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IRB GRAND ROUNDS SOCIAL AND BEHAVIORAL RESEARCH: NEED TO KNOW

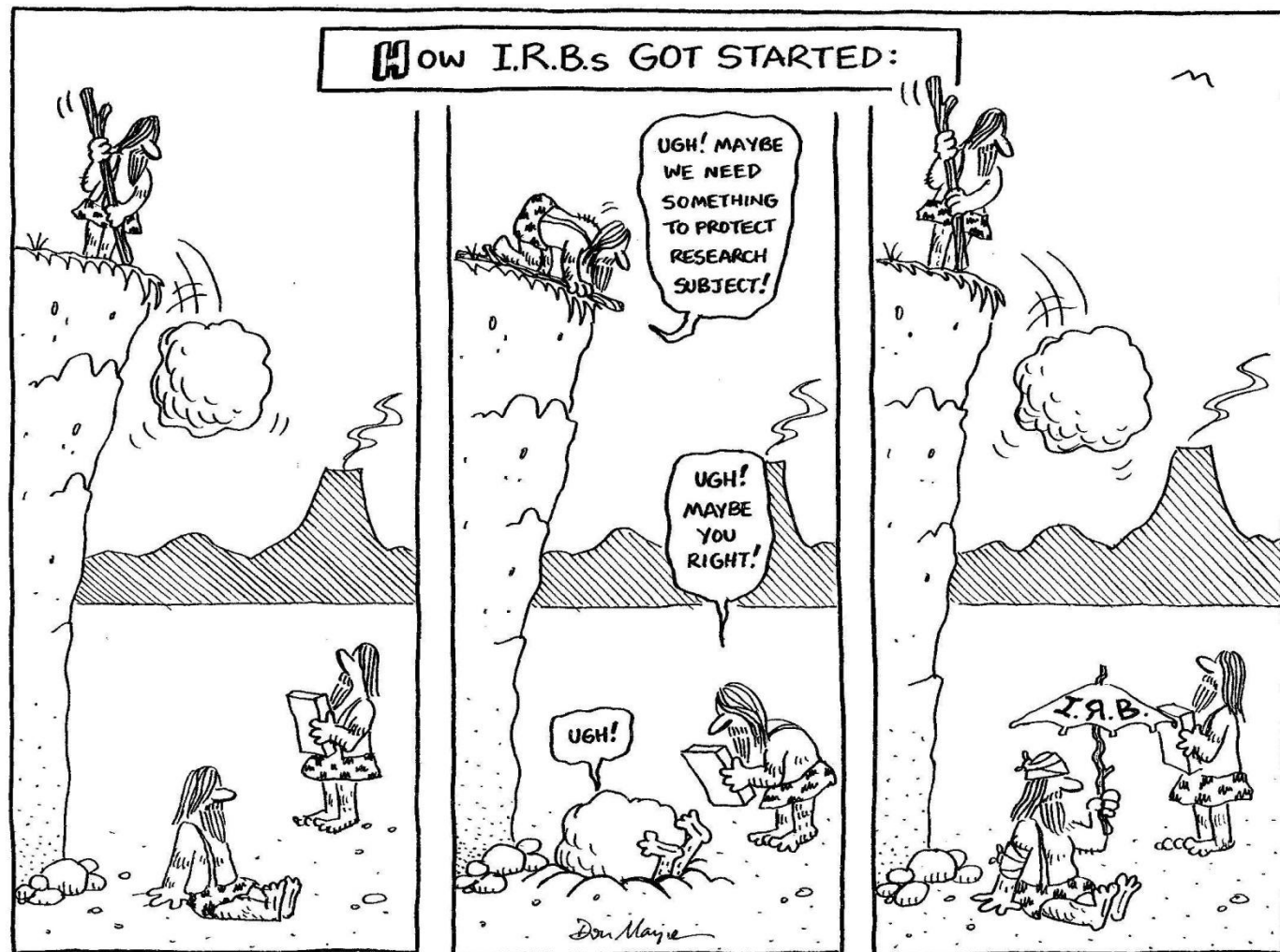
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ASSURANCE AND REGULATIONS

- The University of Miami requires review and approval by an IRB of all research involving human subjects, if any UM faculty, staff, or students are engaged as key personnel in that research (FWA Policy 2.4, Revised May 10, 2011)... conducted in accordance with its FWA (binding agreement with DHHS, OHRP and FDA, when applicable).
 - FWA authorizes review of research regardless of funding source.
- DHHS Code of Federal Regulations 45 CFR 46 (“the Common Rule”) and its subparts B, C and D.
 - Additional FDA regulations found in 21 CFR 50, 54, 56, 312, 600, and 812.

ALL HUMAN SUBJECT RESEARCH AT UM= IRB APPROVAL

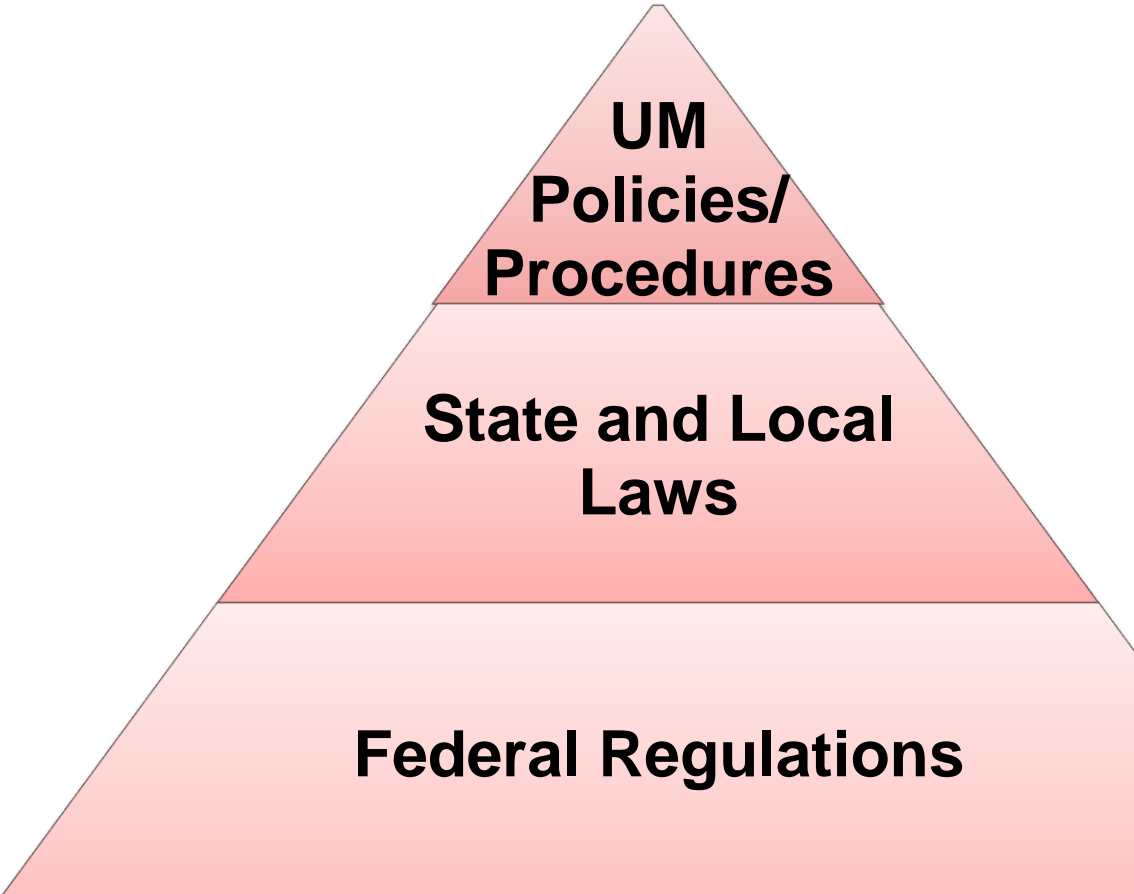
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SECTION 3

GUIDING PRINCIPLES OF REVIEW PROCESS

OTHER REGULATIONS, POLICIES AND GUIDELINES THE IRB MUST FOLLOW



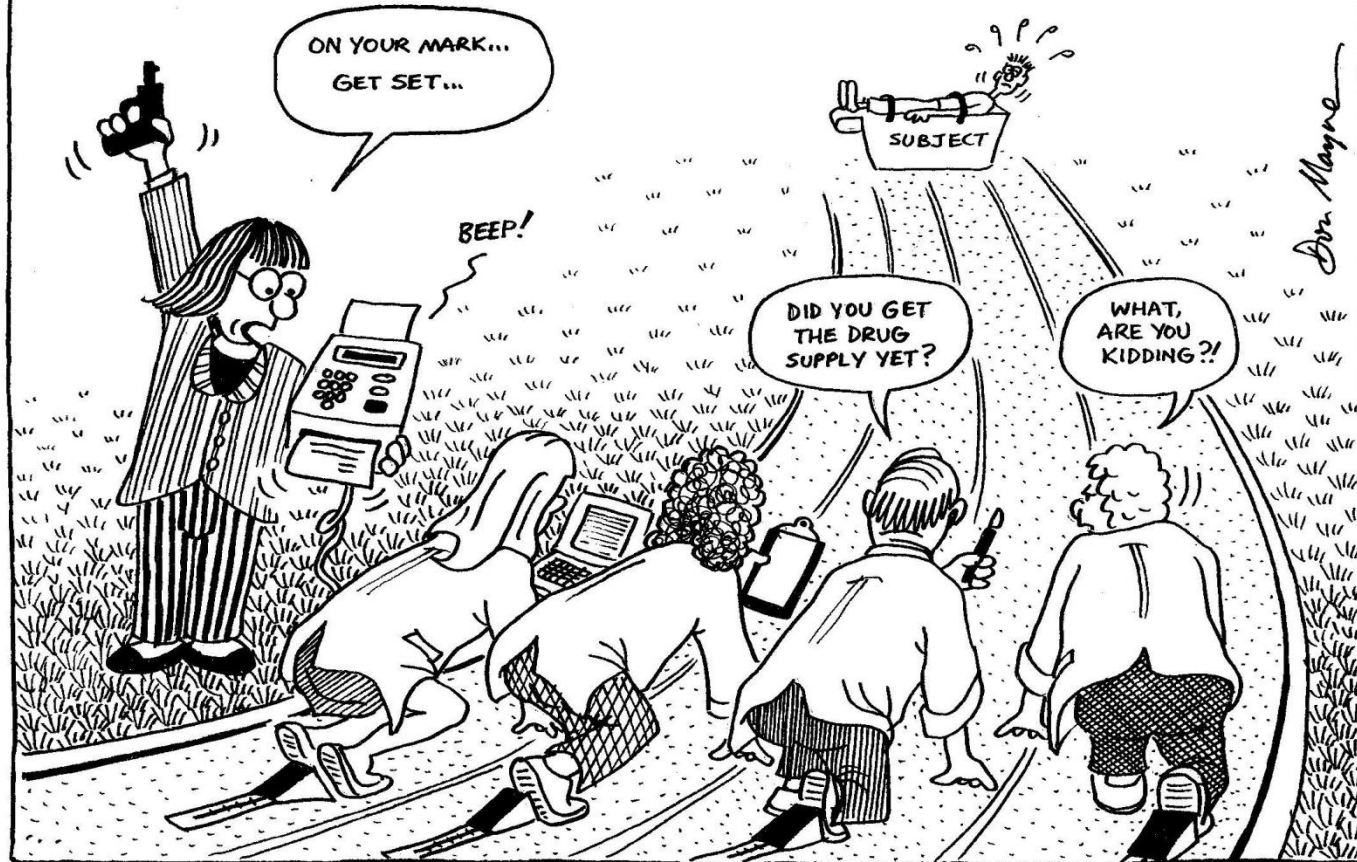
**UM
Policies/
Procedures**

**State and Local
Laws**

Federal Regulations

- HHS 45 CFR 46, Subpart A, B, C, D
- FDA 21 CFR 50 (Informed Consent)
 - FDA 21 CFR 56 (IRB)
- Veteran's Affairs 38 CFR 16
- Federal Agency Policy
- ICH (Good Clinical Practice)
- Joint Commission on Accreditation of Healthcare Organizations (JCAHO)
- Family Educational Rights and Privacy Act (FERPA)
- International policies and ethic codes
- Other funding agencies

WAITING FOR THE IRB APPROVAL LETTER...



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SECTION 4

IRB REVIEWS

REVIEW CONTINUUM



**Level of risk helps determine route of review*

EXEMPT RESEARCH

- Six categories defined by 45 CFR 46
- Research must fall into one or more of the categories to be exempt
- IRB has the responsibility to determine exemption, PI cannot make determination
- May still require consent or other safeguards
- How is data being collected?
 - Is there a code that links data to subjects (easily identifiable)?

EXEMPTION CATEGORIES

- (1) Educational research
- (2-3) Tests, surveys, interviews or public observation
- (4) Research on existing public or anonymous data or specimens
- (5) Federal demonstration projects
- (6) Taste and food evaluation

EXPEDITED REVIEW

- Expedited review procedure may be used to review either :
 - Some or all of the research appearing on **the list** and found by the reviewer(s) to involve **no more than minimal risk**
 - **Minor changes** in previously approved research during the period (of one year or less) for which approval is authorized
- Expedited does not mean quicker – rigor of review is the same, number of reviewers different
- Review carried out by IRB chair or designee
- Reviewers may approve or modify, not disapprove

ELIGIBLE FOR EXPEDITED REVIEW: (INITIAL REVIEW)

- (1) Clinical studies: IND/IDE not required
- (2) Blood sample collection
- (3) Prospective collection of biological samples (noninvasive means)
- (4) Data collected through noninvasive means (routinely practiced in clinical settings)
- (5) Materials (data, documents, specimens) have been collected or will be collected for non-research purposes
- (6) Collection of voice, video or digital data
- (7) Individual or group behavior, surveys, interviews, oral histories

ELIGIBLE FOR EXPEDITED REVIEW: (CONTINUING REVIEW)

- (8) Continuing review of research with no further direct subject participation
 - Long-term follow up for survival
 - No subjects have been enrolled
 - Data analysis
- (9) Continuing review of minimal risk research (not under IND or IDE) where no additional risks have been identified

FULL REVIEW MEANS:

- A full quorum is assembled (at least half of the members plus one, includes nonscientist)
- All members participate in discussion and make comments (plenary review)
- Decision is rendered by a majority of the assembled quorum
- No member with a conflict of interest participates in the decision
- Numerical vote is taken and recorded

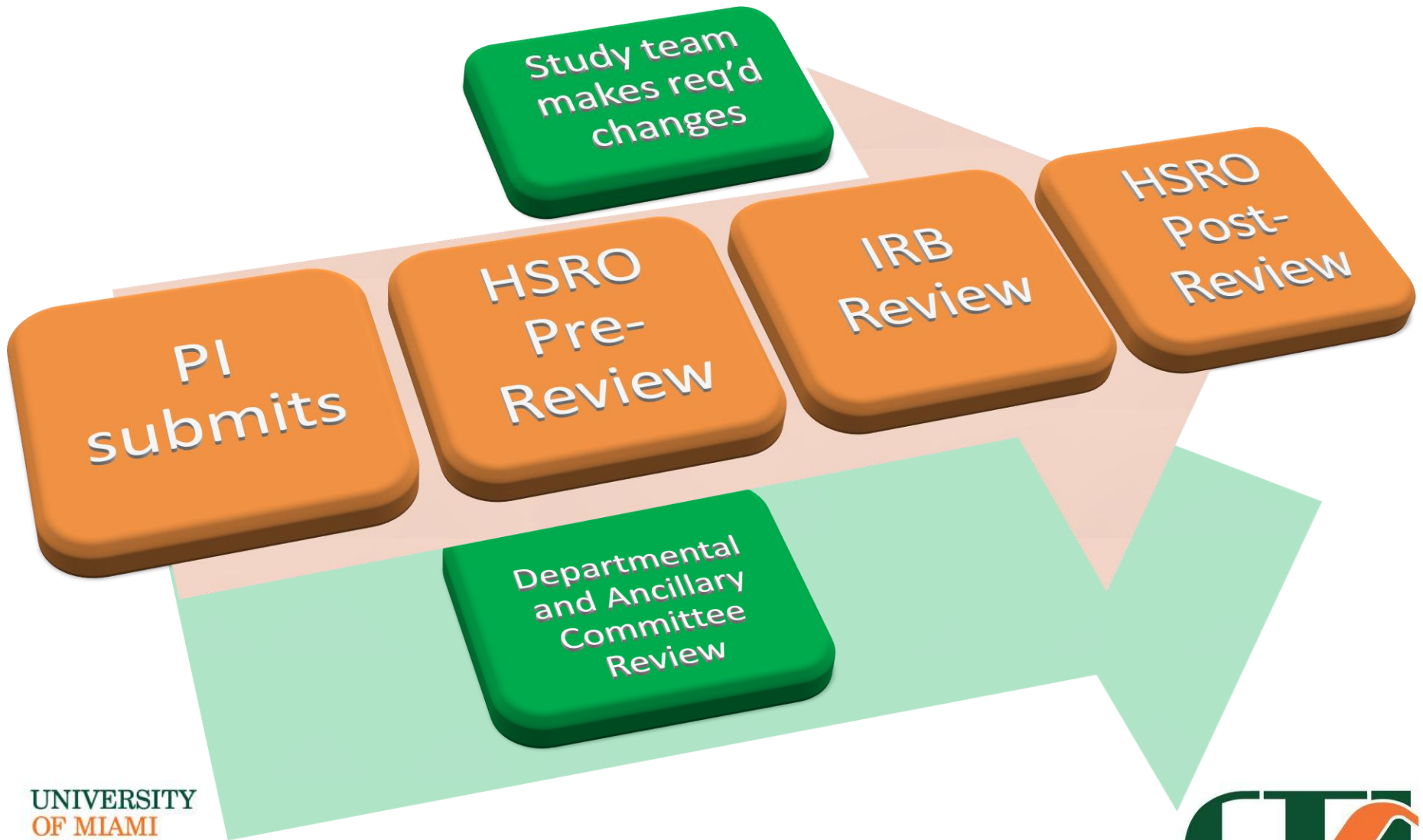
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WRITING A STUDY PROTOCOL/ THE PROTOCOL TEMPLATE



IRB 7.2 BASIC WORK FLOW



CREATING A NEW STUDY

- New study information is entered into a series of online forms, the number of which may change based on the answers you provide
 - Note: A continuing review, modification, or RNI (reportable new information) submission can be handled similarly to a study
- Before you begin, gather files and information about your study such as:
 - Supporting information files
 - Financial interest status for each of your study team members
 - Contact information and IRB oversight information for external sites involved in the study

SAMPLE PROTOCOL TEMPLATE

SECTION-BY-SECTION

1. Protocol Title
2. IRB Review History
 - Details of any prior review including IRB name, dates and contact info
3. Objectives
 - Purpose, specific aims and objectives
4. Background
5. Inclusion and Exclusion Criteria
 - Populations with additional requirements: adults unable to consent; infants, children, teenagers; pregnant women; prisoners
6. Number of Subjects
7. Study-Wide Recruitment Methods
8. Study Timelines
9. Study Endpoints
10. Procedures Involved
11. Data and Specimen Banking
12. Data Management
13. Provisions to Monitor the Data to Ensure the Safety of Subjects
14. Withdrawal of Subjects
15. Risks to Subjects
16. Potential Benefits to Subjects

AIMS & PROCEDURES

DO

- Detail what the study aims to achieve.
- Provide Step-by-Step procedures with a description of ALL procedures involved in the study- Be Concise and not verbose!
- Provide your research flexibility (don't be restrictive)*:
 - Dates, Timeframe, # of participants
 - “Some or all of these procedures might be completed.”
- Provide all measures administered to participants (including demographic forms & guides: observation, focus group, & interview).

Don't

- Reference dissertation proposals or other documents (grants, SOW, informed consent) for HSRO and/ or IRB to piece together study activities.
- Copy & paste grant and/or other documents to the application (ICF)!!!

RECRUITMENT PROCESS

DO

- Detail who will be recruiting and his/her role in the patient's/ participant's environment.
 - Is it a potentially coercive relationship?
 - How can the perceived coercion be reduced- physician/ nurse introduces the study and research associate consents for the research?
- Recruitment methods/ materials must be consistent with the protocol.
- Recruitment materials must follow HSRO policies on advertisement.

Don't

- No Cold-Calling!
 - Potential participants should not have their charts (medical or student) reviewed by research associates and called without prior notifications.
 - Send a letter/ have a nurse/ "known individual" let the potential participant know someone will call them about a potential research study.

CONSENTING PROCESS

DO

- Detail who will be consenting and their role in the patient's/ participant's environment.
 - Is it a potentially coercive relationship?
 - Students are not vulnerable by virtue of being students; however, a teacher/ professor consenting students for his/ her own research not appropriate.
 - Doctor consenting his/ her own patients?
- If this is a one-time survey/ focus group, would the study qualify for a waiver of SIGNED consent?
- Translations? English must be approved first and then translations.
- Short Forms- only applicable for other languages where minimal participants are expected (less than 5).
- Keep Informed Consent Forms/ Documents consistent with protocol!

Don't

- Copy the procedures onto the consent form.
- A waiver of signed consent still requires a consent document- it is not a waiver of informed consent! Consent is still undertaken in some manner; script/ language is still required to be reviewed by the IRB.

WHAT TO EXPECT AFTER SUBMITTING

Submitting information to the IRB initiates a series of activities that may include:

- Review within your department
- Pre-review by an IRB staff member
- Review by the IRB committee or a designated reviewer
- Communication of the IRB decision to the investigator

*Any of these may lead to a request for the investigator to take further action, such as providing clarifications or modifying the study. **Whenever you need to act, you receive an e-mail notification, and the study appears in My Inbox when you log in to the IRB system.***

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RISKS IN BEHAVIORAL RESEARCH & METHODS OF MINIMIZING RISK



RISKS IN BEHAIORAL RESEARCH

- Risks are inevitable but regulations require that they be reasonable and minimized.
 - By using procedures which are consistent with sound research design and which do not necessarily expose subjects to risk.
 - Whenever appropriate, by using procedures already being performed on the subjects.

MINIMIZING RISK IN BEHAVIORAL RESEARCH

- Psychological risk
 - Psychologists, physicians available to reduce participant distress.
 - If the psychological risks are high, IRB will require a protocol in place for reporting, especially when research associates are interacting with the participants.
 - Debriefing participants at the conclusion of the study to assess psychological state.
 - Limits of disclosure when child/ elderly abuse is present and suicidality.

MINIMIZING RISK IN BEHAVIORAL RESEARCH

- Confidentiality
 - Use sound procedures in place to reduce the possibility of disclosure.
 - Certificate of Confidentiality- when very sensitive information is being gathered.
 - IDs in place of names in data-gathered materials.
 - Appropriate storage procedures: no portable drives, no cloud storage if data is sensitive.
 - Would the data that you are accessing normally be accessible to you (from charts, other studies)?
 - If you are audio or video recording, how will these materials be stored?

MINIMIZING RISK IN BEHAVIORAL RESEARCH

- Avoiding Duplication
 - If data are gathered clinically/ standard of care, access those records.
 - Collaborate with other investigators that obtain information PIs are mutually requesting (add each other as key study personnel to the protocols).
 - Set up a “screening” protocol where initial data are gathered and shared (normally seen with research “labs”).

MINIMIZING RISK IN BEHAVIORAL RESEARCH

- Recruitment/ Consenting
 - If recruitment involves active screening (waiver of signed consent granted and measures are given) avoid obtaining personal information unless eligible.
 - If the study involves sensitive information, avoid methods of identification or disclosure of participant's personal information (HIV on ads and recruitment letters).
 - If letters are being mailed- vagueness on the topic to avoid disclosure would be preferable while adhering to HSRO recruitment policies.
 - Note- the IRB is charged with the final determination on reducing risks and can require modifications and can alter documentations to meet these requirements.

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THE NEW FRONTIER: INTERNET-BASED AND SOCIAL MEDIA RESEARCH



WHAT IS INTERNET-BASED/ SOCIAL MEDIA RESEARCH?

- Internet-based research is research which utilizes the Internet to collect information through an online tool.
- Social media is a group of internet-based applications that build on the ideological and technological foundations of Web 2.0 and that allow the creation and exchange of user-generated content.

BIG ISSUES

- What is “private”?
 - Joining groups to conduct research implies level of privacy.
 - Public blogs.
- What is “identifiable?”
 - Can individual pieces of information lead to privacy?
- How to protect subjects’ privacy and confidentiality interests?
- Minimizing risk when using sensitive online data.
 - Current vs future sensitivity.
 - Informational risks
 - Data Security.

EVALUATING THE USE OF THE INTERNET FOR PARTICIPANT RECRUITMENT

- Internet-based procedures for advertising and recruiting potential study participants (e.g., internet advertising, e-mail solicitation, banner ads) must follow the IRB guidelines for recruitment that apply to any traditional media, such as newspapers and bulletin boards.
- Investigators requesting to recruit through the mass email system at the University of Miami must follow the appropriate procedures for review and approval by the UM Technology Department (305-284-3961) in addition to IRB approval.

KEY CONSIDERATIONS FOR REVIEW

- What is the type of venue?
- Expectations of privacy?
- Consent procedures (*normally* documentation of signature is waived and consent is not fully waived)?
- Sensitivity of data (would there be extra encryption levels required)?
- Harm/ risk? (warning participants to complete procedures in a private setting and close the browser).
- Age verification (data integrity)?
- Authentication of participants?
- Identification of participants?
- Storage/ transmission of data?

PROTECTIONS FOR INTERNET-BASED/ SOCIAL MEDIA RESEARCH.

- The use of online surveys must include mechanisms, if applicable, for withdrawal such as how to retrieve and discard responses from a participant who has decided to withdraw.
- Because there is no standard for identifying distressed participants online, the IRB must take into consideration potential participant experiences (the sensitive nature of the research) that may be distressing when evaluating the risk/benefit ratio.
 - Mechanisms in place to reduce risk- National Hotline numbers? PI has some access to information to follow-up on distressed participants.
- Data transmitted via e-mail cannot be anonymous without the use of additional steps. Because respondents' electronic addresses are typically provided when they return such surveys by e-mail, PIs should devise a plan for stripping such information to maintain the confidentiality and anonymity of respondents' names. Refer to <http://www.miami.edu/bb/privacy/> for sample language that can be adapted to describe other instructional sites.
 - Informed consent language should always include the limits of confidentiality!

PROTECTIONS FOR INTERNET-BASED/ SOCIAL MEDIA RESEARCH.

- The researcher should also state how the confidentiality of the data will be maintained, for instance, when a survey will be posted online through a third party such as Survey Monkey or Qualtrics, so that email addresses or web URLs will not be noted by the researcher.
- When recruiting from Social Media sites use caution on how you “pose” - are you a user/ person, a “site”? Can other “likers” “Followers” access the list of other followers?
- It is recommended that for online data collection a professionally-administered survey server be used and monitored by IT professionals.

Thank You