Early Feasibility Study (EFS) Contracting Resource: Negotiation Range Process and Language Libraries

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*Disclaimer: This resource does not represent the official view of the U.S. Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), or any part of the U.S. Federal Government. No official support or endorsement of this article by the FDA and/or CDRH is intended or should be inferred.
Executive Summary

Aligning with its strategic priority of facilitating First-in-World patient access to safe and effective new technologies of significant health importance, the FDA’s Center for Devices and Radiological Health (CDRH) released its final Guidance titled Investigational Device Exemptions (IDEs) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies in October of 2013. Understanding that support during the earliest phases of medical device testing encourages medical device innovation and access for U.S. patients, the Medical Device Innovation Consortium (MDIC), as the first public-private partnership focused on medical devices, supported this CDRH strategic priority through the development of an Early Feasibility Study (EFS) working group. MDIC’s ability to facilitate collaborations among FDA, industry, physician researchers and other stakeholders provided a unique environment in which to develop tools supporting broad participation in the CDRH EFS program.

Specifically, the MDIC EFS working group identified that EFS clinical studies provide early insights into an innovative medical technology, which often serves as a critical step in device innovation. To facilitate participation in the EFS program, the early MDIC EFS working group developed and published the MDIC “Blueprint for Early Feasibility Study Success,” a best practices roadmap for navigating EFS complexities. Building on the success of this EFS Blueprint, MDIC recommissioned the EFS working group in 2017 to understand the EFS program’s utilization and identify improvement opportunities. In a first-of-its-kind effort, this MDIC EFS working group, including CDRH and industry partners, collaborated in developing an EFS Performance Metric Baseline, in which the contracting process for EFS trials was identified as a significant blocker towards efficient EFS performance. The MDIC responded by creating an EFS Contracting working group charged with developing tools to mitigate this bottleneck.

This EFS Contracting Resource is the output of that EFS Contracting working group. The tools contained intend to drive efficient and consistent contracting processes among clinical sites and sponsors collaborating in clinical trials gaining IDE approval through the EFS program within CDRH. This Resource begins by outlining a proactive EFS Negotiation Range process encouraging sponsors and sites to:

1) Initiate EFS contracts from a reasonable starting point, and consider acceptable backup positions,
2) Empower Contract negotiators to efficiently finalize contracts within acceptable negotiation ranges, and
3) Engage Legal subject matter experts through a “right time, right scope” approach

In addition to the EFS Negotiation Range process, this tool set includes EFS Contract Clause Language Libraries. Each Library contains several clause language examples which have proven acceptable to both the sponsors funding EFS trials and clinical sites conducting EFS trials. Importantly, in addition to language examples, these EFS Language Libraries provide commentary describing the considerations and negotiation points relative to each party during the EFS contract negotiation.

These tools, either alone or in combination, have demonstrated effectiveness in removing contracting bottlenecks related to EFS clinical trial.
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Introduction

Definition of an Early Feasibility Study

An Early Feasibility Study (EFS) is a small clinical study designed to provide early insights into an innovative medical technology, before starting a larger clinical trial. An EFS often serves as a critical step in device innovation. Benefits of conducting an EFS in the U.S. include:

- Facilitates interactive collaboration among FDA, sponsors and innovators early in a product’s lifecycle
- Provides U.S. patients with First-in-World access of novel medical technologies
- Familiarizes regulatory review teams and care providers with the innovative technology earlier in the product development process
- Facilitates Just-in-Time Testing (JITT)
- Captures U.S. demographics data, directly supporting subsequent U.S. clinical studies (e.g. Pivotal, etc.)
- Enables use of a single IDE across U.S. clinical studies: EFS, Traditional Feasibility and Pivotal trials; provides the ability to request initiating a new phase of study under the same IDE number

How to Use These EFS Contracting Tools

First and foremost, this is not a clinical trial contract template and is not intended to be used as one. There are many reliable clinical trial contract templates freely available.

These tools are intended to bring efficiencies into the clinical trial contracting process; with specific attention those trials gaining IDE approval through the EFS program within CDRH. The tool set begins with a process. Specifically, a proactive process encouraging sponsors and sites to:

1) Avoid starting negotiation positions which are expected to be unacceptable to the other party before negotiations begin. Contract negotiations initiated from extremes are both time and resource consuming. By considering a reasonable starting point, as well as an acceptable backup position, contract negotiation teams can focus on any novel aspects related to the technology and related trial.

2) Empower Contract negotiation teams to efficiently finalize contracts within acceptable negotiation ranges.

3) Encourage efficient use of Legal resources through an only when needed approach

In addition to the above process, this tool set includes Language Libraries. These Language Libraries target the small number of EFS Contract Clauses which MDIC EFS working group members identified as the most resource intensive to finalize. Specifically, this tool set contains Language Libraries for: 3rd Party Insurance, Indemnification, Intellectual Property and Subject Injury. Each Library contains several examples of clause language which has proven acceptable to both sponsors and sites in the conduct of real EFS trials.

Importantly, in addition to examples of successful language, these Libraries provide commentary/narratives describing important considerations and negotiation points relative to each party to the EFS contract negotiation. These narratives, when combined with a proactive contracting process, have been demonstrated to bring efficiency to the EFS clinical trial contracting process; thereby removing one of the largest blockers to efficient and effective EFS trial conduct.
Process: EFS Contract Negotiation Ranges

Objective: Contract Negotiation Ranges

This EFS Contract Negotiation Range tool serves three objectives:

1) Proactively consider (a) reasonable starting, and (b) acceptable backup positions for EFS contracts.
2) Illustrating a proactive EFS Contracting process; documenting contract Terms & Conditions empowers negotiators (internal or external) to (a) consistently negotiate within acceptable parameters, and (b) optimize Legal resources with Just-in-Time subject matter expert engagement, only when needed.
3) Highlighting selected contract Terms & Conditions (not exhaustive) important in EFS negotiations

Tool: EFS Contract Negotiation Ranges

EFS Negotiation Ranges: Audits and Publications

<table>
<thead>
<tr>
<th>Key Terms &amp; Conditions</th>
<th>Starting/Initial Position</th>
<th>Proposed Back-Up/Final Position</th>
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<tbody>
<tr>
<td>Audits</td>
<td>Standard Investigational Device Exemption (IDE) audit and inspection language. Sponsor will not pay for any audit-related costs.</td>
<td>Sponsor will agree to cover administrative costs associated with Not-for-Cause Sponsor and regulatory audits. Flat rate per 1/2 day can eliminate cumbersome tracking/billing.</td>
</tr>
<tr>
<td>Publications</td>
<td>The initial publication position that will be offered in the template Clinical Trial Agreement (CTA) is that a multi-center publication will be the first publication released or presented. However, the study center will be allowed to publish their individual center’s data under the following conditions: 1. A multi-center publication is not released within one year after completion of the study at all study centers. 2. Sponsor has been allowed to review the center’s publication to determine whether confidential information is disclosed and been allowed to protect its rights in patentable or copyrightable materials, and to check for technical correctness of Sponsor information. The center must provide the publication to Sponsor 60 days prior to submission or presentation of their publication and Sponsor can delay a center’s publication up to 90 days to protect its right in patentable or copyrightable material</td>
<td>If a site insists that these time limits must be changed, Contract Analyst will inform Clinical Study Manager who will then determine whether some concession can be made.</td>
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## EFS Negotiation Ranges: Intellectual Property, Confidentiality, Indemnification and Subject Travel

### EFS Contracting Process: Negotiation Range

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<th>Key Terms &amp; Conditions</th>
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<tr>
<td><strong>Intellectual Property</strong></td>
<td>The initial intellectual property (IP) position that will be offered in the template CTA is that the participating institution agrees to assign all IP arising from, or relating to, the study or derived from confidential information to Sponsor (Eliminate need to for IP assignment)</td>
<td>Language acknowledging clinical expertise for physician thought leaders in the therapeutic area related to the EFS, as applicable.</td>
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<td></td>
<td><em>See the related MDIC EFS Indemnification Language Library</em></td>
<td></td>
</tr>
<tr>
<td><strong>Confidentiality</strong></td>
<td>Standard language, which requires sites to maintain the confidentiality of confidential information indefinitely.</td>
<td>Contract Analysts will seek legal and Clinical Study Manager approval for any differing language not addressed in the Alternative Language Manual.</td>
</tr>
<tr>
<td><strong>Indemnification and Insurance</strong></td>
<td><em>See the related MDIC EFS Indemnification Language Library</em></td>
<td></td>
</tr>
<tr>
<td><strong>Subject Travel Reimbursement</strong></td>
<td>Template Agreement will not include subject travel reimbursement.</td>
<td>Sponsor will review these requests on a case-by-case basis. For studies where follow-up is non-standard-of-care and compliance is a concern, consider offering flat rate for all subjects and then upon request and documentation, pass-through IRS mileage rate for subjects traveling over XX miles roundtrip.</td>
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### EFS Negotiation Ranges: Adverse Event Related Costs

#### EFS Contracting Process: Negotiation Range

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</table>
| **Adverse Event (AE) Related Costs** | Standard template language. | A. A significant number of institutions that have policies whereby they will not agree to submit any expenses for adverse events (AE)s to the subject’s insurance (Medicare or private insurance) where the AE is related to the investigational product or the study procedures.  
B. Rather, these costs are submitted directly to the sponsor for payment.  
C. Therefore, approval is requested for an alternate subject injury position where Sponsor will reimburse the study site for the expenses incurred for the reasonable and necessary medical services to treat Therapy Risks without requiring the site to first submit those costs to insurance.  
D. Rate at which Sponsor will pay medical costs:  
  • Some institutions have an established research rate for payment of medical costs related to adverse events and insist on their established rates instead of the local Medicare rates.  
  • Approval is requested for the established and documented research rate for the institution (a documented discount rate off their costs) or if none, up to 100+XX% of their local Medicare rate*.  

*this is the same upper range for the budget for healthcare costs

See also the related MDIC EFS Subject Injury Language Library
## EFS Negotiation Ranges: Provision of Study Device and Implant-Related Reimbursement

### EFS Contracting Process: Negotiation Range

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| Provision of Study Device and Implant-Related Reimbursement | Template Agreement will not include reimbursement for implant related charges in the event of payer denials. | A. Sponsor will review any requests for such language on a case by case basis and will require approval of the Clinical Study Manager.  
B. Language for this backup position should be drafted in advance, specific to the requirements of the protocol. Any alterations of that language negotiated by sites will require both the approval of the Clinical Study Manager and Legal.  
C. Suggest that Sponsor have objective, pre-defined criteria for considering these requests.  
D. Sponsor can offer waiver of device cost, but not procedures: The Affordable Care Act (ACA) requires most insurers to cover Standard-of-Care procedures for clinical trial subjects. |

*See also the related MDIC EFS 3rd-Party Payer Language Library*
EFS Contract Clauses: Language Libraries

Objective: EFS Language Libraries

The following EFS Language Libraries are intended to facilitate customizations to the Key Terms & Conditions suggested in the above proactive Negotiation Range process. Given the uniqueness of EFS technologies, these Language Libraries are intended to facilitate flexibility in thinking about EFS contract language, reflective of the medical technologies themselves. Accordingly, these EFS Language Libraries are neither prescriptive, nor exhaustive, EFS contracting templates. Instead, these Language Libraries target the small number of EFS Contract Clauses which MDIC EFS working group members identified as requiring the greatest amount of resources to negotiate: 3rd Party Insurance, Indemnification, Intellectual Property and Subject Injury.

While each Library does offer examples of clause language which has been acceptable to both sponsor and sites in the conduct of actual EFS trials, perhaps the most important feature of these Language Libraries is their respective Commentary sections. These commentaries describe important considerations and negotiation points, direct from some of the subject matter experts who engage in EFS contract negotiations. When combined with a proactive contracting process, these Language Libraries facilitate efficient EFS clinical trial contracting, and ultimately improve the execution of EFS trials in the U.S.

Tools: EFS Language Libraries

EFS Language Library: 3rd Party Insurance

3rd Party Insurance Library: Clause Examples A - E

A. Institution shall not (individually or jointly) submit any charge to any governmental agency (including Medicare or a state agency such as Medicaid which reimburses for health care services) or any other payor, including Study subjects, for any device, equipment, tests, or other Study materials that are provided by sponsor at no charge, replaced at no charge, or which are reimbursed by sponsor under this Agreement.

B. If the Sponsor provides any free products or items for use in the Study, Institution and Investigator agree that they will not bill any Study subject, insurer or governmental agency, or any other third party, for such free products or items.

C. Institution and Investigator agree that they will not bill any Study subject, insurer, or governmental agency for any visits, services or expenses incurred during the Study for which they have received compensation from Sponsor, or which are not part of the ordinary care they would normally provide for the Study subject, and that neither Institution nor Investigator will pay another physician to refer subjects to the Study.

D. Neither Institution nor Principal Investigator shall bill any third party for services provided to subjects in connection with the Study for which payment is made by the Sponsor as part of the Study.

E. Institution and Investigator acknowledge and agree that notwithstanding the investigational status of the Device, certain medical procedures required under the Protocol represent reasonable and necessary medical procedures, and accordingly should be medical services covered by third party health insurance, for the diagnosis and/or treatment of the medical condition(s) being addressed in subjects who are qualified for participation in the Trial. Institution shall submit to subjects and/or their third party payors
or other responsible persons, complete and accurate claims for payment of all reasonable and necessary medical expenses as determined to be appropriate by Institution. Institution and Principal Investigator shall not, and shall ensure that its/his/her respective Trial Personnel do not (a) submit claims for payment by any subject, third-party payor or other person or entity for any item, procedure or service that has been paid for or furnished without charge by Sponsor, or (b) seek or retain payment from Sponsor for any item, procedure or service that is reimbursed by any subject, third-party payer or any other person or entity.

3rd Party Insurance Library Commentary: Key Considerations

- Ensure consistency of coverage for study-related items regardless of type of insurance coverage
- Avoid language/practices which risk an institution’s study billing processes are in violation of Medicare payment rules (secondary payor issues)
- Promote practices which avoid inadvertent double billing: either of insurance companies or sponsors
- Examples A – E demonstrate achieving these goals through a variety of language options.

EFS Language Library: Indemnification

Indemnification Library: Purpose

Company will indemnify, defend and hold harmless the University, the Hospital, the IRB, and their respective subsidiaries, affiliated hospitals, trustees, directors, officers, faculty, agents, employees, and students, including the Principal Investigator and any sub-investigator, (individually an “Indemnitee” and collectively, the “Indemnites”) from and against any and all actions, suits, claims, proceedings, investigations, demands, costs and expenses (including reasonable attorney fees), judgments, liabilities, losses, personal injuries (including death), or other damages (collectively “Losses”), of all types whatsoever, that are asserted to have arisen from or are related to the performance of the Research and any other activities to be performed under this Agreement. The Company’s obligation to indemnify, defend and hold harmless an Indemnitee will be reduced to the extent that any Losses are finally adjudicated to have been directly caused by: (i) a material failure by such Indemnitee to comply with the Protocol, allowing for deviations for Study patient safety, and/or with state or federal statutes or regulations, including Food and Drug Administration regulations; or (ii) the negligence of such Indemnitee, provided that complying with the Protocol, Sponsor’s instructions, or the terms of this Agreement shall not be considered negligence for purposes of this exception. Without limitation, Company will bear all liabilities arising from or related to its and/or its contractor’s or agent’s performance of the Research, or its use or commercialization of the Research results, whether or not the exceptions referenced in the preceding sentence apply.

Indemnification Commentary: Key Purpose Considerations

The above language is an example of common Indemnification language. The Site, Investigator and research staff are looking to limit their liability related to activities performed for the purpose of the study. Additionally, this site team is confirming leeway to deviate from study protocol and/or procedures to address justified patient safety concerns, if applicable.
From the sponsor perspective, the above provision is acknowledging caveats related to coverage for significant, non-patient safety-related protocol deviation and/or negligence. It is important to note here that the obligation to defend/indemnify any single Indemnitee may be reduced, while still fully indemnifying the Site and/or other Site staff. Exceptions are not intended to reduce indemnification of any other Indemnitee who did not "commit" an action/inaction falling under the exceptions.

- Narrowing Indemnification: From (i) anything occurring under performance of the Research to (ii) an itemized list - (a) through (z). Consider for EFS, the risk and or uncertainty level is higher.
- Sponsors’ may desire to limit claims to those made by third parties, which may or may not be acceptable.
- Exceptions to Indemnification: May allow objective determinations of applicability to be made by mutual agreement vs. final adjudication. May also agree to judicial determination as opposed to final judicial determination.

**Indemnification Library: Process**

The University/Hospital will promptly notify Company of any indemnifiable action, suit, or claim (“Claim”) of which it becomes aware, and each Indemnitee will cooperate with Company and its insurance carrier in the defense of any such Claim. Company agrees, at its sole expense, to diligently defend against any such Claim against any Indemnitee whether or not such Claim is rightfully brought or filed. With respect to any Claim as to which Company has irrevocably acknowledged a duty to indemnify the Indemnees, Company will be entitled to conduct and direct defense of the Indemnees against such Claim using qualified attorneys of Company’s own selection, but Company will consult with the Indemnees on litigation strategy and any proposed settlements. Company will not enter into a settlement agreement of any such Claim without the Institutions’ prior written approval unless the settlement agreement: (i) includes a full and unconditional release of each Indemnitee and (ii) has no finding or admission of any violation or wrongdoing by any Indemnitee. At the individual option of an Indemnitee, such Indemnitee may defend itself at its own expense.

**Indemnification Commentary: Key Process Considerations**

From the Site/Indemnitee perspective, they are securing sponsor coverage for Claim defense; the defending actions and/or resources included in Indemnification from the preceding provision (Purpose). The Site/Indemnitee also is looking to have input into the Claim defense strategy and/or settlement, and if the Sponsor agrees on a settlement, to be released of wrongdoing.

The Sponsor is looking for timely Claim Notification to fulfill the indemnification responsibilities, the leeway to select resources (attorneys), and to determine the defense and/or settlement pathway.

- Litigation Strategies: Consider flexibility around requiring consultation with the Institution
- Defense at Indemnitee’s own expense: There may be reasons to go silent on this provision
Indemnification Library: Alternative Language

Without reducing Company’s obligations and the Indemnitees’ rights to enforce the indemnity and defense obligations, with respect to any Claim as to which Company has not irrevocably acknowledged a duty to indemnify Indemnitees, the Institutions and the other Indemnitees will be entitled to conduct and direct their own defense and that of other Indemnitees using attorneys of their own selection. Company’s duty to defend the Indemnitees in such instance shall consist of reimbursing the Indemnitees on a current basis for all reasonable legal, expert and other defense fees and costs incurred by the Indemnitees in conducting their defense. In addition, Company will reimburse the Institutions for their costs and expenses enforcing this Section. The indemnity obligations under this Section will not be construed to negate, abridge, or otherwise reduce any other obligation of indemnity or liability that would apply to Company under applicable law.

Indemnification Commentary: Alternative Language Considerations

This is not a preferred provision as ideally all instances requiring Indemnification would be addressed by the preceding provision (Process). However, here the Site/Indemnitee is addressing instances when a claim is brought, yet indemnification is NOT addressed under the preceding provision (Process). In such cases, the above provision clarifies the Indemnitees are able to defend themselves with attorneys of Indemnitee selection, and with cost coverage by the Sponsor as the claim is still related to the study.

The Sponsor’s primary interest with this clause is Notification of a Claim.

Use of this provision means the Site/Indemnitee loses the financial promise of Sponsor to cover defense expenses which are not clearly indemnifiable by Sponsor. If the prior Indemnification provisions have been narrowed, by limiting the scope of indemnifiable Losses from Research/Agreement to (a) to (z), further limiting defense expense coverage increased risk to the Indemnitee.

EFS Language Library: Intellectual Property

Intellectual Property Library: Pre-existing Intellectual Property (IP)

Each party to this Agreement shall retain all right, title and interest in any patent, patent application, trade secret, know-how, trademarks, copyrights, and other intellectual property (“Intellectual Property”) that was owned by such party prior to the date of this Agreement and no license grant or assignment, express or implied, by estoppel or otherwise, is intended by or shall be inferred from, this Agreement. Neither Institution nor Sponsor shall adopt, use or register any words, phrases or symbols, which are identical to or confusingly similar to any of the other party’s trademarks.

Intellectual Property Commentary: Pre-existing IP

The preceding is an example of a simple statement confirming that each party has prior knowledge and IP. This protects what each party brings to the agreement. This is typically acceptable to both parties.
**Intellectual Property Library: Results and Future Intellectual Property**

Sponsor owns all right, title and interest in the study data and all Intellectual Property arising from the performance of the Study. Site and Investigator, as applicable, shall assign and hereby does assign such Intellectual Property to Sponsor. The parties agree that no other ownership interests are contemplated pursuant to the terms of this Agreement.

Any invention, innovation, discovery, improvement, design, apparatus, practice, process or method (whether or not patentable or copyrightable), made, perfected, devised, conceived or reduced to practice, by any investigating party/site as a result of the use of the device or any study materials or the performance of the study (“Intellectual Property”) shall be promptly disclosed, in writing, to the Sponsor and shall be the sole property of the Sponsor and each investigating party/site hereby assigns to Sponsor, all right, title and interest in and to said Intellectual Property. Each investigating party/site shall, upon the Sponsor’s request and at the Sponsor’s expense, execute such documents and take such other actions as the Sponsor deems necessary or appropriate to obtain patent or other proprietary protection.

**Intellectual Property Commentary: Results and Future Intellectual Property**

In many cases the Site/Investigator is receiving funds from a Sponsor and therefore this language may be requested. Consideration would be given to the involvement of the parties and the intended use of the results. Site/Investigator may be performing independently of any input from Sponsor and thus this clause may not be necessary.

The Scope of the project will strongly influence the language regarding future IP. Typically, the party that contributes the most background IP, funding, facilities and/or other resources will own the IP while the other party may receive a limited, non-exclusive license. In the event the project is related to device application, the Site/Investigator may seek to expand their access to the results for non-commercial academic research, subject to confidentiality obligations.

**Intellectual Property Library: Intellectual Property (IP) Assignments and Joint IP**

A. **Definitions Joint Intellectual Property**

1. **IP Definition.**
   The parties agree as follows with respect to any potentially patentable invention or discovery conceived, and Reduced to Practice in the performance of the Study or conceived in the performance of the Study and Reduced to Practice within the immediate six (6) months following the close of the Study at Institution (“Intellectual Property” or “IP”).

2. **Reduction to Practice.**
   For the purposes of this Agreement, concepts of inventions or discoveries that are described in sufficient detail, e.g. written descriptions and/or drawings, for one skilled in the art to understand or practice the invention without additional research shall constitute Reduction to Practice (Reduce(d) to Practice).

3. **Sponsor IP.**
Title to any IP defined in XX conceived and Reduced to Practice solely by Sponsor or its employees, or agents, in the performance of the Study shall vest exclusively in Sponsor.

4. **Institution IP.**
   Title to any IP as defined in XX conceived and Reduced to Practice solely by Institution or its employees, agents or contractors (including principal investigator or any sub-investigators, as applicable) which:
   a) was not derived from, does not consist of or does not otherwise relate to the study device, or
   b) was not contemplated by the protocol, or
   c) does not use the study data or other Sponsor Confidential Information shall vest exclusively in Institution.

5. **Joint IP.**
   Intellectual Property as defined in XX conceived and Reduced to Practice jointly by Sponsor or its employees, agents, and Institution or its employees, agents or contractors (including principal investigator or any sub-investigators, as applicable) which:
   a) was not derived from, or does not consist of or does not otherwise relate to the study device, including but not limited to a use, improvement or manufacture of the study Device, or
   b) was not contemplated by the protocol, or
   c) does not use the study data or other Sponsor Confidential Information provided by Sponsor, shall be jointly owned by Institution and Sponsor (“Joint IP”);

B. The parties will consult with each other regarding whether an application or applications for patent or other IP rights should be prepared, filed and prosecuted, and maintained once issued in such Joint IP. The parties will discuss in good faith to determine which party shall control the process of preparing, filing and prosecuting the application or applications, and maintaining the issued patent or patents, related to such Joint IP.

C. Sponsor acknowledges and agrees: (i) that one or more of Institution’s affiliated scientists are prolific researchers in the area of [INSERT CONDITION OR SCIENTIFIC AREA]; (ii) that these researcher(s)’ work in this area will continue in other contexts outside this Study; and (iii) that this Agreement is not intended to convey and shall not be construed as granting to Sponsor any right, title or interest to any inventions, discoveries or works of authorship made by these researcher(s)” to which Sponsor would not otherwise have a viable claim of inventorship, authorship or ownership under U.S. patent law.

*Intellectual Property Commentary: Intellectual Property (IP) Assignments and Joint IP*

The Intellectual Property language provides three scenarios for IP, independently owned by the Investigator, Sponsor, or Joint ownership. The language in item “C” is reflective of a situation where the Institution may have various internal policies that control IP ownership, and/or in recognition that an Investigator’s prior knowledge and/or expertise is paramount to successful outcomes related to the EFS investigation and/or product.
If there is IP expected from the project the parties should discuss if there is an interest in patent filing. Paragraph “B” addresses patent applications, and is intentionally brief to allow supplementation by either party. Commonly, the Sponsor will be interested in patent protection as their long-term interest is in developing the IP into a commercial product. The parties may explore who pays for patent filing, prosecution, and maintenance of the patent, and options for royalty payments for their ownership in the development of the IP.

Considerations during Intellectual Property negotiations for the agreement to address any or all of the following aspects and mechanics resulting from exclusive or joint IP as a result of the relationship:

- Who decides the form of IP protection (design, utility, trade secret and/or copyright)?
- Who pays for any IP filings or registrations?
- What notice of IP is required and what are the time periods for notice and review?
- Who directs prosecution of any IP filings?
- Who decides in which jurisdictions such IP filings are made?
- Who can enforce the IP?
- Who can license the IP to whom?
- Who gets any royalties earned as a result of licensing the IP?
- Who can practice the IP, and in what field(s)?

**EFS Language Library: Subject Injury**

*Subject Injury Library #1: Base Language*

Site will offer or will coordinate medical care to Subjects who suffer an adverse reaction, illness, or injury during the Study. Sponsor will reimburse Institution or other medical provider for the reasonable and necessary costs of providing such medical treatment, to the extent the adverse reaction, illness or injury was arising from the use of the Study Device in accordance with the Protocol or procedures performed in accordance with the Protocol. Notwithstanding the foregoing, Sponsor’s obligation to reimburse Institution will not apply where such adverse reaction, illness, or injury is attributable to: (i) the negligence or misconduct of Institution, Investigator, or their respective employees and agents; (ii) failure to adhere to the Protocol (it being understood, however, that emergency medical care shall not be deemed a violation of the Protocol), other written instructions provided by Sponsor, or applicable laws, rules, guidance, or regulations by Institution, Investigator, or their respective employees and agents; or (iii) a pre-existing medical condition or underlying disease of the Subject.

*Subject Injury #1 Commentary: Base Language Considerations*

The foregoing provision is an example of relatively typical SI reimbursement language. The sponsor's primary concern is limiting their liability to only those injuries and illnesses that truly result from their study. Sponsors obviously seek to limit the scope of the reimbursement obligation to those injuries and illnesses resulting from the study device. However, it is a reasonable response to request that the obligation extend to injuries and illnesses arising from "procedures performed in accordance with the Protocol." The exceptions from the sponsor's reimbursement obligation are also fairly standard – if the institution has caused an injury or illness through our inappropriate acts, the sponsor should not be held liable for that injury/illness.
Subject Injury Library #2: Additional Restrictions

XX.1 Sponsor will reimburse Institution for reasonable and necessary medical expenses incurred by Subject(s) as a result of an illness or injury that results from the Study Device provided by Sponsor and used in compliance with the Protocol and this Agreement, or results from the performance of a Protocol-required procedure that such Subject(s) would not have undergone but for his/her participation in the Study, provided, however, that Sponsor shall not be obligated to pay Institution such expenses to the extent that the illness or injury arises out of or is caused by (a) an Institution Indemnitee’s (i) failure to comply with any applicable federal, state or local laws, regulations, or guidelines, or to conform to reasonable and prudent clinical practices, including GCPs as applicable to clinical studies for the Study Device; (ii) wrongful or negligent acts or omissions; or willful misconduct or use of the Study Device not in compliance with the Protocol and any Instructions for Use provided to Institution and Principal Investigator in writing; (iii) failure to comply with the Protocol or other reasonable written instructions provided by Sponsor or its representatives; (b) treatment rendered by Institution Indemnitees prior to the Study; or (c) such Subject’s failure to follow the instructions provided within the Protocol and required to be listed in the Informed Consent.

XX.2 In the event that it has not been demonstrated that the injury or illness in question resulted from the use of the Study Device or the performance of a Protocol-required procedure, Sponsor, in its sole discretion, may reimburse Institution for any portion of the expenses of care or treatment of any illness or injury to such Subject. Sponsor’s agreement to reimburse Institution under this Section XX.2 is being provided as reasonable consideration to Trial subjects willing to participate in the Study and does not constitute an admission of liability for any injury, which ultimately could be determined only through an adjudication process, or as a settlement or compromise of any potential future liability claim. For purposes of this Section XX.2 only, expenses for care will be reimbursed directly to Institution at no greater rate than the Institution’s Medicare rate for the items or services as specified above. The parties shall ensure that the subject injury section of the Informed Consent is consistent with Sections XX.1 and XX.2.

Subject Injury #2 Commentary: Additional Restrictions

This language provides an example of a sponsor that was more strict regarding their SI reimbursement obligation. For example, they have limited the scope of injuries and illnesses that they are liable for – where the first provision includes all injuries and illnesses arising from procedures performed in accordance with the study protocol, this provision narrows the sponsor’s obligation to only those procedures that are required by the protocol and that the subject would not have undergone but for his/her participation in the study. This is a common addition in studies which involve standard of care procedures, as the sponsors do not want to be required to pay for a procedure that the subject would have undergone even if they were not participating in the study. This is a reasonable edit and not overly concerning as there are generally other sources of payment for standard of care procedures.

Section XX.1 also includes two exceptions from the sponsor’s reimbursement obligation that are relatively unique, and which were included in this case to address particular concerns of this sponsor.

- At subsection (b) the language omits injuries and illnesses resulting from treatment received prior to the study. As this treatment would not have been performed at the direction of the sponsor or using the sponsor's investigational product, this is a reasonable exception.
Additionally, at subsection (c), the sponsor excepts injuries and illnesses resulting from the subject's failure to comply with the instructions they received via the informed consent form. Because the purpose of the SI reimbursement provision is to hold the sponsor responsible for the adverse reactions caused by its property (the investigational product and the study protocol), it is logical that the sponsor would not be expected to be financial responsible when the sponsor's property has functioned correctly, and the injury was caused by the subject's own negligence.

Section XX.2 is not common language, and is not something many institutions typically request. In this case it was offered by the sponsor and provides an opportunity for additional reimbursement. So, it was beneficial to the institution to accept.

**Subject Injury Library: Alternative Payment Option**

Should any Subject suffer an injury or illness resulting from an adverse reaction to or otherwise caused by the Study Device following its administration or use in accordance with the Protocol or the performance of any procedure required by the Protocol ("Subject Injury(ies)"), Sponsor will pay for the reasonable and necessary costs of diagnostic, therapeutic and medical treatment including hospitalization costs ("Treatment Costs") for such Subject Injury(ies). In the alternative, Sponsor may reimburse the Institution and/or Subjects for such Treatment Costs depending upon who incurred such Treatment Costs. Notwithstanding the forgoing, Sponsor will not be responsible for paying for or reimbursing Treatment Costs if (i) the Subject Injury(ies) is attributable to the negligence or misconduct of any agent or employee of the Institution or Investigator, or the failure of such persons to comply with the Protocol, (ii) the Treatment Costs arose as a result of the treatment of normal progression of the Subject's disease or injuries resulting from interventions that the Subjects would have incurred had they not participated in the Study.

**Subject Injury Commentary: Alternative Payment Option**

This language provides an alternative option for payment, whereby the sponsor may either reimburse the treating provider directly, reimburse the Institution for the cost of treatment, or reimburse the patient for the cost of treatment. This language also addresses the provision of standard of care treatments, though in this case these injuries were excluded rather than limited via the definition of "participant injury(ies)."

**Subject Injury Library: Attribution, Standard of Care Determinations and Reimbursement Rates**

Sponsor agrees to reimburse Institution for those reasonable and necessary medical expenses incurred by Clinical Trial subjects arising from or in connection with personal injury or illness that, in the reasonable judgment of Investigator following consultation with Sponsor, is the direct result of the implantable Product or a Protocol-required procedure that the patient would not have undergone but for his/her participation in the Clinical Trial (for clarity, the fusion surgery (i.e., the non-Product surgery) and associated procedures are not procedures that the patient would not have undergone but for his/her participation in the Clinical Trial) performed in accordance with the Protocol, Sponsor's reasonable written instructions, and generally-accepted standards of medical practice. Sponsor shall not be obligated to pay Institution such medical expenses to the extent that such personal injury results from any Site Indemnitee's (a) failure to comply with any applicable
federal, state or local laws, regulations, or guidelines, or to conform to reasonable and prudent clinical practices; (b) wrongful or negligent acts or omissions; or willful misconduct or use of the Product not in compliance with the Protocol; or (c) failure to comply with the Protocol, this Agreement or written instructions provided by or on behalf of Sponsor. As used in the section, the term “subject injury” does not include the natural progression of an underlying or pre-existing condition or events that would have been expected from the standard treatment using currently approved therapies for the subject’s condition. Sponsor will not provide compensation for lost wages or for any other damages, expenses or losses. Sponsor’s agreement to reimburse Institution under this Section is being provided as reasonable consideration to subjects willing to participate in the Clinical Trial and does not constitute an admission of liability for any injury, which ultimately could be determined only through an adjudication process, or as a settlement or compromise of any potential future liability claim. For purposes of this Section 14.5, expenses for care will be reimbursed at no greater rate than the Institution’s research rate for the items or services as specified above.

Subject Injury Commentary: Attribution, Standard of Care Determination and Reimbursement Rates

This provision addresses a common concern raised by sponsors – who determines whether the injury/illness was caused by the sponsor’s product/protocol and therefore is subject to this SI reimbursement obligation? Though many SI reimbursement provisions do not directly address this question, a number of institutions have experienced an argument from some sponsors that sponsors should determine the cause of the injury or illness. This is something that most institutions understandably resist as it would put the sponsor in a clear conflict of interest – i.e. they have a strong disincentive to determine that the injury/illness resulted from their product or protocol; otherwise they are financially liable for the treatment costs. This provision, which provides that the investigator will make the determination in his reasonable judgment and following consultation with the sponsor, represents a compromise. Many institutions will agree that the sponsor may have an opportunity to review the information and state their opinion, but the investigator should make the final determination as to causation using his/her medical judgment.

Additionally, this provision contains specific reference to procedures which will be considered standard of care for purposes of this reimbursement obligation. This language also goes into more detail to specify that the sponsor will be responsible only for the costs of treatment – indirect damages such as lost wages will not be included in the reimbursement obligation. The sponsor also included language explicitly specifying that their agreement to undertake the reimbursement obligation did not equate to an admission of fault for the injuries covered by the reimbursement obligation.

Finally, the last sentence of this provision also highlights another infrequent issue raised by sponsors in SI reimbursement provisions – what will the reimbursement rate be? Generally institutions benefit from avoiding establishment of a particular rate as this provides flexibility to when billing the sponsor. However, many sponsors push to specify a rate. The most common sponsor-suggested language is the Medicare rate or the lowest rate at which the institution bills for the treatment. However, many institutions counter with a higher rate by suggesting a multiplier (in the form of a percentage greater than 100%) of the Medicare rate.