Research Registry Template

* **If you believe your activity may not meet the definition of “Human Research” subject to IRB oversight, complete and submit the Determination of Human Subject Research Form in IRBNet.**
* **This template should be used for research registries**
* **Be sure that all submitted materials/documents are correct and consistent with the information in this protocol.**
* **Instructions and/or sample text is provided in *blue font* to generate ideas of what should be included in some of the sections. This should be deleted and substituted with information that pertains to the actual registry.**
* **An example protocol is given as sample text in *green font*, delete this example. Additional example text is provided in *purple* text.**
* **The italicized bullet points below serve as general guidance to investigators on the kinds of information that may be applicable to include in each section. Please DELETE the italicized text in the protocol before submitting.**
* **Note that, depending on the nature of your research, some sections below will not be applicable. Indicate this as “N/A.” Do not delete the section.**
* **Slight adjustments may be made to the section headings text to better reflect specific registry design. Be sure to update the Table of Contents accordingly.**
* **Appendices, if used, should be added after the Reference section.**
* **Delete this “Instructions” section from your final protocol.**

***This template should be used for establishing a research registry. A research registry is an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure. Enrolling in a research registry does not affect a patient’s clinical care.***

***Establishing a research registry is generally for: (a) describing the natural history of a condition/disease, (b) analyze clinical effectiveness, (c) assessing safety, harm or other measures (e.g. cost, long-term effects of prior intervention), (d) measuring or improving quality of care.***

***NOTE – Registry data cannot be queried for research beyond the stated purpose in the Registry Protocol. A separate protocol must be written to address additional research questions that will be asked of the data set, which do not meet the original intent of the research registry.***

***Click on this link to download "***[***Registries for Evaluating Patient Outcomes: A User's Guide***](https://drupal02.floridahospital.org/researchadmin/sites/drupal02.floridahospital.org.researchadmin/files/Registries%20for%20Evaluating%20Patient%20Outcomes%20A%20User%27s%20Guide.pdf)***," which is an excellent resource for conceptualizing and planning Research Registries.***

**Research Registry Protocol Title:**

*Be consistent with the Title throughout your research application, protocol, and IRB documents.*

**Research Registry Sponsor:**

Florida Hospital

*Florida Hospital is the default response. Please change if needed.*

*The sponsor is the person or organization that employs the person who is responsible for the research registry. The sponsor develops/writes the protocol or has it developed on its behalf. The sponsor is responsible for satisfying all legal and regulatory requirements concerning registry approvals, subject safety, and privacy. The sponsor is generally responsible for conducting the registry or overseeing the conduction of the registry. The sponsor is responsible for integrity of data collection, storage, and analysis of data generated from the registry. The sponsor has the right to publish results from the registry.*

**Principal Investigator:**

Principal investigator:

**Table of Contents:**

*In order to have Word automatically create or modify your Table of Contents, do the following:*

1. ***Make sure that any additional sections are labeled as Heading 1 (Home Tool Bar above) – put cursor at the front of the Heading and click Heading 1. Subsections should be listed as Heading 2 (Home Tool Bar above).***
2. ***When all sections are entered, come to this page and click on the References tab, under Table of Contents, pick Update Table. Select Update entire table and click ok.***

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# List of Abbreviations:

*Include commonly used abbreviations and acronyms.*

# Introduction

*The introduction should open with remarks stating that this document is a research registry protocol. The registry that will be conducted in compliance with the protocol, Good Clinical Practices (GCP),* *International Conference on Harmonization (ICH) Guidelines (E6) for GCPs standards as adopted by the Food and Drug Administration (FDA), and associated Federal regulations, and all applicable institutional research requirements. The rest of the introduction is broken out into subsections. Example language for the first paragraph under “Introduction” is given below.*

*If you state you are following GCP or other regulations, please be sure that you are familiar with these as the conduct of your research registry will be reviewed against these standards (*[www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM129515.pdf](http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM129515.pdf))*.*

*Sample Text: This document is a protocol for a human research registry. This registry is to be conducted according to US standards of Good Clinical Practice in accordance with applicable Federal regulations and institutional research policies and procedures.*

# Background Information and Scientific Rationale

*Provide and summarize published (or available unpublished) data in the literature to build a rationale for the research question(s), registry objectives, and research design.*

## Definition and Epidemiology

*Describe the disease or condition, diagnosis and provide information currently available regarding the etiology.*

## Summary of Published Information

*Describe available scientific information*

*You may include a summary of epidemiological data, if relevant.*

*Describe the disease or condition, diagnosis and provide information currently available regarding the etiology.*

## Rationale

*Why is this registry necessary?*

*Justify creation of this registry based on existing knowledge and the research question(s).*

# Registry Objectives/Aims/Goals

*In a general fashion, summarize the purpose, aim, or objective of the research registry.*

## Primary Objective/Aim/Goal

*Select the appropriate term (objective/aim/goal) for your research area and be consistent throughout the registry protocol. Make adjustments to headers, as needed, to reflect the appropriate terms.*

*Include the details of your primary objective (which is your main purpose for establishing this registry and should be focused on* ***one question****), outcome measures and method by which outcomes will be determined.*

*Sample Text: To objectively measure baseline patient characteristics, such as self-reported symptoms, pain levels, physical function, psychological distress as a result of their pain and quality of life for patients with fibromyalgia.*

## Secondary Objective/Aim/Goal

*Include secondary objectives (include as many as relevant). These objectives may be dependent or independent of the primary objective.*

*Sample text: To investigate the potential for distinct subtypes of fibromyalgia based on patient characteristics.*

*Sample Text: To identify patients who may be eligible for participation in future research studies.*

*NOTE TO RESEARCHER: please remember that the data generated from the registry can only be used to answer the Primary and Secondary Objectives. If you later discover another possible research question for the data, then a new research protocol must be submitted. Please refer to IRB Standard Operating Procedure (SOP) on Research Registries.*

# Registry Design

## Research Design

*Provide a general description of the research registry and include a brief description of the research registry population. You will be providing greater detail about subjects in the Subject Selection section.*

*Sample text: This registry will prospectively collect data from fibromyalgia patients to describe the natural history of fibromyalgia.*

*Sample text: This registry will collect both retrospective and prospective data to determine clinical effectiveness of healthcare services in patients with heart failure.*

*Sample text: This registry will prospectively collect data to measure quality of care in patients who do not have health care insurance and are frequent users of the Emergency Department.*

## Description of Medication, Device, Intervention, or Clinical Program

*Indicate n/a if there are no medications, devices, interventions or programs included in the registry.*

*Make adjustments to headers, as needed, to reflect the appropriate terms.*

This section should be used to describe any medication, device, intervention, or clinical program that may be a component of this research registry.

*If you are retrospectively reviewing an intervention (behavioral, educational, social, etc.), provide a general description of the intervention being studied in this proposed research registry.*

*A clinical program is referring to special “clinics” or “programs” designed as sub-specialties to properly follow and treat patients with a particular disease, on a particular treatment, or with a specific device. For example: Lipid Clinic, Diabetes Clinic, Coumadin Clinic, or Pacemaker Clinic.*

## Registry Site(s)/Location(s) and Number of Subjects

*Include the following information about number of sites and number of subjects. Keep in mind that you can have 1 site with multiple locations within that site. For example, Florida Hospital is a single site but can have multiple locations such as campuses, outpatient clinics, outpatient surgery, imaging centers, or physician offices.*

*Florida Hospital site locations (campus, physician offices, etc): (list)*

*Estimated number of subjects at Florida Hospital sites: (indicate #)*

*Name of external site(s) outside of Florida Hospital: (list)*

*Estimated number of subjects at external sites: (indicate #)*

*Total number of all sites: (indicate #)*

*Estimated number of subjects at all sites combined: (indicate #)*

*Sample Text:*

*Florida Hospital site locations (campus, physician offices, etc): Centre for Family Medicine, Winter Park, Florida Hospital Orlando and Celebration Health*

*Estimated number of subjects at Florida Hospital sites: approximately 100*

*Name of external site(s) outside of Florida Hospital: n/a*

*Estimated number of subjects at external sites: 0*

*Total number of all sites: 1*

*Estimated number of subjects at all sites combined: approximately 100*

## Multi-Site Research Logistics/Communication Plan

*Indicate n/a if there are no other sites other than Florida Hospital.*

*This section will be applicable to registries that are housed at Florida Hospital (any location) and external institutions or facilities not affiliated with Florida Hospital.*

If this is a multi-site registry where you are the lead investigator and Florida Hospital is the coordinating center, describe the processes to ensure communication among sites, such as:

* All sites have the most current version of the protocol, consent document, and HIPAA authorization.
* All required approvals have been obtained at each site (including approval by the site’s IRB of record).
* If an external site is not using their IRB of record or does not have an IRB of record to use, please describe what IRB will be used for that external site.
* All modifications have been communicated to sites, and approved (including approval by the site’s IRB of record) before the modification is implemented.
* All engaged participating sites will safeguard data as required by local information security policies.
* All local site investigators conduct the research registry appropriately.
* All non-compliance with the registry protocol or applicable requirements will be reported in accordance with local policy.

Describe the method for communicating to participating sites:

* Problems
* Interim results
* The closure of the registry

If this is a multi-site registry where Florida Hospital is a participating center, describe the processes to ensure communication with the coordinating center.

*Sample Text: n/a*

## Community-Based Participatory Research Registry

*Indicate n/a if there is no community involvement in the design or conduct of the research registry.*

*Describe involvement of the community in the design and conduct of the research registry.*

Note: “Community-based Participatory Research” is a collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings. Community-based Participatory Research begins with a research topic of importance to the community, has the aim of combining knowledge with action and achieving social change to improve health outcomes and eliminate health disparities.

*Sample Text: n/a*

# Subject Selection

## Vulnerable Populations (if applicable)

 *Indicate n/a if there are no vulnerable populations in the registry.*

*Provide Justification if including any of the following populations in your registry.*

*Include a description of additional safeguards in place to protect the rights and welfare of any of the vulnerable populations. Any populations lacking justification may NOT be included.*

Cognitively Impaired Adults: (If the research involves cognitively impaired adults, review the **“**[**CHECKLIST: Criteria for Research Involving Cognitively Impaired Adults**](https://drupal02.floridahospital.org/irb/content/checklist-and-worksheets)**”** to ensure that you have provided sufficient information.)

Children: (If the research involves persons who have not attained the legal age for consent to treatments or procedures involved in the registry (“children”), review the [**“CHECKLIST: Criteria for Research Involving Children”**](https://drupal02.floridahospital.org/irb/content/checklist-and-worksheets) to ensure that you have provided sufficient information.)

Pregnant Women: If the research registry involves pregnant women, review the [**“CHECKLIST: Criteria for Research Involving Pregnant Women”**](https://drupal02.floridahospital.org/irb/content/checklist-and-worksheets) to ensure that you have provided sufficient information.

Neonates of non-viable or uncertain viability: If the research registry involves neonates of uncertain viability or non-viable neonates, please contact the IRB.

Prisoners: If the research registry involves prisoners, review the [**“CHECKLIST: Research Involving Prisoners”**](https://drupal02.floridahospital.org/irb/content/checklist-and-worksheets) and address each of the criteria for approval.

*Employees: When FH (or FH affiliate) employment status is part of the inclusion criteria, the FH Researcher must be able to provide a rationale other than convenience for selecting the FH employee as a subject. The recruitment method must not lead FH employees, especially when they are in a subordinate job position, to believe they will be compromised in any way by not participating. The compromised circumstances and fear of retribution, even subtle cues of compromise, can place FH employees in a position of involuntary participation in a research project. You must explain your plan to avoid coercion and make it clear that non-participation will not affect their employment status.*

*Recruitment through bulletin board advertisements (screened and approved by the IRB), or recruitment through a third party unassociated in a power/supervisory relationship with the employee are usually the best strategies.*

*NOTE: When a FH employee is recruited to be a registry participant, but FH employment is not an inclusion criterion, it is suggested that during the consent procedure the relationship between the subject’s employment status and research participation be addressed so that it is made clear that non-participation will not affect employment status.*

Students: Provide a plan to avoid coercion when recruiting students and be clear that non-participation will not affect the potential subjects’ academic status.

## Participant Selection

### Inclusion Criteria

*Create a numbered list of criteria subjects must meet to be eligible for registry enrollment (e.g. age, gender, target disease, concomitant disease if required, etc.). This list should generally include items such as: “subjects are capable of giving informed consent”, or if appropriate, “have an acceptable surrogate capable of giving consent on the subject’s behalf.”*

*Sample text:*

1. *Age 18 – 89*
2. *Capable of giving informed consent*
3. *Diagnosis of fibromyalgia within past 2 years*
4. *Able to travel to office/hospital for study visits*

##

### Exclusion Criteria

*Create a numbered list of criteria that would exclude a subject from registry enrollment.*

*Sample text:*

1. *Current epileptic seizures*
2. *Alcohol/substance abuse within the past 6 months, patient reported*
3. *Serious mental illness that might preclude subject’s ability to comply with treatment*
4. *Life expectancy of less than 1 year*

## Consent Procedures

*Indicate n/a if you are applying for a Waiver or Alteration of Informed Consent.*

*In this section, provide a general description of consent procedures. Give careful consideration to the level of detail included as providing too much detail may increase risk for protocol deviations.*

* Where will the consent process take place (e.g. patient hospital room, PI office, private exam room, etc)
* Any waiting period available between informing the prospective subject and obtaining the consent. Include whether or not the subject will receive an advanced copy of the consent prior to signing the consent. (e.g. mailed to the subject or able to take home for review)
* How much time will be devoted to the consent discussion
* What steps will be taken to minimize the possibility of coercion or undue influence
* What steps will be taken to ensure the subjects’ understanding
* What steps are in place to ensure ongoing consent
* Include whether or not the participant will be contacted in the future. Future contact may be for invitation to participate in additional research studies.

Sample Text: After speaking with qualified researcher who has provided an overview of the registry, if the patient would like to participate in the research registry, the patient will be given a copy of the informed consent to review. The patient will be informed that their participation in the registry is voluntary and will not in any way change their relationship with Dr. Jones or the sub-Investigator. Sufficient time for review of the informed consent paperwork will be given prior to answering questions about the registry. The informed consent form will then be signed by the patient and the person obtaining informed consent. Subject will be provided with a copy of the signed and dated consent.

*Sample Text: Subjects will be offered two levels of consent. Subjects will be asked to enter the registry for research purposes. An additional level of consent will allow future contact [for further follow-up / for invitation to participate in additional research studies]. Additionally, patient and legal guardian contact information will be collected to facilitate future contact.*

**Non-English Speaking Subjects**

If your registry will be targeting non-English speaking subjects or if it is reasonable to expect non-English speaking subjects in your research registry population, then complete this section.

* Indicate what language(s) other than English are understood by prospective subjects or representatives.
* Describe the process to ensure that the oral and written information is provided to those non-English-speaking subjects in their native language. Indicate the language that will be used by those obtaining consent.

*Sample Text: The pain clinic’s patient population is primarily English speaking. In the unlikely event that a non-English speaking patient meets criteria for enrollment, then IRB Short Form procedures will be initiated.*

## Waiver of Written Documentation of Consent or Waiver of Consent

**Waiver of Written documentation of Consent (consent will be obtained but signatures will not be required)**

*Indicate n/a if you are obtaining Informed Consent*

* Indicate if you wish to request a Waiver of Written Documentation of Consent
* Review the [**“CHECKLIST: Criteria for Waiver of Written documentation of the Consent Process”**](https://drupal02.floridahospital.org/irb/content/checklist-and-worksheets) to ensure your registry qualifies for the waiver.

**Waiver or Alteration of the Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception)**

*Indicate n/a if you are obtaining Informed Consent.*

* Indicate if you wish to request a Waiver or Alteration of Consent
* Review the [**“CHECKLIST: Waiver or Alteration of the Consent Process”**](https://drupal02.floridahospital.org/irb/content/checklist-and-worksheets)
* Complete and submit the **Waiver or Alteration of the Consent Process Form**
* If PHI is being used or disclosed, please complete and submit the **Waiver of HIPAA Authorization Request Form**

## Documentation of Informed Consent Process

*Indicate n/a if you are applying for a Waiver or Alteration of Informed Consent.*

*In this section, describe how you will document the Informed Consent process.*

*Sample Text: Documentation of the informed consent process is required to establish that the subject was accurately and adequately informed and that no registry-related procedures were initiated prior to obtaining informed consent.  A research team member will note in the source documentation the consent process, date consent was obtained and that consent was obtained prior to initiating any registry-related procedures.*

# Registry Procedures

## Specific Training

*Describe the process to ensure that the research registry study team and all other persons assisting with the registry are adequately informed about the protocol, the registry procedures, and their duties and functions.*

## Recruitment of participants

If this is a multicenter registry and subjects will be recruited by methods not under the control of the local site (e.g., call centers, national advertisements), describe those methods, in addition to the methods employed at the local site.

Describe the methods that will be used to identify potential registry participants.

Describe when, where, and how potential registry participants will be recruited.

Describe materials that will be used to recruit subjects. (Include copies of these documents with the IRB submission. For advertisements, include the final copy of printed advertisements. When advertisements are taped for broadcast, include the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.)

*Note: If you plan to access medical records for study development or feasibility, Reviews Prep to Research Form must be completed and submitted* ***PRIOR*** *to any access of medical records.*

*Note: If you plan to access medical records for recruitment purposes prior to obtaining informed consent, Reviews Prep to Research Form must be completed and submitted* ***WITH*** *the initial application.*

*Sample Text: Patients contacting the pain clinic to schedule an appointment for evaluation of fibromyalgia will be informed about the registry and will be given the option to participate. When the patient comes to the clinic for their visit, information regarding registry participation will be provided by a qualified research staff member. This oral information will be provided while the person is in a private room.*

## Data Collection Schedule

*In this section, identify all the data points that will be collected from each patient encounter. A detailed description of the data points should be included in the Registry Data Points section below. Create a registry data collection flowchart/table that describes the activities and procedures to be followed at each patient encounter, if appropriate. A resource for data collection is Chapter 6 in "Registries for Evaluating Patient Outcomes: A User's Guide," – the link is provided on page 1 of this document.*

*Sample text (for a clinical program): All data points collected for the registry will be collected as part of the lipid clinic.*

*Enrollment: Prior to initial visit, the patient will be consented. Medical history, lipid panel, vital signs, risk assessment, height, weight, BMI and current medications (including herbal supplements) will be collected. Identify ideal target range based on risk assessment.*

*Subsequent appointments: Lipid panel, vital signs, risk assessment, height, weight, BMI and current medications (including herbal supplements) will be collected. Assess progression to goal or at goal.*

*Sample Text: Patients will be consented at the initial visit and registry data will be collected at follow-up visits according to standard of care. The following table identifies the procedures in relation to the registry timeline.*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| *Data Collection SCHEDULE* | *Data Source* | *Visit 1**Enrollment* | *Visit 2 & 3**(3 and 6 month follow-up)* | *Visit 4**(9 month follow-up)* | *Visit 5**(12 month follow-up)* |
| *Inclusion and Exclusion Criteria* | *Clinic records* | *X* |  |  |  |
| *Informed Consent* | *Original signed document* | *X* |  |  |  |
| *Physical assessment* | *Clinic records* | *X* |  |  |  |
| *Blood test results* | *Clinic records* | *X* |  | *X* |  |
| *Urine test results* | *Clinic records* | *X* |  | *X* |  |
| *Medical history* | *Patient reported and clinic records* | *X* |  |  |  |
| *Pain questionnaire* | *Patient reported* | *X* | *X* | *X* | *X* |
| *Symptom and Quality of Life Questionnaire* | *Patient reported* | *X* | *X* | *X* | *X* |

## Registry Duration

*Include a projected start date.*

*Include the duration to enroll all registry subjects.*

*Provide the total length of time participants will remain in the research registry.*

*Provide an estimated date for investigators to complete the registry (includes analysis).*

*Sample Text: Patients will remain active in the registry for a period of 12 months, after that time, no additional information will be collected. Registry enrollment will be for a period of 4 years. Registry analysis will be completed in 6 years.*

*Sample Text: Patients will remain active in the registry until they voluntary withdraw or expire. Registry enrollment will be ongoing.*

## Materials of Human Origin: Collection, Preparation, Handling and Shipping

*If the collection and analysis of Materials of Human Origin is a component of the registry data collected please contact the ORA/IRB. Materials of Human Origin can be used in a research registry when there is a research question related to those materials. Materials of Human Origin cannot be used in a research registry when there is no specific purpose for those materials or when the purpose is to conduct future research using those materials and that future research is undefined in the current protocol.*

*Describe the process for obtaining access to the materials of human origin, and the plan for the physical security of the materials after they are obtained, including:*

1. *How and from where it will be obtained.*
2. *Where the biological materials will be stored.*
3. *Who will have access to the stored biological materials and how will such access be secured and controlled?*
4. *What chain of custody for the Materials of Human Origin will be used throughout the trial, and how will the transfer of custody between departments, people, and/or institutions be documented?*
5. *Will the biological materials be sent anywhere outside of the Florida Hospital system? If so, identify all locations.*
6. *What are your plans for disposition of data or human biological specimens that are identifiable in any way (directly or via indirect codes) once the registry has ended?*

#

# Data Management and Quality Plan

## Data De-identification

*Indicate n/a if you are not de-identifying data.*

If data will be de-identified, there will be a process of developing a code to be used for research registry subject numbers. This code usually consists of numerals, and may be a combination of numerals and letters. However, the code must not contain any unique identifiers. Please provide the following information related to this process.

* *How are unique identifiers being generated? Describe the format or taxonomy of the chosen code.*
* *How is data being linked to subjects’ identifying information?*
* *How and when will the link be used?*
* *Where will the linked data be stored?*
* *Who will have access to the linked data?*
* *How long will the linked data be stored?*
* *Will the link ever be destroyed so that the data or the samples will become de-identified?*
* *Describe any circumstances under which the link between the subject’s identity and assigned registry subject number could be used to break the code.*

*Sample Text: Data will not be de-identified.*

## Data Confidentiality, Storage, and Retention

*Describe how you plan to maintain confidentiality of registry data.*

* Describe how data and records of any media type (e.g., paper, electronic, audio recordings, video recordings, blogs, and photographs) will be stored during and after the registry has been completed.
* Describe data security measures for the storage of records (e.g., locked filing cabinet, password protected computer, etc.)
* Describe who will have access to the data and records.
* Describe if and how data will be shared with others outside the research team.
* Describe how long data and records will be retained.
* Describe how data and records will be disposed.

*Sample Text: Registry documentation and paperwork will be stored at the Pain clinic in a locked file cabinet. Registry records will be retained for 7 years after the completion of the registry. After that period of time, all individual patient information will be shredded according to the Pain Clinic policy.*

## Data Quality

*Indicate n/a if you do not have a plan for insuring data quality.*

*Describe how the data quality is going to be checked.*

*Describe data collection procedures and quality control measures to insure data accuracy and integrity.*

*Sample text: Quality control procedures for this research registry include source data verification by randomly selecting 10% of registry participant records with comparison between the paper case report form (CRF) and the electronic database record of those same data. If errors are common, data will be completely checked prior to data analysis.*

## Data Sharing (outside of Florida Hospital)

*Indicate n/a if you are not sharing data outside of Florida Hospital.*

*If information is going to be shared with any other individual, organization or institution outside of Florida Hospital, please complete this section. State the purpose of data sharing and provide a detailed description of all data elements that will be shared. (Note: Consult the ORA regarding appropriate legal documents.)*

# Sample Size Determination

*Describe how the sample size was determined for this registry. The sample size should be based upon the primary objective. If the authors have determined that sample size estimation could not be computed, please provide the rationale.*

*Sample Text: Sample size determination was based on expert knowledge of the fibromyalgia patient population seen at the Florida Hospital locations. Approximately 700 patients have been seen at the Pain clinic with a diagnosis of fibromyalgia during the previous 3 years. Estimating only 50% of patients would consent to be in the registry and available for follow-up, the registry size should be approximately 350 patients.*

# Registry Data Points

*Depending on your registry, you may have endpoints, outcome measures, or both. For example, if your registry is collecting data on cancer patients, your endpoint might be progression of disease. If your registry is observing outcomes of a clinical treatment, your endpoint might be reduction of disease as measured by change in blood pressure.*

*Make adjustments to headers, as needed, to reflect the appropriate terms.*

*Describe the primary and secondary endpoints/outcome measures. These may be designated variables or may be safety related values (such as specific time points, evidence of liver toxicity, or patient death). In this section, provide a list of the endpoint/outcome measures to be studied along with a description of the endpoint/outcome measure and the source of the data.*

*Make adjustments to headers, as needed, to reflect the appropriate terms.*

*Sample text: Initial baseline demographics of age, gender and race/ethnicity group will be collected from clinic records.*

*Sample text: Medical history (infection history, thyroid problems, physical trauma, emotional trauma, sleep disturbances, depression, chronic fatigue, chronic back pain, chronic neck pain, headaches, anxiety and Lyme disease will be collected from clinic records and patient interview.*

*Sample text: Data from physical examination (tenderness tested in 18 areas), blood and urine tests results will be taken from clinic records.*

*Sample Text: Beck Depression Inventory-II (BDI-II): The BDI-II is a 21-item self-reported instrument designed to assess symptoms of depression. Each item requires the research subject indicate which of 4 statements bests describes a symptom of depression that the research subject has experienced over the past 2 weeks. The BDI-II will be completed by the patient during clinic visits.*

*Sample Text: Quality of Life Questionnaire (QLQ): The QLQ is a patient reported outcome measure that has 5 major domains: General Well-Being, Interpersonal Relations, Organizational Activity, Occupational Activity, and Leisure and Recreational Activity. The QLQ will be completed by the patient during clinic visits.*

*Sample Text: Short Form McGill Pain Questionnaire: The McGill Pain Questionnaire is a patient reported outcome measure consisting of 15 descriptors that the patient ranks on a 4-point intensity scale. The McGill will be completed by the patient during clinic visits.*

#

# Statistical Analysis Plan

*Describe the statistical approach to the primary and secondary objectives of the registry. The section should contain the key elements of the analysis plan. Describe how you will manage missing data.*

## Primary Objective Analysis

*Sample Text: The primary objective is to review the changes in pain levels, physical functioning, psychological distress and quality of life for fibromyalgia patients enrolled in the registry. Repeated measures analysis of variance will be used as the statistical testing appropriate for this data.*

## Secondary Objective Analysis

*Sample Text: The secondary analysis will be focused on identification of sub-types within the fibromyalgia population. Regression and cluster modeling will be used to determine possible sub groups.*

# Potential Risks and Benefits

## Potential Benefits

*Describe potential benefits to the individual research registry participant (economic, physical, or other) as well as the benefits to science for this registry.*

Indicate if there is no direct benefit.

*Sample text:*

*There are no direct benefits to subjects for participating in this research registry. However, information regarding characteristics related to fibromyalgia may be obtained.*

## Potential Risks

List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related to their participation in the research registry.

Include as many as may be useful for the IRB’s consideration, describe the probability, magnitude, duration, and reversibility of the risks if these can be quantified/determined.

Consider physical, psychological, social, legal, and economic risks, and other risks as applicable to the registry.

If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable.

If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant.

If applicable, describe risks to others who are not subjects.

*Sample text:*

*This research represents a registry documenting fibromyalgia. The most likely risk posed to participants would be a breach of confidentiality if someone other than the research team obtained access to the data.*

## Mitigation of Risks

*Describe what procedure(s) will be implemented to reduce subject risk(s) described above.*

Describe the availability of medical or psychological resources that subjects might need as a result of an anticipated consequence of participating in the research registry.

***Sample Text:*** *There are security measures in place to prevent breach of confidentiality from happening (e.g. locked cabinets, password protected files).*

***Sample text:*** *Patients’ responses to the depression inventory scale will be monitored. Referrals will be made for those at risk for suicide as determined by the principal investigator.*

## Provisions to Protect the Privacy Interest of Registry Participants

*Privacy is a subject’s ability to control how other people see, touch, or obtain information about the subject. Violations of privacy can involve circumstances such as being photographed or videotaped without consent, being asked personal questions in a public setting, being seen without clothing, disclosing information about abortions, HIV status, illegal drug use, etc.*

*Describe what precautions will be used to ensure subject privacy is protected.*

*Sample Text: All precautions will be taken to make sure that only authorized individuals will be accessing subject research records. The collection of sensitive information about subjects is limited to the amount necessary to achieve the aims of the research registry, so that no unneeded sensitive information is being collected.*

*Sample Text: A private room will be provided for patients to complete questionnaires.*

# Early Withdrawal of Subjects

## Investigator Withdrawal of Subjects

*NOTE: This section is* ***not*** *related to when a subject withdraws consent. This section is designed to describe the scenarios under which the* ***investigator*** *may withdraw a subject’s data prior to the expected completion of the registry (e.g., disease progression, loss to follow-up, etc.) Describe the process to determine when a subject is lost to follow-up (e.g. number of phone calls to subject, phone calls to next-of-kin if possible, certified letters, etc.).*

*Sample Text: Patients are followed every three months in the pain clinic as part of their standard of care. If a patient does not return to the clinic for any regularly scheduled visit, the patient will not be withdrawn but visits will be considered as missing data in the data set.*

## Subject Request for Withdrawal from Registry

*Describe the process in which a subject may request withdrawal from the registry.*

*Sample Text: Patients wishing to withdraw their data from the research registry will be directed to contact the principal investigator. From the point of withdrawal, no further data will be collected from the patient or their medical records. However, any data collected up to the point of withdrawal will be maintained for integrity of the research registry. Patients will be made aware of their rights in the consent form.*

## Data Collection and Follow-up for Withdrawn Subjects

*Even though subjects may be withdrawn prematurely from the registry, it is important to describe how data will be handled for withdrawn subjects and be sure that this is consistent with information in the Informed Consent form.*

*Sample Text: Patients who request withdrawal or who are withdrawn by the PI from the registry will have their data maintained in the research database up to the point of withdrawal. This data will be included in subsequent analysis.*

#

# Adverse Event Reporting

## Adverse Events

*NOTE: If the purpose of the registry is to follow patients with a specific diagnosis or condition to understand more about the condition, this section may not apply; please indicate n/a.*

*NOTE: If the purpose of the registry is to follow patients that have been exposed to a specified biopharmaceutical product or device or a specific event (e.g., needle stick, exposure to Creutzfeldt-Jakob disease) then provisions for detection, processing and reporting possible adverse events must be made. If relevant, add sections for a Safety Monitoring Plan (include Safety Monitoring and Data Safety and Monitoring Board DSMB or Equivalent). Consult with the IRB for additional information.*

*An* ***adverse event*** *(AE) is any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject’s participation in the research, whether or not considered related to the subject’s participation in the research.*

*Adverse events will be documented as anticipated or unanticipated; minor or serious; and, related or unrelated to study intervention. List all adverse events, and if possible, identify serious adverse events separately.*

*Serious Adverse Event (SAE): A Serious Adverse Event is defined as an AE meeting one of the following outcomes:*

* *Death during the period of protocol defined surveillance*
* *Life Threatening Event (defined as a participant at immediate risk of death at the time of the event)*
* *Inpatient hospitalization or prolongation of existing hospitalization during the period of protocol defined surveillance*
* *Results in congenital anomaly or birth defect*
* *Results in a persistent or significant disability/incapacity*
* *Define any other Serious Adverse Event (SAEs) based on the specifics of the study.*

*All adverse events that do not meet any of the criteria for* ***serious,*** *should be regarded as* ***minor adverse events****.*

*A preexisting condition is one that is present at the start of the study. A preexisting condition should be recorded as an adverse event only if the frequency, intensity, or the character of the condition worsens during the study period.*

*If relevant to the study, a clinical laboratory abnormality should be documented as an adverse event if any one of the following conditions is met:*

* *The laboratory abnormality is not otherwise refuted by a repeat test to confirm the abnormality*
* *The abnormality suggests a disease and/or organ toxicity*
* *The abnormality is of a degree that requires active management; e.g. change of dose, discontinuation of the drug, more frequent follow-up assessments, further diagnostic investigation, etc.*

*If relevant to the study, any adverse event that results in hospitalization or prolonged hospitalization should be documented and reported as a serious adverse event unless specifically instructed otherwise in this protocol. Any condition responsible for surgery should be documented as an adverse event if the condition meets the criteria for and adverse event.*

*Neither the condition, hospitalization, prolonged hospitalization, nor surgery are reported as an adverse event in the following circumstances:*

* *Hospitalization or prolonged hospitalization for diagnostic or elective surgical procedures for a preexisting condition. Surgery should* ***not*** *be reported as an outcome of an adverse event if the purpose of the surgery was elective or diagnostic and the outcome was uneventful.*
* *Hospitalization or prolonged hospitalization required to allow efficacy measurement for the study.*
* *Hospitalization or prolonged hospitalization for therapy of the target disease of the study, unless it is a worsening or increase in frequency of hospital admissions as judged by the clinical investigator.*

*Sample Text: n/a (This section is deemed n/a for the fibromyalgia example because this registry is not following patients that have been exposed to a specified biopharmaceutical product or device or a specific event.*

## Recording of Adverse Events

*Sample Text: At each contact with the subject, the investigator will seek information on adverse events by specific questioning and, as appropriate, by examination. Information on all adverse events should be recorded immediately in the source document. All clearly related signs, symptoms, and abnormal diagnostic procedures results should recorded in the source document.*

## Notification of Adverse Events

*Sample Text: All adverse events will be reported according to Florida Hospital IRB guidelines.*

# Ethical Considerations

*Indicate n/a if you do not have any Ethical Considerations.*

*Identify any ethical concerns and how you will address these.*

## Sharing of Results with Subjects

Describe whether results (general results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the subject’s primary care physicians) and if so, describe how it will be shared.

# Funding Source

*Indicate n/a if you do not have a funding source.*

*This section should describe how the study will be financed, but should not contain specific dollar amounts.*

*Sample Text: This registry will be supported by funding from National Institute of Neurological Disorders and Stroke and the National Center for Medical Rehabilitation Research (RO1 NS050506). Florida Hospital has received a subaward from Duke University, who is the Prime Recipient of this grant. The IRBNet # for this grant is 412345.*

*Sample Text: This registry will funded in part by a gift given to the Florida Hospital Foundation.*

# Subject Stipends or Payments

*Indicate n/a if you are not providing subject stipends or payments.*

*Describe any subject stipend or payment or gift here. Describe the amount and timing of any payments to subjects. If there is no subject stipend/payment, state that participants will not be reimbursed for their participation.*

# Publication Plan

*Indicate n/a if you do not have a publication plan.*

*Describe the plan for publication. Note: To the extent possible, roles and responsibilities of each research team member should be determined in advance. Additionally, if the research registry results will be published, there should be an additional plan that describes assignment of authorship and the contributions of each author. International Committee of Medical Journal Editors (ICMJE) has a policy to guide authorship; the details are provided on the ORA website under Protocol Development tab (Worksheet for Identifying Investigators and Authorship.doc)*

# References

*This is the bibliography section for any information cited in the protocol. It should be organized as any standard bibliography.*

1. Author, Title of work, periodical and associated information.
2. Author, Title of work, periodical and associated information.

Note: Appendices should be included after references.