A Business Plan for Research Associates, LLC

Research Associates, LLC
1234 Main St
Las Vegas, NV 89888

by

Brian Beames, MT (ASCP)
Manager, Sole Member

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School of Business Management

National University

Dr. Gurdeep Chawla

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Legal Page

Confidentiality Agreement

The undersigned reader acknowledges that the information provided by _____ in this business plan is confidential; therefore, reader agrees not to disclose it without the express written permission of _____.

It is acknowledged by reader that information to be furnished in this business plan is in all respects confidential in nature, other than information which is in the public domain through other means and that any disclosure or use of same by reader may cause serious harm or damage to _____.

Upon request, this document is to be immediately returned to _____.

_____
Signature

_____
Name (typed or printed)

_____
Date

This is a business plan. It does not imply an offering of securities (Palo Alto Software, 2010).

DISCLAIMER

Though an investor has a significant risk to lose all of his investment, this Business Plan divulges what the managers of Research Associates, LLC know about the risks, markets and status of Clinical Research. We recommend any serious party allow a professional clinical trial researcher to examine this service after signing an NDA (Stoddard, 2010).

Please note: Research Associates, LLC is required to only offer this investment opportunity to Accredited Investors. All money invested must be money that can be 100% lost. No person should invest who can be harmed in any way by losing all of their investment. There is no representation that this project will succeed and that the investor's money will ever be recovered (Stoddard, 2010).

Research Associates, LLC

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I. Executive Summary

Research Associates, LLC is a startup Clinical Research Organization (CRO) that will perform clinical trials in Las Vegas, Nevada. Clinical trials help to prepare drugs and medical products to be approved by the FDA. This company follows after a long history of clinical trial being performed throughout the world. The company will also follow all rules and regulations that have been set up through organizations such as the World Medical Association (WMA) and the International Council for Harmonization (ICH). The primary objective of the company is to be recognized locally and within the industry for the excellence, effectiveness, and efficiency in our work. This will be accomplished through aggressive patient recruitment and accuracy in our work. The company will also conduct all phases of clinical trials except the first phase and was registered in the state of Nevada as a Limited Liability Corporation (LLC) through the company Corporate Direct. Research Associates, LLC will apply for a federal trademark and will apply for a domain name to create its presence on the internet.

Research Associates, LLC is in an industry which is expected to grow. It is known that there is a demand for clinical trials in the local area due to the fact that there is competition there and that money has been made from this industry in the local area.

The team of Research Associates, LLC will initially start up with an intern, a Medical Director with an MD degree, a Clinical Research Coordinator (CRC), and a manager. Operation of the company will include things such as well kept records, security, and insurance. The company is expected to grow in the environment that it is in and will do its best in order to eliminate risk.

Research Associates, LLC will seek out sponsors looking for sites (such as Research Associates, LLC) to perform clinical trials. The company will also perform advertising

including radio, TV, newspaper, internet, and other advertising venues. It will also develop a webpage to perform various functions including advertising.

Despite the fact that there are six different competitors in the Las Vegas area, Research Associates, LLC seeks to distinguish itself from others through creating a great working environment for the workers which it is anticipated that this will in turn create an environment for great productivity.

It is anticipated that $17,000 will be needed in order start operations at Research Associates, LLC. This money will hopefully be obtained through the owners' personal money as it is the goal of Research Associates to not seek out investors in order to get the company going. This will eliminate the need for the company to get into debt which is always hard to pay off. Research Associates, LLC will seek to obtain funding directly from the customers (sponsors) themselves. Start-up money is needed in order to pay for the wages for a clinical research coordinator and for doctors in the initial stages of the company. Other start-up expenses are anticipated such as building costs and insurance.

It is expected that Research Associates, LLC will definitely succeed in its endeavors once it commences its operations.

A Business Plan for Research Associates, LLC

II. Introduction

Participating in the industry of clinical trials is good to be a part of. They are at times performed in companies called Clinical Research Organizations (CRO). Research Associates, LLC seeks to become a CRO that will perform these tasks. The purpose of goal of this business plan is to help to dictate how this company is to be run. It also seeks to capitalize on the market opportunity that exists out in the market place.

III. Industry and Market Demand

History and Evolution of the Industry

There is a long-standing history in the industry of Clinical Trials. One of the earlier times a clinical trial was performed was through James Lind.

> In 1747, he found that the addition of citrus fruits could prevent scurvy. He administered the same general diet to scurvy patients on board a British naval vessel but supplemented the diet with various additional items, such as cider, elixir vitriol, vinegar, seawater, nutmeg, and citrus fruit (oranges and lemons). In 6 days, those who had received the citrus fruit were cured. Interestingly, although the results were indisputable, Lind hesitated to recommend the widespread use of citrus fruits because they were too expensive; it took 50 years before the British Navy made lemon juice a requisite part of the seaman's diet, which was later switched to the less expensive lime juice. (International Psoriasis Council, 2016, p. 1)

However, as time went on, the methodology by which clinical trials are done today began to develop. Quoting again from the International Psoriasis Council:

> The first direct comparison of an active treatment to placebo was performed by Austin Flint in 1863. Flint administered a placebo remedy to 13 hospital inmates with rheumatic fever and compared the results to the previously described effects of an active treatment. In 12 of 13 patients, no significant differences between the placebo and active therapy were observed; in the 13th case the possibility was raised that the active treatment might have been effective in preventing the complications that had emerged (pericarditis, endocarditis, pneumonia). Prior to this investigation, outcomes from a particular

> intervention had been weighed against the natural history of untreated disease. (International Psoriasis Council, 2016, p. 1)

Eventually, the U.S. government got involved with regulation of how clinical trials were to be performed. For example:

> In 1862, President Lincoln created the Division of Chemistry, the predecessor of the FDA, as part of the new Department of Agriculture. Starting in 1867, the Division of Chemistry began investigating the corruption of agricultural commodities. Harvey Washington Wiley in his role as chief chemist expanded the investigative role of the Division of Chemistry in 1883. He was instrumental in the enactment of the Biologics Act of 1902 in response to the deaths of several children caused by contaminated smallpox vaccines and diphtheria antitoxins. This Act granted the federal government premarket approval for every biological drug and approval over the process and facility producing such drugs. He also compiled Foods and Food Adulterants, a 10-part study published from 1887 to 1902. In this study he administered varying amounts of the questionable food additives that had been in use to healthy volunteers to determine their affects on health. Based on these results and the filthy conditions described in Upton Sinclair's book, The Jungle, he unified a diverse group that included state chemists, food and drug inspectors, the General Federation of Women's Clubs, and national associations of physicians and pharmacists behind the Pure Food and Drugs Act (also known as the Wiley Act), which was signed into law by President Theodore Roosevelt on June 30, 1906. The 1906 law recognized the privately produced US Pharmacopoeia (USP, originated in 1820) and the National Formulary as the official standards for the strength, quality, and purity of drugs, and defined adulterated drugs as those that were listed in the

> USP but failed USP specifications. The law included provisions against misbranding, but they pertained only to the drug's label and not to any related advertising. The law was tested in 1910 when Dr. Johnson fought prosecution against his "Dr. Johnson's Mild Combination Treatment for Cancer" all the way to the Supreme Court. The Court agreed with Johnson, ruling that therapeutic claim is a matter of opinion. The Sherley Amendment was passed in 1912 to attempt to overcome the limitations imparted by the Supreme Court ruling, but this amendment banned only "false and fraudulent" claims, which necessitated proof of intent to deceive. Wiley resigned in 1912 amid conflict within the incumbent Taft administration. (International Psoriasis Council, 2016, p. 3)

This history of the U.S. government being involved with the regulation of clinical trials led to further developments. For example:

> In 1927, the Bureau of Chemistry was reorganized into the Food, Drug, and Insecticide Administration to oversee regulatory functions, and the Bureau of Chemistry and Soils to conduct nonregulatory research. In 1930, under an agricultural appropriation act, the name of the Food, Drug, and Insecticide Administration was shorted to the familiar "Food and Drug Administration" (FDA). (International Psoriasis Council, 2016, p. 4)

Although regulation from the U.S. government deepened, this did not eliminate the development of problems inside the clinical trial industry. A good example of this was provided from the International Psoriasis Council. Quoting from them:

> Although several other laws and litigation continued to shape the food and drugs landscape, the next significant milestone occurred on June 25, 1938, when President Franklin D. Roosevelt signed the Food, Drugs, and Cosmetic Act. A well-established pharmaceutical company released a new sulfa drug (Elixir Sulfanilamide) without testing

> the solvent (diethylene glycol) used in making the product. As a result, 107 people, mostly children, died before the product could be recalled. This episode was brandished as an example of ineffective federal control, and within months the Food, Drugs, and Cosmetic Act of 1938 was passed by Congress. This piece of legislation brought cosmetics and medical devices under the control of the FDA, mandating premarket approval of all new drugs, prohibiting false therapeutic claims, overseeing food packaging and quality, mandating legally enforceable food standards, authorizing factory inspections, and adding injunctions to the agency's enforcement tools. (International Psoriasis Council, 2016, p. 4)

In addition to the United States' creation of the influential Food and Drug Administration (FDA), other countries have developed similar agencies with the similar goal to regulate the pharmaceutical industry including clinical trials. Two such agencies include "the European Medicines Agency (EMEA) and Japan's Pharmaceuticals and Medical Devices Agency (PMDA)." (International Psoriasis Council, 2016, p. 2)

Additionally, in June 1964 the World Medical Association (WMA) established guidelines and principles that are to be used when performing medical research involving human subjects in an ethical manner. These guidelines were called the Declaration of Helsinki. Some of these principles include "a physician shall act in the patient's best interest when providing medical care" (World Medical Association, 2008, p. 1) and "the health of my patient will be my first consideration" (World Medical Association, 2008, p. 1). There have been several amendments to the Declaration of Helsinki since that time.

In 1990, the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) was created at a conference. Before this Council was

created, pharmaceutical companies had to take a pharmaceutical through the regulations for several countries in order to market internationally. These companies had to fulfill the particular regulations for each individual country they wished to take part in. This created duplication of testing for one product to be approved in several different countries. This conference streamlined those procedures and created one unified process to approve pharmaceutical drugs on an international level to avoid the duplication of work (International Council for Harmonisation, 2016).

Size of the Industry and Where the Industry Is Expected To Be In 5 or 10 Years

One fact that shows that clinical trials has grown in the last 30 years is that the number of physicians involved in clinical trial "studies climbed from 4,000 in 1990 to a staggering 20,250 in 2010" (Perry, 2012).

In addition to this, the industry is expected to grow going into the future. According to Sapna Rani, of the Clinical Leader:

> The global CRO market in 2014 reached approximately $27 billion and is expected to grow at a [compound annual growth rate (CAGR)] of 6.6 percent to reach $32.7 billion by 2017…More than 78 percent of the global CRO market revenue comes from the clinical CRO market. The clinical CRO market reached $21.2 billion in 2014 and is expected to grow at a CAGR of 6.4 percent to reach $25.5 billion by 2017. This market growth is directly related to around 50 percent of Phase 2 through 4 activities already being outsourced by [pharmaceutical] companies…As the cost of conducting clinical trials in emerging countries is around 40 to 60 percent less than that of developed countries, the CRO market in emerging countries is growing in double digits with growth mainly driven by China which holds approximately 7 to 10 percent of the global share.

> USA and Europe hold 43 and 40 percent of the CRO market, growing only in single digits. (Rani, 2015, para. 2-3)

Also, it is expected that "in the next 5 years the clinical trials market will show a stable low growth of 2-2.5% per year" thus reaching 12% growth by 2020 (Corex, 2016, para. 2).

Barriers to Entering the Market

There are a few barriers to entering the market. One potential barrier is that it might be hard to find a Medical Director to help to aid in the performing of clinical trials. Another barrier is the ability to start the company without going into debt or taking on a loan. One factor that will lower the barrier to entry is the fact that large-scale consolidation has not occurred in the industry (Investopedia, 2016). However, competition for profits is high which does create somewhat of a barrier (Bernard, 2009).

Demand for This Target Market

The best way to determine whether or not there is demand for your product or service is through sales inside the company (Gleeson, 2016). However, since the company currently doesn't have any revenue coming in, proving there is demand for this service through this method isn't useful. Regardless, there are other ways to show there is demand for your product or service. For example, the presence of competitors in your local area is a good indicator for demand for your product or service (Gleeson, 2016). Currently, there are six different competitors in the Las Vegas metropolitan area. This shows that the demand to perform clinical trials in Las Vegas is sufficiently high to perform clinical trials there.

Total Sales in Geographic Areas of Nevada and U.S. As a Whole

According to Pharmaceutical Research and Manufacturers of America, which gave out a profile for the Biopharmaceutical Research Industry for 2015, in 2013 the estimated economic impact from industry-sponsored clinical trial sites across the United States and District of Columbia amounted to a total of $25 billion in economic activity. Of that $25 billion for 2013, $100 to $499 million of economic activity occurred in the state of Nevada (Pharmaceutical Research and Manufacturers of America, 2015). Considering the fact that the state of Nevada is sparsely populated especially in desert terrain, the majority of that income is made in high density population centers such as Las Vegas and Reno.

Total Sales Expected in 5 to 10 Years

The following data set on sales was used in a computer program called Statdisk (version 12.0.2) (Triola, 2013) to get a correlation and regression to project sales 5 and 10 years from now. The data came from figures provided below. They are as follows:

Year:	Sales:
1	1336500
2	1500000
3	1750000
4	3500000

The results from that analysis are as follows.

Sample size, n: 4
Degrees of freedom: 2

Correlation Results:
Correlation coeff, r: 0.8700699
Critical r: ±0.9499999
P-value (two-tailed): 0.12993

Regression Results:
Y= b0 + b1x:
Y Intercept, b0: 336500
Slope, b1: 674050

Total Variation: 3.000862e+12
Explained Variation: 2.271717e+12
Unexplained Variation: 7.291447e+11
Standard Error: 603798.3
Coeff of Det, R^2: 0.7570216

Therefore, utilizing the equation y = mx +b for this set of data, you get the equation:

Y=674050x +336500

If the number of year (x) is 5, then the projected sales for that time frame are $3,706,750. If the number of year (x) is 10, then the projected sales for that time frame are $7,077,000.

Percentage of Demand This Business Expects to Capture

The estimated total equity after 4 years from projections given below is about 5.3 million. If the 2013 economic activity for the state were to remain the same in the fourth year that Research Associates, LLC were to remain in business then this company would have captured 1% (5.3/499 = 0.0106) to 5.3% (5.3/100 = 0.053) of the market share.

IV. The Business

Key players in the Industry

From the history of clinical trials written above, it is clear that one of the key players in the clinical trial industry is the FDA. Additional key players are sponsors and CRO's.

Unsatisfied Need That Creates the Business Opportunity

In order for drugs and medical products are to be approved by the FDA, it first has to be determined whether they are both safe and effective. This is done through conducting clinical trials. This need helps to create business opportunities for clinical trials to be performed at Clinical Research Organizations (CRO). There are many facets in conducting these trials. They are always done by following a protocol which dictates how the clinical trials are to be done in terms of dosing and prerequisites of patients. The protocol is always written by the sponsor, a separate company that seeks to have the drug approved by the FDA. The protocol is then taken to several CRO's to perform the trial on a subset population in a local area. All sponsors and CRO's must abide by guidelines as set forth by the FDA and ICH (International Conference of Harmonization) which dictate how clinical trials are to be done. The ICH guidelines provide a more detailed account of whom does what in clinical trials and how things are to be done. These guidelines, or procedures, are provided in Appendix D of this business plan. Appendix B contains some miscellaneous guidelines and procedures that Research Associates, LLC would like to do and to perform.

Service/Product Description

A sponsor has to take the drug through various phases before the product can be approved. The descriptions of those phases are given below. Research Associates, LLC will

perform phases two, three, and four. A description of phase one was given for information purposes only.

Phase I clinical evaluation. The first testing of a new compound in human subjects, for the purpose of establishing the tolerance of healthy human subjects at different doses, defining its pharmacological effects at anticipated therapeutic levels, and studying its absorption, distribution, metabolism, and excretion patterns in humans.

Phase II clinical evaluation. This phase involves controlled clinical trials of a compound's potential usefulness and short-term risks. A relatively small number of patients, usually no more than several hundred subjects, enrolled in Phase II studies.

Phase III clinical evaluation. This phase involves the controlled and uncontrolled clinical trials of a drug's safety and effectiveness in hospital and outpatient settings. Phase III studies gather precise information on the drug's effectiveness for specific indications, determine whether the drug produces a broader range of adverse effects than those exhibited in the small study populations of Phase I and II studies, and identify the best way of administering and using the drug for the purpose intended. If the drug is approved, this information forms the basis for deciding the content of the product label. Phase III studies can involve several hundred to several thousand subjects.

Phase IV. The Phase IV clinical trial involves post market surveillance. Quoting from Centerwatch.com:

> [Phase IV clinical trials] are conducted after a drug or device has been approved for consumer sale. Pharmaceutical companies have several objectives at this stage: (1) to compare a drug with other drugs already in the market; (2) to monitor a drug's long-term effectiveness and impact on a patient's quality of life; and (3) to determine the cost-

> effectiveness of a drug therapy relative to other traditional and new therapies. Phase IV studies can result in a drug or device being taken off the market or restrictions of use could be placed on the product depending on the findings in the study. (Centerwatch.com, 2016)

Product Life Cycle

In reference to the product life cycle, Research Associates, LLC is a service company which aids in the development of biopharmaceutical products. The company does not in and of itself participate in the product life cycle of these drugs or products that are being tested through clinical trials. However, Research Associates, LLC does help out in the processes that are both necessary and preliminary to the introduction stage of the product life cycle (Product Life Cycle Stages, 2016). Therefore, this business plan should be affected very little based upon the position that Research Associates, LLC is in as pertaining to the product life cycle.

Supply Chain

The Supply Chain in the case of performing clinical trials consists of finding and recruiting patients all the way until completion of the study. This also consists of completing all necessary paperwork that is required to be done both before and after the studies.

Industry Life Cycle

According to Stan Bernard, MD from PharmExec.com, there are four phases for the industry lifecycle. Those phases are, in consecutive order, Commencement, Commercialization, Competition, and Commoditization. The U.S. pharmaceutical industry, according to Dr. Bernard, is in the Competitive stage which has been characterized by “a relatively consistent decline in sales growth over the past decade,… increasing marketing and R&D costs, more

sophisticated buyers, greater competition, and decreasing profits" (Bernard, 2009, para. 5). The effect that this position in the industry life cycle has on this business plan it will be harder to make a profit in this industry with increased competition.

Mission Statement

The mission of Research Associates, LLC is to perform clinical trials in a professional and excellent manner that aims to work for the well-being and benefit of mankind. This includes becoming a company that is developed into a system which is run independent of the owner of the company. An additional goal or objective is to be recognized on a national level as a company that is reliable to perform clinical trials.

Legal Structure

Research Associates, LLC is a privately owned limited liability corporation that is manager-managed that was incorporated on January 26, 2016. It is a start-up company formed with the aid from the company Corporate Direct. The company is currently owned by one individual. This means the business owner is the sole member of the company. This entity was chosen to grant tax advantages towards any potential investors and especially the business owner. If any investors are involved with this company then it is recommended that they not have part ownership of the company but are to be rewarded monetarily.

The legal structure of the company will start out as an LLC for tax advantages and to pay off any potential investors. The company then might migrate towards an S or C corporation so that the business owner can keep the profits.

The business owner can also choose to elect to have the business be taxed as if it were a C or S corporation by filing Form 2553. This generally should not be done until you start to hire other people.

Two states Colorado and California don't provide charging order protection for single-member LLC's. Therefore, it would be wise to have the LLC owned by more than one person even if it is owned by 1/10th of 1%.

Intellectual Property Description

The company will obtain the domain name www.researchassociates.com and will apply for the federal trademark registration of the name Research Associates, LLC. There is not the need for any copyrights or patents for this company. The company will also develop a trademark and get it approved from the U.S. government.

Board of Directors

Research Associates, LLC will not have any Board of Directors while it is registered as an LLC. However, this may change in the event that the company decides to switch to a different legal entity, more specifically an S or C Corp. This is to help to fulfill the legal requirements of that Corporation. Once that change has been made, a board of directors may be sought after along with all other associated officers that pertain to that corporation (CEO, CFO, etc.).

Initial Management and Employee Structure

A college intern will initially help out in finding and collecting a lot of information. The most important piece of information to be found is to find a willing Medical Director to aid in performing the clinical trials for the company. Other information the intern may also help to collect are office locations that the trials may possibly be performed at. The intern will initially be sought after utilizing Outlier Labs located in St. George, UT.

The Medical Director will examine the patients and must have an MD degree. It is anticipated that the Medical Director will work through a contract.

After the Medical Director has been found, Research Associates, LLC will find a qualified Clinical Research Coordinator (CRC) also known as a Clinical Research Associate (CRA).

The CRC will conduct the trials and must be certified from either the Society of Clinical Research Associates (SOCRA) or the Association of Clinical Research Professionals (ACRP) to be qualified for this job. Certification requires at least two years of clinical research experience and successful passing of a certification exam. It is anticipated that the CRC will be an employee of the company.

The manager will manage all the business aspects of the company and initially will primarily be the business owner. Payroll and accounting will be outsourced to outside companies.

Future Additions

As the company grows there will be a variety of options for growth and expansion. More CRC's may be hired to perform more studies. A secretary may be hired to perform the front office work. Another individual may be hired to perform all the advertising for the company. Another individual may be hired to perform the financial aspects of the company. More doctors may also be recruited in order to examine more patients according to their specialty. A manager may also be hired in order to manage the business portion of the company.

Location

The company will be based in the Las Vegas metropolitan area that is accessible to both doctors and patients. The building will include patient waiting areas, patient examination rooms,

and offices to accommodate personnel. The hours of operation will be normal business hours in order to be convenient to all parties involved.

Doctors will be sought out to have the clinical trials be performed at their offices that are currently in existence. This will greatly reduce the overhead cost to start the business as a location will not have to be found that specializes in providing the right environment to provide patient care. Materials will also not have to be purchased in order to perform the clinical trials. An office to perform business matters will either be done in a home or in a business complex that is designed for entrepreneurs.

Records

Well kept records are a mandatory requirement for this business and will consist of two parts. The first is the records on the business and these will be kept at the home office of the business owner. The second are the records on the individual trials. The CRC will be in charge of these records. The records will be divided up according by the study. Each patient will have their own folders to ensure medical records are kept in an orderly manner.

Security

Security is fairly minimal including typical security of a building. One important aspect of security in performing clinical trials is to ensure the lock up the drugs to ensure that unauthorized personnel do not have access to them.

Litigation

Neither the company nor management is subject to any existing or threatened litigation (Sutton, 2005).

Insurance

Insurance will be bought for several items including Workman's Compensation Fund, health insurance, and public liability and property damage coverage for any building that the trials may take part in.

Research and Development Activities

Since this company is a service company and is not seeking to develop any products, there will be no research and development activities to bring about any new products to the market place. It is the responsibility of the sponsor to bring to us the new product to be tested on human subjects.

Strengths, Weaknesses, Opportunities, and Threats

Strengths. There are several strengths to this company. One is that employees of this company will mostly be professional people. Excellent documentation will be kept as the trials will be conducted. Rules on how to conduct the trials are already established based upon the rules set forth by ICH and the Code of Federal Regulations. Therefore, the re-inventing of the wheel will not need to be done in order to figure out how to conduct the trials.

The strength is that drug companies are always motivated to produce new drugs that need to be studied and subjugated to the approval process as dictated by the FDA.

Weaknesses. A weakness is that you have to submit your advertising to an Investigational Review Board (IRB) and as such the growth of the company will be limited by the number of clinical trials that are done. This prevents this service from going viral and as such the growth of the company will be linear rather than exponential.

Another weakness is that a building would have to be found that could provide rooms where patients can be seen. This would create additional upfront costs to start the business. The

company is limited on the number of trials that can be performed due to the number of employees on staff.

The business owner lacks business ownership experience or track record of results. This can be overcome by creating an advisory board of seasoned entrepreneurs who are committed to guiding you through the inevitable ups and downs of a start-up business. This is a common weakness among new businesses.

Opportunities. A prominent factor as to why there is such an opportunity for the existence of this company is that expiration of patents on drugs occurs on a frequent basis. Consequently, drug companies seek out new drugs to gain rights on a patent. On occasion, innovative new drugs are developed due to new discoveries that are made. As these drugs are being developed trials will need to be performed to determine the safety and efficacy of these drugs.

A large city is an important factor for doing clinical research to enable you to get a large patient base as different diseases occur at different frequencies per capita. Finding these patients is crucial in order to complete the various studies. Sponsors that desire to have the studies done are found on the national level. Therefore local considerations are inconsequential in regards to the sponsors.

Threats. A threat to the company is that new legislation can be passed by the government negatively affecting the market of the drug industry. The seriousness of this threat is about average. It is highly unlikely that laws will be changed that will affect the testing of drugs ensuring the safety for the public. However, laws changing the healthcare industry as a whole remain uncertain at this time.

Factors in the Macro-Environment

There are factors in the macro-environment which affects both this business and this business plan. These factors include the demographic environment, economic environment, natural forces, technological forces, political forces, and social and cultural forces (Ahmed, 2014). The demographic environment has to be such that the population is high enough to support clinical trials. Diseases usually have rates of occurrence. For example, the diabetes may occur in 1 of 200 people (theoretically speaking). Therefore, large population centers are needed so that study participants can be found. This is why you find CRO's in fairly large cities and is the reason why Research Associates, LLC chose Las Vegas to perform the clinical trials. Clinical trials are subject to economic environment factors. It is anticipated that clinical trials will thrive during times of economic downturn. This is because the overall healthcare industry does fairly well because people always get sick whether or not the economy is booming or busting. In addition to this, in times of economic downturn, people may seek for sources of income such as clinical trials due to their inability to find jobs. The only major natural forces which would affect Research Associates, LLC may possibly be drought. Hurricanes, tornados, and earthquakes are fairly infrequent in the area. The reason why severe drought may affect the business is because drought may, in severe cases, drive out the population in the Las Vegas area. However, the risk of this is low due to the excellent reservoir systems of the Colorado River drainage system. Technological forces which would affect Research Associates, LLC are cyber-security risks such as hack attacks, phishing, and identity theft. However, computer software such as antivirus and identity theft protection services can help to reduce the risk of these occurrences. A political force which may affect this business is legislation that affects the clinical trial industry as a whole. An additional political force could be that individuals may

wish to take boycotts or threaten lawsuits against the business owner due to the political leanings of the business owner. Social and cultural forces which affect this business could possibly be riots that occur outside on the streets. There could also be shootings that occur inside the business due to a disgruntled worker. The frequency of these events is low. In addition to this, the business can also carry protection in times of rare need. It is anticipated that other cultural factors will not affect this business.

Risk Factors

The business to be operated is speculative and involves a number of significant risks (Sutton, 2005). You should carefully consider the following factors before making an investment decision (Sutton, 2005).

> This Business Plan contains forward-looking statements and information that is based on our beliefs as well as assumptions make from information currently available to us. When used in this Business Plan, words such as "anticipate, ""believe," " estimate," "expect," and, depending on the context, "will," "intends" and similar expressions, are intended to identify forward-looking statements. Such statements reflect our current assumptions with respect to future events and are subject to certain risks, uncertainties, and further assumptions, including the specific risk factors described herein. If one or more of these risks or uncertainties materialize, or if underlying assumptions prove incorrect, our actual results may vary materially from those anticipated, believed, estimated or expected. (Sutton, 2005)
>
> **Loss control. [**Research Associates, LLC] will seek to minimize loss. This will be accomplished by utilizing the review of accountants and lawyers when needed of critical documents (such as this business plan) to bring to attention any possible areas of the

business which may cause trouble. When these troubles arise, Research Associates, LLC will address them to minimize any potential loss. (Sutton, 2005)

Retention of personnel. Research Associates, LLC will seek to keep the retention of personnel through competitive compensation. Research Associates, LLC will also seek to establish a positive work environment by seeking out both professionals and advice from the Studer Group which specialize in principles to aid in that goal.

New venture. Our team does have experience. However, we are a new entity and are advancing into an entirely new venture for our management team. Our success will depend in part on our ability to deal with the problems, expenses and delays frequently associated with establishing a new business venture, as well as some problems that are specific to the clinical research industry. General economic conditions, including employment levels, economic activity in our business area, and other general economic factors may affect the value of an investment in us. It is impossible to predict with any certainty the economic outlook or future of our business or the national economy as a whole. (Sutton, 2005)

Limited operating history. We were incorporated on January 26, 2016.

To date we have been in the preliminary planning stages of our business and have not yet conducted any active business operations. This means that our operating history is minimal, and it will be difficult for you to evaluate our business and future prospects. In your evaluation, you must consider the risks, expenses and difficulties that we will face and that are frequently encountered by new companies, as well as special considerations that we will face operating a business. (Sutton, 2005)

To address these risks we must, among other things, raise enough money to fully fund our business. We need and must attract highly skilled and experienced personnel to help us manage and operate the business. We can make no assurances that we will be successful in addressing these risks, and the failure to meet these challenges could have a material adverse effect on us. (Sutton, 2005)

Dependence upon offering. The development of a business is capital intensive. Because we are a developing business, we have no immediate sources of revenue and have only a limited amount of working capital. We intend to use the monies raised under the Offering as working capital to complete the preliminary business activities set out in "Use of Funds." However, we can make no assurance that all or enough of the Units will be sold to meet our projected costs. Even if all of the Units are sold, we may still need to raise additional capital to fund our business. (Sutton, 2005)

Reliance upon officers, directors, and key personnel. We are largely dependent on the efforts of Brian Beames, Manager to bring our project to fruition (Sutton, 2005).

Management strategy. We will be required to adjust our management levels, operations and human resources, and work closely with third parties to manage costs. Our operating results could be materially and adversely affected if we are not able to manage our resources through various periods of growth and contraction. We cannot guarantee that our management systems and controls will be adequate in the future to respond to changing industry conditions. (Sutton, 2005)

Non-registered securities; no public market; liquidity. We are a privately held entity and our shares are not traded on any exchange or bulletin board. There is not current public market for the shares and we do not know if such a market will develop. The

> shares have not been registered under the Securities Act or under any state securities law in reliance upon certain exemptions provided in such laws. The shares cannot be resold in any state unless they are subsequently registered or unless an exemption from registration is available. There is no definite plan to register the shares in the future and you will have no right to require us to make such a registration. Consequently, you may not be able to liquidate your investment in us and may be required to hold your shares for an infinite period of time. Accordingly, investing in our stock is not suitable if you need investment liquidity. (Sutton, 2005)

Restriction on transfer; right of first refusal. In addition to requiring an exemption under securities laws, additional transfer restrictions will apply. The shares must be acquired for investment only and not with a present view to resale or other distribution (Sutton, 2005).

> **No guaranteed distributions.** There can be no assurance that we will make cash distributions. Failure to make cash distributions could result if we fail to achieve our projected results of operations. Distributions will be made only from our net profits, if there are net profits available to distribute. (Sutton, 2005)

Arbitrary offering price. The purchase price for the Units was arbitrarily set by our Founders. It is not based on earnings, operating history assets, book value or any other recognized valuation method (Sutton, 2005).

Because our shares are not publicly traded, we cannot tell what the future value of the shares will be (Sutton, 2005). The value of our shares will continue to be subject to our discretionary determination in accordance with what we expect to be a reasonable value (Sutton, 2005).

Projections. We have prepared financial projections that are contained within this Business Plan. While these projections were prepared by us and a qualified third party, they have not been reviewed by any accountants or auditors. We make no guarantees at all with respect to the accuracy and forecasting ability of our projections. (Sutton, 2005)

Control by the officers and directors. Management of our business affairs is vested in our officers and directors. Shareholders, as defined in our bylaws, are entitled to vote only upon certain issues. Accordingly, our officers and directors have and will continue to have significant control over our business operations. As well, our officers and directors will own a majority of the shares, meaning they will continue to control the company's management in the future. (Sutton, 2005)

Tax risks. We have not sought any ruling from the Internal Revenue Service or obtained an opinion of counsel in regard to any tax matters. Each investor should satisfy himself as to the tax consequences of his or her investment in the shares. Prospective investors are urged to consult their tax advisors before investing in the shares and to take into account the cost of obtaining any necessary tax advice in evaluating their potential investment. (Sutton, 2005).

V. Marketing

Markets

The market for this service will be good due to ever increasing demand for new medicines and medical products which sponsors must pay clinical research companies to perform in order for these products to be approved.

Target Market

The target market for Research Associates, LLC is to seek out sponsors who seek sights such as Research Associates, LLC to perform their clinical trials to have their products approved by the FDA. It should be beneficial for Research Associates, LLC to seek out as many sponsors as possible in order to increase the revenue for the company. Once these sponsors have been found and it is mutually agreed upon that trials will be performed at our site, it will be necessary to find patients that fit the criterion set forth by the study protocol. These patients are found by performing advertising approved by an Institutional Review Board (IRB). Getting recognized on a local and a national level from sponsors is very important.

In addition to performing advertising that is approved by the IRB, advertising for the company on very general terms will also be performed including newspaper and radio advertisements. More details on how much attention is to be paid to each of these facets is provided in the financial section of this business plan.

In order to recruit more studies to be done by the staff, sponsors will be sought out in order to find more studies to be performed.

It is anticipated that the number of clinical trials performed will start at about 1-2 trials in the first year. It is also anticipated that the number of clinical trials performed will be increased

by one or two every subsequent year as the company grows and more staff are hired to perform the trials. It is anticipated that each trial will bring in about $70,000 per trial.

One task which will be performed at the company is that when potential patients come in for a specific trial we will ask them to voluntarily fill out a form asking them trials that they may potentially be interested in. This information would then be transferred into a database so that when a new trial does come along we already have a potential list of patients that may be interested in participating in the new trial.

Marketing Strategies

Marketing for a specific trial will be done in accordance with standards set forth by ICH and the code of federal regulations (21 CFR Part 56). Consequently, all patient recruitment advertisement for the trial must be approved by the Institutional Review Board (IRB) for approval. Once approved, advertising will be performed according to the guidelines set forth by the IRB.

Advertising will also be performed in which the advertisement will speak of the trials being performed in a general sense. For example, the advertisement will mention that the company is performing studies in diabetes, cancer, and other health related matters but will not speak of the studies specifically. These advertisements do not need to be approved by the IRB.

Advertisement media for both these types of advertising will include radio, TV, newspaper, internet, and other advertising venues.

Competition

The competitors in the Las Vegas metro area include: AB Clinical Trials (annual sales of $180,000), Nevada Cancer Institute, Steljes Cardiology Research Center, Clinical Research Center of Nevada, Nevada Alliance Against Diabetes, and Radiant Research - Las Vegas.

Keeping a competitive edge is accomplished by finding more research subjects than another company if that company is performing the same study. It is also accomplished by performing a wide variety of studies. The company also seeks to increase the number of trials that will be performed and to recruit a large number of patients in order to conduct the trials.

Distinctive Core Competencies

In some ways Research Associates, LLC is similar to other CRO's in that they have to follow proper procedures in how clinical trials are done. These procedures are the ones set forth by the International Committee of Harmonization. However, one thing that Research Associates aims to do to separate itself from other CRO's is to develop a working environment that is very healthy to work in. This will be accomplished by following the advice found from the Studer group. Research Associates will also seek to separate itself from other companies in that it will follow the principles of Lean Six Sigma.

Competition Strengths and Weaknesses

A strength that the competitors of Research Associates, LLC have is that their businesses is in full operation and does not have to go through the troubles of start-up procedures. Another strength that they have is that they may be larger and thus able to perform a wide range of clinical trials that can be performed at a start-up CRO

The weaknesses of the competitors of Research Associates, LLC is simply not known but may include things such as ineffective managers and a poor working environment. It is important to emphasize that all sites that perform the same clinical trial have to obey the same procedures in order to make the trials effective.

Distribution and Sales

Nothing should be sold to the patients in order to prevent a conflict of interest. Patients may be reimbursed financially for their volunteer efforts to participate in the study as established by the study protocol. Consequently, it is important to treat the patients very well in order to create an environment where future participation won't be discouraged.

Website Plan/HTML Text

The website will give basic information on the company such as location, employees within the organization, and current studies that the company is either performing or will perform. The website will be up and running once the studies start. The website may also have a questionnaire that will inform potential participants if they are eligible for a clinical trial. The website will be created through Intuit company services and as mentioned above, will aim to have the domain name of www.researchassociates.com.

VI. Financials

This is a high risk project. This plan is Research Associates, LLC best assessment, but every investor must determine if these are accurate, if there are more risks, and assess the risk-reward profile (Stoddard, 2010).

Warning and Disclaimers on All Representations

The foregoing and preceding materials do not constitute an offer by Research Associates, LLC to sell, or a solicitation of an offer to buy, any securities of the company (Stoddard, 2010).

Any securities of the company shall be offered if at all only upon the completion of definitive documentation regarding, among other things, the purchaser's suitability and status as an accredited investor, and typical and customary purchase documentation for investments in emerging technology companies (Stoddard, 2010).

> This foregoing and preceding materials contain "forward-looking statements," these statements can be identified by introductory words such as "believes," "may," "should," "anticipates," "expects," "plans," "will," "estimates," "forecasts," "projects," or words similar in meaning, and by the fact that they do not relate strictly to historical or current facts. (Stoddard, 2010)
>
> Forward looking statements frequently are used in discussing research associates' growth strategy, operating and financial goals and development programs. Many factors may cause actual results to differ from the company's forward-looking statements, including inaccurate assumptions and a broad variety of risks and uncertainties, some of which are known and others which are not (Stoddard, 2010).

No forward-looking statement is a guarantee of future research associates' results or events, and one should avoid placing undue reliance on such statements (Stoddard, 2010). These

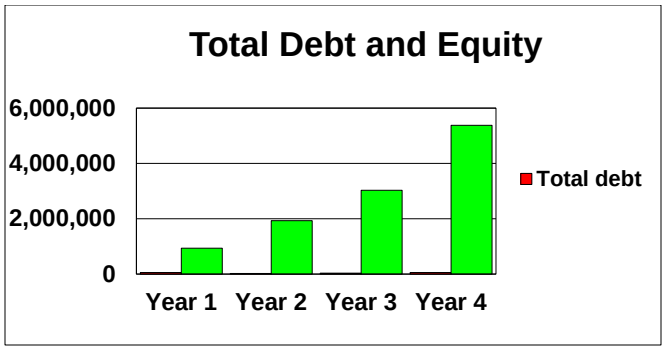
forward-looking statements are based on current expectations, and research associates' assumes no obligations to update this information (Stoddard, 2010).

Due to our ongoing business operations, the numbers shown in our financial projections may vary as we refine projections from reality (Stoddard, 2010). An exact match between figures of the 5 Year P&L and the full Financial Model is desired and should be similar (Stoddard, 2010).

Exhibit A: Projected Balance Sheets (four years)

Exhibit A
Research Associates, LLC
PROJECTED BALANCE SHEETS

	Year 1 Per Sched. A-1	Year 2	Year 3	Year 4
Cash (per Cash Flow)	967,097	1,956,503	3,060,108	5,438,462
Accounts receivable	0	0	0	0
Inventory	19,800	0	0	0
Total Current Assets	986,897	1,956,503	3,060,108	5,438,462
	0			
Office Equipment	0	0	0	0
Other depreciable assets	0	0	0	0
Other depreciable assets	0	0	0	0
Less: accumulated deprec	0	0	0	0
Total Assets	986,897	1,956,503	3,060,108	5,438,462
Accounts & expense payable	55,000	25,000	29,167	58,333
Short-term loans (Cash Fl)	0	0	0	0
Long-term liab. (Cash Flow)	0	0	0	0
Total liabilities	55,000	25,000	29,167	58,333
Paid-in capital (Cash Flow)	17,745	17,745	17,745	17,745
Retained earnings at beginning of year	0	914,152	1,913,758	3,013,196
Net profit - current year	914,152	999,606	1,099,438	2,349,188
Total equity	931,897	1,931,503	3,030,941	5,380,129
Total liabilities and equity	986,897	1,956,503	3,060,108	5,438,462
	-	-	-	-
	-	-	-	-



Schedule A-1: Balance Sheet First Year

Schedule A-1
Research Associates, LLC
PROJECTED BALANCE SHEET - FIRST YEAR

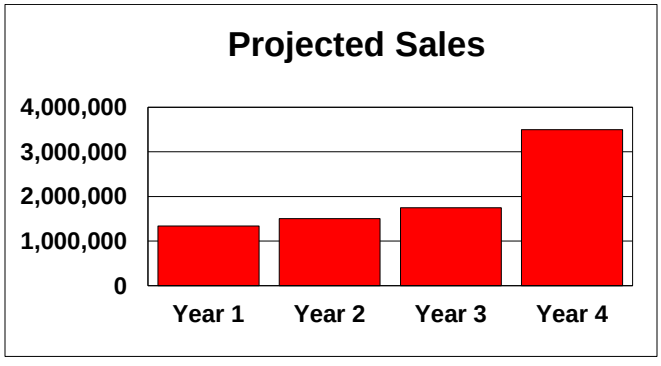
	Beginning Balances	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Cash (per Cash Flow)	745	1,782	8,782	25,918	55,710	92,382	149,520	228,333	328,321	449,584	592,021	755,634	967,097
Accounts receivable		0	0	0	0	0	0	0	0	0	0	0	0
Inventory		19,800	19,800	19,800	19,800	19,800	19,800	19,800	19,800	19,800	19,800	19,800	19,800
Other current assets													
Total Current Assets	745	21,582	28,582	45,719	75,510	112,182	169,320	248,133	348,121	469,384	611,821	775,434	986,897
Office Equipment		0	0	0	0	0	0	0	0	0	0	0	0
Other depreciable assets		0	0	0	0	0	0	0	0	0	0	0	0
Other depreciable assets		0	0	0	0	0	0	0	0	0	0	0	0
Less: accumulated deprec		0	0	0	0	0	0	0	0	0	0	0	0
Total Assets	745	21,582	28,582	45,719	75,510	112,182	169,320	248,133	348,121	469,384	611,821	775,434	986,897
Accounts & expense payable		2,200	3,300	5,500	8,800	11,000	16,500	22,000	27,500	33,000	38,500	44,000	55,000
Short-term loans (Cash Fl)		0	0	0	0	0	0	0	0	0	0	0	0
Long-term liab. (Cash Flow)		0	0	0	0	0	0	0	0	0	0	0	0
Total liabilities	-	2,200	3,300	5,500	8,800	11,000	16,500	22,000	27,500	33,000	38,500	44,000	55,000
Paid-in capital (Cash Flow)	745	17,745	17,745	17,745	17,745	17,745	17,745	17,745	17,745	17,745	17,745	17,745	17,745
Retained earnings at beginning of year		0	0	0	0	0	0	0	0	0	0	0	0
Net profit - current year		1,637	7,537	22,474	48,965	83,437	135,075	208,388	302,876	418,639	555,576	713,689	914,152
Total equity	745	19,382	25,282	40,219	66,710	101,182	152,820	226,133	320,621	436,384	573,321	731,434	931,897
Total liabilities & equity	745	21,582	28,582	45,719	75,510	112,182	169,320	248,133	348,121	469,384	611,821	775,434	986,897
	-	-	-	-	-	-	-	-	-	-	-	-	-

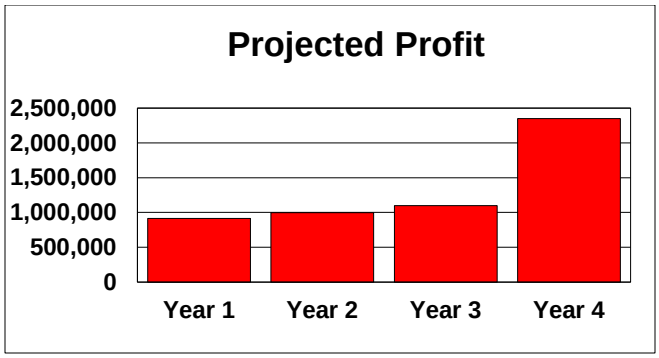
There are no major purchases of useful assets for the businesses. If there are any major purchases necessary in order to carry out the clinical trials they shall be purchased from the sponsor. In the event a depreciable asset is obtained the depreciable rate will be obtained from a reliable source and then figured into the expenses. A good depreciable rate may possibly be 20%.

Exhibit B: Projected Income Statements (four years)

Exhibit B
Research Associates, LLC
PROJECTED INCOME STATEMENTS

	Year 1	%	Year 2	%	Year 3	%	Year 4	%
	Per Sched. B-1							
Sales	1,336,500	100.0%	1,500,000	100.0%	1,750,000	100.0%	3,500,000	100.0%
Cost of sales (Sched. B-3)	267,300	20.0%	300,000	20.0%	350,000	20.0%	700,000	20.0%
Gross Profit	1,069,200	80.0%	1,200,000	80.0%	1,400,000	80.0%	2,800,000	80.0%
Operating expenses:								
Officers salaries	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Other payroll (Sched. B-5)	71,564	5.4%	107,346	7.2%	161,019	9.2%	241,529	6.9%
Payroll taxes	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Employee benefits	21,684	1.6%	32,526	2.2%	48,789	2.8%	73,183	2.1%
Advertising (Sched. B-6)	40,295	3.0%	40,295	2.7%	60,443	3.5%	90,664	2.6%
Commissions	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Depreciation	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Insurance - liability	1,800	0.1%	2,700	0.2%	4,050	0.2%	6,075	0.2%
Insurance - casualty	2,400	0.2%	3,600	0.2%	5,400	0.3%	8,100	0.2%
Legal and accounting	1,945	0.1%	2,918	0.2%	4,376	0.3%	6,564	0.2%
Rent	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Supplies	7,300	0.5%	10,950	0.7%	16,425	0.9%	24,638	0.7%
Telephone	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Utilities	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Website	60	0.0%	60	0.0%	60	0.0%	60	0.0%
Start-up costs/ttc-llc	8,000	0.6%	0	0.0%	0	0.0%	0	0.0%
Total operating expenses	155,048	11.6%	200,394	13.4%	300,562	17.2%	450,812	12.9%
Profit before interest and taxes	914,152	68.4%	999,606	66.6%	1,099,438	62.8%	2,349,188	67.1%
Less: Interest expense	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Profit before taxes	914,152	68.4%	999,606	66.6%	1,099,438	62.8%	2,349,188	67.1%
Less: income taxes	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Net profit	**914,152**	**68.4%**	**999,606**	**66.6%**	**1,099,438**	**62.8%**	**2,349,188**	**67.1%**
Sales needed to break even [Fixed expenses / contribution margin ratio]	193,810		250,493		375,702		563,515	





Schedule B-1: Income Statement - First Year

Schedule B-1
Research Associates, LLC
PROJECTED INCOME STATEMENT - FIRST YEAR

	Total	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Sales (per Sched. B-2)	1,336,500	11,000	16,500	27,500	44,000	55,000	82,500	110,000	137,500	165,000	192,500	220,000	275,000
Cost of sales (Sched. B-3)	267,300	2,200	3,300	5,500	8,800	11,000	16,500	22,000	27,500	33,000	38,500	44,000	55,000
Gross Profit	1,069,200	8,800	13,200	22,000	35,200	44,000	66,000	88,000	110,000	132,000	154,000	176,000	220,000
Gross Profit %	80.0%	80.0%	80.0%	80.0%	80.0%	80.0%	80.0%	80.0%	80.0%	80.0%	80.0%	80.0%	80.0%
Operating expenses:													
Officers salaries	0	0	0	0	0	0	0	0	0	0	0	0	0
Other payroll (Sched. B-5)	71,564	1,100	1,650	2,750	4,400	5,083	8,083	8,083	8,083	8,083	8,083	8,083	8,083
Payroll taxes 0%	0	0	0	0	0	0	0	0	0	0	0	0	0
Employee benefits 30%	21,684	333	500	833	1,333	1,540	2,449	2,449	2,449	2,449	2,449	2,449	2,449
Advertising (Sched. B-6)	40,295	330	495	825	1,320	1,650	2,675	3,300	4,125	4,950	5,775	6,600	8,250
Commissions 0%	0	0	0	0	0	0	0	0	0	0	0	0	0
Depreciation	0	0	0	0	0	0	0	0	0	0	0	0	0
Insurance - liability	1,800	150	150	150	150	150	150	150	150	150	150	150	150
Insurance - casualty	2,400	200	200	200	200	200	200	200	200	200	200	200	200
Legal and accounting	1,945	845	100	100	100	100	100	100	100	100	100	100	100
Rent	0	0	0	0	0	0	0	0	0	0	0	0	0
Supplies	7,300	2,000	2,000	1,000	500	500	500	200	200	100	100	100	100
Telephone	0	0	0	0	0	0	0	0	0	0	0	0	0
Utilities	0	0	0	0	0	0	0	0	0	0	0	0	0
Website	60	5	5	5	5	5	5	5	5	5	5	5	5
Start-up costs/ttc-llc	8,000	2,200	2,200	1,200	700	300	200	200	200	200	200	200	200
Total operating expenses	155,048	7,163	7,300	7,063	8,708	9,528	14,362	14,687	15,512	16,237	17,062	17,887	19,537
Profit before interest and taxes	914,152	1,637	5,900	14,937	26,492	34,472	51,638	73,313	94,488	115,763	136,938	158,113	200,463
Less: Interest expense	0	0	0	0	0	0	0	0	0	0	0	0	0
Profit before taxes	914,152	1,637	5,900	14,937	26,492	34,472	51,638	73,313	94,488	115,763	136,938	158,113	200,463
Less: income taxes 0%	0												0
Net profit	914,152	1,637	5,900	14,937	26,492	34,472	51,638	73,313	94,488	115,763	136,938	158,113	200,463
Net profit %	68.4%	14.9%	35.8%	54.3%	60.2%	62.7%	62.6%	66.6%	68.7%	70.2%	71.1%	71.9%	72.9%

Research Associates, LLC will try to find doctor's offices that are already in existence and the doctor's are already doing other patient care as their main source of income. This is why the rent is set at $0. Telephone and utilities are also $0 since those services are already in place through the doctor's offices.

Since there are currently no other officer's that is a part of Research Associates, LLC, there will be no officer payments. All profits of the business will go towards the business owner.

Since the company is a service company the sales commission rate is 0. Nevada doesn't have any payroll or income tax withholding (Sure Pay Roll, 2016) due to the gambling that occurs in the state. They employee benefits rate on gross wages is 30.3 (United States Department of Labor, 2016) (Employee Benefit Research Institute, 2016).

Research Associates, LLC is not planning on utilizing loans in order to finance their activities. This is under the premise that interest rates are an unnecessary cost to the business. Therefore, the interest rate to payback any long-term or short-term interest rates is 0 for this business plan. However, in the event that Research Associates, LLC does take on debt the goal will be to get the lowest rate possible.

Schedule B-2: Sales Forecast - First Year

Schedule B-2
Research Associates, LLC
SALES FORECAST - FIRST YEAR

	Year 1 Total	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Unit Sales													
1 patient	243	2	3	5	8	10	15	20	25	30	35	40	50
-	-												
-	-												
-	-												
-	-												
-	-												
Unit Prices [from "Assumptions"]													
1 patient	-	5,500.00	5500.00	5500.00	5500.00	5500.00	5500.00	5500.00	5500.00	5500.00	5500.00	5500.00	5500.00
-	-	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
-	-	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
-	-	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
-	-	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
-	-	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Total Sales													
1 patient	$ 1,336,500	11,000	16,500	27,500	44,000	55,000	82,500	110,000	137,500	165,000	192,500	220,000	275,000
-	-												
-	-												
-	-												
-	-												
-	-												
Totals	$1,336,500	11,000	16,500	27,500	44,000	55,000	82,500	110,000	137,500	165,000	192,500	220,000	275,000

The amount of money a site receives per patient varies due to therapeutic area, phase of development, country, advertising, time, and electronic data capture. On average they receive about $5500 per patient (Gray, 2016) and include both direct and indirect costs. Direct costs are costs directly associated with performing the clinical trial whereas indirect costs accounts for overhead (Yoo, HyeJong; AstraZeneca, 2011).

Schedule B-3: Cost of Goods/Services - First Year

Schedule B-3
Research Associates, LLC
COST OF GOODS/SERVICES

	Year 1 Total	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Unit Sales [from Sales Forecast Sched B-2]													
1 patient	243	2	3	5	8	10	15	20	25	30	35	40	50
-	0	0	0	0	0	0	0	0	0	0	0	0	0
-	0	0	0	0	0	0	0	0	0	0	0	0	0
-	0	0	0	0	0	0	0	0	0	0	0	0	0
-	0	0	0	0	0	0	0	0	0	0	0	0	0
-	0	0	0	0	0	0	0	0	0	0	0	0	0
Unit Cost [from Costing Sched B-4]													
1 patient	$1,100.00	$1,100.00	$1,100.00	$1,100.00	$1,100.00	$1,100.00	$1,100.00	$1,100.00	$1,100.00	$1,100.00	$1,100.00	$1,100.00	$1,100.00
-	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
-	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
-	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
-	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
-	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Total Cost [calculated]													
1 patient	$267,300	2,200	3,300	5,500	8,800	11,000	16,500	22,000	27,500	33,000	38,500	44,000	55,000
-	0	0	0	0	0	0	0	0	0	0	0	0	0
-	0	0	0	0	0	0	0	0	0	0	0	0	0
-	0	0	0	0	0	0	0	0	0	0	0	0	0
-	0	0	0	0	0	0	0	0	0	0	0	0	0
-	0	0	0	0	0	0	0	0	0	0	0	0	0
Totals	$267,300	2200	3300	5500	8800	11000	16500	22000	27500	33000	38500	44000	55000

Schedule B-4: Costing of Goods or Services

Schedule B-4
Research Associates, LLC
COSTING OF GOODS OR SERVICES

	1 patient	-	-	-	-	-
Unit Price [from "Assumptions"]	$5,500.00	$0.00	$0.00	$0.00	$0.00	$0.00
Unit Costs, if applicable:						
Payment of Medical Director or Doctor	1,100.00					
Total variable cost per unit	**$1,100.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**
Gross profit per unit	$4,400.00	$0.00	$0.00	$0.00	$0.00	$0.00
Gross profit margin %	80.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Achievable Gross Profit Margin %						

The way that the Medical Director (or the physician) will be compensated is through the fee-for-service compensation model. This model incentivizes physicians to find multiple patients, incentivizes them to provide additional treatments, and enhances productivity (Dr. Christiansen, 2014). Due to this payment model, the cost to pay the physician falls under a unit per patient cost and is part of the costing of goods or services schedule. However, the payment of the Medical Director shall not exceed the typical wage of physicians. As of February 22, 2016 the median annual Generalist Physician salary is $188,223, with a range usually between $162,939 - $210,554 (Salary.com, 2016). Currently, Research Associates, LLC has 20% if income per patient going towards the payment of the Medical Director.

There are two types of costs associated with a clinical trial. The first is that there are patient care costs which "include doctor visits, hospital stays, clinical laboratory tests, x-rays, and any other medical costs that occur regardless of whether a patient is participating in a clinical

trial or receiving standard treatment" (The University of New Mexico, 2016). Research Associates, LLC will not have to cover those costs because these costs are usually covered by third party private health insurance (The University of New Mexico, 2016). The second costs associated with clinical trials are research costs "such as data collection and management, research physician and nurse time, analysis of results, and tests performed purely for research purposes (The University of New Mexico, 2016). Research Associates, LLC will not have to pay for these costs as these are usually paid for by the sponsor (The University of New Mexico, 2016). Since these costs are already accounted for from other sources the costing of goods or services (besides the payment of the Medical Director) is 0.

Schedule B-5: Payroll Expense - First Year

Schedule B-5
Research Associates, LLC
PROJECTED PAYROLL - FIRST YEAR

	Total	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
A - Number of persons in each category (excluding Officers and Owner/Managers)													
Secretary							1	1	1	1	1	1	1
CRC		1	1	1	1	1	1	1	1	1	1	1	1
B - Average monthly gross pay per person													
Secretary		3,000	3,000	3,000	3,000	3,000	3,000	3,000	3,000	3,000	3,000	3,000	3,000
CRC		1,100	1,650	2,750	4,400	5,083	5,083	5,083	5,083	5,083	5,083	5,083	5,083
C - Total (A times B)													
Secretary	$21,000	0	0	0	0	0	3,000	3,000	3,000	3,000	3,000	3,000	3,000
CRC	50,564	1,100	1,650	2,750	4,400	5,083	5,083	5,083	5,083	5,083	5,083	5,083	5,083
	0	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0	0	0
	$71,564	**1,100**	**1,650**	**2,750**	**4,400**	**5,083**	**8,083**	**8,083**	**8,083**	**8,083**	**8,083**	**8,083**	**8,083**
D - Less: any direct labor cost already included on the "Costing" Schedule B-4 (use Minus sign)													
	0	0	0	0	0	0	0	0	0	0	0	0	0
Total "Other Payroll", to Income Statement):													
	$71,564	**1,100**	**1,650**	**2,750**	**4,400**	**5,083**	**8,083**	**8,083**	**8,083**	**8,083**	**8,083**	**8,083**	**8,083**

It is the goal of Research Associates, LLC to first hire a medical director. After this the CRC will be hired and then finally, an office staff identified as a Secretary.

The payment of the CRC will be proportional of the profits until the profits reach the typical wage of the CRC. A Clinical Research Associates range of pay is $40K-$88K with a median wage of $61K (Payscale, 2016). Currently, Research Associates, LLC has 10% if income per patient going towards the payment of the CRC for the first four months of operation. At month five the CRC reaches the typical wages of a CRC and will be paid $5083 per month. Appendix A contains two diagrams that show the payment schedule of a CRC as a cost per unit cost for the entire year.

As of February 22, 2016, the median annual Secretary salary is $35,816 (rounded up to $36,000), with a range usually between $31,905-$40,382 (Salary.com, 2016). The Secretary will be hired on approximately halfway through the first year as the need for the Secretary arises.

Schedule B-6: Advertising and Promotion - First Year

Schedule B-6
Research Associates, LLC
PROJECTED ADVERTISING AND PROMOTION - FIRST YEAR

	Year 1 Total	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Newspaper	5,825	330	495	500	500	500	500	500	500	500	500	500	500
Radio	22,270	0	0	325	820	1,150	2,175	2,800	3,000	3,000	3,000	3,000	3,000
TV	0												
Trade shows	0												
IRB approved	12,200								625	1,450	2,275	3,100	4,750
Other	0												
Other	0												
Totals	$40,295	$330	$495	$825	$1,320	$1,650	$2,675	$3,300	$4,125	$4,950	$5,775	$6,600	$8,250

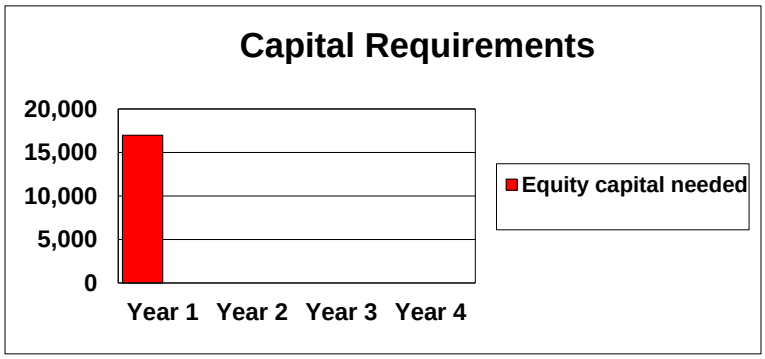
Research Associates, LLC will follow the advice of some marketing experts and will have 3% of revenue go towards marketing (Boykin, 2016). Not more than $500 will be used

towards newspaper advertisements and not more than $3000 will be used towards radio announcements. The rest will be towards IRB approved studies.

Exhibit C: Projected Cash Flows (four years)

Exhibit C
Research Associates, LLC
PROJECTED CASH FLOWS

	Year 1 Per Sched C-1	Year 2	Year 3	Year 4
Net profit [per Income Statement]	914,152	999,606	1,099,438	2,349,188
Add:				
Depreciation	0	0	0	0
Less:				
Increase in receivables (-)	(0)	0	0	0
Increase in inventory (-)	(19,800)	19,800	(0)	(0)
Add:				
Increase in accounts payable	55,000	(30,000)	4,167	29,167
Cash from operations	949,352	989,406	1,103,605	2,378,354
Cash used for investment (use MINUS sign)				
Office Equipment	0	0	0	0
Other depreciable assets	0	0	0	0
Other depreciable assets	0	0	0	0
Cash used for investing	0	0	0	0
Cash from financing activities				
Capital paid in by owners	17,000	0	0	0
Long-term borrowing (repaid)	0	0	0	0
Short-term borrowing (repaid)	0	0	0	0
Cash from financing	17,000	0	0	0
Net increase (decrease)	966,352	989,406	1,103,605	2,378,354
Cash - beginning balance	745	967,097	1,956,503	3,060,108
Cash - ending balance	967,097	1,956,503	3,060,108	5,438,462



Schedule C-1: Projected Cash Flows - First Year

Schedule C-1
Research Associates, LLC
PROJECTED CASH FLOWS - FIRST YEAR

	Total	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Net profit [per Income State.]	914,152	1,637	5,900	14,937	26,492	34,472	51,638	73,313	94,488	115,763	136,938	158,113	200,463
Add:													
Depreciation	0	0	0	0	0	0	0	0	0	0	0	0	0
Less:													
Increase in receivables (-)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
Increase in inventory (-)	(19,800)	(19,800)	0	0	0	0	0	0	0	0	0	0	0
Add:													
Increase in accounts payab	55,000	2,200	1,100	2,200	3,300	2,200	5,500	5,500	5,500	5,500	5,500	5,500	11,000
Cash from operations	949,352	(15,963)	7,000	17,137	29,792	36,672	57,138	78,813	99,988	121,263	142,438	163,613	211,463
Cash used for investment in capital assets (**use MINUS sign**)													
Office Equipment	0												
Other depreciable assets	0												
Other depreciable assets	0												
Cash used for investment	0	0	0	0	0	0	0	0	0	0	0	0	0
Cash from financing activities													
Capital paid in by owners	17,000	17,000	0	0	0	0	0	0	0	0	0	0	0
Long-term borrowing (repai	0	0	0	0	0	0	0	0	0	0	0	0	0
Short-term borrowing (repai	0	0	0	0	0	0	0	0	0	0	0	0	0
Cash from financing	17,000	17,000	0	0	0	0	0	0	0	0	0	0	0
Net increase (decrease)	966,352	1,037	7,000	17,137	29,792	36,672	57,138	78,813	99,988	121,263	142,438	163,613	211,463
Cash - beginning balance	745	745	1,782	8,782	25,918	55,710	92,382	149,520	228,333	328,321	449,584	592,021	755,634
Cash - ending balance	967,097	1,782	8,782	25,918	55,710	92,382	149,520	228,333	328,321	449,584	592,021	755,634	967,097

-

Exhibit D: Projected Financial Statement Ratios

Exhibit D
Research Associates, LLC
PROJECTED FINANCIAL STATEMENT RATIOS

Industry	Industry Average	Year 1	Year 2	Year 3	Year 4
Pharmaceutical - Clinical Research Organizations					
Profitability Ratios					
Gross Profit Margin (if applicable)	44.1%	80.0%	80.0%	80.0%	80.0%
Net Profit Margin	10.5%	68.4%	66.6%	62.8%	67.1%
Return on Assets (= ROI)	4.8%	92.6%	51.1%	35.9%	43.2%
Return on Equity	10.0%	98.1%	51.8%	36.3%	43.7%
Asset Management Ratios					
Receivables turnover		1.E+09	NA	NA	NA
Number of days to collect receivables		0.0	NA	NA	NA
Inventory turnover	5.18	13.5	1.0E+09	1.0E+09	1.0E+09
Debt Ratios					
Debt to Net Worth (Debt to Equity)	0.56	0.1	0.0	0.0	0.0
Debt to Assets		0.1	0.0	0.0	0.0
Liquidity Ratios					
Current Ratio	1.25	17.9	78.3	104.9	93.2
Quick Ratio	0.73	17.6	78.3	104.9	93.2

Projected business ratio averages by their inherent nature reflect what is anticipated to occur in the future and does not reflect what has happened in the past. This is a good explanation as to why there are significant difference between the projected business ratios for Research Associates, LLC and the industry average provided in the graphs. Another reason for the significant difference is the low use of debt in order to finance the company. Even though on the financial worksheets it shows that there is a need for $17,000 in funding to start off the company, it is the goal of Research Associates to utilize zero debt in order to start off the company. It is also the aim of the company to seek funding from their customers rather than from investors in order to fund their activities.

All industry averages were obtained from MSN (MSN, 2016). The industry averages comes from the Clinical Research Organizations classification.

Notes on Financials

The company will use the accrual method of accounting.

A contract will be bought with ttc-llc (http://www.grantplan.com/) to help with getting appropriate pay rates for performing clinical trials. Research Associates is anticipating paying $200 per month for this service.

More than 50% of total sales are for cash or credit card. Less than 50% of revenue is from sale of merchandise. In other words, there is no major inventory sold to customers in the performing of clinical trials.

Indirect Cost Rate. Indirect costs for human clinical studies and all other industry-sponsored studies are assessed at the flat rate of 30% of direct costs (Rutgers, The State University of New Jersey, 2016).

It is the policy of Research Associates, LLC to charge industry sponsors for all direct and indirect costs incurred in the conduct of industry-supported clinical trials. All potential sponsors of clinical trial programs must be informed of this policy before beginning negotiation of research project budgets that will be included in the research contract (Rutgers, The State University of New Jersey, 2016).

To calculate indirect cost when the direct costs are known, add 30% of the direct costs. The sum of these two figures is the per-patient amount (Rutgers, The State University of New Jersey, 2016).

For example: If $1,000 is needed to cover per-patient direct costs, 30% ($300) should be added for indirect, bringing the total to $1,300 per patient (Rutgers, The State University of New Jersey, 2016).

Uses of Funds

The uses of funds will initially go towards a photocopier, wages of hired employees, medical supplies, and also a building fee. It is estimated that start-up costs will be around $300,000 (including legal costs, stationary, logo design, advertising, and related expenses). Payroll will be managed through Intuit software. The company will use QuickBooks and Turbotax to handle accounting services and will seek an accountant when necessary. Intuit products will be used for Payroll, website services. The Wells Fargo Bank account that is currently in existence will serve as the place in order to perform check services.

Start-up costs will include things such as Standard Operating Procedures purchased on Centerwatch.com ($700), “Business in a Box” software ($200-$300), software to help run clinical trials such as Oracle, TurboTax (tax software) $120, QuickBooks (accounting software), photocopy machine/scanner, trademark fee $400, scanner/fax machine, Adobe software (Adobe pdf on docs), and finally, business licenses and permits (already purchased).

Recurring costs include workers compensation, payroll, materials and office supplies (binders, book cases, computers, telephones, and fixtures), rent or mortgage payments, telecommunications, maintenance, transportation and delivery, loan payments (if any), utilities, insurance, creation of website $5/month for website service by intuit, leased equipment (if any), and finally, fees to attorneys, accountants, and consultants.

VII. Conclusion and Recommendations

In conclusion, it has been determined that Research Associates, LLC is a viable business venture. Research Associates, should pursue the path under investigation. The reason for this is because there is a market in order to perform clinical trials and the probability for success for this business venture is high.

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IX. Appendices

Appendix A: Costing for Payment of Clinical Research Coordinator

Schedule B-4
Research Associates, LLC
COSTING OF GOODS OR SERVICES

	1 patient	-	-	-	-	-
Unit Price [from "Assumptions"]	$5,500.00	$0.00	$0.00	$0.00	$0.00	$0.00
Unit Costs, if applicable:						
Payment of Clinical Research Coordinator	550.00					
Total variable cost per unit	**$550.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**
Gross profit per unit	$4,950.00	$0.00	$0.00	$0.00	$0.00	$0.00
Gross profit margin %	90.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Schedule B-3
Research Associates, LLC
COST OF GOODS/SERVICES

	Year 1 Total	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Unit Sales [from Sales Forecast Sched B-2]													
1 patient	243	2	3	5	8	10	15	20	25	30	35	40	50
-	0	0	0	0	0	0	0	0	0	0	0	0	0
-	0	0	0	0	0	0	0	0	0	0	0	0	0
-	0	0	0	0	0	0	0	0	0	0	0	0	0
-	0	0	0	0	0	0	0	0	0	0	0	0	0
-	0	0	0	0	0	0	0	0	0	0	0	0	0
Unit Cost [from Costing Sched B-4]													
1 patient	$550.00	$550.00	$550.00	$550.00	$550.00	$550.00	$550.00	$550.00	$550.00	$550.00	$550.00	$550.00	$550.00
-	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
-	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
-	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
-	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
-	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Total Cost [calculated]													
1 patient	$133,650	1,100	1,650	2,750	4,400	5,500	8,250	11,000	13,750	16,500	19,250	22,000	27,500
-	0	0	0	0	0	0	0	0	0	0	0	0	0
-	0	0	0	0	0	0	0	0	0	0	0	0	0
-	0	0	0	0	0	0	0	0	0	0	0	0	0
-	0	0	0	0	0	0	0	0	0	0	0	0	0
-	0	0	0	0	0	0	0	0	0	0	0	0	0
Totals	$133,650	1100	1650	2750	4400	5500	8250	11000	13750	16500	19250	22000	27500

Appendix B: A Few Policies and Procedures

To help safeguard against litigation it is very important to follow the study protocol. If an employee does not make corrections as suggested by the study monitor then punishment will be considered including termination.

A study will not be performed within the company unless indemnification has been established before the trial begins.

In addition to ICH the company will follow the code of federal regulations including 21 CFR Part 11, 21 CFR Part 50, 21 CFR Part 54, and 21 CFR Part 56. This list is not all inclusive and includes other portions of the CFR which governs clinical trials.

The company needs to be waived by CLIA and/or CMS verifying that it will not perform laboratory tests.

The company will follow other policies and procedures that are commercially available from Centerwatch.

The company will report all clinical trials being performed to the government at clinicaltrials.gov

Research Associates, LLC would, with the approval of a lawyer, have individuals sign a form which states that this company is a right to work company and that either the employer or the employee has the option to terminate the employment at will.

Appendix C: Notes for the Business Owner

Take the research to the physician offices

Susan Lezivich is the business owner of Chrysallis that does clinical trials here in St. George.

Do a survey to some of the local doctors to find if they have an interest
Read the business plan book again after completing the business plan to the best of my ability.
Before you give out your business plan make sure that you are both registered and have your domain.
Have your legal entity in place before you register your trademark.
Departments to consider:
Franchise
Research and development
Manufacturing
Inventory, warehousing, or storage
Transportation
Purchasing
Sales
Marketing
Customer Service
Information Technology
Finances and accounting
Human resources
Facilities
Join ACRP, and then find out what software is best to use for clinical trials.
I need to use an accountant to help me out with the financial sections of my business plan.
Business plan will also be reviewed by a lawyer when everything is completed.
I need to do market research by doing it myself, hiring a consultant, or a research firm
Find entrepreneur office here in St. George
I need to have a vendor and supplier section in the business plan. I need to have a place on where I send the laboratory work, where I can get medical supplies, and other services.
I need to remain anonymous in the business plan in terms of who the owner is.
Oracle Clinical is a good place to get software in order to do clinical trials
Find out how much it costs to do contract work for a physician
You should also subject your business plan to an intellectual property attorney before you start the business.
Other sections to include in the Business Plan:
Endorsements
ROI
Appendix

I should include endorsements in the Business plan
Business plan should cover two sides of cashflow analysis: how it earns and where it spends
Get your intellectual rights before you distribute your business plan.

Key questions to answer:
What will your workforce look like
What will you costs and income be
What expansions and new technologies will you have introduced?
What will your loan balances be?
Will you have investors?
Who will be your customers?
What will your market share be?
What will your advertising and/or marketing look like and how will it be used?
What will your role be in the business?

10k annual reports of companies are a great source for entreprenueurs to get benchmark costs and strategies.

CRO Business Risks

Economic Risks
Competition
Lack of Demand

Risk factors include potential exposure to infectious disease.

Local associations:

Dixie Business Allieance's
Small business Develoopment Center

Southern Utah University's
business Resource center

SCORE

http://smallbusiness.chron.com/percentage-gross-revenue-should-used-marketing-advertising-55928.html

The U.S. Small Business Administration recommends spending 7 to 8 percent of your gross revenue for marketing and advertising if you're doing less than $5 million a year in sales and your net profit margin — after all expenses — is in the 10 percent to 12 percent range. Some marketing experts advise that start-up and small businesses usually allocate between 2 and 3 percent of revenue for marketing and advertising, and up to 20 percent if you're in a competitive industry. Still other marketing experts counsel a range between 1 percent and 10 percent, and even more depending on how long you've been in business, competitive activity and what you can afford. It's apparent from these differing opinions that the percentage of gross revenue for marketing and advertising depends mainly on whom you ask. They're probably all correct if you know their assumptions.

2 phases
Initial start up costs
Moving into office

List of expenses that I may not use but were listed in a book or somewhere else
Initial supplies and starting inventory
Software licensing fees
Installation costs for equipment and fixtures
Tenant improvements
Signage
Printing
Equipment lease payments

Look into community development companies as sources of funding

There are two types of costs that will be considered for this business. The first is start-up costs and the second is recurring costs.

Include chart on start-up costs

What relationships do you have with suppliers, support businesses, customers, advertisers, and the like?
What is your market share (your net revenues divided by the net revenues of the industry)
What resources (monetary and otherwise) do you currently have on hand for your business?
Where is the business located
Do you have plans for acquisitions or expansions
What risks do you forsee and how will you prepare for them
Discuss your business goals

Mention that management and ownership is just me for the moment

You may want to do an organizational chart
Take some space in your plan to show that you are thinking of the future

Via book make sure that you state when the business was begun and then how the business was begun (include any licenses, contracts, agreements, charters, and the like in the supporting documents). Indicate if it was a startup. Write about how you came to the conclusion that you wanted the legal entity that you have chosen. Write also about how you plan to meet your corporate obligations. Write about if you plan to change your legal structure and explain the how and why.

General business risks

I need to put in the brief biographical sketches here and then reference the resumes or CV.

Biographical sketches and resumes would be a great addition to the business plan.

Talk about your own personal debt and how you have overcome it.

https://www.uaa.alaska.edu/budfin/osp/direct-vs-indirect-costs.cfm
Above reference describes direct vs indirect costs

http://www.businessinsider.com/how-much-salary-does-a-doctor-make-2015-4

Projected Income Statement

Your income statement is just a snapshot of how much money you are making at one point in time.

As of Tuesday, January 26, 2016 there is no money coming in and no money going out of the company.

Projected Statement of Cash Flow

This tells about the movement of cash: where it is coming from and where it is going

Compare against industry average for your financial statements

Projected Break Even Analysis

Break-even=fixed expenses+(1-viariable expenses/sales)

Payroll for the business owner will be fairly minimal if any at all until the business is running and all debt is paid off.

Identify the need for clinical trials to be done on a national level

The way to start off is to pay them in-kind. It is also known as sweat equity. You could form some sort of an agreement where they get paid quite a bit of money to begin with in turn for their not getting paid in the beginning.

The following was in the outline up above:
Supporting Documents

- A few policies and procedures
- Website Plan/HTML text
- My own resume
- My credit report
- Credits of those that helped me out on the business plan
- ICH
- Company bylaws as given by Corporate Direct (Any info from Corporate Direct)
- Business License
- My story
- Resume of any other entrepreneur

Credits
Mark Stoddard for assistance and guidance for this business plan (provided some of the wording for this business plan)
Rich Dad/ poor Dad book
Garrett Sutton, Esq., "The ABC's of Writing Winning Business Plans. How to prepare a business plan that others will want to read-and invest in." 2005.
Business Plan Pro software for helping me out with the business plan

Inside the Executive Summary:

Talk about the experience of the team and the history that they have to verify the fact that you have experience to back you. Emphasize you and your team's track record.

The business owner is simply not in a financial position to accommodate these start-up costs.

Research Associates, LLC seeks to raise money from investors to commence operations. Investors will receive a priority return of their money from first profits and upon repayment shall receive the current federal interest rate plus one percent.

Research Associates, LLC seeks to raise capital from investors to commence operations. Investors will receive a priority return of their money from first profits and upon repayment shall receive the current federal interest rate plus one percent.

Appendix D: ICH Guidelines

This is provided electronically as a PDF file.