MICHR
Michigan Institute for Clinical & Health Research

Improving, Expediting and Tracking Informed Consent

University of Michigan and US Initiatives

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Lunchtime Seminar
28 June 2011
Oxford University

UNIVERSITY OF MICHIGAN

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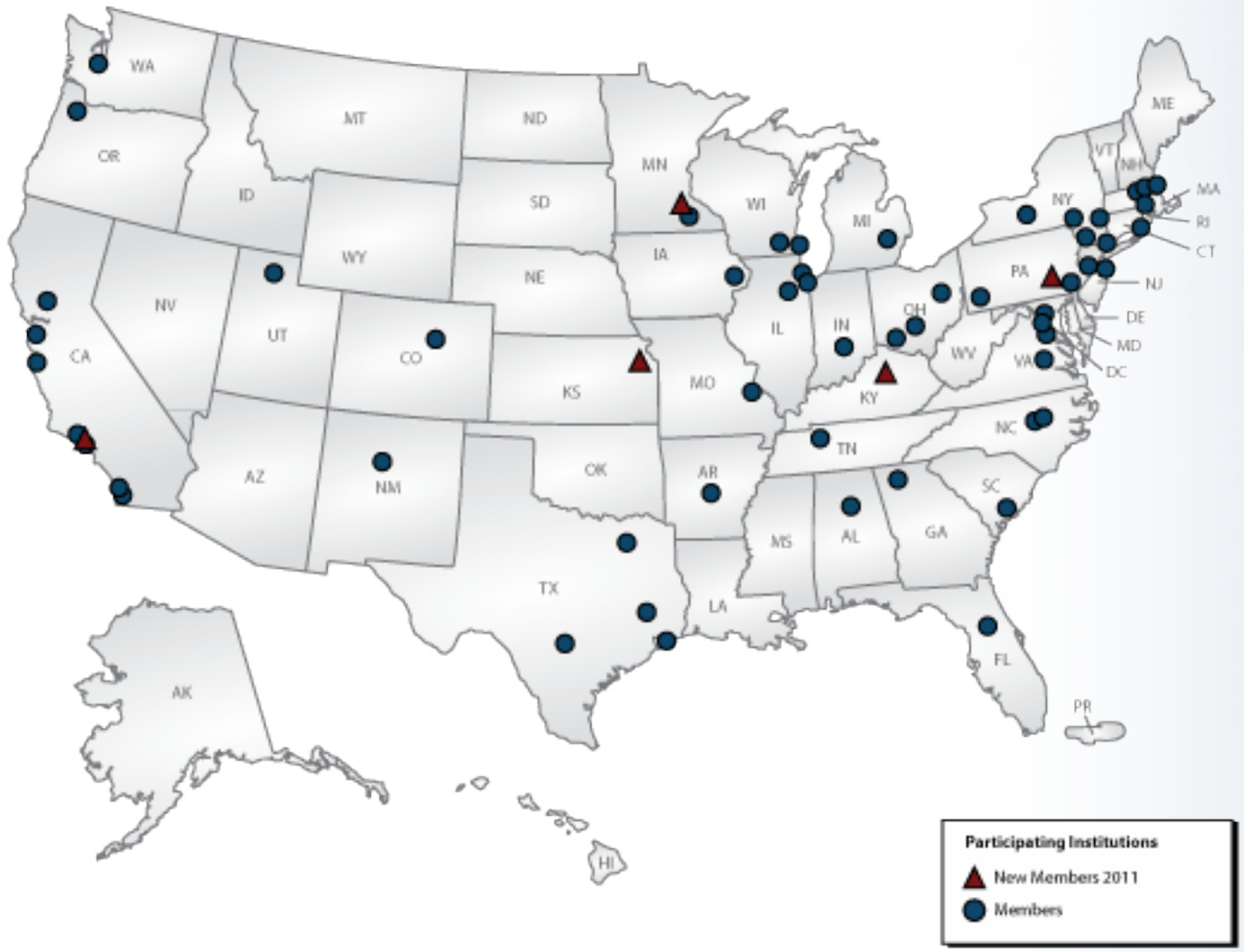
Michigan Institute for Clinical & Health Research

Clinical & Translational Science Awards



CTSA Clinical & Translational Science Awards ®
Translating Discoveries to Medical Practice

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University of Michigan

CTSA Clinical Research Ethics KFC

1. Education
2. Biobanks
3. Community engagement
4. Consults
5. Collaboration
6. IRB Quality

Human subjects research

- ✓ Most not complicated
  - Minimum risk (80-90% at Michigan)
- ✓ Some poses real dilemmas (no best answer)
  - Example, re-use of cardiac pacemakers
- ✓ Some areas need more study
  - Informed consent

Why informed consent?

- ✓ Nuremberg Code
  - The voluntary consent of the human subject is absolutely essential
  - Consent must be informed
- ✓ Primary goal/mission of ethics committees
- ✓ Significant shortcomings in current process
  - Focus has been primarily on specific cases
  - This presentation will focus on systemic problems

Informed consent dilemma

- ✓ As research becomes more complex
  - Longer IC forms
  - More complex IC forms
  - Less understanding
- ✓ Research has shown
  - IC forms not written at understandable levels
  - Longer IC forms ——> less understanding
- ✓ Dilemma: The need to document understanding in IC forms has reduced subject understanding of the research

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MICHR Genomic DNA BioLibrary Project

Two goals:

1. RESOURCE for translational research
2. RESEARCH LABORATORY for study of ethical and policy issues

Primary Goal: Service

- ✓ Collect, store and share biological materials & health information
- ✓ Specific goals:
  - Initially genomic DNA; may broaden later
  - Serve MICHR researchers and through them broader collaborations
  - Large collection – 100,000 samples
  - Safely stored
  - ...and shared

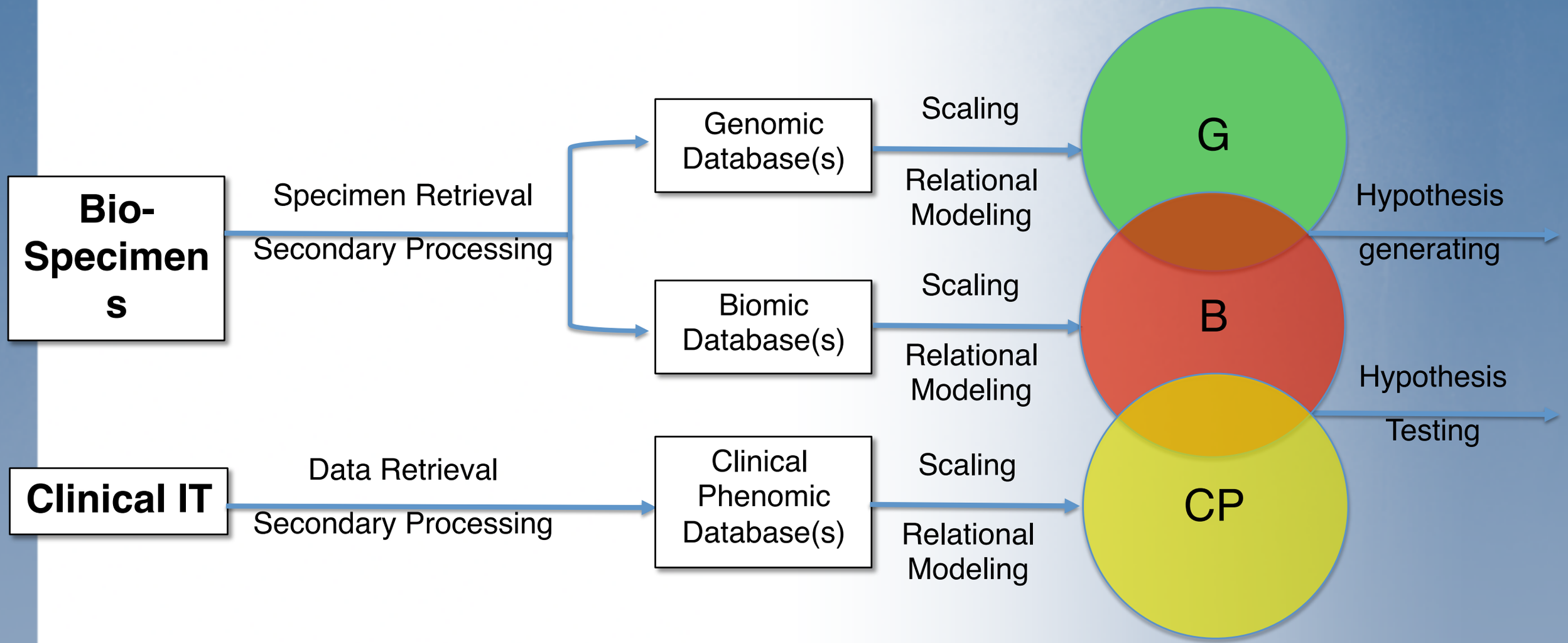
Secondary goal: Research

- ✓ Hypothesis: can establish and maintain a scientifically *useful* and *ethically responsible* Genomic DNA BioLibrary
- ✓ Aims:
  - Establish and validate a process/system to collect, isolate, annotate, store and retrieve samples of genomic DNA
  - Establish and validate a process/system to distribute and share samples of genomic DNA
  - Determine the scientific and societal value of the BioLibrary at both an institutional and national level

Why BioLibrary?

- ✓ Set tone for project, considered:
  - (BIO) Repository: a place for storing things
  - (Bio) Bank: brings in concept of security
  - (Bio) Trust: Sense of collaboration/trust between two parties
- ✓ Library
  - Talk in terms of donating “books”
  - Books contain useful information
  - Information in books is regularly shared
  - Libraries are a community resource
- ✓ Emphasize community (social) over individual

Bioinformatics, Sequential Logic Model



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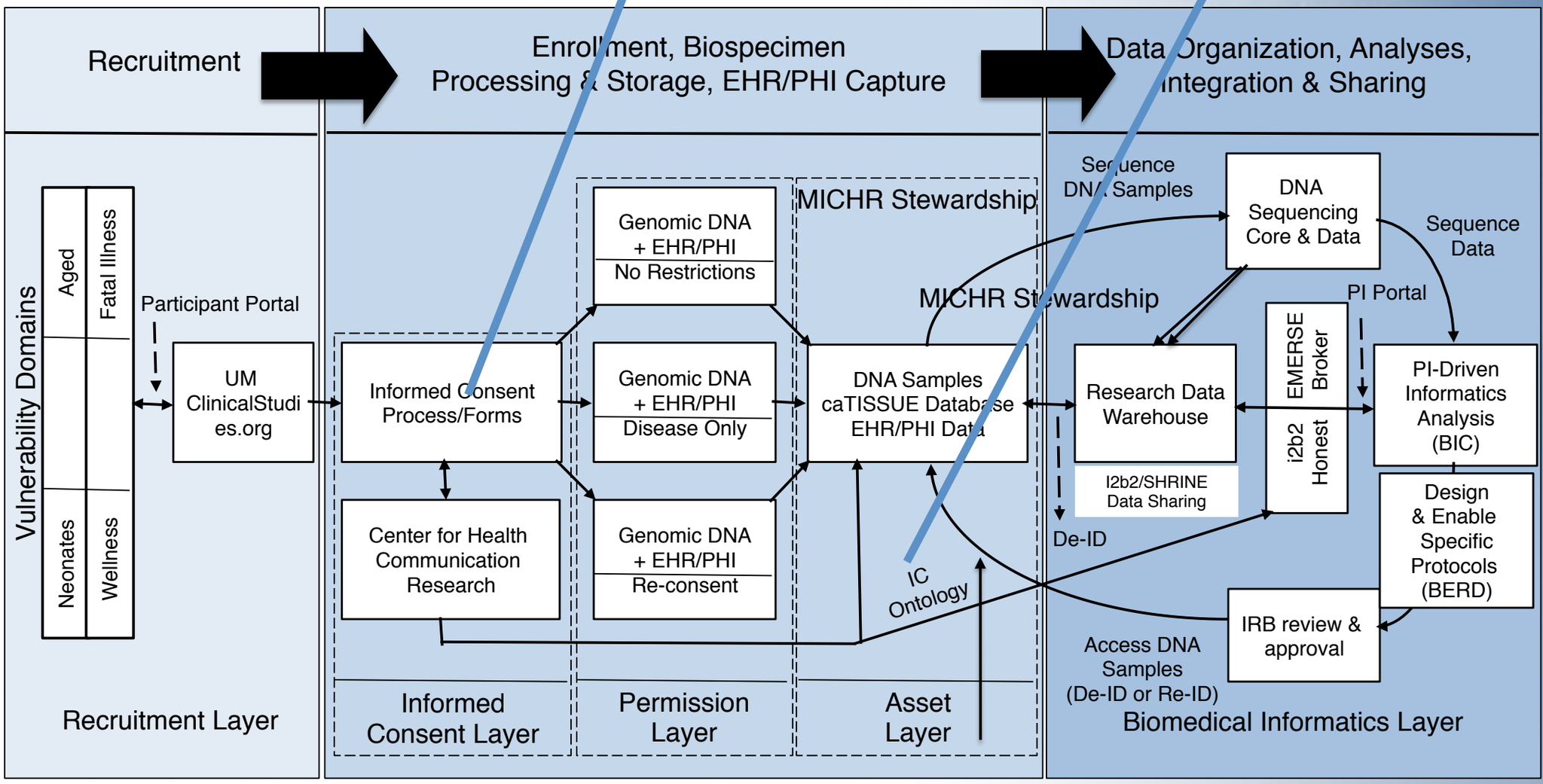
1. Informed Consent

2. Ontology

Organizational Model



Project 1: Informed consent

- ✓ Major challenge: enrolling 100,000 subjects
- ✓ Options:
  - Opt-out without REC (IRB) approval
  - Opt-out with REC (IRB) approval
  - Opt-in with REC (IRB) approval
- ✓ Goal: greatest efficiency without compromising ethics
- ✓ Poll: which option?

Opt-out without RE approval

- ✓ Use excess materials from routine visits
- ✓ De-identify, which exempts from US regs.
- ✓ Use “honest broker” to link with health record
- ✓ Provide opt-out option during admission
- ✓ Objections:
  - Participants want information and choice
  - No evidence that participants understand their choice

Opt-out with approval

- ✓ Bring to REC for approval
- ✓ Provide participants full information, validated for effectiveness
- ✓ Present choice as an opt-out option
- ✓ Objections:
  - Choice based on presumed higher enrollments
  - Enrolling subjects who might do so if asked to opt-in
  - Not setting highest ethical standard

Opt-in with REC approval

- ✓ Slow, expensive, slows research
- ✓ Solution: improve informed consent process
- ✓ Approach:
  - Separate “informing” from “consenting”
  - Validate informing process
  - Integrate into clinical workflow
- ✓ Goal: validated consent as part of normal clinical workflow

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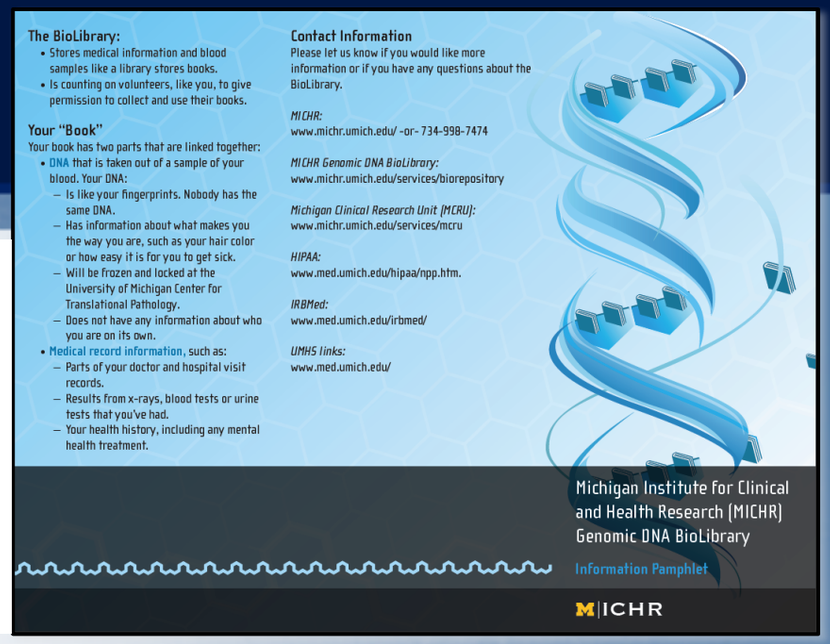
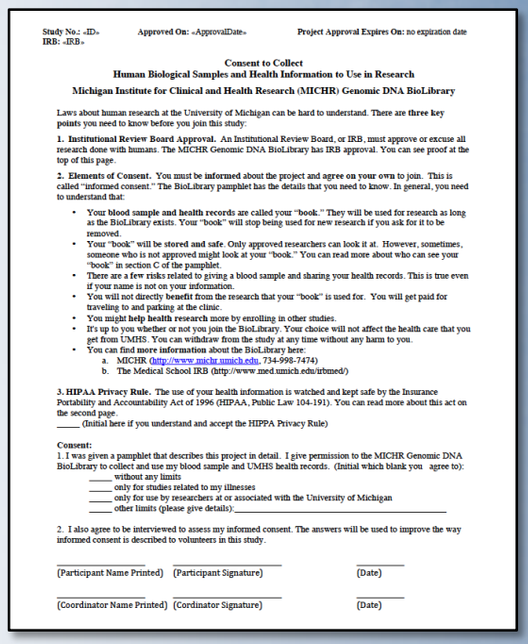
✓ BioLibrary Pamphlet

- Include essential information about trial
- Designed to convey understanding
- Validate prior to use



✓ Current IC Forms

- Include essential information about trial
- Often long & complex
- Studies show do not convey understanding



Study No.: «ID» Approved On: «ApprovalDate» Project Approval Expires On: no expiration date
IRB: «IRB»

Consent to Collect
Human Biological Samples and Health Information to Use in Research
Michigan Institute for Clinical and Health Research (MICHR) Genomic DNA BioLibrary

Laws about human research at the University of Michigan can be hard to understand. There are **three key points** you need to know before you join this study:

1. **Institutional Review Board Approval.** An Institutional Review Board, or IRB, must approve or excuse all research done with humans. The MICHR Genomic DNA BioLibrary has IRB approval. You can see proof at the top of this page.

2. **Elements of Consent.** You must be **informed** about the project and **agree on your own** to join. This is called "informed consent." The BioLibrary pamphlet has the details that you need to know. In general, you need to understand that:

- Your **blood sample and health records** are called your "book." They will be used for research as long as the BioLibrary exists. Your "book" will stop being used for new research if you ask for it to be removed.
- Your "book" will be **stored and safe**. Only approved researchers can look it at. However, sometimes, someone who is not approved might look at your "book." You can read more about who can see your "book" in section C of the pamphlet.
- There are a **few risks** related to giving a blood sample and sharing your health records. This is true even if your name is not on your information.
- You will not directly **benefit** from the research that your "book" is used for. You will get paid for traveling to and parking at the clinic.
- You might **help health research** more by enrolling in other studies.
- It's up to you whether or not you join the BioLibrary. Your choice will not affect the health care that you get from UMHS. You can withdraw from the study at any time without any harm to you.
- You can find **more information** about the BioLibrary here:
  a. MICHR (http://www.michr.umich.edu, 734-998-7474)
  b. The Medical School IRB (http://www.med.umich.edu/irbmed/)

3. **HIPAA Privacy Rule.** The use of your health information is watched and kept safe by the Insurance Portability and Accountability Act of 1996 (HIPAA, Public Law 104-191). You can read more about this act on the second page.
_____ (Initial here if you understand and accept the HIPPA Privacy Rule)

Consent:
1. I was given a pamphlet that describes this project in detail. I give permission to the MICHR Genomic DNA BioLibrary to collect and use my blood sample and UMHS health records. (Initial which blank you agree to):
____ without any limits
____ only for studies related to my illnesses
____ only for use by researchers at or associated with the University of Michigan
____ other limits (please give details):_____

2. I also agree to be interviewed to assess my informed consent. The answers will be used to improve the way informed consent is described to volunteers in this study.

_____ _____ _____
(Participant Name Printed) (Participant Signature) (Date)

_____ _____ _____
(Coordinator Name Printed) (Cordinator Signature) (Date)

✓ BioLibrary IC Forms

- Essential regulator information
- Signatures
- Record

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Pamphlet

The BioLibrary:

- Stores medical information and blood samples like a library stores books.
- Is counting on volunteers, like you, to give permission to collect and use their books.

Your "Book"

Your book has two parts that are linked together:

- DNA that is taken out of a sample of your blood. Your DNA:
  - Is like your fingerprints. Nobody has the same DNA.
  - Has information about what makes you the way you are, such as your hair color or how easy it is for you to get sick.
  - Will be frozen and locked at the University of Michigan Center for Translational Pathology.
  - Does not have any information about who you are on its own.
- Medical record information, such as:
  - Parts of your doctor and hospital visit records.
  - Results from x-rays, blood tests or urine tests that you've had.
  - Your health history, including any mental health treatment.

Contact Information

Please let us know if you would like more information or if you have any questions about the BioLibrary.

MICHR:
www.michr.umich.edu/ -or- 734-998-7474

MICHR Genomic DNA BioLibrary:
www.michr.umich.edu/services/biorepository

Michigan Clinical Research Unit (MCRU):
www.michr.umich.edu/services/mcru

HIPAA:
www.med.umich.edu/hipaa/npp.htm.

IRBMed:
www.med.umich.edu/irbmed/

UMHS links:
www.med.umich.edu/

Michigan Institute for Clinical and Health Research (MICHR) Genomic DNA BioLibrary

Information Pamphlet

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Consent

A. IRB approved
B. Elements of Consent
C. HIPAA
D. Options
E. Record

Study No.: «ID» **Approved On:** «ApprovalDate» **Project Approval Expires On:** no expiration date
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_____	_____	_____
(Participant Name Printed)	(Participant Signature)	(Date)
_____	_____	_____
(Coordinator Name Printed)	(Cordinator Signature)	(Date)

Validation process

- ✓ Recruiting through UMclinicalstudies.org
- ✓ Email pamphlet, ask if interested
- ✓ If yes, schedule visit
  - Consent (one page, BioLibrary and HIPAA)
  - Understanding assessment
  - Further explanation of misunderstandings
  - Opportunity to withdraw
  - Provide blood sample

Results of validation process

- ✓ Participation / 100 potential subjects contacted:
  - 45% respond, agree to participate, schedule appointment
  - 99% of those who visit clinic provide a sample
  - Pamphlet provides essential information, few misunderstandings
- ✓ Limitations:
  - Study population has already agreed to participate in research
  - Literate, university-oriented population (selected by zip codes)
- ✓ Next step to broaden to other populations
  - First University clinics, then community settings

Clinical workflow study:

- ✓ Challenges:
  - Recruiting ~ how and when to introduce the study
  - Space/time ~ can't slow patient flow, occupy valuable space
  - Expertise ~ training clinical staff to respond to questions
- ✓ Ethical issues ~ coercion and distraction
  - Increasing pressure to recruit during clinical visits
  - Physician has authority and can have conflicts of interest
  - Participant's first concern is person health, not research
- ✓ Launching workflow study in 3 clinical settings

Cost-benefit study

- ✓ Nuremberg
  - The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, …
- ✓ Two questions:
  1. Do “BioLibraries” yield fruitful results, unprocurable by...”?
  2. Is “opt-in” too expensive to justify taking moral high road?
- ✓ Cost-benefit of biobanks not carefully studied
  - Opt-in may add as little as $8.00/sample

Project 2, Informed consent ontology

- ✓ ICs are complex documents
- ✓ Information in ICs is largely not shareable
  - At Michigan, scanned and put is patient/participant file
  - Image file, not possible to access content
- ✓ Why is this important?
  - Vital to sharing samples and information (biobanks)
  - Essential for regulatory oversight
- ✓ Goal: to create a framework for collecting, storing and sharing IC information

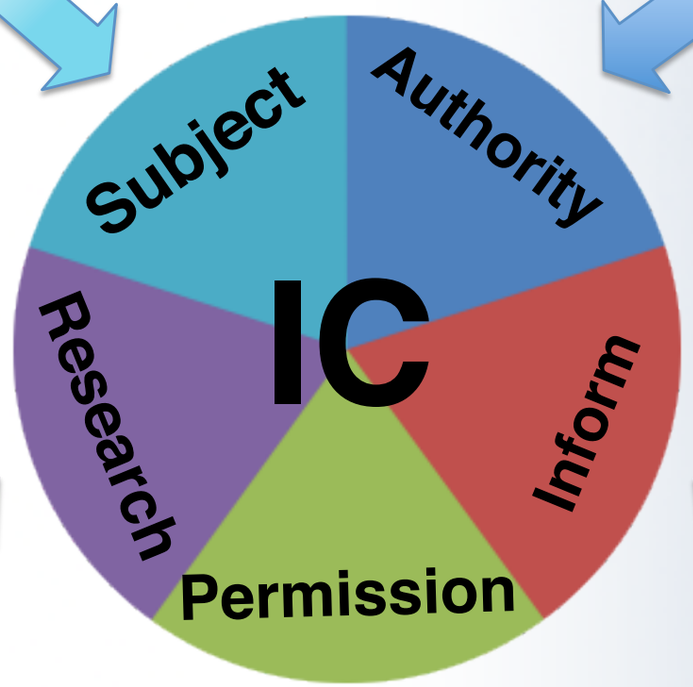
IC = Authorized Informed Permission to conduct Research on research Subjects

Authorized?	Informed?	Permission?	Research?	Subject?
Authority	Process	Scope	Methods	Age
Institution	Elements	Duration	Materials	Race
Method	Validation	Contact	Data	Gender
		Privacy	Storage	Ethnicity
			Security	Capacity

Two purposes: Organize & Guide

Patient Record

Institutional Records



Protocol

REC

Informed Consent Form

Challenges

1. Developing a comprehensive ontology
2. Connecting the ontology with research, patient and institutional records

Questions