

# The Grant Project Life Cycle

A Grant Subcontract Management Guide

July 15, 2016



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## PREFACE

With the support of the [Federal Office of Rural Health Policy \(FORHP\)](#), the [Technical Assistance and Services Center \(TASC\)](#), a program of the [National Rural Health Resource Center \(The Center\)](#), has developed this guide to provide practical advice on contract management to State Office of Rural Health (SORH) Directors and state Medicare Rural Hospital Flexibility (Flex) Program Coordinators. The guide supports Flex grantees by assisting them with improving contract management skills and helping them to meet core competencies. The goal is to further support the Flex grantees in demonstrating measurable program outcomes.

The information presented in this guide is intended to provide the reader with general guidance. The materials do not constitute, and should not be treated as, professional advice regarding the use of any particular technique or the consequences associated with any technique. Every effort has been made to assure the accuracy of these materials. The Center, TASC and the authors do not assume responsibility for any individual's reliance upon the written or oral information provided in this guide. Readers and users should independently verify all statements made before applying them to a particular fact situation, and should independently determine the correctness of any particular planning technique before recommending the technique to a client or implementing it on a client's behalf.

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## PURPOSE OF THE GUIDE

The Medicare Rural Hospital Flexibility Program, or Flex Program, was established by the Balanced Budget Act (BBA) of 1997. Typically housed in the State Office of Rural Health (SORH), the program enables states, through federal funding, to meet the Flex Program goals of improving quality of care and financial and operational outcomes of critical access hospitals (CAHs). The Flex Program also enables states to assess the community health and emergency medical service (EMS) needs of CAHs, improve community/population health, improve time critical diagnoses identification and management, improve EMS capacity and performance, and support the financial and operational transition to value-based health care models. The administration of the Flex grant objectives tends to lend itself naturally to strategic state partnerships and subcontracting of certain aspects of the grant to entities that are considered subject matter experts (SME) in the grant's priority areas of focus.

This guide is designed to target common opportunities within the Flex grant to improve the scope of work (SOW) requirements for subcontracted vendors and consultants. It will assist state programs in building greater accountability with their subcontractors to deliver more meaningful information, which ideally, should further improve program deliverables, reporting and outcomes. SORH Directors and Flex Program Coordinators should use this guide to strategize the steps necessary to ensure that their grants are successfully developed, coordinated and implemented within their states.

This guide will help SORH Directors and Flex Program Coordinators with:

- Developing and defining clear contract expectations within the SOW
- Outlining expected timeline for deliverables and planning for consequences in the event that deliverables are not met
- Establishing reporting requirements that demonstrate impact of services

This content is aimed at assisting SORH Directors and Flex Program Coordinators to navigate the project life cycle of grant administration and provide helpful tips on achieving the greatest value from the Flex grant activities. This guide walks step-by-step through the Project Life Cycle to assist state Flex Programs to deliver successful projects from start to finish.

## PHASES OF PROJECT LIFE CYCLE

Project management methodology helps to define the project scope, timeline, resource allocations and deliverables of any given project. To deliver successful projects from start to finish, this guide walks through the Project Life Cycle step-by-step to assist state Flex Programs with using similar project management processes for delivering on the objectives of the various state-based Flex Programs. The goal of using these methods is to complete the tasks required for the project more effectively and with strategies in place to handle issues that may arise.

**Graph 1: The 4 Phases of the Project Life Cycle**



Source: <http://www.method123.com/project-lifecycle.php>

## Initiation Phase



The first phase in any Project Life Cycle is the Project Initiation Phase, when the project manager conceptualizes the project. This phase outlines the basic processes that must be performed to start the project and should begin to specify what the project output is to accomplish.

For the Flex Program activities, this phase will typically take place pre-grant award. This is the time for the project team to begin to outline the scope of services necessary to execute the objectives outlined in the grant proposal. Prior to grant award, it is recommended that the Flex Program Coordinator and the SORH Director work together to identify the portions of the grant where the state Flex Program does not deem that they have access to the appropriate level of expertise within their organization and identify those program activities that they will need to subcontract. The [Core Competencies for State Flex Program Excellence Self-Assessment](#) is a method to identify the strength of Flex Program management.

After review of the program activities, the team can then start to assemble various categories of work that require common skill sets to complete. This begins the process to define the deliverables for any given subcontract. As the work performed under the grant funding reaches across the health care sector, it is necessary to develop detailed subcontractor selection criteria in order to facilitate the method of selecting the most appropriate subject matter expert (SME) for the given tasks.

### Selecting a Subcontractor

Once the deliverables have been outlined, the next step is to determine the skill set(s) needed to complete the subcontracted program activities. This is a great opportunity to send out a Request for Proposals (RFP) to state partners to identify field experts with a known and demonstrated knowledge base in the area(s) of required expertise. If local partners are not available, the project team can also send out RFPs to nationally recognized SMEs. If at all possible, it is always best to utilize the skills of subcontractors that are recognized as field experts and have demonstrated success with working on similar projects with similar audiences. Networking and relationship

development are key components of identifying individuals or entities to partner with to bring known talent to the project.

Potential state partners for subcontracting activities include but are not limited to state hospital associations, state rural health associations, quality improvement organizations (QIOs), area health education centers (AHECs), state primary care associations (PCAs), state ambulance alliances, etc. In addition, there are national resources that are available for consultation or for suggestions of experienced consultants, those include but are not limited to the National Rural Health Resource Center, Technical Assistance and Services Center, National Rural Health Association (NRHA), Health Resources and Services Administration Federal Office of Rural Health Policy (FORHP), Rural Quality Improvement Technical Assistance (RQITA), National Organization of State Offices of Rural Health (NOSORH), Joint Committee on Rural Emergency Care (JCREC), etc.

## **Subcontractor Selection Criteria**

When selecting a new subcontractor for grant activities the following list of attributes can help to guide the decision making process:

1. Good written and oral communication skills
  2. An established and trusted relationship with rural hospitals
  3. Obtaining references from trusted sources
  4. Clear understanding of project deliverables
  5. Availability to perform work load within grant time constraints
  6. Social media or web based presence
  7. Following states' guidelines for subcontractors (if available)
- Additional useful information can be found in a toolkit developed by the Rural Hospital Performance Improvement Program, through the support of FORHP, titled [Assessing, Selecting and Contracting with Electronic Health Record Vendors for Best Results](#). This guide provides information on how to select the right vendor and negotiate contracts for electronic health record projects. However, these recommendations, such as the "Top 10 List for Vendor Selection" can be universally applied to Flex grant work. Key steps for vendor selection include:

- Obtaining references and feedback from other clients
- Requesting demonstrations of products and reports
- Utilizing vendor questions to vet experience, costs, training, timeframe of deliverables.

## Planning Phase

The Project Planning Phase represents the second phase in the Project Life Cycle. The purpose of project planning is to define the project resource, financial quality and risk plans. It is also a great time to address communication and the deliverable completion acceptance process. The planning process will help guide the project team through the execution and closure phases of the project. The time and effort spent during this phase will assist in managing time, cost, quality, risk and issues.



Now that some potential subcontractors have been defined, the selection process can begin with the team's focus shifting to identifying the timing necessary for the selection and execution of subcontracts. The planning phase of the Flex Program is where the bulk of the individual subcontracted projects will be defined through SOW, project timeline and specific contract deliverables.

## Implementation Timeline

An assessment of Flex Program Coordinators reflects that it is best to begin the subcontracting selection process activities in advance of the fiscal year (FY) start of the grant cycle, if state guidance allows. By drafting subcontracts and executing agreements in advance of FY start of the grant cycle, the project activities will be ready to begin in the first month of the start of the new FY. In the event state guidance does not allow for an early start on subcontracting, consider pre-drafting the subcontracts to be ready to execute at the start of the FY of the grant cycle. Timelines are critical to work towards completion of Flex Program activities by the end of the program year and reduce unobligated grant balances.

## **Scope of Work**

Developing an effective SOW (also known as Scope of Services) with clearly defined deliverables that are tied to a definitive timeline and delivery dates is imperative to executing a successful relationship with a subcontractor for the completion of grant activities. The subcontract's SOW should establish expectations for deliverables including:

- Defining the outputs (contract deliverables) versus the outcomes of the project (intervention provided by the contractor)
- Establishing benchmarks to set baseline measures
- Method for tracking key performance indicators for determining outcomes and impact of services
- Documenting and delivering tracked measures and data to illustrate outcomes and impact of services aligning with Flex Program reporting requirements such as the Performance Improvement Measurement System (PIMS) or the Medicare Beneficiary Quality Improvement Project (MBQIP)

## **Defining Deliverables**

All subcontracts should include contractual clauses for building accountability and holding subcontractors accountable for ensuring all contracted deliverables are met. The timeframe for the agreements should include the contract execution date, milestone dates and deliverable/completion dates. Developing milestones can be achieved by breaking longer projects down into events or processes that show timely progress of the work to be completed.

Failure to build this accountability into the subcontractor agreements has resulted in ambiguous deliverables that do not address the intent of the original agreed upon work output in previous Flex grant awards. It is imperative that there is a clear understanding of what the Flex Coordinator is contracting for and the services that are expected to be provided. During an assessment of Flex Coordinators, it was recommended that the subcontractor should deliver a response to a Request for Proposal (RFP), thereby communicating the expected deliverables in their own words for consumption, editing and approval by the Flex Coordinator.

## **Project Payments**

All payments should be tied to specific deliverables. By structuring payments in this fashion, the Flex Coordinator maintains a greater ability to hold subcontractors accountable to the delivery of quality, timely work. If the clearly defined deliverables are not met in accordance with the timelines defined in the contract then delaying, modifying and withholding of payments are all options to incentivize underperforming subcontractors. Options that can be exercised for withholding payment if deliverables are not met in timely fashion include:

- Partial payments for missed/delayed deliverable dates
- Non-payment for work not performed per contract specification
- Termination of the agreement for failing to comply with the terms of contract.

These terms should be clearly outlined in the executed contracts.

## **Data Sharing Agreements**

A key objective of the Flex Program is to improve the delivery of health care in rural areas through established benchmarks and examining progress toward improving key performance indicators. Flex Program Coordinators should consider including statements within subcontractor's SOW to utilize available data through programs such as the Flex Monitoring Team (FMT) data reports and Medicare Beneficiary Quality Improvement Project (MBQIP) data as appropriate to support assessments and projects. In addition, several other sources of data reside within the operations of various potential state partners, including but not limited to state hospital associations, state rural health associations, QIOs and state health information exchanges.

Most state statutes or regulations do require the inclusion of additional state language for data disclosure statements and data release forms in any state issued subcontract. In instances of this occurrence, it is advisable to seek guidance from the State Office of the General Counsel for the State Department of Health or the Division of Administration with legal counsel to inform of the correct process to ensure compliance with state statutes and regulations and provide contract language.

To move forward with the sharing of data with subcontractors, data use agreements (see example in Appendix A) and/or non-disclosure agreements (see examples in Appendix B) should be included in subcontracts to address how a subcontractor will access confidential information or will support data sharing. Executing a data use agreement and/or non-disclosure agreements is an important step in the subcontracting process to ensure that all sensitive hospital information will be kept confidential. In the event of a breach of the data, the data use agreement and/or the non-disclosure agreement provides the Flex team with a means to pursue corrective action or remediation for damages in the case of negligence on the part of the subcontractor. A verbal agreement is not an adequate substitute for a formally executed data use agreement and/or non-disclosure agreement.

### **Historical and Legacy Contracts**

Due to the longevity of the Flex Program, there are often situations that arise in which a Flex Coordinator must review and modify “legacy”, “inherited” or “historical” contracts. In these situations, the importance of tracking of services and determining outcomes from previous projects is a definite benefit. By having the ability to demonstrate the impacts of services provided through project established pre- and post-values and changes, the Flex Coordinator will have data to support any decisions related to underperforming subcontractors.

The process for deciding to modify contracts with existing subcontractors or coming to the decision to terminate a legacy contract and find a new subcontractor is always a difficult decision in situations where state partnerships are established and valued. This is one great reason why demonstrating value derived from grant invested funds has added value. In addition to demonstrating the success of the grant, it enables state Flex Programs and SORHs to make data driven decisions on the continuation of funding specific project activities through historical contracts. Flex Coordinators may find it useful to utilize the information gathered from CAH satisfaction assessments to inform decisions regarding the quality of work performed by subcontractors.

Whether the subcontractor is an established state partner or a newly identified resource, it is imperative that the planning phase for Flex grant

activities include clearly defined SOW, timelines and deliverables with payments tied to timely completion of milestones and deliverables.

## Execution Phase



The Project Execution Phase of the Project Life Cycle is typically the longest phase and involves implementing the plans created during the Project Planning Phase. While the work defined in the subcontracts is being executed, a series of management processes are undertaken to monitor and control the deliverables being output by the project to ensure the timely management of the completion of the work required to meet the program objectives. The Flex Coordinator is now responsible for ensuring that the activities of the grant are kept on time, on budget and within the defined SOW.

### Key Performance Indicators

An important activity in monitoring the Flex Program to determine the overall success and contribution to rural communities is to establish benchmarks and track key performance indicators against those benchmarks. To aid in the establishment of baseline data and targets for achieving success through the grant objectives, it is imperative that available data sources be leveraged. By ensuring that available data is utilized by subcontractors to supplement and support their work, the Flex Coordinator is able to achieving the following project objectives:

- Increase efficiency
- Reduce duplication of services
- Contain costs
- Provide baseline information for determining trends

### Data Sharing

An abundance of data exists and is available for use in the Flex grant through the FMT. A recent article from the FMT features the availability of the Flex Monitoring Team Data Summary Report, [Critical Access Hospital \(CAH\) Financial Indicators Report: Summary of Indicator Medians by State.](#)

The report presents state and national median values of the 22 financial indicators included in the CAH Financial Indicators Report (CAHFIR). Hospital-specific CAHFIRs that were distributed annually to each CAH administrator are now available via real-time access to the [Critical Access Hospital Measurement & Performance Assessment System \(CAHMPAS\)](#). Each CAH administrator has received a personal login code that can be retrieved by contacting the FMT office for assistance. The state medians presented in the report utilize the 2013 Medicare Cost Report data. Hospital and State MBQIP Data Reports are sent to state Flex Programs quarterly from FORHP. These are excellent data resources to track the outcomes of the Flex grant activities.

### **Technical Monitoring**

Subcontractors should report progress on all established key performance indicators and the timely completion of contract deliverables to the Flex Program Coordinator at regular intervals throughout the life of the contract. Quarterly reports are generally used in federal grants or accompanying invoices as a deliverable. An assessment of Flex Program Coordinators suggested conducting quarterly status meetings with subcontractors or monthly calls is a useful and effective method to track the timely progression of work toward completion of deliverables. This communication is best if in writing and inclusive of an update on the progress of all work included in the SOW.

The Center has previously produced a helpful toolkit that provides tips on working with Flex Program subcontractors, stakeholders and partners addressing methods to demonstrate outcomes. The content of the [Engaging Subcontractors and Partners in Demonstrating Outcomes](#) toolkit includes templates for budget tracking and program activity sheets as well as an example contract for services with a subcontractor.

### **Financial Monitoring**

To manage the revenue cycle of a subcontract, the submission of invoices for payment should only take place upon the demonstration of timely completed deliverables. For project activities that span a greater time period, the establishment of milestones to track completion and trigger

payment for work completed is advised with the largest payment being tied to the completion of the entire SOW. In the event that a milestone is missed or the subcontractor fails to meet the contract deliverables, payment should be withheld or delayed until the subcontractor satisfactorily demonstrates completion in accordance with the contracted SOW.

The [Flex Program Sub-Contract Tracking Spreadsheet](#) is a valuable toolkit that includes tools, tips and communication strategies with an emphasis on financial management or the “revenue cycle” of a contract. This is helpful information to assist in guiding the monitoring of the financial performance of the grant.

## Closure Phase

The final phase in the Project Life Cycle is the Project Closure Phase which includes the submittal of closeout notices, submission of final deliverables and final invoices. This phase will be predetermined by the end of the subcontract timeline or the end of the grant FY. The Flex Program Coordinator is responsible for ensuring that all subcontracted work is to be completed within this time frame and to alert the subcontractors as to the final date invoices will be accepted for processing.



So what happens when a contract deliverable has not been met for any of the following reasons?

- Deliverable timeline not met
- Scope of work not completed
- Data/reports not delivered
- Failure to provide benchmarking tools or demonstrate outcomes of project

The state Flex Program and the SORH do have the right to withhold payment for services if a subcontractor fails to deliver on any of the above reference items. In having tied payments to milestone completion and defined deliverables, the state Flex Program and SORH can maintain program integrity and are in an informed position to only make payments upon the successful completion of tasks. The subcontractor should only be paid upon the completion on deliverables.

However, wrapping up the activities of the work performed to support rural health through the Flex Program and SORH should be a time to celebrate. By investing the time in the front end of the project life cycle to put a detailed SOW, timeline and defined deliverables in place and then carefully monitoring of the progress of the project, the closing of the project will be a time to celebrate the documented success of the grant and its contributions to improve rural health care in the state and nationally.

## CONCLUSIONS

In conclusion, this guide has been designed to target common opportunities within the Flex Program or SORH to improve upon the development of the SOW requirements for subcontractors. Its focus is to assist state grantees in building a higher level of accountability with their contracts and subcontractors to deliver more meaningful information to further improve program deliverables, reporting and outcomes. SORH and Flex Program coordinators should focus their time and efforts in the beginning stages of the grant life cycle on developing and defining clear contract expectations within the SOW, outlining expected deliverables for the work plan and timeline.

By planning in advance for consequences in the event that deliverables are not met, the state grantee is in an excellent position to actively monitor and hold subcontractors accountable for delivering quality, measureable, outcome-driven work on time.

In establishing reporting requirements that provide data and demonstrate impact of services, the overall impact of the execution of the Flex Program will be improved. An important part of the Flex Program is telling the stories of how the program has and continues to make a positive impact of the delivery of safety net health care services in rural America. It is imperative that the rural community demonstrate the impact of the federal investment of resources through activities such as the Flex Program. Through tracking and demonstrating success through benchmarks and utilization of available data, the overall Flex Program is strengthened.

## References

**[Project Management Institute](#)** - The PMI provides services including the development of standards, research, education, publication, networking-opportunities in local chapters, hosting conferences and training seminars, and providing accreditation in project management. PMI utilized volunteers to create industry standards, such as "[A Guide to the Project Management Body of Knowledge](#)", which has been recognized by the [American National Standards Institute](#) (ANSI).

**[Health Resources & Services Administration, Federal Office of Rural Health Policy](#)** - created in 1987 to advise the Secretary of the U.S. Department of Health and Human Services on health care issues impacting rural communities.

**[National Rural Health Resource Center](#)** - provides technical assistance, information, tools and resources for the improvement of rural health care. It serves as a national rural health knowledge center and strives to build state and local capacity.

Additional related resources:

[Assessing, Selecting and Contracting Electronic Health Record Vendors](#)

[Engaging Subcontractors and Partners in Demonstrating Outcomes](#)

[Flex Program Sub-contract Tracking Spreadsheet](#)

**[Flex Monitoring Team](#)** - consortium of the [Rural Health Research Centers in Minnesota, North Carolina, and Maine](#). We are funded by the Federal [Office of Rural Health Policy](#) to evaluate the impact of the Medicare Rural Hospital Flexibility Grant Program (the [Flex Program](#)). The team's efforts aim to improve the accessibility, viability, and quality of health care for rural residents and communities.

Additional related resources:

[State-level Quality, Financial, and Community Engagement Data](#)

# APPENDICES

## Appendix A: Data Use Agreement Template

*INSTRUCTIONS: Delete these instructions upon completing the data use agreement. The Data Use Agreement template is to be used for research that exchanges limited Personal Health Information (PHI) with a non-provider based entity. The PHI being shared/exchanged should qualify as a limited data set. A limited data set may be used for the purpose of research, public health or health care operations. A limited data set is PHI that excludes direct identifiers of the individual or of relatives, employers or household members of the individual.*

### **DATA USE AGREEMENT**

This Data Use Agreement ("Agreement") is made and entered into as of this \_\_\_\_\_ day of \_\_\_\_\_, 20\_\_ by and between \_\_\_\_\_ ("Covered Entity"), and \_\_\_\_\_ ("Data Recipient").

### **WITNESSETH:**

WHEREAS, Covered Entity may Disclose or make available to Data Recipient, and Data Recipient may Use, Disclose, receive, transmit, maintain or create from, certain information in conjunction with research or program activities; and

WHEREAS, Covered Entity and Data Recipient are committed to compliance with the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and regulations promulgated thereunder; and

WHEREAS, the purpose of this Agreement is to satisfy the obligations of Covered Entity under HIPAA and to ensure the integrity and confidentiality of certain information Disclosed or make available to Data Recipient and certain information that Data Recipient Uses, Discloses, receives, transmits, maintains or creates, from Covered Entity.

WHEREAS, User agrees to limit its use of the Limited Data Set and protect the Limited Data Set in accordance with the terms of this Agreement and the HIPAA Privacy and Security Rules.

THEREFORE, in consideration of the mutual agreements, terms and conditions herein contained, Covered Entity and User agree as follows:

### **A. DEFINITIONS**

Terms used but not otherwise defined in this Agreement shall have the same meaning as those terms in the Privacy Rule.

1. Individual shall have the same meaning as the term “individual” in 45 CFR Sect. 164.501 of the Privacy Rule and shall include a person who qualifies as a personal representative in accordance with 45 CFR Sect. 164.502(g) of the Privacy Rule.
2. Limited Data Set shall have the same meaning as the term “limited data set” in 45 CFR 164.514(e) of the Privacy Rule.
3. Privacy Rule shall mean the Standards for Privacy of Individually Identifiable Information at 45 CFR Part 160 and Part 164, Subparts A and E, as amended from time to time.
4. Protected Health Information or PHI shall have the same meaning as the term “protected health information” in 45 CFR Sect. 164.501 of the Privacy Rule, to the extent such information is created or received by Data Recipient from Covered Entity.
5. Required by Law shall have the same meaning as the term “required by law” in 45 CFR Sect. 164.501 of the Privacy Rule.

**B. SCOPE AND PURPOSE**

1. This Agreement sets forth the terms and conditions pursuant to which Covered Entity will Disclose certain PHI to the Data Recipient.
2. Except as otherwise specified herein, Data Recipient may make all Uses and Disclosures of the Limited Data Set necessary to conduct the research described herein:

\_\_\_\_\_ (“Research Project”).

3. In addition to the Data Recipient, the individuals, or classes of individuals, who are permitted to Use or receive the Limited Data Set for purposes of the Research Project, include:

\_\_\_\_\_  
\_\_\_\_\_

**C. OBLIGATIONS AND ACTIVITIES OF DATA RECIPIENT**

1. Data Recipient agrees to not Use or Disclose the Limited Data Set for any purpose other than the Research Project or as Required by Law.

2. Data Recipient agrees to use appropriate safeguards to prevent Use or Disclosure of the Limited Data Set other than as provided for by this Agreement.
3. Data Recipient agrees to report to the Covered Entity any Use or Disclosure of the Limited Data Set not provided for by this Agreement of which it becomes aware, including without limitation, any Disclosure of PHI to an unauthorized subcontractor, within ten (10) days of its discovery.
4. Data Recipient agrees to ensure that any agent, including a subcontractor, to whom it provides the Limited Data Set agrees to the same restrictions and conditions that apply through this Agreement to the Data Recipient with respect to such information.
5. Data Recipient agrees not to identify the information contained in the Limited Data Set or contact the individual.
6. Data Recipient will indemnify, defend and hold harmless Covered Entity and any of Covered Entity's affiliates, and their respective trustees, officers, directors, employees and agents ("Indemnitees") from and against any claim, cause of action, liability, damage, cost or expense (including, without limitation, reasonable attorney's fees and court costs) arising out of or in connection with any unauthorized or prohibited Use or Disclosure of the Limited Data Set or any other breach of this Agreement by Data Recipient or any subcontractor, agent or person under Data Recipient's control.

#### **D. TERM AND TERMINATION**

Term of this Agreement shall be effective as of the date entered above and shall terminate when all of the Limited Data Set provided by Covered Entity to Data Recipient is destroyed or returned to Covered Entity. If it is infeasible to return or destroy the Limited Data Set, protections of this Agreement shall extend to such information, in accordance with the termination provisions in Section 2(b).

Upon Covered Entity's knowledge of a material breach by User, Covered Entity shall have the right to immediately terminate this Agreement.

(a) Except as provided in paragraph (b) of this subsection, upon termination of this Agreement or upon request of Covered Entity,

whichever occurs first, User shall return or destroy the Limited Data Set received from Covered Entity. This provision shall apply to a Limited Data Set that is in the possession of subcontractors or agents of User. Neither User nor its subcontractors or agents shall retain copies of the Limited Data Set.

(b) In the event that User determines that returning or destroying the Limited Data Set is not feasible, User shall provide to Covered Entity notification of the conditions that make return or destruction infeasible. Upon mutual agreement of the Parties that return or destruction of the Limited Data Set is infeasible, User shall extend the protections of this Agreement to such Limited Data Set and limit further uses and disclosures of such Protected Health Information to those purposes that make the return or destruction infeasible, for so long as User maintains such Limited Data Set.

## **E. MISCELLANEOUS**

1. A reference in this Agreement to a section in the Privacy Rule means the section as amended or as renumbered.
2. The parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for Covered Entity to comply with the requirements of the Privacy Rule and HIPAA.
3. The respective rights and obligations of Data Recipient under Section C of this Agreement shall survive termination of this Agreement.
4. Any ambiguity in this Agreement shall be resolved to permit Covered Entity to comply with the Privacy Rule.
5. There are no intended third party beneficiaries to this Agreement. Without in any way limiting the foregoing, it is the parties' specific intent that nothing contained in this Agreement gives rise to any right or cause of action, contractual or otherwise, in or on behalf of the individuals whose PHI is Used or Disclosed pursuant to this Agreement.
6. No provision of this Agreement may be waived except by an agreement in writing signed by the waiving party. A waiver of any term or provision shall not be construed as a waiver of any other term or provision.

7. The persons signing below have the right and authority to execute this Agreement and no further approvals are necessary to create a binding agreement.
8. In the event of any conflict between the terms and conditions stated within this Agreement and those contained within any other agreement or understanding between the parties, written, oral or implied, the terms of this Agreement shall govern. Without limiting the foregoing, no provision of any other agreement or understanding between the parties limiting the liability of Data Recipient to Covered Entity shall apply to the breach of any covenant in this Agreement by Data Recipient.
9. This Agreement shall be construed in accordance with and governed by the laws of the State of Missouri.

**IN WITNESS WHEREOF, the parties have executed this Agreement effective upon the Effective Date set forth above.**

**Covered Entity**

**Data Recipient**

Name: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

Date: \_\_\_\_\_

## Appendix B: Non-Disclosure Agreement Template

*A confidentiality agreement (also called a nondisclosure agreement or NDA) is a legally binding contract in which a person or business promises to treat specific information confidential and promises not to disclose the information to others without proper authorization.*

This Nondisclosure Agreement (the "Agreement") is entered into by and between \_\_\_\_\_ with its principal offices at \_\_\_\_\_ ("Disclosing Party") and \_\_\_\_\_, located at \_\_\_\_\_ ("Receiving Party") for the purpose of preventing the unauthorized disclosure of Confidential Information as defined below. The parties agree to enter into a confidential relationship with respect to the disclosure of certain proprietary and confidential information ("Confidential Information").

**1. Definition of Confidential Information.** For purposes of this Agreement, "Confidential Information" shall include all information or material that has or could have commercial value or other utility in the business in which Disclosing Party is engaged. If Confidential Information is in written form, the Disclosing Party shall label or stamp the materials with the word "Confidential" or some similar warning. If Confidential Information is transmitted orally, the Disclosing Party shall promptly provide a writing indicating that such oral communication constituted Confidential Information.

**2. Exclusions from Confidential Information.** Receiving Party's obligations under this Agreement do not extend to information that is: (a) publicly known at the time of disclosure or subsequently becomes publicly known through no fault of the Receiving Party; (b) discovered or created by the Receiving Party before disclosure by Disclosing Party; (c) learned by the Receiving Party through legitimate means other than from the Disclosing Party or Disclosing Party's representatives; or (d) is disclosed by Receiving Party with Disclosing Party's prior written approval.

**3. Obligations of Receiving Party.** Receiving Party shall hold and maintain the Confidential Information in strictest confidence for the sole and exclusive benefit of the Disclosing Party. Receiving Party shall carefully restrict access to Confidential Information to employees, contractors, and third parties as is reasonably required and shall require those persons to

sign nondisclosure restrictions at least as protective as those in this Agreement. Receiving Party shall not, without prior written approval of Disclosing Party, use for Receiving Party's own benefit, publish, copy, or otherwise disclose to others, or permit the use by others for their benefit or to the detriment of Disclosing Party, any Confidential Information. Receiving Party shall return to Disclosing Party any and all records, notes, and other written, printed, or tangible materials in its possession pertaining to Confidential Information immediately if Disclosing Party requests it in writing.

**4. Time Periods.** The nondisclosure provisions of this Agreement shall survive the termination of this Agreement and Receiving Party's duty to hold Confidential Information in confidence shall remain in effect until the Confidential Information no longer qualifies as a trade secret or until Disclosing Party sends Receiving Party written notice releasing Receiving Party from this Agreement, whichever occurs first.

**5. Relationships.** Nothing contained in this Agreement shall be deemed to constitute either party a partner, joint venturer or employee of the other party for any purpose.

**6. Severability.** If a court finds any provision of this Agreement invalid or unenforceable, the remainder of this Agreement shall be interpreted so as best to effect the intent of the parties.

**7. Integration.** This Agreement expresses the complete understanding of the parties with respect to the subject matter and supersedes all prior proposals, agreements, representations, and understandings. This Agreement may not be amended except in a writing signed by both parties.

**8. Waiver.** The failure to exercise any right provided in this Agreement shall not be a waiver of prior or subsequent rights.

This Agreement and each party's obligations shall be binding on the representatives, assigns, and successors of such party. Each party has signed this Agreement through its authorized representative.

**Disclosing Party**

By: \_\_\_\_\_

**Receiving Party**

By: \_\_\_\_\_

Printed Name: \_\_\_\_\_

Printed Name: \_\_\_\_\_

Title: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

Date: \_\_\_\_\_