

# Institutional Review Board Policies and Procedures Manual

## SECTION 10: SUBJECT RECRUITMENT AND INTERNET AND SOCIAL MEDIA

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## 10.1 SUBJECT SELECTION AND RECRUITMENT

### A. Equitable Selection of Subjects

The selection of subjects for a research project should be equitable, ensuring that the burdens and benefits of research are fairly distributed. Federal regulations state that, when assessing methods of subject selection and recruitment, *“the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons.”* 45 CFR 46.111(3) and 21 CFR 56.111(3)

In addition, social justice requires that there be a hierarchy of preference in the selection of subjects when the research involves more than minimal risk. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (National Commission) recommends that studies that involve more than minimal risk be conducted in animals and adults before children, competent individuals before incompetent individuals, and non-institutionalized persons before institutionalized. In order to assess the appropriateness of the subject population for a particular research protocol, the IRB will evaluate the characteristics of the chosen subject population - considering age, gender, and population diversity - and the methods and materials that investigators propose to use to recruit subjects.

#### i. Inclusion of Women and Minorities

The NIH requires that its grantees include women and minorities in study populations *“so that the research findings can be of benefit to all persons at risk of the disease, disorder, or condition under study.”* Women and minorities should be appropriately represented (in proportion to the demographic makeup of the eligible community) unless there is sound medical or scientific justification for their exclusion.

#### ii. Inclusion of Minors

The NIH requires that its grantees include children in study populations with the goal *“to increase the participation of children in research so that adequate data will be developed to support the treatment modalities for disorders and conditions that affect adults and may also affect children.”* Children should be included in a research protocol unless there is compelling medical or scientific reason for their exclusion.

### B. Recruitment Principles

The IRB reviews an investigator’s proposed recruitment methods in order to ensure that the procedure for recruiting subjects to a study is not unduly coercive. In addition, the IRB must review all recruitment materials, including electronic materials, to ensure that advertising for the study does not promise or imply a certainty of favorable outcome (e.g., cure) or other benefits beyond what is outlined in the consent document and the protocol. This review is especially critical when a study involves subjects who are likely to be vulnerable to undue influence.

#### i. Minimizing Coercion and Undue Influence During Recruitment

Patients may be hesitant to opt out of participation for fear of disappointing the doctor who presents the research. In order to minimize coercion or undue influence (if not

avoid it altogether), the IRB suggests that investigators make information about the study available and let interested patients contact the research team. Recruitment flyers describing the research (and includes contact information of the research staff) can be distributed by outside physicians or posted in offices. Where appropriate, other members of the research team can inform patients about the study and direct them to talk with their physician if interested.

ii. Protecting Privacy During Recruitment

In the process of recruiting for a research study, investigators must uphold the privacy of potential subjects and the confidentiality of their medical records. The Privacy Rule applies to such activities and sets limits and conditions on the uses and disclosures of protected health information (PHI) that may be made without patient authorization. Typically, employees of the covered entity (i.e., the Institution) may access PHI needed in order to contact patients in order to obtain HIPAA authorization. However, no PHI may be used for research without HIPAA authorization or a waiver (full or partial) from the IRB. Recruiting Subjects by Telephone

In studies involving a telephone interview to determine basic eligibility for a study, the IRB requires that investigators submit the telephone script for review. The script must indicate that participation in the research is voluntary and that the telephone interview can cease at any time the subject feels uncomfortable, or wishes to end the interview for any reason. Additionally, the IRB reviews the investigator's plans for protecting the confidentiality of the collected data and privacy during this telephone interview.

### C. Special Circumstances in Recruitment

The IRB recognizes that some populations are more vulnerable to coercion and undue influence than others are. Accordingly, special consideration is given to studies that involve any of the following circumstances.

i. Recruitment of Children

Since the majority of children are in a dependent relationship to adult caregivers, they are particularly vulnerable to undue influence. When recruiting children, an investigator must take extra steps to ensure that the child's decision to participate in research is voluntary. Children should always be engaged in the assent process, to the level of their understanding. Written assent is required for children between the ages of 12 and 17.

The investigator is expected to minimize the possibility that a child's parent(s) or legal guardian(s) will pressure him or her to participate. Children should not be made to feel that refusal to participate will bear negative consequences, but likewise should not be offered incentives to participate that could cloud their ability to assent (incentives may differ substantially from those which influence adults).

ii. Recruitment of an Investigator's Patients

As there may be the potential for conflict of interest, a recruiting investigator who is also the treating physician of potential subjects must take special precautions to present the study information without undue influence or pressure. Ways to minimize undue influence include waiting to introduce the possibility of research participation until

after standard care options have been presented to a patient; offering patients the opportunity to discuss the research option with an uninvolved physician or staff member; and giving patients an appropriate amount of time to consider their participation. Investigators must detail the steps that will be taken to emphasize the voluntary nature of research participation in the clinical setting.

iii. Recruitment of Family Members

The identification and recruitment of family members of subjects for participation in research can be particularly sensitive, such as studies of genetics that require the participation of multiple family members. In many cases, a single subject is first identified and if that individual is a good candidate for the study, they can be provided with written informational materials to share with family members. The relatives may initiate contact with the research team, or let the study subject know that they would be willing to be contacted by the research team.

In addition to concerns about the privacy of individuals, investigators and the IRB should consider that the nature of family studies inherently exerts pressure on family members to take part. The investigator should be aware of potential for invasions of privacy and the appearance of coercion, both from the subject and from the investigator.

iv. Recruitment of Employees or Colleagues

When employees, colleagues and/or their families are recruited for participation in a research study, they may be vulnerable to perceived but unintentional pressures to appear cooperative and motivated. In extreme cases, they may feel that their participation is necessary in order to avoid jeopardizing their job or relationship with the investigator. Employees and colleagues must not be pressured to participate in research due to fear of job loss, delayed promotion or other influence of an investigator. It is particularly important to be sensitive to coercion when an individual is in a direct reporting relationship to an investigator.

Therefore, investigators requesting to directly recruit employees or colleagues as research subjects will be carefully reviewed by the IRB and the investigators' plan to minimize coercion must take into account these considerations. Investigators are encouraged to post flyers in the hospital or advertise using IRB approved global e-mails in lieu of direct solicitation so that any employee who is interested may initiate contact with the research team (if applicable).

v. Recruitment of Patients for Research at External Institutions

Recruitment of subjects for a study taking place at an outside institution is allowable when permission has been obtained from the department/division in which recruitment materials will be distributed/posted. The person authorizing the distribution of the materials is responsible for ensuring that the study/recruitment materials were reviewed and approved by an external IRB.

When Lurie Children's is not engaged in the research, our IRB does not need to perform an additional review of the recruitment materials for such studies. Lurie Children's is not considered engaged in a study, if the activity of our employees is limited to the following:

- informing prospective subjects about the availability of the research;
- providing prospective subjects with information about the research (which may include a copy of the relevant informed consent document and other IRB approved materials) but the Institution's employee(s) does directly not obtain the subjects' consent for the research or act as representatives of the investigators from the external institution;
- providing prospective subjects with information about contacting external investigators for information or enrollment; and/or
- seeking or obtaining permission from prospective subjects for external investigators to contact them.

vi. Investigator Self-Experimentation

All research involving human subjects must undergo IRB review to protect the rights and welfare of participants and the integrity of the research. Faculty and staff members who wish to act as participants in their own research protocols should consider themselves human subjects. Federal regulations do not allow for an exception when the investigators or staff elect to participate in their own research. Alternatives to self-experimentation are encouraged when available (i.e., use of discarded, deidentified clinical specimens, specimens from biobanks, etc.). Prior to commencing any research activity that involves self-experimentation (i.e., blood draws, sample collection) the investigator must obtain IRB approval.

The IRB will review the protocol and determine the appropriateness of the research, the type and level of self-experimentation, and the potential risks and benefits to the investigator/staff as research participants. The primary purpose of IRB review for studies involving self-experimentation is to: 1) protect investigators and staff from taking unwarranted risks, and 2) ensure junior investigators/staff do not feel undue influence or coerced to participate. The IRB will review each protocol and request additional safeguards for the research participants if necessary (e.g., specify who can obtain informed consent, type and frequency of testing, etc.). A standard consent form must be developed that includes all required elements of consent as outlined in 45 CFR 46.116 and/or 21 CFR 50.25.

#### **D. Compensation and Reimbursement**

Investigators may offer compensation for participation in research or reimbursement of expenses incurred. Study compensation is intended to offset the inconvenience of participation, but should not be at a level that would be perceived as coercive or exert undue influence on participation. The amount offered should be appropriate to the length and nature of the subject's participation, and must be clearly outlined in the informed consent form. In evaluating the appropriateness of the compensation or other incentives, the IRB will consider factors likely to affect the decision of the eligible population. In addition, compensation should not be contingent upon the subject completing the study. Any subject who withdraws from the study or is withdrawn from the study should receive payment for the portion of the study (i.e., visits) completed in a manner described at the time of enrollment and in the informed consent document. Reimbursement is payment to cover expenses incurred by the participant because of clinical trial participation (most often travel related).

The Institution's preferred method of payment of study compensation is via gift/debit cards. Payment by cash and/or check is discouraged (due to costs, etc.), but may be allowed when pre-approved on an individual basis. The investigator/study team is responsible for keeping a record of all study payments regardless of the method of payment made to each research participant.

Please note that the IRS requires study compensation payments of \$600 or more in a calendar year be reported as taxable income. It is the responsibility of the investigator to obtain a complete W-9 form (including social security or tax id number) from the participant when study compensation meets this level regardless of the method of payment. The W-9 form can be found at <https://www.irs.gov/pub/irs-pdf/fw9.pdf>. The completed W-9 should be forwarded via e-mail to Accounts Payable at [ap@luriechildrens.org](mailto:ap@luriechildrens.org). The Institution will generate a form 1099-MISC and send a copy to the IRS and the participant.

Reimbursement of expenses is typically made by check based on receipts/costs incurred and is not considered taxable income. The Institution's Accounts Payable Department requires that a W-9 form accompany any check request (for reimbursement and/or compensation) regardless of the amount. However, the participant's social security or tax ID number does not need to be completed on the W-9 when: 1) the check request is for reimbursement of expenses, or 2) the cumulative study compensation is less than \$600 in a calendar year.

NOTE: The Ensuring Access to Clinical Trials Act of 2015 (S. 139/H.R. 209) (EACT) is a law which allows individuals who participate in rare disease clinical trials to receive up to \$2,000 of compensation, without those funds counting against their income eligibility for Medicaid and SSI.

## **E. Advertisement for Research Subjects**

### **i. General Guidelines**

As a general rule, anything that is intended to be directly seen or heard by prospective subjects and/or parent, should be reviewed/approved by the IRB.

Direct advertisements for research subjects, regardless of the medium, (e.g., flyers, global e-mails, solicitations by e-mail, social media, etc.) are an extension of the informed consent and subject selection processes. Advertisements for the recruitment of research subjects require IRB approval. The IRB will review the advertisement and the mode of its communication to assure that it is not unduly coercive and does not promise a certainty of cure beyond what is outlined in the consent and the protocol. Only IRB approved documents may be used for recruitment.

Note that "Dear Doctor" or doctor-to-doctor letters (even when soliciting for study subjects) are **not** considered advertising and do not require approval by the IRB. Information that is available to the general public (i.e., news stories, press releases, public websites such as [clinicaltrials.gov](http://clinicaltrials.gov), etc.) that are not created specifically for the study are not considered advertising.

The IRB reviews advertising and recruitment materials with Initial applications or as Modifications in Cayuse IRB any time during the study. The IRB will take into consideration the procedures, amounts, population, time commitments, location where ads will be placed, and determine what is most appropriate for all recruitment methods. Advertisements that are to appear on television or other predominately public locations

may be subject to review by the hospital's media relations department. The IRB does not consider "cold calling" an acceptable recruitment practice (e.g., calling subjects with whom no previous in person contact was made and no mailing of study information was sent).

ii. Content of Recruitment Materials

Any proposed notice or advertisement for subject recruitment must contain the following information:

- a. The condition under study and/or the purpose of the study
- b. Who can participate in the study, i.e. summary of eligibility criteria
- c. Brief description of what study participation will entail (i.e., number of visits, length of participation, general study procedures)
- d. If reimbursement for expenses or payment for time and effort will be provided, these may be included as long as the dollar amount is not overemphasized
- e. The location of the research and the person or office to contact for further information
- f. Required approval verbiage (this is to appear on all approved recruitment, and may be modified with explicit approval from the IRB): "This study is Lurie Children's IRB #, TITLE, Principal Investigator Name. The content of this flier/brochure/e-mail/etc. has been approved by the Lurie Children's IRB."

The IRB will approve a recruitment document only if the following conditions are met:

- a. The form and method of advertising are not unduly coercive and do not imply the certainty of a favorable outcome or benefit.
- b. The use of investigational drugs or devices is explicitly stated, when applicable. Claims are not to be made about the safety or effectiveness of the investigational product.
- c. The advertisement does not make claims that that the test article or therapy is known to be equivalent or superior to other articles and therapies
- d. The advertisement is to be professional in appearance
- e. The advertisement does not include exculpatory language

Advertisements should **not**:

- a. Include the terms "new treatment," "new medication" or "new drug" to describe into investigational drugs, biologics, or devices without explaining that the test article is investigational. Such terms leads study subjects to believe they will be receiving newly improved products of proven worth.
- b. Promise "free medical treatment," when the intent is only to say subjects will not be charged for taking part in the investigation. Do not use terms such as "free care" or "free assessments"

iii. Submission and Approval Procedures after Protocol Approval

If the original Initial application/protocol did not include advertising for the research subjects, the research investigator must submit a Modification in Cayuse IRB and provide for review all recruitment materials and methods for dissemination of the materials. The use of the recruitment materials/methods may not begin until IRB review and approval is provided.

iv. Recruitment Utilizing Clinical Trial Websites

Clinical trial websites provide a significant opportunity not only to recruit subjects, but also to foster informed consent by increasing the amount of information that is available to an individual interested in a clinical trial. The websites, such as the National Cancer Institute or CancerNet, can often generate a large number of site visits by individuals wanting to learn more about clinical trials. In some cases, the information provided on these websites may constitute the earliest components of the informed consent process.

When information posted on a clinical trial website goes beyond directory listings with basic descriptive information, such information is subject recruitment therefore requires IRB review and approval. The basic descriptive information includes title, purpose, protocol summary, basic eligibility criteria, location(s), and contact information. Information included beyond these basic listings will require review and approval by the IRB. For complete guidance, please see the OHRP guidance at <http://www.hhs.gov/ohrp/policy/clinicaltrials.html>. FDA guidance mirrors these principals and can be found at <http://www.fda.gov/oc/ohrt/irbs/toc4.html#recruiting>.

IRB review and approval of listings of clinical trials on the internet is not required for listing services such as the National Cancer Institute listing, the government-sponsored AIDS Clinical Trials Information Service, Clinicaltrials.gov, etc. However, if you plan to add additional descriptive information that is beyond the listing, IRB review and approval is required.

#### **F. Payment Arrangement among Sponsors/Organizations, Investigators and Others**

Payment in exchange for referrals of potential subjects (finder's fees) and payments designed to accelerate recruitment tied to the rate or timing of enrollment (bonus payments) is generally unacceptable. It is impermissible to accept bonus payments. The Institution's physicians and employees cannot accept personal payments from sponsors or other researchers in exchange for accelerated recruitment or referrals of patients.

## **10.2 INTERNET AND SOCIAL MEDIA**

### **A. Using Internet and Social Media to Conduct Research Activities**

The internet has become an increasingly popular tool for conducting research and recruiting subjects. Computer- and internet-based methods of collecting, storing, utilizing, and transmitting data in research involving human subjects are developing at a rapid rate. As these new methods become more widespread in research, they present new opportunities for potential enhancement of the dissemination of surveys, obtaining informed consent, subject tracking, and direct participation, while also presenting new compliance challenges to the protection of research subjects. The purpose of this chapter is to guide investigators in addressing the ethical and practical considerations needed for protecting human subjects when

using the internet for research activities including data collection, online surveys and interacting with subjects for research-purposes. The guidelines are comprised of requirements and recommendations that are consistent with the basic IRB principles applied to all research involving human subjects.

The IRB believes that computer- and internet-based research methodology must address fundamentally the same risks (e.g., violation of privacy, legal risks, and psychosocial stress) and provide the same level of protection as the more traditional non-electronic methods of research involving human subjects. All protocol submissions reviewed by the IRB, including those using computer and internet technologies, must:

- i. Ensure that the procedures fulfill the principles of voluntary participation and informed consent.
- ii. Provide rationale that supports the necessity of utilizing the proposed technology or platform.
- iii. Maintain the confidentiality of information obtained from or about human subjects, to the extent that is possible given the nature and use of the platform utilized in the study. This includes the method and location(s) of data storage and accessibility of all study data (e.g. storage on local servers, third-party servers, or cloud-based storage). In addition, adequate plans to avoid collection of PHI or personal identifying information (PII) over the internet without verification of secure transmission and prior consent and authorization must be provided. The protected health information (PHI) from a social network site could lead to privacy, confidentiality, and potentially HIPAA concerns.
- iv. Adequately address possible risks to subjects including risks of participation directly related to the specified technology utilized. The use of third party applications or platforms in the research must be fully vetted for privacy and confidentiality risks to subjects, including describing the limits and use of user-data proposed by such third parties. The use of data and activity on the third party platform must be disclosed to subjects and if applicable, the Terms of Use or End-User License Agreements that subjects may be required to accept in order to participate may be requested by the IRB for review.
- v. The management plan in place to monitor content, information, comments, etc. if the platform or application allows for community member-generated content that will be used for research-purposes and can be accessed by other subjects enrolled in the study. For example, if the research study utilizes an online community where subjects can post communications about their participation in a clinical trial, the investigator must include a plan for monitoring posts and provide an action plan to address specific scenarios and/or remove information (such as when a subject discusses an adverse event). All communications provided and received within these interactive platforms are presumed to public may be directly identifiable. Some platforms utilize monikers (or avatars) in place of names, while others require real names. Communications should be monitored to ensure that users are not intentionally or unintentionally prompted to provide sensitive information that may affect their rights or welfare and a plan should be in place to remove, correct, or attribute any such communication.
- vi. Meet the regulatory and ethical criteria for approval.

## **B. Online Recruitment**

Computer- and internet-based procedures are increasingly being used by investigators for advertising and recruitment of study subjects. In addition, new technologies have emerged that allow direct contact with potential subjects within public and private networks. Such technologies, such as social media, forums, and group/population messaging platforms and applications allow investigators to interact directly potential research subjects.

### **i. Non-interactive Recruitment Accessible via the Internet**

When reviewing recruitment materials that will be published on non-interactive media on the internet, the same principles apply as the more traditional non-electronic methods of subject recruitment as described above. IRB review is required for the language and content of this recruitment material published on non-interactive media.

### **ii. Interactive Recruitment and Social Media**

Social media is a computer-mediated platform that allows the creation, sharing, and exchange of information, ideas, and pictures/videos in virtual communities and networks. These platforms can be either public or semi-private in which membership must be sought. When recruiting subjects for research using social media or other interactive platforms, there are additional responsibilities and requirements that investigators are to consider and apply in order ensuring that basic principles of research protections are maintained. When social media or another form of interactive media is used for recruitment purposes, the investigator is to provide in the Cayuse IRB Initial Application:

- a. The name of all sites/applications/platforms that will be utilized
- b. The content of the post that will be published on the website/application/platform that meets the requirements for recruitment as outlined above.
- c. If the social media site is governed by an administrator (i.e. for private or semi-private sub-groups within the social media site/application), permission has been obtained from the administrator and the groups policies and rules will be upheld
- d. The name and owner of the account from which the recruitment will be posted. This includes the explanation if the post will be made from the investigator's personal account or one that is maintained by the Institution. Adequate justification must be provided if the investigator wishes to post from a personal account.
- e. Confirmation that the frequency of each post is kept to the minimum number of posts necessary to achieve exposure.
- f. The plan to monitor replies, sharing, and "likes" of recruitment posts and answering questions to posts; which includes confirmation from investigators that persons who share or comment to posts will not be directly solicited/contacted for direct recruitment and that questions are responded to with a statement that indicates who that person can contact to have this question answered directly. In addition, if the investigator plans to delete comments or replies to interactive posts, information will be requested on the applicability of this monitoring and the lines of authority for this editing. Investigators and other members of the study team must not "tag" specific individuals in posts or replies/comments.

- g. Assurance from the investigator that if any PHI or other PII is posted in response to recruitment posts that this information will not be collected for part of the study data.

### **C. The Inclusion of Minors in Online Research and Recruitment**

The Children's Online Privacy Protection Act (COPPA), effective April 21, 2000, applies to the online collection of personal information from children under 13. The new rules spell out what a web site operator must include in a privacy policy, when and how to seek verifiable consent from a parent and what responsibilities an operator has to protect children's privacy and safety online.

COPPA applies to individually identifiable information about a child that is collected online, such as full name, home address, email address, telephone number or any other information that would allow someone to identify or contact the child. COPPA also cover other types of information - for example, hobbies, interests and information collected through cookies or other types of tracking mechanisms - when they are tied to individually identifiable information.

Before collecting, using, or disclosing identifiable personal information from a child, an investigator must obtain verifiable parental consent from the child's parent. This means an investigator must make reasonable efforts (taking into consideration available technology) to ensure that before identifiable personal information is collected for research purposes from a child, a parent of the child provides permission. In-addition, re-consent of parent's will be required when the terms of data collected for research purposes has changed from the original research plan.

The full description of the provisions and requirements of website operators for compliance with COPPA that can be found at <http://www.coppa.org/comply.htm>.

### **D. Online Surveys**

The IRB reviews protocols that propose to use the Internet on a case-by-case basis to determine whether the use of the Internet is appropriate. When developing a survey that will be conducted via the Internet, it is important to recognize that not all types of surveys are appropriate candidates for online data collection. A survey that requests highly sensitive information or one that may cause emotional distress or anxiety may not be suitable for the Internet. When conducting surveys via the Internet, the researcher and subject do not have the benefit of the face to face, in person experience.

A risk of collecting data via the Internet is the disclosure of information that could cause significant harm or embarrassment to the subjects. The most common source of risk is the breach of confidentiality, as it is not possible to guarantee the security of the data transmitted over the Internet.

In designing a study where the Internet is used, the PI needs to consider the subject population and their access to computers so as not to exclude individuals who may otherwise be able to participate. It might be appropriate to offer the survey both electronically and on paper so as not to introduce bias in the subject sample population.

Investigators are advised that authentication - that is, proper qualification and/or identification of respondents - is a major challenge in computer- and internet-based research and one that

threatens the integrity of research samples and the validity of research results. If the respondent population is not the population that is originally targeted by the research, the resulting data may not reflect what the research was originally intending to assess. Researchers are advised to take steps to authenticate respondents. For example, investigators can provide each study subject (in person or by mail) with a Personal Identification Number (PIN) to be used for authentication in subsequent computer- and internet- based data collection. For research that excludes minors, the IRB may ask the researcher to describe the procedures to be employed to authenticate that the subjects are adults. Some options are using Internet monitoring software or using Adult Check systems that can screen out minors.

#### **E. Informed Consent Process for Online Survey-based Research**

The IRB has developed an informed consent template for online survey research that should be included when developing consent forms and the consent process for online surveys. See the IRB website for additional information. For some protocols, the IRB will allow the consent for surveys to be obtained via the Internet.

IRB requirements pertaining to informed consent and disclosures for conducting online survey research include:

- i. Internet consent documents and/or disclosure should be written like a cover letter and should include all the required elements consent, including the confidentiality disclaimer given below. The consent form or disclosure statement should include a method for subjects to indicate whether they agree to participate in the survey. For example, the consent form can include a statement that states, "I want to take part in this research and continue with the survey" and include check boxes for the subject to indicate yes or no. Other Internet-based surveys include "I agree" or "I do not agree" buttons on the website for subjects to click their choice of whether or not they consent to participate.
- ii. The following statements are required to be included in the consent form or in the disclosure statement:
  - a. A statement that lets subjects know that information transmitted over the Internet can never be completely anonymous and confidentiality cannot be completely guaranteed. For example, the consent form or disclosure statement could state, "Confidentiality will be maintained to the degree permitted by the technology used. Your participation in this online survey involves risks similar to a person's everyday use of the Internet."
  - b. "If you have any questions about the research methods, you should contact the principal investigator, (*name*), or colleagues (*identify who*) by contacting (*telephone number or e-mail address*) during a workday or (*telephone number*) at night or on weekends. Direct questions about your/your child's rights as a research subject to the Vice President and Chief Operating Officer of the Research Institute (*identify name, and contact information*).
- iii. The consent must disclose that if a subject completes an anonymous survey and then submits it to the investigator, that the investigator will be unable to extract anonymous data from the database should the subject wish it withdrawn.

- iv. Unless completion of an entire survey is a requirement of participation, internet-based survey instruments should be formatted in a way that allows subjects to skip questions if they wish or provide a response such as “I choose not to answer.” At the end of the survey, there should be buttons that give subjects the option to discard the data or to submit it for inclusion in the study. If completion of an entire survey is a requirement of participation, the consent document must clearly state this requirement and remind prospective subjects that they may choose not to participate or can stop participation in the research at any time.

#### **F. E-mail, Message Boards, and Forums**

Email is not a secure communication mechanism and PIs and research staff must take into account the risks associated with contacting subjects via email. It is important to keep in mind that a subject’s email account may be shared with another individual, such as a spouse or family member, or may be monitored by an employer. Researchers are advised against including sensitive information in emails including the subject line. When collecting the subject’s email address as part of the contact information, investigators should remind the subject of these considerations and risks.

Another risk is sending an email to the wrong address. Investigators should take reasonable steps to make sure the email is received by the correct person. In general, email should not be used to collect data. All outgoing emails should be from the hospital’s server and contain instructions relating to whom to notify if received in error.

Caution should be taken when communicating with research subjects via message boards or other online forums that do not ensure privacy. The IRB encourages investigators to review the terms of use of any venue before utilizing it.

#### **G. Electronic Data Storage**

The Institutional Administrative Policy on Classification and Handling of Information requires that laptops and computers that contain research data must be password protected and encrypted. When appropriate, the individual data files should also be password protected. Personally identifiable information (PII) should be stored separately from the data. Research data containing PHI or any of the HIPAA identifiers may not be placed on any personal use devices including home computers, laptops, or tablets.

Investigators must include in the Cayuse IRB Initial application a description of how long the data will be kept electronically and any provisions for destruction of the data and/or identifiers. Copies of electronic data files may be kept for back-up and security purposes and thus not destroyed.

#### **H. Data Transmission and Security**

The Institution requires that any data containing any of the eighteen HIPAA identifiers or otherwise sensitive information collected from human subjects over computer networks be transmitted in encrypted format of at least 256 bit. This ensures data security during transmission from the subjects’ computer to the Web. Researchers who are planning to collect and transmit PHI and/or sensitive data via the Internet are required to contact Information Technology to assess the internet security arrangements for the Internet site(s) the study seeks to use.

