2

A doctoral student in the College of Public Health wants to access an existing, federal dataset. The data will be analyzed for her dissertation. It has already been established that the project meets the definition of research under the federal regulations.

Does she need review?
Does it involve *human subjects* according to DHHS regulations?

Questions to ask-

- Is information about living individuals collected?
- Exactly what data is being collected? From where/who? How?
- Are the sources public or private?
Additional information

- All data can be accessed and downloaded directly from the website, without any special permissions.
- Student will not access a restricted version of the dataset or any versions requiring special permissions/approvals.
Not Human Subjects Research

As all data can be accessed and downloaded directly from the website, it is considered freely available to the public and therefore the project does not include human subjects as defined by the federal definition (i.e., there is no identifiable, private information accessed or utilized).
But what if…

the student wanted to access a restricted (or non-public) version of the dataset?

• Then it could be human subjects research requiring review. We would need to know what additional data points were going to be provided, and if the addition of those data points could make the information potentially identifiable

Note: Data holders sometimes mandate IRB review for restricted versions of datasets (even if otherwise de-identified)
Case 3

A faculty member contacts ORRP about a federal award received for a collaborative research project. Ohio State investigators will only be analyzing de-identified specimens, but there is some work being done with identifiable data at other institutions. Our investigator states that the external investigators are obtaining their own IRB approvals and asks if Ohio State IRB approval is also required.
Is Ohio State engaged in human subjects research requiring review?

Questions we ask:

• Is non-exempt human subjects research funded by the grant, even if these activities take place outside of Ohio State and are conducted by non-Ohio State investigators?
• Is the project FDA regulated?
• Is Ohio State engaged in the human subjects research activities? What are we actually receiving?
• Is Ohio State the direct awardee on the grant?
Additional information

• Ohio State is the primary awardee on the federal grant. The other sites will receive funds through Ohio State.

• The project is not FDA-regulated.

• The investigators confirm that non-exempt human subjects research activities are occurring at the other institutions.
Ohio State is engaged in human subjects research (DHHS) requiring review

- The fact that Ohio State receives a federal award for work that involves non-exempt human subjects research automatically engages our institution in human subjects research requiring review (DHHS definitions)
- Ohio State IRB review is required (in limited circumstances, IRB review may be ceded to one of the other participating institutions, but this is done through a formal process facilitated by ORRP)
But what if…

Ohio State was not the primary awardee on the grant?

• Then we need to know more about Ohio State’s exact role in the project, and more details about the biospecimens and data points (if any) Ohio State investigators would receive

• If the primary awardee was an institution other than Ohio State, the project was not FDA-regulated, and our role was only the analysis of completely de-identified materials with a data use agreement (DUA) in place that stated identifiers would never be released to Ohio State investigators, then Ohio State would not be engaged, and no human subjects review at Ohio State would be required
Review is Required: Exemption or IRB Review
Once we establish review is required, we ask these questions to determine the level of review required:

<table>
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<tr>
<th>Definitions</th>
<th>Yes</th>
<th>No</th>
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</thead>
<tbody>
<tr>
<td>Do all activities for the project fall under one or more of the six <strong>exemption</strong> categories?</td>
<td>Stop (submit exempt application)</td>
<td>Continue</td>
</tr>
<tr>
<td>Do all activities fall under one or more of the seven initial <strong>expedited</strong> IRB review categories?</td>
<td>Stop (submit expedited IRB application)</td>
<td>Stop (submit regular IRB application to proceed with convened review)</td>
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</tbody>
</table>
Applicable Categories of Exempt Review
Secondary Use General Exemption Requirements

Reminder: Revised Common Rule Effective Jan 2019

- All activities must fit in one or more of the exempt categories

- Research that includes both exempt and non-exempt activities cannot be split apart in order to request exemption for one activity. This stipulation is true both internally and when collaborating with outside universities.
Secondary Use General Exemption Requirements (cont.)

Reminder: Revised Common Rule Effective Jan 2019

• No research involving prisoners
• No research subject to FDA regulations
• Research must be minimal risk
Exempt Category #1

Reminder: Revised Common Rule Effective Jan 2019

Research conducted in established educational settings involving normal educational practices

- Regular and special education instructional strategies; or
- Effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods
Exempt Category #1 Reminders

Reminder: Revised Common Rule Effective Jan 2019

• Normal educational practices (not just using data collected in/from schools for other purposes)
• Data can be prospective, retrospective, or both
• Data can be identifiable or potentially identifiable (identifiable should not pose risk to participants)
• Consent should be obtained when possible
Exempt Category #1 Examples

• A research study involving the collection of student data to compare student performance on a professional exam before and after a new required course is implemented

• A research project looking at student records, demographics, satisfaction, and graduation rates in field X across institutions

• A research project analyzing standardized testing data over several years
Exempt Category #4

Reminder: Revised Common Rule Effective Jan 2019

Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.
Existing

Materials must be “on the shelf” by the time the research is submitted

• There must be no plans for ongoing collection

• Serial applications (e.g., intending to submit an application at the end of each year to obtain the year’s data) are not permitted
Individually Identifiable

Materials are considered “individually identifiable” when the identity of the participant is, or may readily be ascertained by, the investigator or the investigator’s staff, or associated with the information.

For research involving use of or access to protected health information (PHI), this means that no HIPAA identifiers (which include dates, zip codes, etc.) can be collected or received.

**Note:** Limited data sets released from data repositories with IRB approval to release such data sets to other investigators (such as the Information Warehouse at Ohio State) may not be considered individually identifiable with data use agreements in place.
Individually Identifiable (cont.)

In order for a project involving patient information to be considered to be de-identified at Ohio State, there must be more than 25 potential subjects that fit the inclusion criteria.

Please note that projects with more than 25 individuals may still be considered potentially identifiable. The ability to de-identify data depends on the specific project, the data point(s) in question, and the potential for indirect identification. Materials are considered de-identified when all direct personal identifiers are permanently removed (e.g., from data or specimens), no code or key exists to link the information or materials back to their original source(s), and the remaining information cannot reasonably be used by anyone to identify the source(s).
Exempt Category #4 reminders:

Reminder: Revised Common Rule Effective Jan 2019

- Cannot be FDA regulated (no device development, research results cannot be held for review or intended for submission to the FDA in support of a report or marketing permit)

- “Existing data or specimens” means that the materials must be “on the shelf” at the time (or before) the research is submitted for an exemption determination

- No identifiers can be collected as part of the data intended for analysis
Exempt Category #4 reminders (cont.):

- In some instances, investigators can create and use a temporary list or key to access information from more than one location, but only if it is part of the same record (e.g. the patient’s regular Ohio State medical record information is housed in two different databases, or exists partially in paper, partially electronically). Only a simply list (e.g., a list of MRNs) or a simple key (e.g., MRN = random study number) can be created, and this list/key must be destroyed immediately after collection, prior to any analysis, processing, or use of the data/specimens. If investigators need to retain a link, IRB review is required.

- The link can only be used to access information for a single source (e.g. the patient’s Ohio State medical record), and it cannot be used to combine completely separate sources of data (e.g. the Ohio State medical record with data from the patient’s nursing home record, QI record, school record, work record, and/or private physician’s record).
Exempt Category #4, example 1:

A research project that involves data collection from IHIS to investigate the relationship between age, medication type, and outcomes of three common medications used to treat diabetes

- The date range of data to be collected is 01/01/2012 – 01/01/2018

- Only age, race, gender, medication type, dose, comorbidities, and outcome are collected (no HIPAA identifiers)

- Investigators will create a separate, temporary list of MRNs to aid in data collection, but the list will be destroyed immediately after collection, prior to any analysis
Exempt Category #4, example 2:

An employment agency conducts a survey of temporary employees and employers after each placement. The surveys contained basic demographics, including some identifiable information, and 10 questions on general responsibilities and satisfaction. A researcher wants to access the materials to obtain de-identified materials for research purposes:

• The researcher accesses the surveys onsite and only records the responses to the 10 satisfaction questions (which contain no identifiers) to use for her research

• The date range of data to be collected is 01/01/2016 – 01/01/2018

• Investigators will create a separate, temporary list of employee names to aid in data collection, but the names will be destroyed as data is collected, prior to any analysis
Applicable Categories of IRB Review
Expedited IRB Category #5:

Reminder: Revised Common Rule Effective Jan 2019

Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes, such as medical treatment or diagnosis

Note: Some research in this category may be exempt from the DHHS regulations for the protection of human subjects. This listing refers only to research that is not exempt
How does expedited category #5 differ from exempt category #4?

Reminder: Revised Common Rule Effective Jan 2019

Expedited IRB Category #5 is used when:

- Separate sources need to be combined (e.g., education records with medical record)
- Fewer than 25 individuals at Ohio State meet the inclusion criteria
- Potential or actual identifiers are needed (HIPAA identifiers, need to retain key during analysis)
- Data needs to be collected that will come into existence after the date the research is proposed
Expedited IRB Category #5, example 1:

A research project that involves data collection from IHIS to investigate the relationship between age, medication type, and outcomes of three common medications used to treat diabetes

• The date range of data to be collected is 01/01/2012 – 01/01/2020 as there is an additional drug that was only recently approved and investigators want to compare data on its outcomes as well

• Investigators need to collect HIPAA identifiers for analysis

• Investigators need to retain a key to identifiers during analysis in case they need to go back and confirm the data collected or determine the need to collect additional data points
Expedited IRB Category # 5, example 2:

An employment agency conducts a survey of temporary employees and employers after each placement. The surveys contained basic demographics, including some identifiable information, and 10 questions on general responsibilities and satisfaction. A researcher wants to access the materials to obtain data for research purposes:

• The researcher accesses the surveys onsite and records all responses to the survey except for employee names, but the data collected (specific demographics, dates of employment, and employing company) is potentially identifiable

• The date range of data to be collected is 01/01/2016 – 01/01/2018, but the investigator may need to go back for more data. Also, though not planned as part of the first phase, the researcher may want to amend the project to conduct some interviews of the employees
Expedited IRB Category #7:

Reminder: Revised Common Rule Effective Jan 2019

Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies

Note: Some research in this category may be exempt from the DHHS regulations for the protection of human subjects. This listing refers only to research that is not exempt
Expedited IRB Category #7 examples:

• Research utilizing existing national datasets where non-public, potentially identifiable (or identifiable) versions are utilized, but the research is intended to study group characteristics or behavior

• Accessing identifiable information and recordings from a private linguistics bank for a secondary study on elements of language X

• Secondary analysis research utilizing existing, identifiable Ohio State research data where the secondary research is intended to study group characteristics or behavior
Full (Convened) IRB Review

Reminder: Revised Common Rule Effective Jan 2019

- Research outside expedited review categories
- Potentially greater than minimal risk
Full (Convened) IRB Review examples:

• Investigators need to access their own research data or banks to collect data to use for a secondary study that does not fall under expedited category #7, and the original sources contain identifiers (even if researchers do not intend to use the identifiers for the secondary project).

• Research that intends to collect and analyze existing, identifiable data that poses greater than minimal risk to individuals (e.g., data about criminal behavior, illegal drug use, etc.)
HRPP Policies, Links, and Guidance
HRPP Polices
http://orrp.osu.edu/irb/osuirbpolicies/hrpppolicies/

HRPP Glossary
http://orrp.osu.edu/irb/osuirbpolicies/hrppglossary/

FAQs
http://orrp.osu.edu/irb/irb-faqs/

Ohio State Research Involving Data and/or Biological Specimens Policy:
http://orrp.osu.edu/irb/osuirbpolicies/hrpppolicies/
FERPA Policy
https://registrar.osu.edu/policies/privacy_release_student_records.pdf

Student Data
http://oesar.osu.edu/

HIPAA Guidance
http://orrp.osu.edu/irb/investigator-guidance/hipaa/

Ohio State University Privacy Officers
http://orrp.osu.edu/files/2016/04/privacyofficers-041416.doc
Summary Overview

- Ask three main questions...in order
- Use available resources
- Contact ORRP for guidance
Total Cancer Care Repository
Original consent form defines the type of secondary research that can be performed

- Patient must consent to secondary use of their leftover samples in original consent form – consider your wording
  - Additional research on colorectal cancer
  - Additional research on cancer
  - Additional medical research

- Consider issues surrounding Return of Results
  - Increasing momentum behind returning results (even research) – if so may need contact person listed & consideration of who will pay for any necessary follow-up appointments or confirmation testing in a CLIA lab

- Consent must outline how additional research requests will be reviewed and approved and whether or not identifiers can be provided with samples or not
OSU IRB now requires a separate biorepository protocol and consent form

• For all of the reasons just described, OSU now requires a separate biorepository protocol and consent form if your research study would like to retain leftover samples/data for future unspecified research

• Consider using Total Cancer Care as your biorepository protocol if it fills your needs (cancer only)

• Past studies that did not include this are encouraged to submit a protocol outlining the procedures for requesting and approving secondary research on their remnant samples, what types of research can be performed (based on the original consent), and whether or not the secondary research can be done with and without identifiers – possibility of rolling these into TCC
Total Cancer Care Protocol

- Total Cancer Care: A *lifetime partnership with patients of the James*

  - Lifetime consent
  - Commercialization
  - Access to medical information
  - Genomic testing
  - Identify and recontact patients
  - Store blood and tissue

The James
TCC at OSU has enrolled over 42,300 patients
Facilitating Research

- Enrollment costs covered by the Cancer Center
- Enrollment staff trained by the Behavioral Measurement Shared Resource at OSUCCC
- Biospecimens – no additional risk protocol due to high volume
  - Additional blood at time of clinically indicated draw
  - Leftover tissue, fluids
  - Ability to obtain additional non-invasive samples (e.g. saliva, urine)
  - Ability to request specimens from previous procedures (FFPE blocks) both from within OSU and outside of OSU
- Biorepository located at OSU Polaris Innovation Centre
  - DNA, serum and plasma extracted from blood – costs covered by the Cancer Center
  - No cost to withdraw data or samples at this time – may be in future
Use of an Honest Broker

- OSU Information Warehouse has an IRB-approved Honest Broker protocol
  - Ability to train other honest brokers at OSU
- OSU Information Warehouse submitted a TCC-specific Honest Broker protocol in conjunction with the TCC biorepository protocol
  - TCC protocol covers patient enrollment, informed consent and sample deposits into the biorepository
  - IW TCC Honest broker protocol covers withdraws from the biorepository
Advantages of Using an Honest Broker

- De-identified data or samples are considered Non-Human Subjects Research
  - No IRB protocol needed to do research using these samples or data (not even exempt status or expedited)
- Caveats which would require an IRB-approved protocol:
  - Minimum sample size = 10; otherwise tumor is likely so rare that everyone knows who the patients are
  - No complete genomic sequencing; considered identifiable
- Honest Broker can keep linking file for 90 days in case researcher thinks of another piece of data or additional sample that they need.
  - After 90 days the linking file must be permanently destroyed
- Identifiable data or samples can be used in research with IRB-approval
  - Ability to transfer samples/data back and forth between another IRB-approved research study at OSU as long as patient is consented to both studies

The James
Benefits to Our Researchers

- Centralized banking and access to more complete and high quality specimens and clinical data
- **No cost** for
  - Recruitment & universal consenting of James patients
  - Acquisition & storage of blood (DNA, serum and plasma), tumor tissue & bone marrow aspirate; other non-invasive specimens
  - Distribution of specimens and data
  - Coordinating with TCC
    - Prospective
    - Retrospective
  - Request and approval process
Working with Existing Biobanks

- Centralized vs. decentralized
- Understand purpose of bank (cell lines, xenografts, fresh/frozen tissue, etc.)
- Explore opportunities to leverage TCC (if applicable)
- Explore opportunities for master bank by disease site + TCC (vs. many smaller banks)
- Messaging to PIs
Protocol Coordination

- Coordination with existing and new protocols
  - Process
  - Advantages for investigators
  - Examples: head & neck, leukemia, endocrine neuroplasia

- Providing advice and guidance to PIs
  - Current/Future Protocols

- Dual consenting
TCC Data and/or Biospecimen Requests

- Enter request through eRAMP (OSUCCC Shared Resource Ordering System).
- It will ask for fund #--you can leave blank as it is free of charge.
- Request will get routed to project manager who will assess feasibility and contact with you amount available, questions.
- Once agreed upon, it goes to a TCC Standing Research Committee with disease-specific representation where it will be approved, disapproved or generate more questions.
- Once approved, distribution begins.
Select the BSSR to access TCC forms
TCC Research Committee

- Reviews all TCC/ORIEN requests for use of specimens and data
- 1 MD & 1 PhD (hem); 1 MD & 1 PhD (solid tumor); TCC PI (non-voting); + Disease-Specific Research Group Leader
- Disease-Specific Research Group Leaders have unilateral veto power
- Interaction primarily via email
- TCC Operations Director and Project Manager manage process
Monitoring and Quality Assurance

- Protocol/Consent
- Consent data
  - EMR
  - Hard copy
- Blood draw orders
  - Placed
  - Released, not drawn
- Tissue procurement
  - Quality
  - Timing
  - Shipping
- Inventory
- Distribution
TCC Core Team

PI: Heather Hampel
    614-293-7240; Heather.Hampel@osumc.edu

Director, Clinical Research Operations: Nancy Single
    614-293-7516; Nancy.Single@osumc.edu

Operations Director: Laura Monovich
    614-293-3675; Laura.Monovich@osumc.edu

Consent Director: Cecilia DeGraffinreid
    614-293-6917; Cecilia.DeGraffinreid@osumc.edu

James Cancer Registry Director: Maria-Teresa Ramirez
    614-293-6657; Maria-Teresa.Ramirez@osumc.edu

BSSR/TCC Biorepository Manager: Jason Bacher
    Jason.Bacher@osumc.edu
Questions?

Protecting Human Subjects in Research at Ohio State

Human Subjects

The Human Research Protection Program is responsible for all Ohio State research involving human subjects. The HRPP’s primary responsibility is to protect the rights and welfare of human research subjects, in accordance with Department of Health and Human Services (DHHS) and Food and Drug Administration (FDA) regulations.