Elements of the IRB Process

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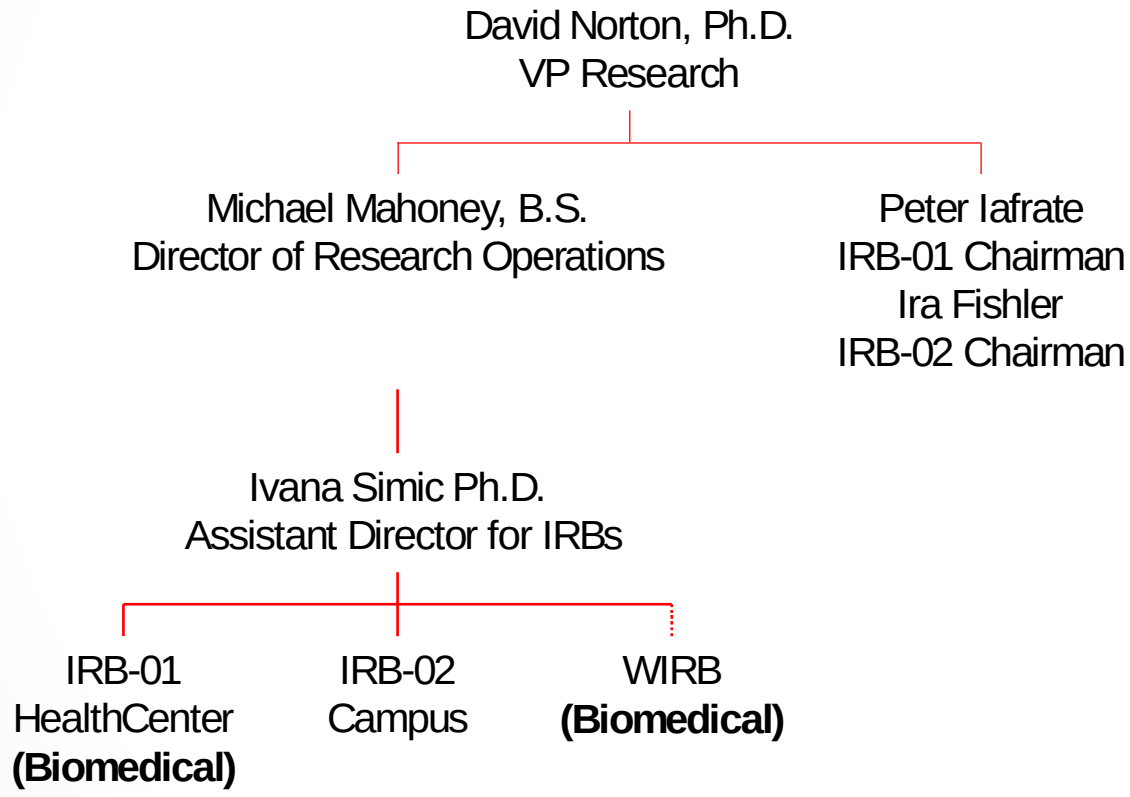
Objectives

- Research at UF (IRB, ancillary committees/offices)
- Why is Research Regulated and Regulatory Frameworks
- What Does It Mean to be Engaged in Research
- Exemptions
- Single IRB/Collaborative Research

UF Office of Research



UF IRBs

- IRB-01: (Biomedical) Health Science Center, Shands, (Gainesville and Jacksonville), VAMC, affiliates (Sacred Heart, Halifax)
  - IRB-01 also serves as the Privacy Board to ensure HIPAA compliance when it comes to approving alternations and/or waivers of HIPAA authorization.

- IRB-02: (Social/Behavioral)
  - No PHI
  - No VA
  - No tissue
  - No nurses
  - No medical devices/drugs

Commercial IRBs

- Western Institutional Review Board (WIRB)(Biomedical)
  - Industry authored, FDA regulated, multicenter clinical trials, with a PI from COM, must submit to WIRB (PI submits directly to WIRB)
  - Federally funded studies that use WIRB must be ceded* to WIRB via a local myIRB submission.

- Advarra
  - Funded studies (federal, industry, foundations) and must be ceded* to Advarra via a local myIRB submission.

Regulations

- Federal Regulations – multiple regulatory frameworks that sometimes apply simultaneously
  - HSS
  - FDA
  - HIPAA, etc.
- State Laws: FL Statutes
- University Policies
- IRB Policies

❖ Among other things, **Federal Regulations** define **research** and **human subject**, structure of IRBs, categories of **exemption,** regulatory oversight for collaborative research, criteria for approval, and much more.

❖ **Local rules** govern implementation of regulations in a specific research context.

Layers of Responsibility

Institution

- Federalwide assurance (FWA: Any institution engaged in Federally-supported human subjects research must commit itself in writing to the protection of those subjects.
  - As a matter of institutional policy UF applies its FWA to all human subject research, regardless of funding.
- UF is responsible for meeting the conditions of its FWA -IO is the signatory official on our FWA.

IRB

- Implementing protection of human research subjects by reviewing, approving, and monitoring research according to regulations.
  - IRB's mission is protection of rights and welfare of human research subjects

Investigator

- Responsible for complying with all Federal, State and Local regulations.
- The best way to meet this responsibility is to be knowledgeable about the rules at your institution and to be very involved in running of the study.

Criteria for IRB Approval

(1) Risks to subjects are minimized

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.

(3) Selection of subjects is equitable.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by, §46.116.

(5) Informed consent will be appropriately documented or appropriately waived in accordance with §46.117.

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

University Ancillary Committees/Reviews

- myIRB is the hub for ancillary reviews (OCR coverage analysis, radiation safety, conflict of interest (personal and **institutional**), institutional **biosafety**, **SRMC**, **COVID-19**, EH&S, International, etc.)
  - **Hard stop** vs. Concurrent review
- Of note: Even if criteria for IRB approval are met per 45CFR46, a study can't be approved until all relevant ancillary reviews are complete and submitted.

  - **Investigators must follow up directly with the relevant ancillary offices about the status of the review.**

When Do I need to Apply for the IRB Approval?

- IRB reviews projects that constitute research on human subjects.
  - IRB reviews some exempt projects
  - Non-Human and some exempt projects are eligible for the Office of Research Auto-Determination Tool. https://research.ufl.edu/research-operations-services/exempttool.html

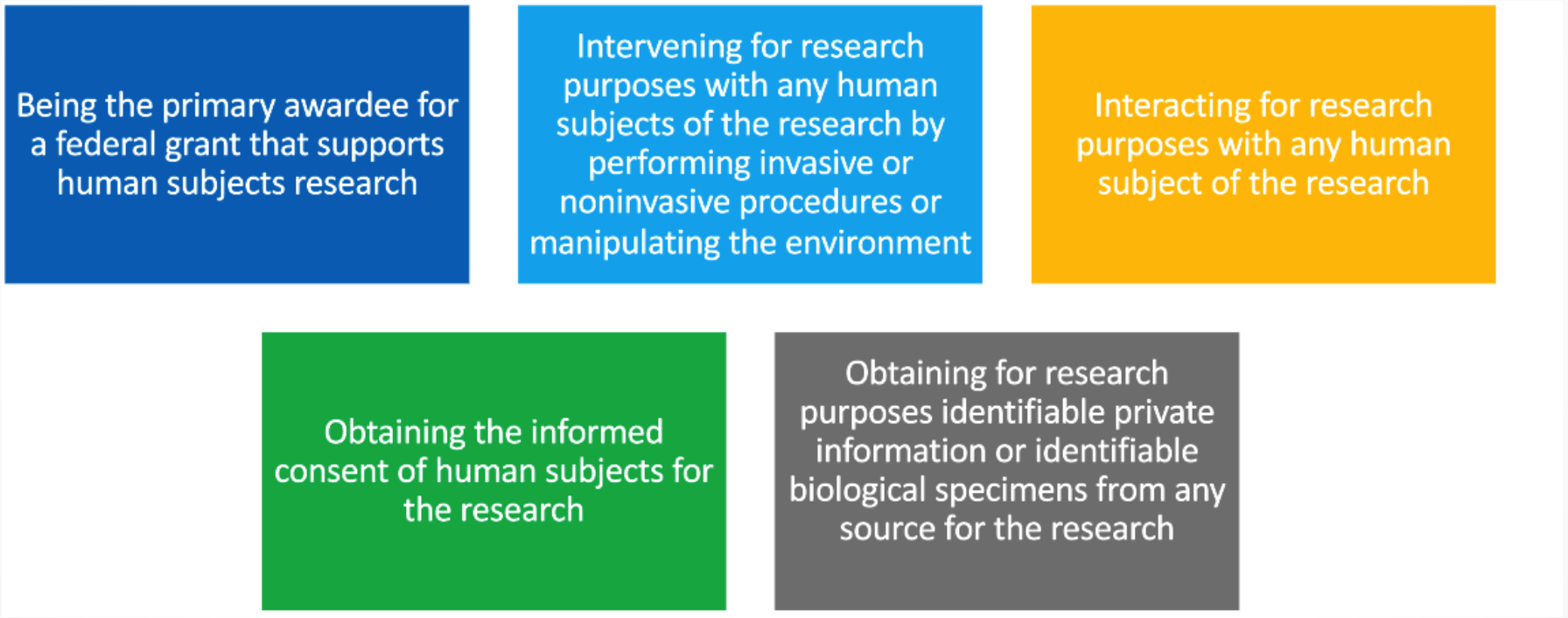
- IRB does not review:
  - Quality only Improvement Projects
  - Case Reports

    - Keep in mind that even if the IRB may not be in the picture, the Privacy office might be.

What does engagement in human subject research mean?

When an institution is *engaged* in non-exempt human subjects research that is conducted or supported by the US Department of Health and Human Services (HHS), it must satisfy HHS regulatory requirements related to holding an assurance of compliance and certifying institutional review board (IRB) review and approval

Examples of activities that engage institutions in human subjects research



Examples of activities that do not engage institutions in research

Institutions

- Whose employees or agents
  - perform commercial or other services for investigators
  - inform prospective subjects about the availability of the research
  - provide prospective subjects with information about the research but do not obtain subjects' consent for the research or act as representatives of the investigators;
  - provide prospective subjects with information about contacting investigators for information or enrollment
  - seek or obtain the prospective subjects' permission for investigators to contact them
  - release to investigators at another institution identifiable private information or identifiable biological specimens pertaining to the subjects of the research
  - obtain coded private information or human biological specimens from another institution involved in the research that retains a link to individually identifying information (such as name or social security number); and are **unable** to readily ascertain the identity of the subjects to whom the coded information or specimens
- That permit use of their facilities for intervention or interaction with subjects by investigators from another institution

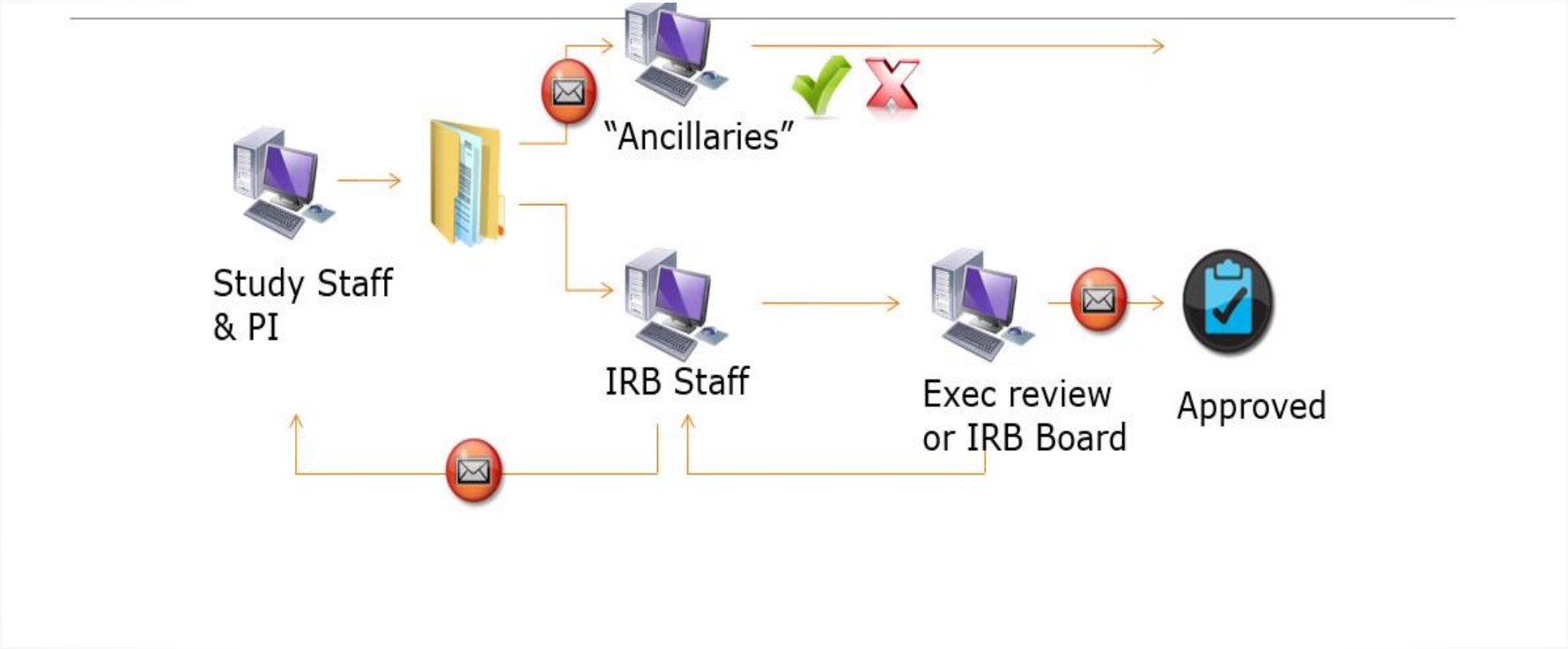
IRB Submission Process

- myIRB registration
- Training IRB803
  - Training exception for non-human research
- Completion of myIRB electronic application

Review Types

- Non-Human consider the auto-determination tool
- Data/Chart Review
- Banking Only
- Exempt consider the auto-determination tool
- Expedited
- Full Board

Workflow


"Ancillaries"
Study Staff
& PI
IRB Staff
Exec review
or IRB Board
Approved

Resources

- Investigator Guidelines
- MyIRB
- Researcher Manual
- Research Roles at UF/PI Qualifications
- Training
- IRB Website
- Contact us

Exemptions from the Regs: What Are Exemptions and Who Makes Exempt Determinations?

Research Definition

- *Research* means a **systematic** investigation, including research development, testing, and evaluation, designed to develop or contribute to **generalizable** knowledge. 45CFR46 102 (l)

Human Subject Definition

- *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research:

(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. 45CFR46 102 e(1)

Varieties of Exemptions

- Exempt because a study does not meet the definition of **'Research'** -- **Quality Improvement**
- Exempt because a study does not meet the definition of **'Human Subject' research – Non-Human**
- Exempt because a study is minimal risk and falls under one of the **exempt categories:** Survey/focus group studies (unless children are involved), educational studies, or benign behavioral interventions, secondary data analysis (publicly available data, review of charts/records, etc.), taste tests.

Non-Human

- NO interventions or interactions with a living person
- Anonymous or coded samples or data only; if data/samples are coded, a Confidentiality Agreement needs to be in place between a recipient and supplier.
- The study does NOT involve an investigational device that uses human specimens

- Approval: 1 time

Exempt

- **Minimal risk** studies that fit one of the following categories: Survey/focus group studies, educational studies, or benign behavioral interventions, secondary data analysis (publicly available data, review of charts/records, etc.), taste tests
- **Special path in myIRB-- Exempt Data/Chart Reviews:** secondary research, from medical records (or research records).

- Approval: 1 time

Who Makes Exempt, Non-Human and Quality Improvement Determinations?

- **NEW:** Non-human and some exempt studies are eligible for auto-determination via a tool https://research.ufl.edu/research-operations-services/exempttool.html
- Non-medical QI projects can also be submitted via the tool
- Medical QI projects are submitted to QIPR

Who Makes Exemptions when a study is not eligible for the tool?

- For studies that are not eligible for the tool submission (funded research, studies that involve PHI, etc.), a trained Board Member makes exempt determinations

How to Submit a Chart Review?

- Choose this review type if you are looking at data from medical records, or specimens or for any secondary research.
- Can be retrospective or prospective
- Can involve PHI
- Approved as exempt unless review involves **identifiable tissue, then expedited**
- See mechanics and the content of submission
  - https://irb.ufl.edu/wp-content/uploads/Chart-Review-Submission-Guide.pdf
  - https://irb.ufl.edu/wp-content/uploads/Data-Chart-Review-Brown-Bag-slides-11.18.20.pdf

Typical Issues with Chart Reviews

- Indicating the time frame for data abstraction
  - The need for and justifying HIPAA wavier for prospective chart reviews when one sees the patients whose records are under study
- De-identification plan (dates, zip codes are identifiers)
- Clinical Relationship requirement to access medical records (Privacy requirement)
- Consistency between the forms indicating data collected and HIPAA wavier scope (PHI indicated as collected under the waiver)
- Don't submit quality only projects as chart reviews.

Cases

- I would like to conduct an anonymous survey with UF residents regarding their residency application process.

- Is this a research study? It depends.
  - If research, since the survey is anonymous, can I submit this via the Non-Human Tool?
    - No. This study does not qualify as non-human, because you will be interacting (albeit remotely) with human subjects. However, the study may be eligible for the Exempt Tool, if research.
- Pediatric ophthalmology physician wants to obtain MRN# from IDR to abstract data from the ophthalmology clinic patients' medical records. Then she'll proceed to call such patients to collect data about whether they preferred contact lenses to glasses and why.

Cases

- I am doing a prospective chart review on patients I see in my clinic. I'll be collecting their data from 3.16.23-3.16.25.
  - Can I have a HIPAA wavier of authorization approved by the IRB?

sIRB, Ceding Review, Reliance

- **Ceding** of a study – an institution's relying on a **single IRB of record** for regulatory oversight of a study.
  - Institutions still review local context matters by leveraging local IRB offices
- Regulations require documenting reliance
- **IRB Authorization Agreement (IAA) is** a legal document between institutions that have an FWA that documents and specifies the terms of reliance between institutions.

NIH Single IRB Policy

- In effect since January 25th 2018
- Applies to **domestic** sites of **NIH funded** multisite studies where each site conducts the **same protocol** involving **non-exempt** human subjects research.

- Does not apply to approved projects before 1/25/2018 (but it does affect competitive renewals)

Revised Common Rule

- In effect since January 20th 2020
- Any institution **located in the United States** that is **engaged** in **cooperative research** must rely upon approval by a single IRB for that portion of the research that is conducted in the United States.
- Does not apply to studies approved by an IRB before January 20th 2020.
  - Common rule exceptions are specified in 45 CFR 46.114(b)(2)(ii) which allows Federal departments and agencies supporting or conducting the research to determine and document that the use of a single IRB is not appropriate for the particular context

SMART IRB IAA

- SMART IRB IAA – a common non-negotiable master agreement.
  - SMART Joinder – a document the signing of which by an Institutional Official evidences that the institution accepts the terms specified in the Master Agreement
  - Study specific checklists, flexibility agreements
- UF uses SMART Master Reliance Agreement, along with 900 other institutions, but **we are not using** the **SMART Tracking system**. We use myIRB for this purpose.
- The sIRB determines which IAA will be used. When UF is sIRB, we use SMART IAA.

Ceding Review to a sIRB: UF Process

What research is eligible for ceding to a sIRB?

- Studies for which use of an sIRB is a requirement of the sponsor or funding agency for participation in the study
- Domestic Multisite or collaborative, non-exempt research studies.
  - UF will consider ceding review to a sIRB for a study meeting the above criteria, provided that the IRB in question **has sufficient standards of review**

What Studies Are Not Eligible For Ceding to a sIRB?

- **Exempt studies (including chart reviews and non-human research)**
- Industry or other non-federally funded studies where sponsor does not require sIRB review.
- Research on UF's Student Athletes
- Research involving the Alachua County School System
- Research involving fetal tissue, and embryonic stem cells
- Review of proposed community consultation plan for studies involving exception from informed consent (EFIC)
- Research studies proposing to defer IRB oversight to an IRB that is not sufficiently qualified (AAHRPP accredited or having equivalent standards to accredited organizations)

Commercial IRBs

- WIRB
- Advarra

- Institutional policy on using commercial IRBs

  - **Industry** authored/sponsored, FDA regulated trials from COM faculty submitted directly to WIRB under the Master Service Agreement

  - **Federally** funded studies ceded to WIRB or Advarra by using SMART IAA (local IRB submission required)

  - Sponsor required sIRB review -- ceded to WIRB or Advarra by using SMART IAA (documentation about sponsor requirement must be submitted with the CED submission in myIRB)

UF Ceding Process - Overview

- When the overall protocol is approved by sIRB create New Ceded Study in myIRB
  - Notice a different nomenclature CED00000xx
  - SmartForms (SF) have rudimentary branching (enough to assess local context issues and trigger relevant ancillaries)
  - If the main study is not approved and IAA needs to be negotiated submitting a CED study is a way to put IAA through the system

- New SmartForm sIRB: IRB of Record Site for Ceded Review
  - The name of the Institution, Overall PI and Coordinator, and IRB Contact information.
  - Upload study specific document(s) requiring institutional sign off to the effect that the institution is willing to cede review
  - If an IAA other than SMART is used, upload executed copy here.
  - The approval letter for the overall study at the institution providing regulatory oversight

Process

- sIRB determines the consent template to be used.
- Local UF information is either captured in the editable portions of the consent (which is usually highlighted or tracked), or there is a consent addendum, or there is a checklist with the local language that the IRB of record used to produce final consent.
    - Local information includes subject cost/injury language, HURRC, HSP, etc, any applicable state laws.
- The study team will work with all the ancillaries (which get myIRB notifications prompting them to review), and insert all necessary language in the consent form.
    - Unlike our regular practice, we'll not be entering the ancillary language into the consent for you as we are not finalizing documents.

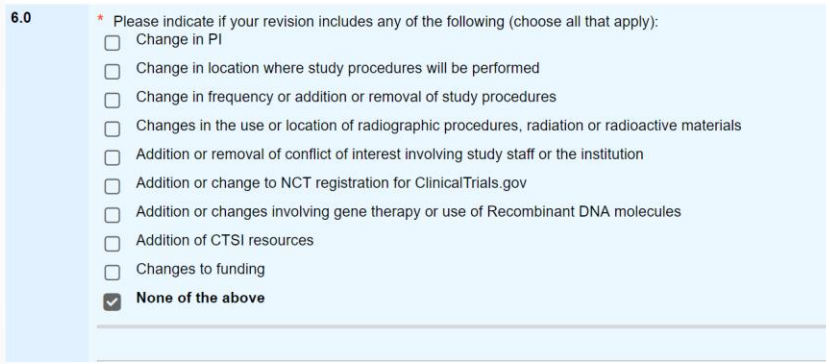
- When local context review is done and all ancillaries are approved, **the study is acknowledged** and in the state of **Awaiting Site Materials**.
- PI submits Acknowledgement Letter to the overall PI who initiates a revision at the IRB of record to add UF as a site.
- Once the revision is approved, a coordinator/PI submits the letter of approval with the approved documents to UF IRB via 'Submit IRB of Record Correspondence'.
- The UF IRB approves ceding of the study.
    - OR if the IRB of record has concerns about local context issues, they might request changes which are also submitted by using 'Submit IRB of Record Correspondence'.
    - The study team addresses issues and the study is acknowledged again, after which UF PI sends the acknowledgment letter to the overall PI who follows up on the submitted revision to the IRB of record.

Q: What are the relying PI responsibilities?

- UF PI has increased responsibilities
- Staying up-to-date with the IRB of record's determinations/communications.
- Communicating institutional determinations to the overall PI.
- Being knowledgeable about the IRB of record's policies and procedures (especially regarding event reporting).
- Ensuring that local institutional rules are observed (e.g. recruitment)

Post Approval

- Revisions
  - Only changes in the local context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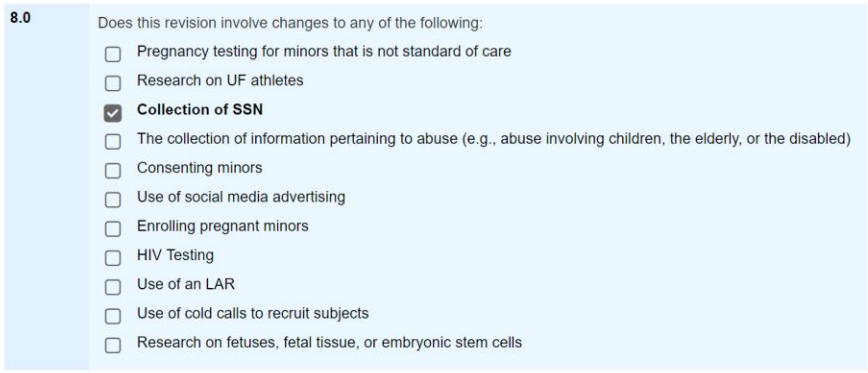
* Please indicate if your revision includes any of the following (choose all that apply):

- ☐ Change in PI
- ☐ Change in location where study procedures will be performed
- ☐ Change in frequency or addition or removal of study procedures
- ☐ Changes in the use or location of radiographic procedures, radiation or radioactive materials
- ☐ Addition or removal of conflict of interest involving study staff or the institution
- ☐ Addition or change to NCT registration for ClinicalTrials.gov
- ☐ Addition or changes involving gene therapy or use of Recombinant DNA molecules
- ☐ Addition of CTSI resources
- ☐ Changes to funding
- ☑ **None of the above**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Does this revision involve changes to any of the following:

- ☐ Pregnancy testing for minors that is not standard of care
- ☐ Research on UF athletes
- ☑ **Collection of SSN**
- ☐ The collection of information pertaining to abuse (e.g., abuse involving children, the elderly, or the disabled)
- ☐ Consenting minors
- ☐ Use of social media advertising
- ☐ Enrolling pregnant minors
- ☐ HIV Testing
- ☐ Use of an LAR
- ☐ Use of cold calls to recruit subjects
- ☐ Research on fetuses, fetal tissue, or embryonic stem cells

- CRs: (Current Protocol, ICF, and Approval letter from the IRB of record)
- Reportable Events:
  - Serious or continuing local non-compliance
  - Local Unanticipated problems and AEs that are serious, unexpected, and related/more likely than not caused by study intervention/participation

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UF serving as a sIRB

UF process

UF | Research

The Initial Process

- PI and staff meet with the IRB Reliance Team in the study planning phase
  - sIRB Intake Form on the IRB Website
- IAA status (SMART, UF Master Agreement)
- The Reliance Team sets parameters.
  - Study team is the link between the IRB and all the sites. The team must be experienced and highly organized and have systems in place for reporting events and ensuring that CR is submitted in time. Implications of study expiring affect all sites.
  - PI responsibilities – PI responsible for all sites

UF Research

Approval

- Study is approved as sIRB but without any sites; sites are added with revisions (this is done via exec review)
  - Study Title and Staff SF declares that the submission is sIRB (UF serves as IRB of Record label is on Study Workspace)
  - Nomenclature the same as other IRB studies (IRBYEARNUMBER)
  - **UF core consent** is used with site addenda.
    - Each **site addendum** has the local institution's logo and captures the local context items; initially only UF addendum is submitted.

UF Research

UF UNIVERSITY of FLORIDA

Revisions to Add pSites

- Revisions to add sites new project type
  - can exist concurrently with other revisions to the main study.
  - *Information needed*
    - *Site information (PI, Coordinator, local IRB Contact Info)*
    - *Attach Exhibit Cs/Smart Acknowledgments (singed by the institutional official or his designee)*
    - *Local Site ICF Addendum*

UF Research

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Revisions CRs, AEs

- As Revisions and Continuing Reviews are approved by the UF IRB, the overall PI is responsible for providing a copy of the UF IRB approval letter and any applicable documents (i.e. stamped consent, protocol, etc.) to the local PI(s) at the relying site(s).
  - Plan CRs so they do not interfere with Revisions and vice versa (revisions and CRs can't be in the system at the same time)
- The main PI, submits reportable events received by the relying site(s) to the UF IRB per UF reporting policy.
- Acknowledged AEs have to be communicated to the local sites by the main PI.

Questions

sIRB – different kind of work.

UF Research

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IRB Review
Expedited and Full Board

Example Study - Rehab following a stroke

- Inclusion criteria - Occurrence of a single unilateral stroke within the previous 6-48 months, 18-80 yo
- Participants will walk over ground over a GAITRite instrumented walkway
- Participants will begin walking on a treadmill. Walking speed will be recorded three times at each assessment.
- Outcome
  - Walking speed - treadmill
  - EMG of leg muscles
  - Bone density

Protocol Review Type

Full Board

- Greater than minimal risk
- Other studies as assigned by an executive reviewer
- Required by funding agency
- 1st and 3rd Wednesdays
- There is a deadline to get onto a meeting date

Executive Review – Chair or Vice Chair

- Minimal Risk
  - Non-human
    - Totally HIPAA de-identifed data or samples
  - Exempt – chart reviews, surveys
  - Expedited – requires some type of consent
- No deadline for submissions

Expedited Categories

1. Studies on drugs not requiring an IND
2. Blood draws in healthy subjects (there is a limit)
3. Non-invasion sample collections
4. Collection of data by non-invasive means
5. Data and\or Specimens that is clinically generated
6. Collection of voice, digital, or images
7. Survey research

Ancillary Reviews – Prior to IRB Review

- **COI** (Conflict of Interest) – if the University might have an institutional conflict of interest in the proposed study
- **SRMC** (Scientific Review and Monitoring Committee) – for all protocols that involve anything under the SRMC jurisdiction, part of the NCI designation.
- **IBC** (Institutional Biosafety Committee) – for all gene therapy protocols
- **SRCWG** (COVID Committee) – for studies involving inpatients only

Ancillary Reviews – Simultaneously with IRB Review

- **HURRC** (Human Use of Radioisotopes and Radiation Committee) - Assess the radiation risk to be disclosed in the informed consent form.
- **OCR** (Office of Clinical Research) – research contracting, billing, and injury review
- **EH&S** (Environmental Health and Safety) – to ensure tissue leaving or coming to UF are handled properly.
- **COI** (Conflict of Interest) – to assess potential investigator COI, and provide the IRB with required disclosures to appear in the consent form.
- **IAA** (IRB Authorization Agreement) – UF signs off on allowing UF to cede review to a non-UF IRB

Ancillary Reviews – Simultaneously with IRB Review

- **ClinicalTrials.gov** – To ensure relevant studies follow these guidelines and posted on CT.gov
- **External Reviews** – various MOUs UF has with external sites (eg. Halifax, Baptist, etc.) require a local review from those external sites and sent to the UF IRB.
- **International Ancillary** – To review any privacy of research rules in other countries that may require additional safeguards.
- **CTSI** – To "approve" the use of any CTSI governed support (eg. REDCap).
- **UF Privacy Office –** Only triggered when the IRB needs input from the Privacy Office typically for a privacy breach resulting from a research project.

The Running of the Full Board Meeting

- Board meetings are on Zoom
- 8:30am – 2:00pm, 1st and 3rd Wednesdays
- Investigator notified – If you want to attend (recommended)
  - Contact Us form (name(s) of who will attend, for what item, and contact phone number(s)
    - You are then sent the zoom link
  - If you have a time conflict (ie: clinic, flight, etc.) email or call the IRB Office, we can adjust if possible
  - You'll be called a few minutes before your protocol, in zoom waiting room until your item is presented.
- During the Meeting
  - Review presented by assigned Board Members
  - Questions or clarifications by P.I\study staff
  - P.I.\Study Staff asked to log off for the final discussion and vote
  - You can call the IRB office for results or wait for your email.

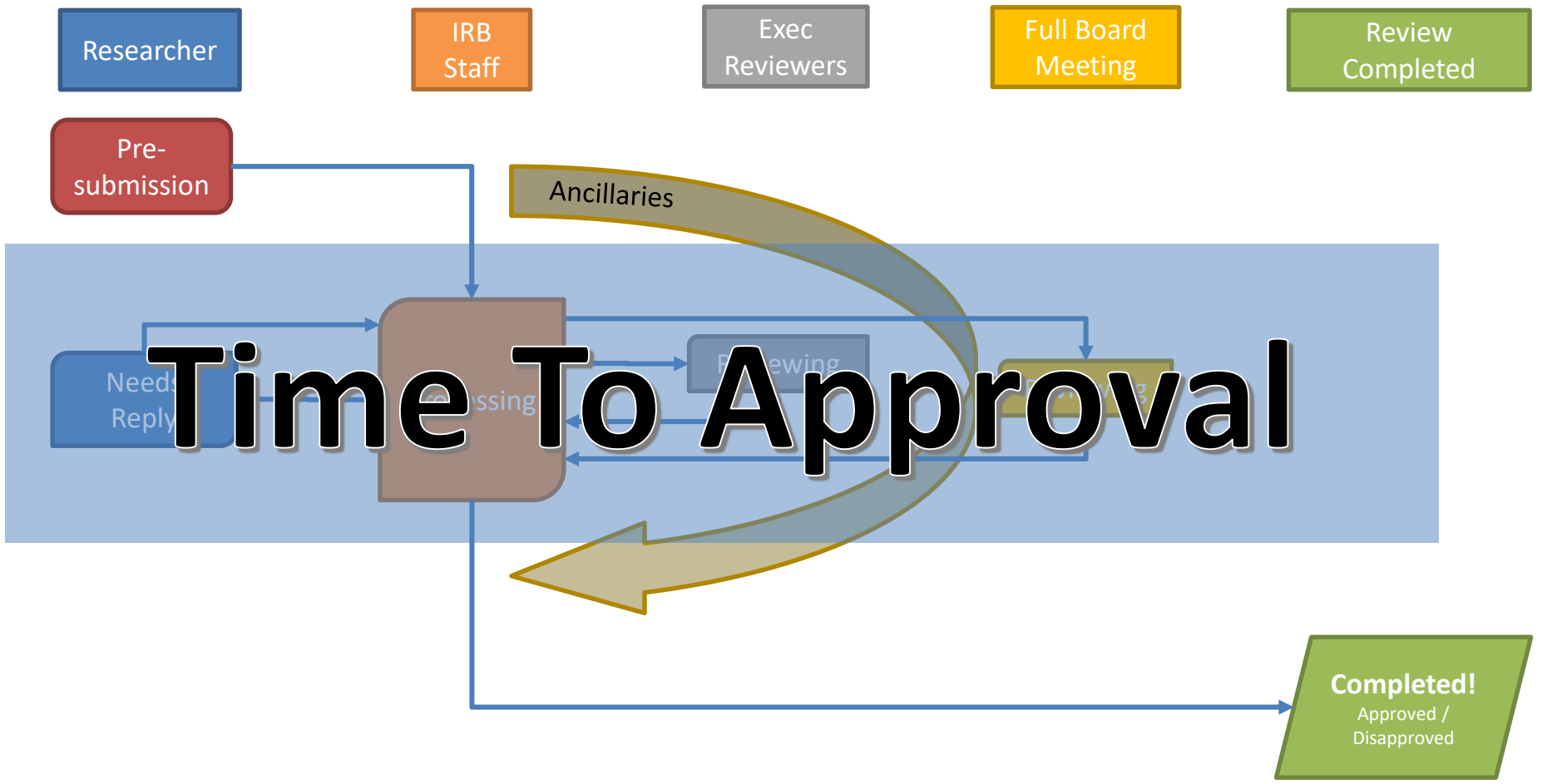
What to expect following an IRB meeting

By Friday of that week you will receive an email with the Board results:

- Approval letter (maximum of 1 year) - *Your study is not approved until you receive your approval letter*
- Approved with Contingencies (does not come back to full Board)
- Tabled letter – response goes back to the Full Board
- Miscellaneous Letters
  - Do not hold up approval
  - Include information the Board requires

Investigator Responsibilities for Human Subject Research

- Follow your approved protocol
- Obtain consent prior to enrolling subject
  - Give copy to subject
  - Keep copies of all consent forms
- Informing IRB on:
  - Adverse events per IRB Policy
  - Any changes in protocol – “no matter how minor” (includes closure of protocol)
  - Any protocol violations
- Read Informed Consent before submitting
- Provide continuing review information on time – Full Board only



Time To Approval

Rehab following a stroke

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- Outcome
  - Walking speed - treadmill
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QUESTIONS???

Informed Consent

R. Peter Iafrate, Pharm.D.
IRB-01 Chairman

Example Study

- The researcher wants to take film from clinically obtain films of kidney stones
- Want to run them through and AI model to see if the model can eventually tell what the kidney stone is made of.

Informed Consent Process

- Informed Consent is not synonymous with simply obtaining a subject's signature on the consent form.
- Informed consent is a process, and involves:
  - Providing a potential subject with adequate information
  - Facilitating comprehension of that information
  - Providing ample opportunity for questions from the subject, and
  - Continuing to provide them information as the clinical investigation progresses.

Signing Informed Consent

- Other than the subject (Legally Authorized Representative – LAR)
  - Proxy
    1. The patient's spouse
    2. An adult child of the patient
    3. A parent of the patient (if an adult)
    4. The adult sibling of the patient
    5. An adult relative of the patient
    6. A close friend of the patient
  - Surrogate
  - Parent of a child
  - Guardian (court appointed ward, not ward of the State)
  - Durable power of attorney
- Must document the type of LAR, and why chosen
- Subject must be consented if they become capacitated.
- Signed and dated prior to enrolling subject
- Subject gets copy

Informed Consent Types

- Waiver of Consent
  - Study subject never knows they are in a research study
- Waiver of Documentation of Informed Consent
  - Consent from the subject is obtain, however
  - No signature is required
  - IRB has a one page template that is reviewed and given to the subject
- Written and Signed Consent
  - Regular (8 page template)
  - Brief (4 page template)
- Banking Consent (4 pages)

Example Study

- The researcher wants to take film from clinically obtain films of kidney stones
- Want to run them through and AI model to see if the model can eventually tell what the kidney stone is made of.

Banking Protocols

R. Peter Iafrate, Pharm.D.
IRB-01 Chairman

Banking Study - Example

- Want to collect leftover samples and data to be banked for future research.
  - We are asking to collect and store any leftover bronchiolar lavage fluid, serum, sputum, throat swab sample or any leftover surgical samples that may or may not include lung tissues as well as nasal brushing and bronchial brushings and
  - Medical information collected in course of routine clinical care at the pediatric pulmonary center. The medical information may include any lung function data, radiology or laboratory data.
- Identifiers include name, MR#, DOB, and study ID
  - Information kept in electronic encrypted password protected database in the research coordinator office that could link samples but actual samples will only have study subject ID label. Samples kept in locked refrigerator in PI's lab

What is a Research Bank?

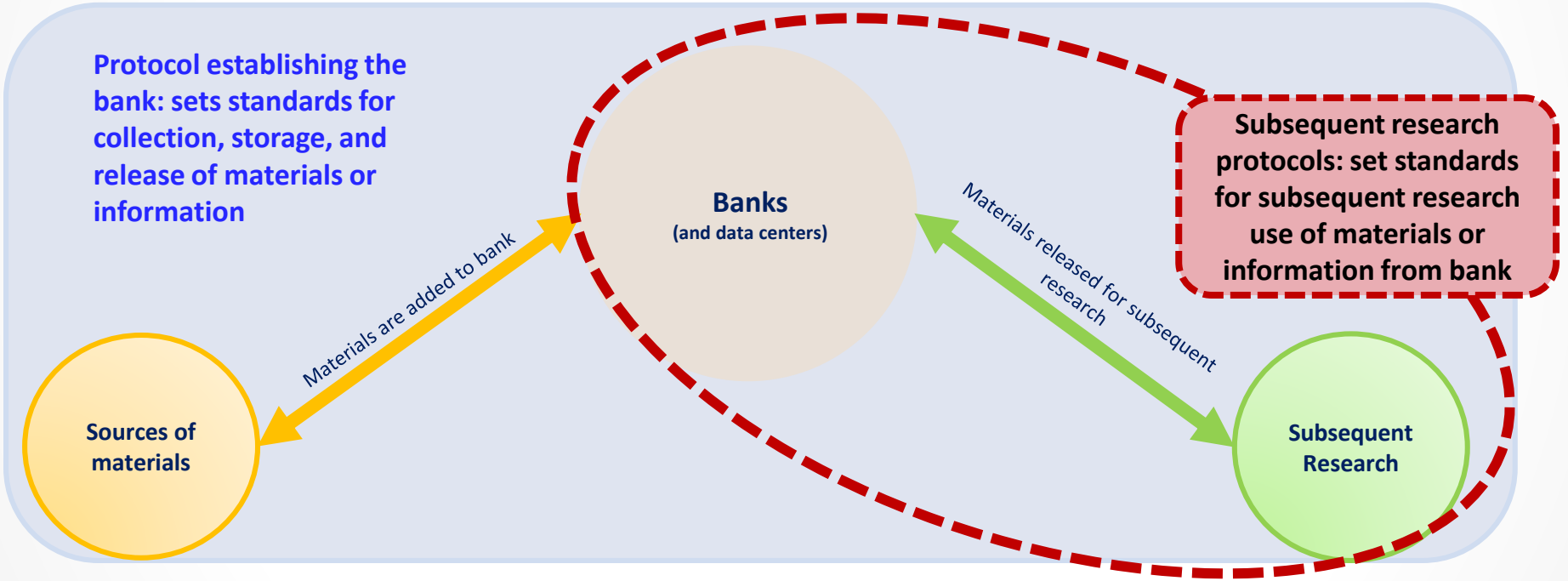
- Collection and storage of Tissue, and\or Data, and\or Contact Information (CI)
  - Conducting a primary research study, then bank what is left over
  - To place directly in a bank for future research only
    - Local bank (at UFHealth)
    - Non-local bank
  - Contact Registry - A list of potential individuals interested in being contacted for future studies (does it include or imply PHI?)

What is not a Bank?

- Tissue or data collected and stored to be used only for the approved study.
  - To analyze at a later date
  - Do batch assay, etc.

Research Banking Activities must Comply with Federal Research Regulations (ie: The Common Rule)

Let's consider what Research Banks (generally) do:



Issues to Consider in the Research Use of Stored Data or Tissues (1996, 1997) www.hhs.gov/ohrp/regulations-and-policy/guidance/issues-to-consider-in-use-of-stored-data-or-tissues/index.html

The UF Process

- Submit like any other protocol
  - Choose “Banking Only” as the protocol type, we ask
    - What you’re going to collect
    - How you will enroll subjects (via consent vs waiver)
    - Where is your “Bank” located, what is the security, etc.
    - Who is/are your Gatekeeper of your bank (who has access)
    - What is your plan to dispense tissue/data
- Mostly minimal risk, some are GMR (invasive collection of tissue [eg. spinal tap])
- Template banking consent/authorization form (4 pages)
  - Potential subject is presented the banking consent alone, or in addition to a primary consent form.
  - Contains all required language for a research bank

UF Banking Consent Form Template

UF | Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM
to Participate in Research, and
AUTHORIZATION
to Collect, Use, and Disclose Protected Health Information (PHI)

We (<name of PI or group> contact information <pi's phone number, including area code>) are asking permission from you,

_____
Printed name of study participant ("study subject")

to store some of your <medical information \ tissue that is not needed for your medical treatment and that would otherwise be thrown away> in order to use it for future research.

The Principal Investigator (the person in charge of this research) or a representative of the Principal Investigator will describe this <medical information \ tissue \ blood sample> bank to you and answer all of your questions. Your participation is entirely voluntary. Before you decide whether or not to take part, please read the information below and ask questions about anything you do not understand. If you choose not to participate in this study you will not be penalized or lose any benefits that you would otherwise be entitled to.

1. What are we asking to store?

If you agree, the following <medical information \ tissue \ blood sample > will be collected and stored in the medical information \ tissue bank: Insert text here

2. Reason for Storing Your <Tissue or Medical information>:

We wish to store your <medical information \ tissue \ blood sample> and potentially use it in future research. Many different kinds of research uses <medical information \ tissue \ blood sample>. Some researchers may develop new tests to find diseases. Others may develop new ways to treat or even cure diseases. In the future, some of the research may help to develop new products, such as tests and drugs. Some research looks at diseases that are passed on in families (called genetic research). Research done with your <medical information \ tissue \ blood sample > may look for genetic causes and signs of disease.

Many medical problems may arise due to the environment or from genetic factors. Your medical condition may come from one or both of these causes. Genetic factors are those that people are born with and that can affect other family members. There may be genetic testing done in the future that would provide information about traits that were passed on to you from your parents or from you to your children. Because the nature and value of any future testing or research cannot be known at this time, this genetic information and any other results obtained from using your medical information \ tissue may not be given to you or your doctor.

3. Can you change your mind?

If you decide that your medical information \ tissue\ blood sample can be kept for future research but you later change your mind, you can contact the Principal Investigator or group listed at the beginning of this consent form who will remove and destroy any of your medical information \ tissue \ blood sample that he/she still has. Otherwise, the samples may be kept until they are used up, or until the University of Florida decides to destroy them. You have the right to see and copy the information that is collected from you and stored in the medical information \ tissue bank. There will be no cost to you for any medical information \ tissue collected and stored.

4. Where will your <medical information \ tissue \ blood sample> be stored?

Your medical information \ tissue will be kept in a secure location in a medical information \ tissue bank \ blood sample called <name title or other descriptor for medical information \ tissue bank> so that it may be used in future research to learn more about your medical condition and other medical problems. <Once collected, you may be called from time to time to update information on your health that is necessary to keep the medical information \ tissue bank \ blood sample current.>

5. Are there any benefits to your participation in this <medical information \ tissue / blood sample > bank?

There is no direct benefit for your participation in this <medical information \ tissue> bank. Even though the research that is done on your medical information \ tissue cannot be used to help you, it might help other people who have a similar medical condition or other medical problems.

6. Are there any risks to your participation in this <medical information \ tissue \ blood sample > bank?

<List any risks here>

Although every effort will be made to keep your information confidential, there is a small risk that an unauthorized person may obtain your information. Therefore, there is a very slight risk that a test result could be linked to your identity and inadvertently disclosed to a third party.

UF Banking Consent Form Template

If you were to receive the result of a genetic test that indicated a problem, it could cause anxiety or other psychological distress. In addition, you might have to decide whether or not to discuss the findings with members of your family. If a third party learned the results, there is a risk of social stigma and of the unpredicted disclosure of this information to others.

There is a Federal law, called the Genetic Information Nondiscrimination Act (GINA), that makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. Additional information can be obtained at: http://irb.ufl.edu/gina.html or call 1-800-669-3362. If you think this law has been violated, it will be up to you to pursue any compensation from the offending insurance company and/or employer.

7. Will your <medical information \ tissue \blood > be shared with others?

The Principal Investigator listed at the beginning of this consent form or their successors will be allowed to collect, use and/or give out your medical information \ tissue. They may give your medical information \ tissue to other researchers whose research is approved by an Institutional Review Board (IRB) (An IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research). They may also give your medical information \ tissue to a study sponsor, the Food and Drug Administration, the Department of Health and Human Services, the Office of Human Research Protections, or other Government agencies. Your <medical information \ tissue, whichever is appropriate> may be shared with other research centers or private companies, in which case the University of Florida may charge the research center or private company a fee in order to recover the University of Florida's costs of sharing your <medical information \ tissue>. There is a risk that information received by these authorized persons or agencies could then be passed on to others beyond your authorization and not covered by the law.

Once this research study is completed, any information that could identify you **might** be removed from any identifiable private information or identifiable biospecimens collected and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

8. How will the researchers benefit?

In general, presenting research results helps the career of a scientist. Therefore, the Principal Investigator may benefit if the results of this study are presented at scientific meetings or in scientific journals. It is possible that new treatments, medicines, therapies or products could be created from studies that use your tissue or medical information. If that happens, the Principal Investigator and the University of Florida could receive significant financial benefits. You will not be offered any payment or any other financial benefit.

9. Signatures:

As a representative of this study, the individual signing below has explained to the participant the purpose, the procedures, the possible benefits, and the risks of the collection, storage, and use of their medical information \ tissue and how the participant's protected health information will be collected used and shared with others:

_____ _____
Signature of Person Obtaining Consent and Authorization Date

You have been informed about the collection, storage and use of your medical information \ tissue \blood sample, possible benefits, and risks; and that you are free not to have your medical information \ tissue \blood sample collected for research purposes. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask other questions at any time.

You voluntarily agree to allow the collection, storage, and use or your medical information \ tissue \ blood sample. You hereby authorize the collection, use and sharing of your protected health information as described above. By signing this form, you are not waiving any of your legal rights.

_____ _____
Signature of Person Consenting and Authorizing Date

Banking Study

- Want to collect leftover samples and data to be banked for future research.
  - We are asking to collect and store any leftover bronchiolar lavage fluid, serum, sputum, throat swab sample or any leftover surgical samples that may or may not include lung tissues as well as nasal brushing and bronchial brushings and
  - Medical information collected in course of routine clinical care at the pediatric pulmonary center. The medical information may include any lung function data, radiology or laboratory data.
- Identifiers include name, MR#, DOB, and study ID
  - Information kept in electronic encrypted password protected database in the research coordinator office that could link samples but actual samples will only have study subject ID label. Samples kept in locked refrigerator in PI's lab

Quality Improvement vs Research

R. Peter Iafrate, Pharm.D.

IRB-01 Chairman

Catheter Connection Sepsis

- Purpose of this project is to introduce the use of 3% chlorhexidine in 70% alcohol swabs for catheter connection antisepsis as the standard od car o the Bone Marrow Transplant Unit.
- All in-patients on the BMTU and Out-patient Bone Marrow Clinic with IV access requiring catheter connection care and maintenance
- Goal is to improve outcomes with less sepsis.

QA vs Research

- Brief overview on terms
- Differences between QA and Research

What is Research??

- Research:

  As defined by 45 CFR 46, “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge”

What is Minimal Risk?

- Minimal Risk:

  As defined by 45 CFR 46, “a risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests”

The risk is an absolute risk, not a relative risk

What is QA/QI??

- No regulatory definition but often QA/QI is described as:
  - “systematic, data-guided activities designed to bring about immediate (or nearly immediate) improvements in local health care delivery”, and
  - “The combined efforts of everyone to make changes that will potentially lead to better local patient outcomes, better local system performance, and better professional development”

It's "Quality" and not "Research"

- When the purpose of an activity is
  - to assess the success of an established program or making an intervention to that program, with a "quality outcome" in mind, and
  - the information gained from the evaluation will be used to provide feedback to improve that local program
- When the evaluation is a management tool for monitoring and improving the program.
- When information learned has immediate benefit for the program, the institution and/or clients receiving the program or services.

Publishing “Quality” Projects

- YES - If a project is a “Quality” only project, there is no IRB prohibition regarding the publishing of that project.

- Issues that could come up:
  - The journal wants something from the IRB saying that IRB approval is not required.
  - What do you do?
    - Send Dr. Iafrate an email, attach the manuscript
    - If a Quality Only project, you will receive a letter you can provide to the journal
    - If not a Quality project, then ……
- You still must follow any HIPAA requirements

Is it quality assurance?
QIPR CERTIFICATE

Quality improvement project registry

*** Only to register Quality Projects conducted at UF Health ***

Quality versus Research

Self Certification Questions

Please answer the following questions about your QI project.

Is the project intended to improve or evaluate the practice or process within a particular institution or a specific program?
[Why are we asking?]

(●) Yes ( ) No

Is this a systematic investigation designed with the intent to contribute to generalizable knowledge (e.g. testing a hypothesis; randomization of subjects; comparison of case vs. control; observational research; comparative effectiveness research; or comparable criteria in alternative research paradigms)?
[Why are we asking?]

( ) Yes ( ) No

Will the project occur regardless of whether individuals conducting it may benefit professionally from it?
[Why are we asking?]

( ) Yes ( ) No

Is this a multi-site project (e.g. there is a coordinating or lead center, more than one site participating, and/or a study-wide protocol)?
[Why are we asking?]

( ) Yes ( ) No

Will the project involve testing an experimental drug, device (including medical software or assays), or biologic?
[Why are we asking?]

( ) Yes ( ) No

Has the project received funding (e.g. federal, industry) to be conducted as a human subjects research study?
[Why are we asking?]

( ) Yes ( ) No

CERTIFICATE OF REGISTRATION

Linda Allen

Your quality improvement project entitled "Standardization of Needleless Valve Changes for CLABSI Reduction: Shared Successes from Staff-Drive Initiatives"
has been registered on 01/30/2017.

The UF Health Sebastian Ferrero Office of Clinical Quality & Patient Safety wishes your team much success in your efforts to improve patient quality.

This registration confirms that you have answered the criteria questions accurately and have not knowingly and willfully made false statements. If your project changes in design or focus, please re-register this quality improvement project. QI Project Criteria includes the following:

- The project is intended to improve or evaluate the practice or process within a particular institution or a specific program.
- It has not received funding to be conducted as a human subjects research study.
- It is not a systemic investigation designed with the intent to contribute to generalizable knowledge.
- It is not a multi-site project.
- You will abide by all HIPAA privacy rules.
- The project will not involve testing an experimental drug, device, or biologic.
- The results of this project are intended for quality improvement at this institution.
- The project will occur regardless of whether individuals conducting it may benefit professionally from it.

UFHealth
UNIVERSITY OF FLORIDA HEALTH

Research Project

UF | Institutional Review Board
UNIVERSITY of FLORIDA

CQI vs Research Determination Form

Continuous Quality Improvement (CQI) is the process whereby quality of care can be monitored and improved. CQI uses scientific methodology to improve performance. Performance can be measured in terms of clinical outcomes, patient satisfaction, error rates, productivity and other metrics. All hospitals and ambulatory clinics, etc. utilize CQI projects to improve patient care. Results are used ***locally*** to improve care by improving the process being monitored. This process does not require IRB approval.

However, if you are considering the publication or presentation of the results of this CQI effort outside of UF\Shands\VAMC, then you must complete this form and submit to the IRB to verify that you will be conducting a CQI effort and that it currently does not meet the definition of human research.

1. Does this project involve any of the following (check all that apply):
   - ☐ Investigational Drug or Device
   - ☐ Randomizing patients
   - ☐ A fixed clinical protocol that may not be altered by caregivers and staff
   - ☐ A non UF\Shands\VA site
   - ☐ Objectives other than producing an improvement in safety or care.

   If any of the above are checked, then this project **cannot be approved by the IRB as a CQI project, and must be submitted and approved by the IRB as a Research Protocol before it can move forward.**

   - ☐ None of the above

2. Which of the following best describes the process that is being evaluated?
   - ☐ The process is currently the standard of care
   - ☐ The process is being introduced at this time as the standard of care
   - ☐ The process is not currently the standard of care, and is prospectively being evaluated compared to the current standard of care. **This project cannot be approved by the IRB as a CQI project, and must be submitted and approved by the IRB as a Research Protocol before it can move forward.**

3. Please describe the CQI Project

   Describe:

4. Please describe the location and\or patient population being evaluated by the CQI project:

   Describe:

5. Please describe the role the individual leading this Project has as it relates to conducting Quality Projects (ie: in charge of quality for department\division, asked to conduct this quality project by institution's Quality Department, etc.).

   Describe:

6. Please list the outcome measures being collected as part of the CQI effort

   Please List:

7. Please describe a) the process by which the quality data will be collected and analyzed, b) how the process being evaluated will be revised based on that analysis, and c) how often will this same collection\analysis process sequence be repeated?

   Describe:

8. At what point will this CQI project be terminated (ie: at what point will your outcome measures indicate that the "quality" of the process is sufficient)?

   Describe:

9. Please list any data being collected that is not part of the CQI effort?

   Please List:

10. Is this project being funded?

    ☐ No

    ☐ Yes: Please indicate funding source:

UF UNIVERSITY of FLORIDA

Institutional Review Board
Health Science Center

1853 Mowry Road
PO Box 100173
Gainesville FL 32610-0173
352-273-9600 Phone
352-273-9614 Fax

3/15/2022

<Name and Title>

Dear Dr. <**Name**>

Thank you for completing the "CQI vs Research Determination Form". This letter confirms my determination that the project you described on this form is not considered human subjects research and does not require IRB approval at this time.

If at any point you decide there is a research question you wish to answer, please let me know and I can guide you through the process. If you have any questions or concerns, please contact me. Thanks for working through this process with the IRB-01.

R. Peter Iafrate

R. Peter Iafrate, Pharm.D.
Chairman, Health Center IRB-01
University of Florida

Cc: QA File

Full Accreditation

Catheter Connection Sepsis

- Purpose of this project is to introduce the use of 3% chlorhexidine in 70% alcohol swabs for catheter connection antisepsis as the standard od car o the Bone Marrow Transplant Unit.
- All in-patients on the BMTU and Out-patient Bone Marrow Clinic with IV access requiring catheter connection care and maintenance
- Goal is to improve outcomes with less sepsis.

Research Subject Recruitment

R. Peter Iafrate, Pharm.D.

IRB-01 Chairman, Health Center IRB
College of Research
University of Florida
iafrate@ufl.edu

Role of the IRB in Study Subject Recruitment

- The federal regulations state, "…The IRB should also review the methods and material that investigators propose to use to recruit subjects."

- Thus, the IRB will review and approve anything used to recruit study subjects since it is "…considered an extension of the informed consent"
  - Fliers
  - Advertisements
  - Recruitment emails, letters, etc.

What the IRB does not have Jurisdiction over regarding Study Subject Recruitment

- How study subjects are recruited
- This is under the jurisdiction of UFHealth Administration

However, the IRB must enforce these requirements

- So what are the limitations?

Recruitment Limitations within UFHealth

- **Patient Referral**: A clinical practitioner may not refer a patient to a researcher for potential inclusion into a research study without the prior written or verbal approval of the patient.

- **No cold calling:** An investigator or his\her co-investigators or study staff must have a clinical relationship with a potential study subject in order to contact him\her for enrollment in a research protocol. This is also referred to as a "warm handoff". It is not a "cold call" if:
  - The patient has been asked by his\her practitioner if they are interested in hearing about a research study, and the patient agrees.
  - If the patient has consented in the "Consent2Share" protocol

Recruitment Limitations within UFHealth

- **Opting Out:** The practice of requiring a potential study subject to contact a study team in order to not be contacted regarding a research study is not permitted. Subjects can “opt in” to a study and then be contacted.

- **Social Media:** Investigators must follow the UF Social Media recruitment policy signed off by Dr. Norton and managed by CTSI staff (currently no staff are available).

Recruitment Limitations within UFHealth

- **Chart Review Studies:** Access to EMRs for chart review only (no patient contact) studies is limited to those investigators who would likely have involvement with that group of patients.

What is Consent2Share?

. . .

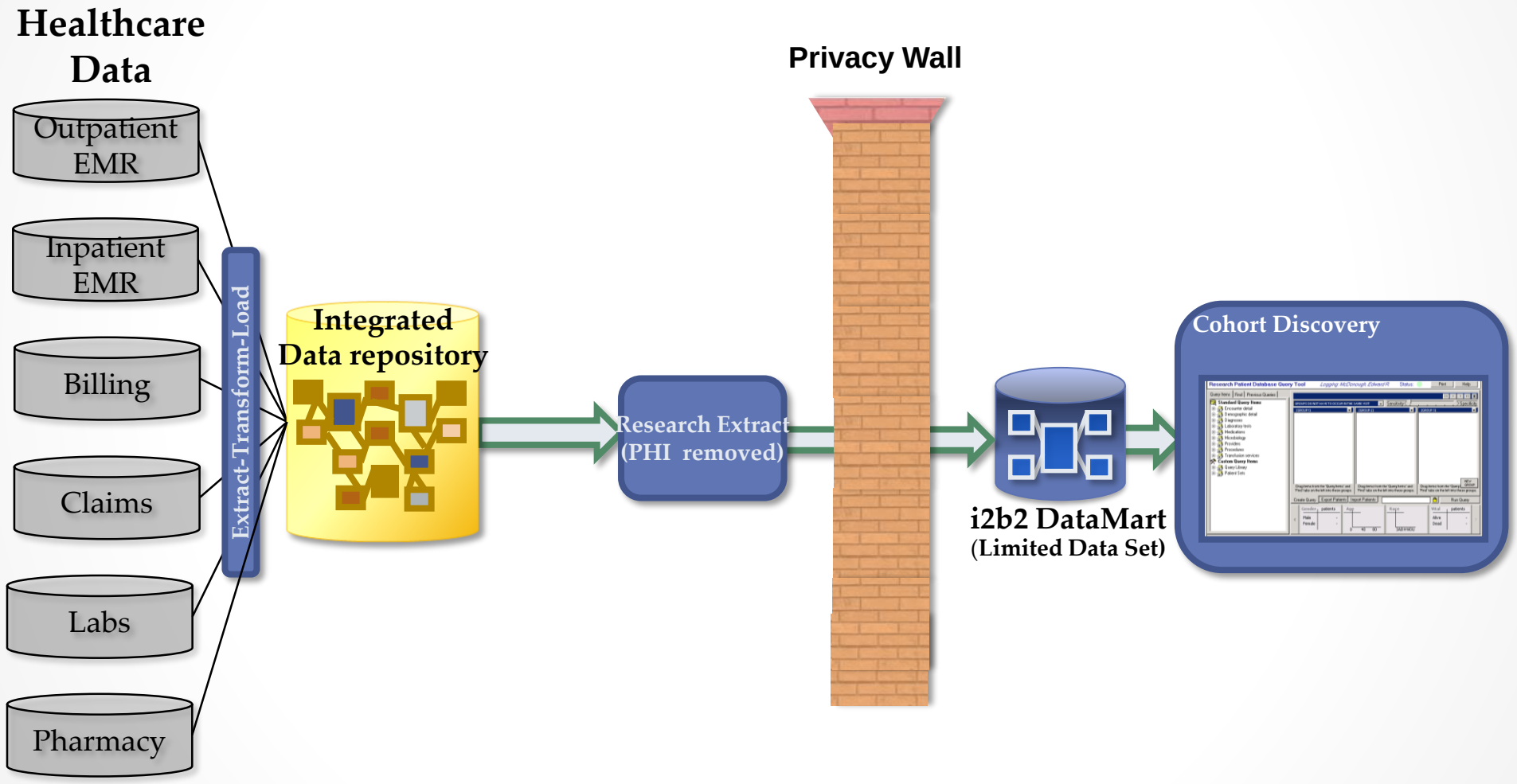
A component of the Integrated Data Repository (IDR)

A Research Protocol “UF&Shands Integrated Data Repository (IRB201601125)”

approved by the

University of Florida IRB in 2011

Integrated Data Repository (IDR)

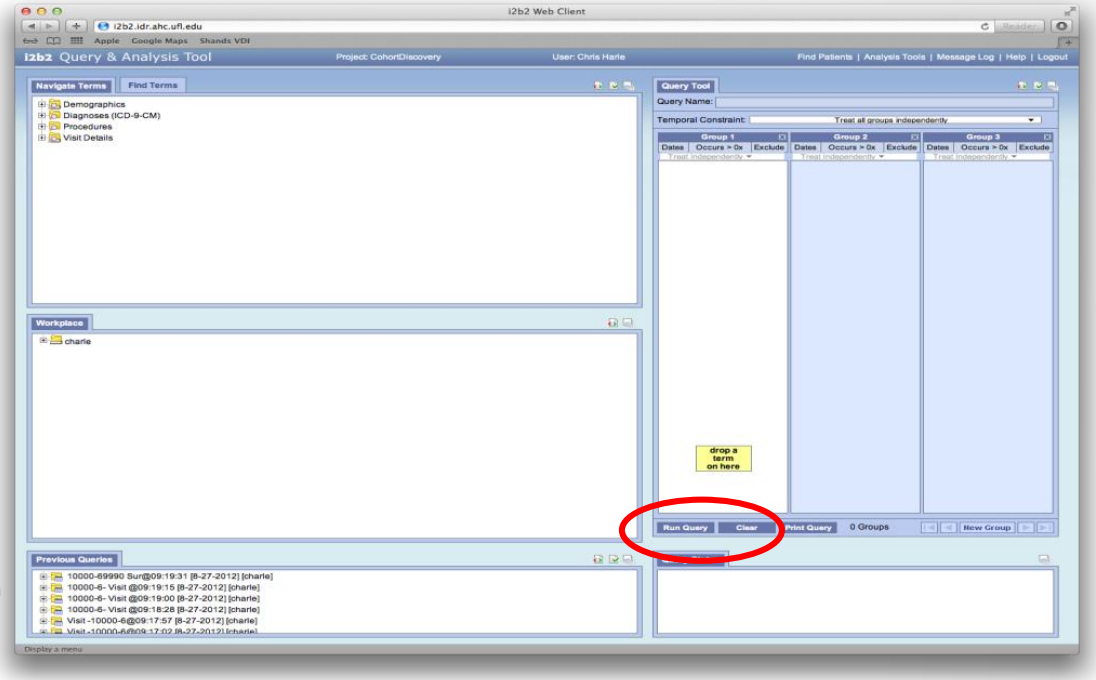


Courtesy: Manini 2013

How many people ages 45+ with a low back pain diagnosis were in the ED in 2013?

i2b2

Informatics for Integrating Biology and the Bedside



N = 3,468 patients

Female: 2,055
Male: 1,413

Black/African American 1,006
White: 2,335
Other: 127

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"Consent2Share"

- A process by which patients in the UFHealth System can agree to be contacted by a researcher in the future to ask the patient if they might be interested in a research study.
- Built into the EMR (EPIC)
- Becomes one of the navigating terms

What Type of Patients Can Agree?

- Any Adult (older than18 years old)
  - Only those that can consent for themselves
  - A wife or husband cannot consent for their spouse
  - Must be “competent” to consent

- Any Child (younger than 18 years old)
  - Parent or legal guardian must agree for child
  - If child is >7, child should also agree by signing consent form.
  - When the child turns 18, they have to then consent for themselves

What are patient's consenting to??

- Periodic review of their medical information to see if they might qualify for a future research study, and if so,

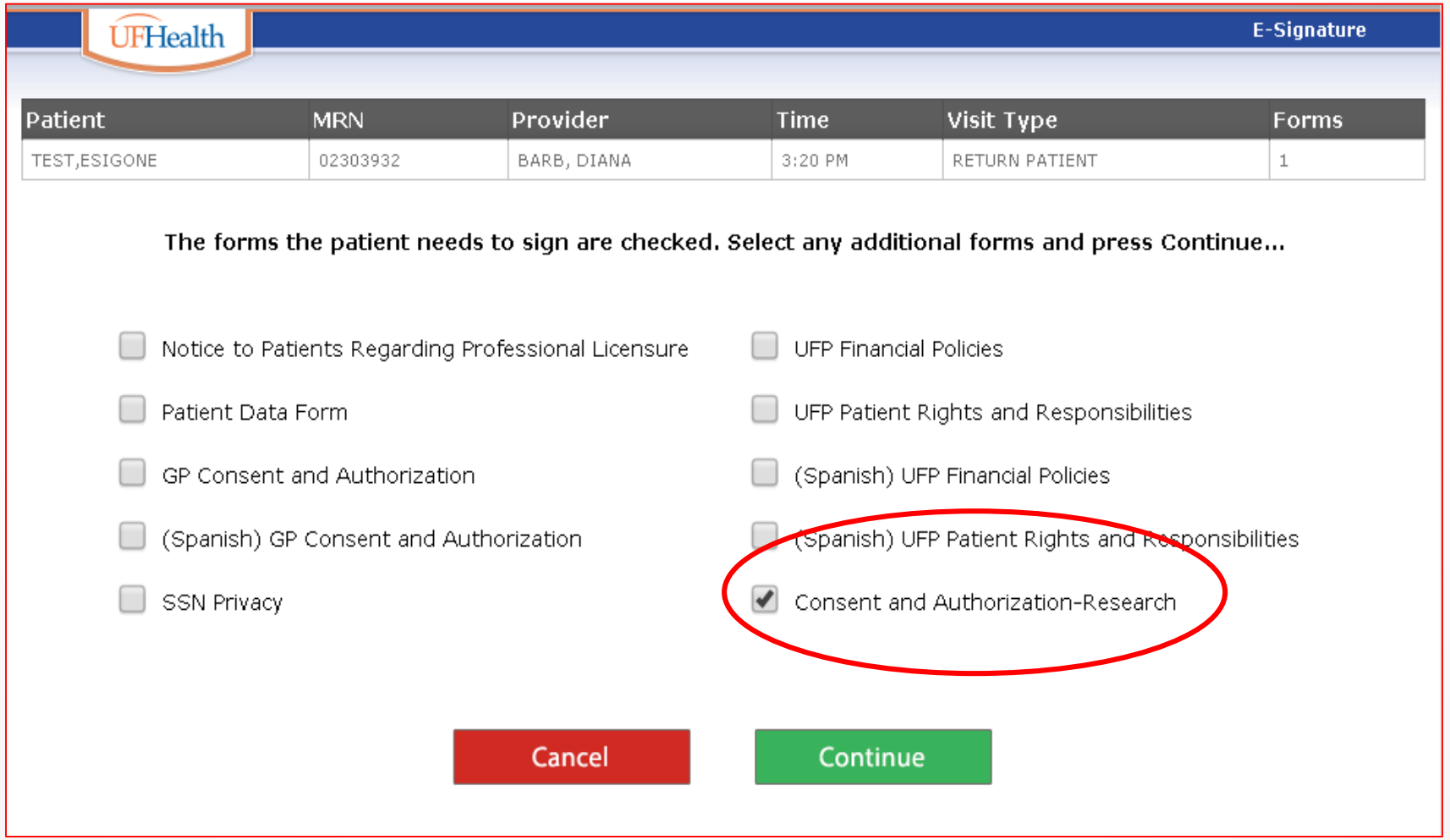
- Be contacted sometime in the future about being part of new research studies at UF Health.

Identifying potential research subjects is a key part to a successful research enterprise.

Consent2Share - Process

1. Consent form (eConsent) is included in the group of consent forms provided on the iPad at admission to the clinic
2. This research consent is always the last consent that will appear.
3. Any straight forward questions are addressed by trained admissions staff, other questions can be referred to either their doctor or the Consent2Share Hotline listed on the consent form
4. Patients are given time to review
5. Offer to print out a copy of the research consent if patient wants one.

eConsent2Share Form



UFHealth

E-Signature

Pediatric Consent

Protocol #349-2011

VOLUNTARY RESEARCH CONSENT

Unlike the other documents you have just signed, the next document is a request to you to be placed on a list to hear about future research. This is an easy way you can help advance health research today: Consider joining our "Consent2Share" research contact list. By joining the list, you are allowing UF Health to share your contact information with UF researchers when the information in your medical records shows you might qualify for a future research study.

It is your choice to answer yes or no on the following consent form. Answering yes or no will have no impact on the care you will receive from UF Health.

Read the following consent form to learn more, including how your information will be protected and potential benefits and risks of saying yes to participating. If you have questions, talk to the person who gave you this iPad. When you are ready, answer "yes" or "no" on the consent form and complete the electronic signature.

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MRN: 02303932 Patient: TEST,ESIGONE Visit Date: 04/24/2015

INFORMED CONSENT FORM
to Participate in research, and
AUTHORIZATION
to Collect, Use, and Disclose
Protected Health Information (PHI)

What they are agreeing to.

Under the name "Consent2Share", the University of Florida and Shands Teaching Hospital & Clinics Inc. (UF Health) are asking for your permission to include you in this Research Contact Registry. If you sign this document, you will agree to:

a. Periodic review of your medical information to see if you might qualify for a future research study, and if so,
b. Be contacted sometime in the future about being part of new research studies at UF Health.

Please read the information below before you decide if you want to participate in this Research Contact Registry. If after you read this, you still have questions, do not sign this form until you talk to your physician or call the Consent2Share Helpline at (352) 265-3282.

The choice to let UF Health review your medical information and contact you later to see if you are interested in joining a future research study is entirely up to you. If you chose not to participate in the registry you will not be penalized or lose any benefits that you would otherwise be entitled to.

If you decide to participate in this research contact registry:

- Your medical record will be flagged as someone who is interested in hearing about research opportunities
- Your name and contact information will be shared with researchers once the researcher has an approved study and your records show that you potentially qualify for the study. Studies are approved by the Institutional Review Board (IRB), which is a committee of scientists, ethicists and community members.
- If you are contacted, you will be told about a specific research study at that time. At that time, you can choose whether or not to be involved in that research project.

Other things you should know:

- Your medical information will be kept in a very safe location (on a password-protected and encrypted computer server).
- If you do not agree, you will not be denied or refused any treatment, payment or enrollment in a health plan, or lose any benefits that you would otherwise be entitled.
- There will be no cost to you for your involvement in this registry.
- Your involvement in this registry might not result in any benefit to you.
- There may be other research studies that involve the review of your medical information, any of which you can choose to participate in.
- You may choose to stop your involvement at any time. You will not be penalized or lose any benefits to which you are otherwise entitled. You can call the Consent2Share Helpline at (352) 265-3282 to have your name removed from the "re-contact" list.
- By signing this document, UF Health will be allowed to collect, use and/or give out your contact and medical information, but only to other researchers whose research is approved by an IRB.

Help line

What are the Risks to Agreeing to be in this Research Contact Registry?

- That your medical data being reviewed by a researcher is given to people that should not have it. Every effort will be made to keep your information secure and confidential. However, there is a small risk that an unauthorized person may see your information. Depending on the information this could affect you and/or your family (for example: embarrass you, cause you anxiety or distress).
- You may be contacted several times for different research studies. If at any time you wish to be taken off the "re-contact registry", you may contact the Consent2Share Helpline at (352) 265-3282.

Signature of Subject providing Informed Consent & HIPAA Authorization
You have been informed about the possible review of your medical information and possible re-contact if you are a potential candidate for a research study. You have also been told of possible benefits and risks, and that you are free not to agree to be in this Research Contact Registry. You have received a copy of this informed consent or have been told where a copy this informed consent is located on a web site. You have been given the opportunity to contact your physician or the Helpline to ask questions before you sign, and you are aware that you can ask other questions at any time.

Please Choose:
If you potentially qualify for a future research study, you agree **to be contacted** about your potential involvement in a research study. These studies will be described to you and you can choose whether or not to participate at that time.

(Please **check** Yes or No, then **sign** below)

Choose "Yes" or "No"

( ) Yes ( ) No

Parent/Adult Legally Representing the Subject. By signing this form, you voluntarily give your permission for the person named above to participate in this study. You hereby authorize the collection, use and sharing of protected health information for the person named below as described above. You are not waiving any legal rights for yourself or the person you are legally representing. After your signature, please print your name and your relationship to the subject.

Consent & Authorization Signature of Parent/Legal Representative:

Name of Legal Representative:

Relationship to Patient: (•) Parent ( ) Court Appointed Guardian

Participants Who Cannot Consent but Can Read and/or Understand about the Study registry. Although legally you cannot "consent" to be in this study registry, we need to know if you want to take part. If you decide to take part in this study registry, and your parent or the person legally responsible for you gives permission, you both need to sign. Your signing below means that you agree to take part (assent). The signature of your parent/legal representative above means he or she gives permission (consent) for you to take part.

Assent Signature of Participant:

☐ **I verify that I am the legal representative for this child, and that my signature is above.**

If you would like a copy of this form, please ask the staff member to print one out for you.

Clear Form | Ask Me Next Time | Continue

Patient's Decisions

- Potential Subject's Outcomes
  - Clear Form -will print again at next clinic visit
  - They choose yes or no
    - "Yes"– indicated in EPIC, consent will not print again
    - "No"- indicated in EPIC, consent will not print again
  - "Ask Me Next Time" – indicated in EPIC, will print again at next clinic visit
- Enrollment decision lasts unless patient changes their mind
- If a minor, will print again after their 18th birthday
- They can still consent to other research studies

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View from the Researcher

- Use i2b2 to query IDR to determine if there are sufficient potential study subjects
- If they need to contact potential subjects, can factor in Consent2Share
- Submit to the IRB, if approved,
- Submit their query to the Consent2Share data hotline – UF Data Management
- List of potential subjects with contact information is provided.

Metrics to Date

- Available in all Gainesville Clinics, Select Jacksonville Clinics
- 58% say YES to the Informed Consent

Patient has MRN at	#Consented
Gainesville	100,892
Jacksonville	5,528
At both Gnv & Jax	38,603
Grand Total	145,023

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ORIGINAL ARTICLE

Consent2Share: an integrated broad consenting process for re-contacting potential study subjects

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Compliance Issues

"or how to stay out of trouble with the IRB"

Informed Consent Deviations

- Common Consent at UF
  - No one signed
  - Wrong study consent form used
  - Out of date consent form (only use stamped copy)
  - Wrong person signed consent, didn't indicate who they were
  - Person obtaining consent not listed on Addendum A
  - Assent issues
  - Misc. (sign on wrong line, don't date, etc.)
- Must Keep Original (no consent, no subject)
  - Consents can be scanned
  - Must scan entire consent form
- Use a REDCap eConsent if possible

Non-compliance Issues:

- Revisions - Any change in your protocol, "no matter how minor" must be reviewed and approved by the IRB prior to implementing that change.
- Assuming Responsibility for an Existing Study – make sure you are in good standing, have all consents!
- Renewing a Protocol – Full Board Only: notified 90 & 45 days prior to the expiration of the protocol
- Expired Protocols: you may not enroll further subjects or conduct any research activities or collect research data. May have funding issues!!
- Subject Compensation: must use the Research Participant Payment Program (RPPP) at UF. Collect SSN for >$199.

Status Report – Non Full Board Studies

- Once approved, unless under FDA oversite, no continuing review is needed.
- The PI and key Study Staff notified at 45 days, 30 days, and 7 days
- Log into your protocol, answer one question – are you still conducting this study
  - Yes – repeats in 3 years
  - No – study is automatically closed
- If we don't hear back
  - Study is administratively closed after the 3-year anniversary date.
  - Notification goes out to PI and key Study Staff notifying them of the closure

Adverse Events

- Must report to IRB within 5 working days
  - Serious (ie: hospitalization, required treatment) and Unexpected (ie: not currently in informed consent) and related or the relationship is more likely than not.
- Everything else, report at continuing review (Full Board Only)

Should I conduct a human research project?

Things to consider

- How much time do you have to conduct your research?
- Would it be better to do some “team” research instead of taking on your own project?
- Do you have a research infrastructure, or does your department
  - How experienced is your study coordinator??
  - Delegate, don’t abdicate your responsibilities

Things to Take Advantage Of

- The IRB Office (273-9600) or website https://irb.ufl.edu/.
- IRB Investigator Guidelines https://irb.ufl.edu/index/irb-policies-guidelines-and-guidances.html.
- Meet with me during your study design to discuss human subjects protection issues.
- Use the Integrated Data Repository (IDR) via i2b2 to find out if you have enough potential study subjects
- Listen to the pre-review IRB staff, make those changes
- Attend the IRB meetings - Answer questions that could result in tabling
- Attend Brown Bag Lunches


Questions!