I, Jami Peets, hereby submit this original work as part of the requirements for the degree of Master of Design in Design.

It is entitled:
A Proposed Model for Successful Design Research Planning

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This work and its defense approved by:

Committee chair: Paul Zender, M.F.A.

Committee member: Mary Privitera, M.Des.

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A Proposed Model for Successful Design Research Planning

A thesis submitted to the Graduate School of the University of Cincinnati in partial fulfillment of the requirements for the degree of

Master of Design

In the School of Design of the College of Design, Architecture, Art and Planning by

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April 2015

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ABSTRACT

This thesis investigates design research planning for product design through researching design literature and interviewing current industry practitioners. Research findings are illustrated through a proposed conceptual model for successful design research planning. This thesis also provides a discussion of current industry challenges and mitigations.

References in design literature regarding design research planning for product design are dispersed and not easily accessible. Successful design research planning provides a framework for obtaining useful design insights, which produces robust design solutions. Design research planning is any activity preparatory to design research, such as making a research plan, conducting stakeholder interviews, and recruiting. This thesis uses design literature and current industry practices in design research planning to propose a model for success. The body of literature that addresses design research planning is mainly in user experience sources, but it also draws from industrial design and general design literature. Seventeen companies in product design participated in interviews (12) or completed a survey (5) about their planning activities and their challenges and how they face them.

The central component of the conceptual model is the research plan. The main items of a research plan consist of: objectives/goals, methodology, stakeholder involvement,
budget and timelines, deliverables, and other items. The plan is created before, during, or after background research is conducted. Fieldwork is driven by the research plan, and the data is analyzed and translated into design insights, which provide actionable design direction. Design insights are documented and communicated through appropriate media and should reflect the objectives in the research plan.

**Key words:** design research, design research planning, planning process, stakeholder involvement, and user research
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CHAPTER 1 - INTRODUCTION

1.1 Problem Statement

References in design literature regarding design research planning for product design are dispersed and not easily accessible. This research investigates design literature and current industry practice to propose a model for successful design research planning. It also provides a discussion of current industry challenges and mitigations.

Design research is a relatively new discipline within the design field. Though the field has been developing since the 1960s, it was not fully recognized its own field until the 1980s (Cross, 2007). One essential component of design research for product design is planning. Planning involves any activity that prepares a designer or researcher to inform their design process. Existing literature for design research planning is mainly written in the “user-experience design” domain. User experience is a broad term that entails user interaction with a product, system, or interface that is observable and measurable (Tullis & Albert, 2013, Ch.1). This thesis also draws from medical device design literature, as regulatory bodies govern design processes, so planning processes need to be well defined (U.S. Food and Drug Administration, 1997). A search of the University of Cincinnati’s library database using key words “design research,” “design research planning,” and “user experience research” returned a wide variety of results. Much of the content of these sources address interactive design (web, mobile, and application design) and not product design (manufacturing or industrial design). Because the design process for interactive and manufacturing design are similar, these
sources can be applied to both disciplines. Using these sources, a narrowed search for design research planning revealed that best practice recommendations were dispersed within each work and disparate among the entire design corpus. By consolidating these recommendations and translating it into a conceptual model for best practice, designers will understand the key principles and process of successful design research planning. Successful design research planning is relevant because it affects companies’ budgets, resources, and project outcomes (Best, 2006).

This thesis also adds insight into the innovation process by providing a foundation for conducting research activities and defining the “fuzzy front end.” The “fuzzy front end” is “the phase between first consideration of an opportunity and when it is judged ready to enter the structured development process” (Kim & Wilemon, 2003). There is also a lack of research on fuzzy front end practices (Koen et al., 2002), which are well needed in the twenty-first century (Mootee, 2011). Sanders and Stappers state that “a very large front end has been growing and gaining in importance over the last ten years” (Sanders & Stappers, 2012, p.22). This is an area of growth, and successful design research planning is a catalyst to strategic innovation.

1.2 Problem Scope

Design phase

Research can be performed at any stage of the design process. Below is a model of the design process developed by the Design Council. It describes four main stages of
product development, from the initial discovery of a problem to the development of a solution.

This thesis focuses on planning for research in the “discover” and “define” stages before any solution or implementation has taken place. Don Norman describes it as “expand[ing] the scope of the problem, diverging to examine all fundamental issues that underlie it...then converg[ing] upon a single problem statement” (Norman, 2013). “Design research” in this study is focused on formative research (research done before design with the goal of discovery), and not summative research (testing of a product or system after it is created to test efficacy).
1.3 Design Research Definition

Nigel Cross, a pioneer of design research created a taxonomy of the field of design as follows:

1. Design epistemology: study of designerly ways of knowing
2. Design praxiology: study of the practices and processes of design
3. Design phenomenology: study of the form and configuration of artifacts

(Cross, 1999, p.6)

This thesis touches on all three categories. Design epistemology is research about designers’ knowledge and thought processes. Design praxiology is research about what designers do and how they do it. In other words, these two categories combined are designers’ cognition and behavior. This thesis explores how designers both prepare (thought processes) and plan and execute (practices and processes) design research. Design phenomenology refers to the application of the two former categories. It is the actual research designers perform in order to inform the design of an artifact or system and is “not intended for generalizable use or application beyond the local context or project for which they are performed (Faste & Faste, 2012).

Findings of this study encompass industry practitioners’ planning processes of design research to inform specific design problems.

Within the design field, the term “design research” has evolved over the last four decades:
Table 1 - Definition of Design Research

<table>
<thead>
<tr>
<th>Author:</th>
<th>Year:</th>
<th>Design Research Definition:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Herbert A. Simon</td>
<td>1969</td>
<td>Science of the artificial (man-made as opposed to natural): how things ought to be in order to attain goals and to function (Simon, 1996, p. 4-5).</td>
</tr>
<tr>
<td>L. Bruce Archer</td>
<td>1981</td>
<td>A systematic inquiry whose goal is knowledge of, or in, the embodiment of configuration, composition, structure, purpose, value, and meaning in man-made things and systems (Bayazit, 2004, p. 16).</td>
</tr>
<tr>
<td>Nigel Cross</td>
<td>1999</td>
<td>Design knowledge resides in people, processes, and products, and fall within the categories of knowledge, practices and processes, and study of form and artifacts (Cross, 1999, p. 6).</td>
</tr>
<tr>
<td>Nigan Bayazit</td>
<td>2004</td>
<td>The objectives of design research are the study, research, and investigation of the artificial made by human beings and the way these activities have been directed either in academic studies or manufacturing organizations (Bayazit, 2004, p.16).</td>
</tr>
<tr>
<td>Michael Biggs Brenda Laurel</td>
<td>2002</td>
<td>The study of design and the process of knowledge production that occurs through the act of design (Faste &amp; Faste, 2012, p.1).</td>
</tr>
<tr>
<td>Daniel Fallman Koskinen</td>
<td>2003</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2007</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2011</td>
<td></td>
</tr>
<tr>
<td>Milton &amp; Rodgers</td>
<td>2013</td>
<td>Design research is not concerned with what exists but with what ought to be...is concerned with the plausibility and appropriateness of proposals...and produces knowledge that can be defined as trans-disciplinary and heterogeneous in nature and that which seeks to improve the world (Milton &amp; Rodgers, 2013, p.11).</td>
</tr>
</tbody>
</table>

The definition of **design research** in this thesis is any activity that informs the design of artifacts or systems by understanding user wants, needs, and behaviors. The definition remains broad in order for interviewees to respond using their concept of “design research.”
CHAPTER 2 - BACKGROUND

2.1 Design Research Planning

Design research planning in this thesis is any preparatory activity to performing design research. It comprises (but are not limited to) the following activities:

Table 2 - Design research planning activities

<table>
<thead>
<tr>
<th>Activity:</th>
<th>Source:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Making a research plan (goals, assumptions, timelines, deliverables, and budget)</td>
<td>(Sanders &amp; Stappers, 2012, p.127)</td>
</tr>
<tr>
<td>Reviewing existing work</td>
<td>(Cooper, Robert, &amp; Cronin, 2007, p.24)</td>
</tr>
<tr>
<td>Choosing the right research methods</td>
<td>(Milton &amp; Rodgers, 2013, p.139-145)</td>
</tr>
<tr>
<td>Framing research questions</td>
<td>(Couch &amp; Pearce, 2012, p.67-82)</td>
</tr>
<tr>
<td>Making checklists</td>
<td>(Milton &amp; Rodgers, 2013, p.139-145)</td>
</tr>
<tr>
<td>Setting key milestones and deadlines</td>
<td>(Best, 2006, p.150)</td>
</tr>
<tr>
<td>External decision-making</td>
<td>(Milton &amp; Rodgers, 2013, p.139-145)</td>
</tr>
<tr>
<td>Establishing goals and objectives</td>
<td>(Karjaluoto, 2014)</td>
</tr>
<tr>
<td>Determining strategy</td>
<td>(Karjaluoto, 2014)</td>
</tr>
<tr>
<td>Crafting the creative brief</td>
<td>(Karjaluoto, 2014)</td>
</tr>
<tr>
<td>Accounting for internal resources, people, and information</td>
<td>(O’Grady &amp; O’Grady, 2006, p.75)</td>
</tr>
<tr>
<td>Making sure the design methodology, process, development, and implemented stages are mapped out in the sequence they need to occur</td>
<td>(Best, 2006, p.150)</td>
</tr>
<tr>
<td>Defining project roles and responsibilities</td>
<td>(Best, 2006, p.150)</td>
</tr>
<tr>
<td>Identifying stakeholder involvement</td>
<td>(Best, 2006, p.150)</td>
</tr>
<tr>
<td>Interviewing stakeholders</td>
<td>(Cooper, Robert, &amp; Cronin, 2007, p.24)</td>
</tr>
<tr>
<td>Setting up a project file and ensuring adequate documentation</td>
<td>(Best, 2006, p.150)</td>
</tr>
<tr>
<td>Performing risk audits to identify problem areas</td>
<td>(Best, 2006, p.154)</td>
</tr>
</tbody>
</table>

Processes in design are rarely linear. The majority of literature in design illustrates the design process in sequential form and a smaller portion uses models or diagrams to
show more dynamic relationships. Below is a chart summarizing the phases of the design process. Because design literature defines the process at such a varying degree (using differing terminology, sequence, and models), there is a need for a baseline of the process. A spreadsheet of the different design models was aggregated from industrial, graphic, web, and user experience design literature (see Appendix C). The phases were coded according to similarity, and six stages emerged from the data: planning and preparation, exploration, framing, embodiment, refinement, and production. Since the chart is a consolidation of both lists and models, the phases listed below are not necessarily in the order presented and are iterative in nature. The purpose of consolidating phases in the design process is to obtain an overview of the design process in order to understand the context in which design research planning exists.

Table 3 – Phases of the design process

<table>
<thead>
<tr>
<th>Design phase</th>
<th>Description</th>
<th>Sources</th>
</tr>
</thead>
<tbody>
<tr>
<td>Embodiment</td>
<td>Create physical</td>
<td>(Burdek, 2005) (Milton &amp; Rodgers, 2013)</td>
</tr>
<tr>
<td>Phase</td>
<td>Description</td>
<td>Sources</td>
</tr>
<tr>
<td>---------------</td>
<td>-----------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Refinement</td>
<td>Iterate, evaluate, and refine design to necessary fidelity</td>
<td>(Milton &amp; Rodgers, 2013) (Kumar, 2013) (Best, 2006) (Curry, 2014) (O'Grady &amp; O'Grady, 2006) (Bennett, 2011) (Sless, 2012)</td>
</tr>
</tbody>
</table>

### 2.2 Literature Review

The literature review covers the following topics:

1. **A Research Plan**
   - a. Goals/Objectives
   - b. Methodology
   - c. Stakeholder involvement
   - d. Budget and timelines
   - e. Deliverables
   - f. Other items

2. **Stakeholder involvement and process management**

3. **Planning tools vs. ambiguity**

4. **Medical device design process regulation**
1) A Research Plan

Before the development of a research plan, projects begin with a business proposal, which can be initiated by the client or the consultancy. This includes the following: project overview and approach, scope of work, assumptions, ownership and rights, project pricing, payment schedule, and acknowledgment and sign-off (Unger & Chandler, 2009, Ch.3). The business proposal provides a context for the research scope and outlines expectations of deliverables, which directs the research effort. A research plan is drafted either before or after initial ethnographic research. If organizations need a sense of the landscape, a research plan is typically created after initial research is conducted. If the product, user, or environment is already defined, a research plan may be written at the onset of the project.

Making a research plan provides “a set of goals and a schedule that stretches limited user research resources; it delivers results when they’re needed most; and it avoids unnecessary, redundant, or hurried research” (Kuniavsky, 2003). In Elizabeth Sanders and Pieter Jan Stappers’ Convivial Toolbox, chapter 5 covers the basics of creating a research plan. They describe a plan as “a concise and clear description of what the goals of the project are, what the different parties involved are expected to do, what resources are needed, what results are expected and how and when they are to be delivered” (Sanders & Stappers, 2012, p.127). According to this and other literature (Best, 2006; Karjaluoto, 2014; Kuniavsky, 2003), a research plan is necessary and contains 1) goals/objectives, 2) methodology 3) timelines, 4) deliverables, and 5)
budget. Depending on the needs of the client, other items may include: an overview, research questions, process, scope, strategy, project roles and responsibilities, team management, stakeholders’ roles and communication, business requirements, constraints, and risk assessment.

An overarching strategy drives the success of a research plan. A strategy outlines the “high-level approach,” and the plan describes how to accomplish the approach. When designers understand the design strategy of the project, they are better able to follow intuitive hunches and stay within the parameters of the research plan (Karjaluoto, 2014, p.100-103).

a. Goals/Objectives

The research plan should center on solving the “right problem.” Instead of assuming that the problem statement given by a manager is the real problem, Donald Norman recommends divergent thinking in order to get to the root of the problem (Norman, 2013, ch.6). The Design Council adds to this by advising to ask the right questions (O’Grady & O’Grady, 2006, p.75) The research question from the design brief can be framed after field research. One way to frame a research question is to state it through multiple perspectives: the system, the end user, and the designed object (Couch & Pearce, 2012, p.67-82). Making sure to involve all stakeholders during this reframing process and using field data will help justify recasting the research question. In Biodesign,
authors recommend an iterative process of identifying problems through clinical observation and then stating the problem and the need it addresses (Zenios, Makower, & Yock, 2010, p.3-32).

Sanders and Stappers emphasize the importance of setting goals and subgoals in order to have the right output at the end of a project. They also note the importance of evaluating the effectiveness of the plan after project completion by having a discussion using a series of questions with the operating team. The discussion centers on questions about objectives, deliverables, schedules, and budget (Sanders & Stappers, 2012). Clients should document and set no more than five goals and be clear and concise in their language. Goals are broad statements that can be long-term hopes and objectives are the actual measurable tasks to accomplish goals. Involving the client in this process makes the client more committed to the project and its outcomes (Karjaluoto, 2014 p.100-101). In “Reliable Design of Medical Devices,” Fries sets the five criteria for team goals: specific, measurable, attainable, realistic, and time framed. He also states for a team to work effectively, the two main skill sets they need to possess are collaboration and communication (Fries, 2012, p.220).

For certain projects, objectives can also come in the form of a product specification document. After market research is conducted to verify need, the design team creates a product specification, that defines parameters and sets goals for cost and performance requirements (Cuffaro & Zaksenberg, 2013,
In order for designers to solve problems, designers need to use divergent thinking in order to reach objectives. Herbert Simon said, “the engineer, and more generally the designer, is concerned with how things ought to be in order to attain goals, and to function” (Simon, 1996, p.5) A goal is a starting point, and the designer bridges the gap to the final solution.

Identifying objectives is important because it allows the proper methodology to be selected (Schumacher, 2010, p.54).

b. Methodology

At the kick-off meeting, all stakeholders need to understand the overall approach or methodology for the project. Choosing methodologies depends on various factors, such as the structure and location of the team, technology, and the collaborative nature of the organization (Unger & Chandler, 2009, Ch.4). In addition, the generated research questions narrows down which methodology to implement.

Choosing a methodology stems from being able to frame a problem adequately (Couch & Pearce, 2012, p.67-82). Milton and Rodgers state that
“selecting concept design proposals is a convergent process and it is frequently highly iterative.” Once the team has come to a consensus, they develop a robust risk management strategy and write a product design specification (PDS) to determine scope parameters (Milton & Rodgers, 2013, p.139-147).

Methodology should include procedures and measures. Procedures are the research activities and measures describe the activities using time, ratings, and rankings (Schumacher, 2010, p.75). Having an toolkit of available methodologies helps designers choose from a variety of options (Buley, 2013, ch.2). Methodologies that come from various disciplines can be instrumental in generative research (Mootee, 2011, p.1).

c. Stakeholder involvement

See “Stakeholder involvement and process management” on p.16.

d. Budget and timelines

Conversations about timelines and budget can occur during a kick-off meeting or through stakeholder interviews. Interviews should be conducted at the onset of a project in order to understand the business goals of a product (Cooper, Robert, & Cronin, 2007, p.52-53). Sanders and Stappers address the issue of having a tight budget and suggest getting the client involved to assist with tasks such as recruiting and scheduling can cut costs greatly. The clients’
ownership of work leads to better results in the end (Sanders & Stappers, 2012, p.127).

When it comes to usability testing for interface design, budgets and timelines need to be planned well before any research takes place. The cost and time of such a study depends on the evaluation method, metrics, participants, and available tools (Tullis & Albert, 2013, Ch.3).

The project manager plans review meetings to make sure the team is pacing itself appropriately. They effectively break larger tasks into smaller activities within each project stage and prioritize the tasks. Key milestones are set for reviews, deadlines, and presentations (Best, 2006). Donald Norman says that “even companies that do intend to search for human needs are thwarted by the severe challenges of the product development process, in particular, the challenges of insufficient time and insufficient money” (Norman, 2013). Managing timelines is important to the process, as well as the budget.

e. Deliverables

Deliverables are any work product promised to the client throughout a project. Proposals and statements of work clearly outline what the client will receive (Unger & Chandler, 2009, Ch.3). Deliverables should be described, but not in too much detail. They should “deliver on the objectives of the research”
Looking back on objectives is a great way to assess the success of research activities after completion. Setting milestones and preparing a schedule (dictated by objectives) is instrumental in making sure deliverables are completed through all phases of development. Schedules need to be flexible as some events or occurrences are unforeseen (Fries, 2012, p.71).

The project manager makes sure stakeholders agree and understand the project brief and deliverables by breaking the project down into manageable project stages (Best, 2006, p.150). In medical device design, a design file documents every step of the design process and when changes are made (Ogrodnik, 2011, p.38). This is available to stakeholders, which keeps everyone up-to-date with the development status. An important deliverable in transitioning from research to medical device production is a product specification, which “specifies what the product will do, how it will do it, and how reliable it will be” (Fries, 2012, p.182). This extends beyond design research and gathers and translates data from engineering, human factors, sales, and marketing into product specifications.

**f. Other items**

Other items can be included in the research plan according to the project and client needs. Items include assumptions (Sanders & Stappers, 2012, p.127),
context history and overviews (Kumar, 2013, p.8-10), risk assessment (Best, 2006), strategy (Karjaluoto, 2014, p. 98-124), internal resources, technical constraints and opportunities, business drivers (Cooper, Robert, & Cronin, 2007, p.52), and global considerations (Schumacher, 2010).

2) Stakeholder involvement and process management

Aside from having a plan, the research lead or project manager (PM) has the responsibility of managing processes and communication with all stakeholders. A stakeholder is defined as “anyone with authority and/or responsibility for the product being designed” (Cooper, Robert, & Cronin, 2007, p.53). The PM needs to ask the right questions, ensure all team members understand the plan, facilitate communication internally and externally, and assemble a diverse team (Best, 2006, p.150). In order to effectively manage the process and its stakeholders, authors also suggest the following: holding regular review meetings, having stakeholder interviews, holding stakeholder workshops, clarifying expectations of roles, responsibilities, and communication, using a shared vocabulary, anticipating problems ahead of time, being proactive, and considering data collection. It is also important for stakeholders to deliberate and argue their point-of-views (Rith & Dubberly, 2007, p.2). When a team runs into problems, stakeholders need to share their perspectives and the team needs to be able to come to a consensus.
Most sources emphasize the importance of engaging stakeholders throughout the whole design process because it “increases the chances that they will act upon its results” (Sharon, 2012, p.xlvii). Sanders and Stappers conclude that “when clients have ownership of the results, there is also an unconscious flow of information through contact for all of the people actually interacting in the study” (Sanders & Stappers, 2012, p.133). In medical device development, performing a stakeholder analysis helps innovators gain an understanding of the needs of all involved parties and translates those needs into design requirements (see “design input” in Figure 2) (Zenios et al., 2010, p.95).

In managing the process, it is important for teams to know that the “path from data to wisdom is not linear, and it is not nearly as “clean” as just described. This path will occur implicitly during design synthesis as [teams] attempt to organize, manipulate, prune, and filter gathered data into a cohesive structure for meaning making” (Kolko, 2011, p.60).

The design process an organization chooses affects all facets of development. In order to improve communication, which aids in the control of design, the use of a concurrent engineering model is effective (Ogrodnik, 2011, p.41). This requires constant collaboration within a design team due to its iterative nature. Ogrodnik encourages use of modern communication tools to communicate with stakeholders. Procedures for medical device design are determined in order to meet requirements for regulatory bodies such as the FDA (U.S. Food & Drug Administration) and to meet

3) Planning tools vs. ambiguity

Design in innovation is often a foray into the unknown. Even when a plan is set in place and objectives are determined, designers make many assumptions during the process; however, there are tools to help mitigate the uncertainty of situations, outline territory, increase clarity of expectations, and to assist in decision-making. Tools used in the planning stage include (but are not limited to): Gantt charts, software applications, checklists, matrix evaluation, critical path analysis, product specification, flowcharts, benchmarking, pilot test, SWOT analysis (Strengths, Weaknesses, Opportunities, Threats), and a QFD matrix (Quality function deployment).

Ideally, planning tools facilitate the design process, but when it comes to practice, designers face a lot of ambiguity. In dealing with the unknown, “little is assured” and “[designers] won’t always know when [they’re] taking the right approach.” Designers should not play hunches until they have a comprehensive understanding of the client’s needs (Karjaluoto, 2014, p.102). Ogrodnik encourages medical device innovators to avoid holding on to “sacred cows,” or ideas that become too precious to let go (Ogrodnik, 2011). This requires stepping into the darkness and exploring all ideas. Medical device innovators should “expect the unexpected” and go into clinical
observations with an open mind and look for issues or problems that haven’t been seen before (Zenios, Makower, & Yock, 2010, p.26-27).

4) Medical device design process regulation

Medical device design processes need to be regulated so that good quality assurance practices are used and are consistent with quality system requirements worldwide (U.S. Food and Drug Administration, 1997, p.i). Medical device design is much more rigorous than consumer product design because such devices need to meet requirements that are set by regulatory bodies such as the U.S. Food and Drug Association (FDA). The design process is similar to that found in Design, but includes more documentation, constant sign-offs at various stages, and post-design testing to ensure the design meets the specified requirements (International Organization of Standardization, 2003). Below (see Figure 2) is the FDA Design Control Waterfall, a diagram that the FDA prescribes as the general process of medical device development.
The design process for medical devices begins with discovering user needs (top left corner) and is further clarified in a Product Design Specification (PDS) (Ogrodnik, 2011). A PDS assists the design team and other stakeholders to come to a consensus of processes, procedures, and output. The designers receive design input (specifications) and begin the design process. This produces a design output (prototype), which will then undergo verification, which is an analysis to make sure the prototype meets specifications. Additionally, a systematic review is performed after each phase. When the prototype gets closer to production quality, it undergoes validation, which ensures that the final product meets user needs. Although this model is illustrated linearly, there are actual feedback loops between phases and is an iterative process. Medical device manufacturers use this model as a guide but
implement it differently according to their protocols and project needs (U.S. Food and Drug Administration, 1997).

Design research planning occurs in the “user needs” phase and converges at the design input (determined specifications). A research plan is created (as mentioned earlier) and a protocol is developed with specific details on how to implement the plan. “The protocol specifies what will be observed and what questions will be asked” (Wilcox, 2012). The protocol is used to determine the tasks that will lead to uncovering and understanding user needs, which are translated into user requirements. Capturing user requirements faces barriers such as “ethical and research governance procedures” and balancing stakeholder voices (J. L. Martin, Murphy, Crowe, & Norris, 2006). In order to do clinical research, health care authorities need to grant permission for these types of activities through a regulated process. Allowing for this process requires planning and preparation before any research can take place.

2.2.1 Summary of Literature Review
The majority of design literature mentions the elements of a research plan: goals, objectives, methodology, stakeholder involvement, budget, timelines, and deliverables. Other relevant topics are process management and stakeholder involvement. Authors have varied recommendations for managing the design process according to different design disciplines. For example, the recommendations for user interface center on iterating, whereas for product design there is a focus on manufacturing. Almost all sources emphasize involving stakeholders early and
throughout the whole design process. Sources that focus on methodology offer planning tools such as Gantt charts, matrix evaluation, critical path analysis, and flowcharts. There is also a discussion of working with ambiguity, especially in innovation. Even though planning tools help to dispel ambiguity, designers constantly have unknown variables and need to be open to a lot of ideas.

There is one key difference between consumer product and medical device development. Planning processes (and design) for medical device are more rigorous and require more design reviews and documentation. All changes to a design are carefully regulated and documented (International Organization of Standardization, 2003).

In reading a score of papers that received accolades in Design Studies, Nigel Cross summed up their shared characteristics, which he deems “best practice” in design research: purposive, inquisitive, informed, methodical, and communicable (Cross, 1999). Even though Cross was referring to basic research instead of design research, these principles apply to design research planning.
CHAPTER 3 - RESEARCH METHODS

3.1 Objective

The objective of this study is to understand what practitioners in both literature and the product design industry do in the planning process in order to produce successful design research efforts. Additionally, it is to understand challenges and mitigations that the organizations currently face.

3.2 Methods

Literature reviews

Design research uses techniques from many fields (Schumacher, 2010, p.11). For this reason, search criteria include sources from the field of Design (graphic, product, interaction, and user experience). In order to find more rigorous planning processes, biomedical engineering sources were researched. Search criteria include recommendations for how to plan design research and were presented in the form of principles, tools, or diagrams.

Books that intertwine design practice and design research methodology were more helpful than reference books. Some books had a chapter or two dedicated to planning, where others had elements of planning embedded throughout the book and were more difficult to find. A spreadsheet was compiled (see Appendix C) of all relevant sources with each author’s recommendations. The areas of overlap and difference will be the main discussion in the next section.
Pilot Interviews

A pilot interview consisting of four questions (see Appendix A) was conducted with four professors from the University of Cincinnati who had either a business or design background. Two professors had industry experience in both design and design research and the other two in business and marketing. The questions aimed to uncover key factors behind successful research planning. The interview also consisted of questions about problems that arise in the planning phase and measures taken to get around those issues. The final question was how to evaluate the effectiveness of a research effort.

The questions proved to produce successful results, but failed to provide a context for the respondents’ viewpoints. Four questions were added (see Appendix B) for the final study to include a description of interviewees’ areas of expertise (organization name, job title, areas of expertise, and years of experience), as well as a detailed breakdown of design activities within a typical work week, month, or year (percent of time spent in design, design research, and design research planning).

Interviews

Design consultancies and corporations involved in medical device design (as well as product design) were interviewed because of the rigor of their research and design process. These organizations adhere to standards dictated by regulatory bodies such as the FDA. In order to comply with these standards, companies need a well-defined
methodology for conducting design research and therefore need an effective planning strategy.

Katherine Bennett, professor at Art Center College of Design specializing in strategic planning and research in product development said, “the quality of the research determines the caliber of the knowledge, and ultimately, the excellence of the design solution” (Bennett, 2011). The quality of the research relies on the framework set in place through planning. Organizations need to implement successful planning practices in order to produce robust solutions.

The final interview guide was used as both a survey and a guide (see Appendix B). It consisted of five survey questions about expertise and percentage of time spent in various work activities. It also consisted of four open-ended questions. A total of 17 practitioners participated in the study: 12 were interviewed (10 recorded) and 5 were given surveys of the same questions. Interviews lasted from 7-23 minutes. All 17 interviewees except one were in attendance November 2014 at the IDSA Medical Device Design Conference held in Tampa, Florida, United States. The latter was contacted after the conference via phone.

3.3 Sampling

A convenience sample was taken at the Industrial Design Society of America (IDSA) Medical Device Design Conference in November 2014. Seventeen interviews were
conducted; 10 interviewees are from consultancies that work partially or completely with medical device companies and seven are from companies that are dedicated to medical device design. Years of experience range from 3-35 years, with an average of 14.5 years. Interviewees’ job titles were grouped in the following: Human Factors Specialist, Design Lead, and Research Lead. Because job titles do not always accurately describe expertise, below is a breakdown of interviewees’ areas of expertise.

Table 4 - Respondent areas of expertise

<table>
<thead>
<tr>
<th>Interview respondent expertise</th>
<th>Areas of Expertise</th>
</tr>
</thead>
<tbody>
<tr>
<td>Job Title</td>
<td>Total</td>
</tr>
<tr>
<td></td>
<td>Usability/ergonomics/human factors</td>
</tr>
<tr>
<td>Human Factor Specialist</td>
<td>4</td>
</tr>
<tr>
<td>Design Lead</td>
<td>6</td>
</tr>
<tr>
<td>Research Lead</td>
<td>7</td>
</tr>
</tbody>
</table>

The majority of interviewees (14) have expertise in design research, which includes the categories: usability testing, ergonomics, human factors, and design research.

### 3.4 Analysis

The interview guide consisted of four questions and served as a tool to take notes of interviewees’ responses. Five respondents were not able to be interviewed due to lack of time and were given the field guide to fill out as a survey.
The data was compiled in a spreadsheet under eight categories: organization name, job title, areas of expertise, years of experience, average time spent in various activities (design, design research, and design research planning), principles of successful design research planning, challenges, and mitigations.

Using grounded theory, first cycle coding included the formation of a list of key words from the spreadsheet interviewees used for each question asked. These were then consolidated into groups of loose themes. The themes then became descriptive codes for second cycle coding of the interview transcripts.

Eleven out of seventeen interviews were recorded and transcribed and given descriptive codes according to the aforementioned themes. The transcripts were then brought into NVivo10 (analysis software) where the data was aggregated according to codes and comparisons and correlations were made.

### 3.5 Limitations

Because a convenience sample was taken from attendees who attended the IDSA Medical Device Design Conference, the demographic was limited geographically or financially. Additionally, not all 17 respondents were interviewed; 12 were interviewed and 5 were given a survey. Those who were interviewed were able to provide a context for their comments through explanations and stories, whereas those given a
survey were limited to what they wrote. Respondents also define “success” very differently and context was needed to understand viewpoints. Participants were also asked to estimate the percentage of time they spend in certain categories. Perceptions vary about time spent in various facets (design, design research, and design research planning) due to differing definitions of design terminology. For example, one respondent may deem usability testing as “design research,” whereas another may not include usability testing and only include background research activities. This required interpretation according to context.
CHAPTER 4 - FINDINGS

The findings of this report are based on literature review and interviews. Below is an overview of the chapter:

4.1 Key principles of successful design research planning
4.2 Current challenges and mitigations in planning
4.3 Evaluating the effectiveness of research effort
4.4 Summary of interview findings
4.5 A model for successful design research planning

4.1 Key Principles of Successful Design Research Planning

The key principles of successful research planning include having effective communication, determining a research process, and using of a plan with a clear objective.

Communicate effectively

In order to communicate effectively, all parties including stakeholders, the client, and the internal team need to stay on the same page from start to finish of a project. This requires keeping open lines of communication and continually giving updates through weekly status meetings, phone calls, or e-mails. It is also crucial to consult with the right stakeholders and make sure there is alignment in objectives and desired
outcomes. This can be facilitated in the workplace, but are typically documented in requests for proposal or statements of work.

Having client buy-in, and having it early in a project makes all facets of the research process go smoother. When clients understand the value of research, they understand how insights lead to actionable outcomes. This helps them have a clearer vision of what to look for during field research and they are more prone to meet research objectives. For example, one company invests time to teach the client the vocabulary and process in order to increase client buy-in. Another organization talked about immersion workshops. Its purpose is to help clients familiarize themselves with the study topic and the gain an understanding of the overall research process. This is also an opportunity for clients to ask questions and gain clarity about the project and the process.

*Have a research process or approach*

Research approaches vary in differing organizations, but do share common critical elements. One element is organizing logistics, such as recruiting, budgeting and scheduling, and preparing for field research and data capture. A common challenge is creating realistic timeframes for activities and deadlines. Allowing enough time to execute research is paramount to obtaining useful findings. In order to save time and resources, one company suggested alternating tailored and generic research methods. “It’s a balance between having readily, recyclable, reusable templates and
components that you can expedite and make things efficient and reuse but also customizing and sometimes it’s more than customizing. Sometimes it’s more like coming up with a new creative approach to design. Designing a study is sort of like designing and object, you have to be clever about it and figure out what’s going to work well.” Even when activities are planned and schedules are set in place, it is important to be open-minded and embrace the unexpected. The ability to be flexible and think creatively about a problem can make both the process and findings richer. One organization suggested embedding different types of thinkers in a research team. For example, for every designer, have an engineer. They do this by embedding their teams within that of the clients, which captures a more holistic view and challenges assumptions.

*Have a research plan and objectives*

Research plans, like research processes vary in organizations. They are tailored to meet client needs and are instructions on how the research team will conduct its research. It contains methodology, protocols, sampling, and other information. The most important part of a plan is research objectives. It gives researchers an understanding of what to look for and provides stakeholders with an idea off what will come out of the research. In order to save time, one company suggests reusing templates, screeners, and protocols.
4.2 Current Challenges and Mitigations in Design Research Planning

Challenges in the planning phase include communication, lack of resources, and facilitating research planning and processes.

**Communication**

Ineffective communication happens both internally within an organization and externally with clients and third party vendors. There may be a lack of information relay, and in cases when it is relayed it can be misinterpreted. Tools like visuals and workshops are used to prevent misunderstandings and make sure there is alignment. Visuals include any media that help convey ideas and can range from the physical prototypes to digital or print media. This provides a more concrete way of presenting ideas and promotes clarity in groups. A workshop is a directed activity with a goal that can range from discussing timelines to prioritizing agendas. It is also a challenge to maintain effective communication if some clients are not dedicated and diligent about it. In those cases, setting communication expectations is helpful. At the onset of the project, it is crucial to come to an agreement about how often information will be disseminated and reported back.

**Lack of time**

The majority of companies interviewed expressed challenges related to time. Schedules may be over aggressive, compromising the quality or comprehensiveness of a study. Also, it may be difficult being able to answer all research questions within
the allotted timeframe. Timing is also difficult when it comes to recruiting and trying to gain access to sites, as those factors cannot always be controlled. One company emphasized the importance of developing strategic partnerships through formal channels when it came to hospital access. Another company talked about being able to accept the caliber of the deliverables within the parameters of the set timeframe. Another company suggested adding extra time at the onset of a project when timelines are being discussed.

**Budget**

Budgets constrain projects and create challenges in instances where more research is needed. Budget estimates are done at the onset of a project along with statements of work and are usually discussed with timelines. Most companies talked about the importance of being able to budget within realistic time frames. In general, dealing with constraints gets better with more experience.

**Facilitating research planning and processes**

Three companies talked about how receiving client feedback is a balancing act between the client as the domain expert and the push for new knowledge. For example, a client may assume that the main problem is user related before any research is conducted and may encourage a focus on the user. An outside research team may then look at the whole system and uncover the real problem doesn’t lie solely in the user, but in the method of delivery to the user. It is fine balance between
acknowledging the client’s expertise and bringing new insights to the table. Another challenge is growing the expertise of the internal team. It is difficult to stay up-to-date on processes and research techniques due to continual time constraints.

4.3 Evaluating the Effectiveness of a Research Effort

In order to evaluate the effectiveness of a research effort, organizations use research or planning tools, apply past knowledge, and connect outcomes to objectives. Even though measures are taken to increase the effectiveness of a plan, companies still face a degree of uncertainty.

Use planning or research tools

Tools such as research plans, protocols, and templates are used to better facilitate research. During the research phase, pilot studies are conducted in order to work out any logistical problems. One company talked about how setting stage gates in the product development phase helps with planning logistics, such as recruiting and locating research sites. In summative testing for FDA approved devices, validation reports are used to evaluate research plans and their outcomes.

Apply past knowledge

In a pilot interview, one respondent stated the importance of asking clients for existing research. Five companies mentioned relying on either past experience or following a gut feeling about the findings, types of questions, and the correct depth of
study. One participant concluded that, “you never know if you have a successful research plan until you actually implement it. If I walk out of an engagement learning something that I didn’t know beforehand, that’s a successful research engagement.” One consultancy talked about using past experience as leverage for an argument in a meeting to clarify the meaning of a written proposal. Two companies felt successful when their clients showed understanding, either in the research insights or in the whole process itself. Deliberate planning and strategy need to be accompanied with intuitive decision-making during the process and build off past experiences in order for a successful research effort to take place.

**Connect outcomes to objectives**

Seven companies expressed uncertainty when asked how they knew if their plan is going to be successful. Companies often make assumptions and don’t fully know the results until they execute the project. Six companies, none of which expressed uncertainty, stated that being able to reach research objectives meant they were successful. Defining objectives with the client and stakeholders was critical at the onset of a project and being flexible when new information came to revise objectives. One consultancy shared, “you want to have the protocol established well enough so that—not that it has to be cast in concrete and you never change it—but the failure of the plan should not be what drives changing the plan.” A key output of successful research was: valuable data, definitive and actionable outcomes, and knowledge whether to proceed or not.
4.4 Interview Findings Summary

In order to understand the relationship between the questions asked in the interviews, an ontology was created. In computer science, ontology is a process of understanding relationships (Breitman, Casanova, & Truszkowski, 2007) “in order to reach a common understanding of a particular domain” (Stuckenschmidt & van Harmelen, 2005). Below is a diagram illustrating the relationship between the three interview questions:

1) What are 3 principles of successful design research planning? (in green)
2) What are challenges do you face in planning? (in purple)
3) How do you evaluate the effectiveness of a research approach? (in blue)

Figure 3 - Interview responses ontology
The following is a summary of the insights from interviews (extrapolated from the diagram above):

1) There is a correlation between the first and third question (in green and blue), as they are very similar. All principles of successful design research planning are implemented through means of a research plan. The themes that were derived from question 1 provide the “keys to success,” and the themes from question 3 describe “how to verify success” after completion of a project. For example, in order to plan design research successfully (see green box in Figure 3), the chosen methodology (research approach/process—see second node) needs to provide satisfactory metrics illustrated in a chart (research/planning tools—see second node attached to the blue box).

2) With each principle named (in green), there is an associated challenge (in purple). If drafting a research plan is so important, why are there problems with the very things that the plan addresses (timelines, budget, and resources)? This suggests a disconnect between the plan and actual execution of research.

3) Identifying objectives at the onset of a project allows for measuring outcomes. It directs the project, provides a focus for the study, and may produce a metric to measure success throughout and at the end of a project.
4) Having an understanding of the research approach or process for a given project assists in planning for data capture and analysis. It provides a framework in which the researcher is able to determine the methodology and protocol to implement and further, which tools best suit the purpose.

5) The ability of personnel is not of any value unless communication is effective. At certain stages, it is crucial to collaborate together as multi-disciplinary teams, as ideas from past experience can build from various viewpoints. The ability to communicate effectively internally and externally affects the success of a research effort, and ultimately the success of a project.

6) For respondents who denoted difficulty in evaluating the effectiveness of a research effort (6), the commonality was a challenge in time management. The main difficulties were: managing expectations of turn-around time, sticking to timelines, having good timing, and aligning schedules. The rest of the challenges were distributed evenly between the other two categories (project planning and research approach). Although the majority (4) stated setting objectives as a key principle in planning, it doesn’t necessarily always lead to clear solutions. These cases faced a variety of challenges such as external unforeseeable variables, miscommunication or lack of communication, and recruiting.
4.5 A Model for Successful Design Research Planning

According to the literature review and interviews, planning research relies on four key principles in order to drive successful research (see Figure 4):

1) Use planning and research tools
2) Have a robust research approach
3) Involve stakeholders throughout
4) Rely on past experience and collaborate.

The whole planning process is supported by diligent communication of all involved parties.

Design Research Planning Key Principles

<table>
<thead>
<tr>
<th>Use planning and research tools</th>
<th>Have a robust research approach</th>
<th>Involve stakeholders throughout</th>
<th>Rely on past experience and collaborate</th>
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</table>

Communicate effectively

Figure 4 - Design research planning key principles

The key principles drive the planning process. Below is the Design Research Planning Process model compiled from the literature review and interviews (see Figure 5). The central component of the conceptual model is the research plan. The main items of a research plan consist of:
1) Objectives/Goals

2) Methodology

3) Stakeholder involvement

4) Budget and Timelines

5) Deliverables

6) Other items

Figure 5 – The Design Research Planning Process

Background research is conducted before, during, or after the plan is created.

Fieldwork is driven by the research plan, and the data is analyzed and translated into
design insights. Design insights are actionable recommendations for design based on field research analysis. The insights are documented and communicated through appropriate media and should reflect the objectives in the research plan. A feedback loop between objectives and design insights is to ensure the objectives and design insights reflect one another.

The model provides a foundation for design researchers and adds to current design literature about design research planning. Additionally, the model defines the “fuzzy front end” of innovation, clarifying the preparatory tasks to product development. Successful design research planning provides a framework for obtaining useful design insights, which produces robust design solutions.
CHAPTER 5 - CONCLUSIONS

5.1 Summary of Thesis

This thesis produced a model for design research planning for product design from design literature and 17 interviews with industry practitioners. It also provided a discussion of current industry challenges and mitigations. Successful design research planning is important because it affects companies’ budgets, resources, and project outcomes (Best, 2006). This work also clarifies “fuzzy front end” practices of innovation for product design, which are well needed in the twenty-first century (Koen et al., 2002) (Mootee, 2011).

5.2 Summary of Findings

Key principles of successful research planning include having effective communication, determining a research process, and using of a plan with a clear objective.

Challenges in the planning phase include communication, lack of resources, and facilitating research planning and processes.

In order to evaluate the effectiveness of a research effort, organizations use research or planning tools, apply past knowledge, and connect outcomes to objectives. Even though measures are taken to increase the effectiveness of a plan, companies still face a degree of uncertainty.
The research process relies on four key principles in order to drive successful research:

1) Use planning and research tools
2) Have a robust research approach
3) Involve stakeholders throughout
4) Rely on past experience and collaborate.

The four principles are grounded on all of the involved parties’ ability to communicate effectively.

The Design Research Planning Process begins with either a research plan or background research. The basic structure of a research plan includes five key elements:

1) Objectives/Goals
2) Methodology
3) Stakeholder involvement
4) Budget and Timelines
5) Deliverables
6) Other items

After research is performed, research outcomes are synthesized and translated into design insights that are actionable. Design insights are documented and communicated in a format that is suitable and understandable to the client. A
feedback loop between objectives and outcomes is to ensure objectives and design insights reflect one another.

### 5.3 Implications for Practice

This model provides a holistic view of the design research planning process and can assist companies who are adding design research as a business offering. The model represents an ideal process in order to demonstrate how to deliver what the research plan promises. When this is achieved, design solutions become more robust and are better able to meet user needs.

As stated in the literature review, a model does not reflect practice where processes are not linear due to iteration, troubleshooting, and timing. “The actual design process in reality is much messier and unstructured” (Leitner, Giovanni, & Yauner, 2013, p.496). The design process is iterative with countless feedback loops and other variables coming into play as well. This model serves as a tool to outline the basis of design research planning for product design and organizations can modify and build upon the structure as needed.

### 5.4 Further Study

This research found that industry practitioners in product design stated that best practices for design research planning were also the very challenges they faced. A
more detailed study observing respondents’ work place activities may be able to resolve this discrepancy and offer suggestions for those challenges.

Since respondents’ experiences were so varied, it became difficult to compare experiences. In interviews, a standard scenario could provide a baseline for all respondents in how they conduct design research planning activities.

Future studies in design research could examine the general landscape of design research for product design and investigate specialty subtopics within the category at greater depth.

1) In order to understand the landscape of design research for product design, a national or international survey could add insight to current research planning activities, challenges, and tools used.

2) Specialty subtopics in design research planning for product design could include: innovative tools and methodology, intuition vs. logic, overcoming challenges, key players, workflows, and stakeholder involvement.
GLOSSARY

Background research: research done usually before a plan is drafted at the beginning of project that produces valuable insights into the landscape and user.

Design epistemology: research about designers' knowledge and thought processes.

Design input: in medical device design, it is the physical specifications of a device to be designed.

Design insight: an actionable recommendation for design based on field research analysis.

Design output: In medical device design, it is the physical manifestation after design inputs have been considered and applied.

Design phenomenology: the research designers perform in order to inform the design of an artifact or system.

Design praxiology: research about what designers do and how they do it.

Design research: any activity that informs the design of artifacts or systems by understanding user wants, needs, and behaviors.

Design research planning: any preparatory activity to performing design research. Some examples include: making a research plan, reviewing existing work, choosing the right research methods, framing research questions, identifying stakeholder involvement, setting key milestones and deadlines, establishing goals and objectives, determining strategy, and performing risk audits.

Fuzzy front end: in innovation, it is the phase between initial conceptualization and development.

Ontology: a process of understanding relationships within a certain domain.

Stakeholder: anyone affected in the development of a product or system.
BIBLIOGRAPHY


Field Guide

October 13, 2014

Research Question

What are the key components of a research planning process to obtain optimal results?

Optimal results: Outputs that meet design goals, or however interviewee defines it

Interview questions:

1. Who is mainly in charge of planning research? One person? A team? What does that typically involve?
2. What are the most important principles of planning for research?
3. How do you know you have successful plan? What does that look like? For example, how many sessions, duration, people involved, who’s leading the meeting...etc. How do you define “success?”
4. Have you ever followed your plan and have it not yield what you wanted it to? What do you do in those situations? Have you ever broken protocol and gone off the research plan?

Scenario if needed (in cases where they can’t share due to confidentiality):

1. A company that sells outdoor equipment approaches you for new product design concepts. They sell a broad range of outdoor equipment, but are now focusing on their rock climbing line.
   a. How would approach planning for this project?
   b. What needs to be done or set in place in order to develop a successful plan?
   c. How do you know your plan will yield useful results?
**Appendix B – Final interview field guide**

<table>
<thead>
<tr>
<th>Interview Guide/Survey</th>
<th>Thesis topic: A model for successful design research planning</th>
<th>Jami Peets - University of Cincinnati</th>
<th>Interview #</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td>Job Title</td>
<td>Organization</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Area of expertise</th>
<th>Years</th>
</tr>
</thead>
</table>

1. **On average, how much of your time is spent doing the following:**

   - **Design Research:** any activity to inform design
   - **Design Research Planning:** any activity to prepare you to do research

   ![](image)

2. **Please list 3 principles (or more) of successful design research planning:**

3. **What are your challenges with planning?**

4. **How do you know if you have a successful plan?**
## Appendix C – Stages of the design process

<table>
<thead>
<tr>
<th>Step</th>
<th>Process</th>
<th>Understanding and Define the Mission (Formulation of the Task)</th>
<th>Opportunity Identification</th>
<th>Plan for the Fieldwork</th>
<th>Sense Intent</th>
<th>Problem Definition</th>
<th>Collect Data</th>
<th>Brief Specification</th>
<th>Gather Data in the Field</th>
<th>Know Context</th>
<th>Understand Problem</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Design process</td>
<td>Plan for the fieldwork</td>
<td>Sense intent</td>
<td>Problem definition</td>
<td>Opportunity identification</td>
<td>Plan for the fieldwork</td>
<td>Sense intent</td>
<td>Problem definition</td>
<td>Collect data</td>
<td>Brief specification</td>
<td>Gather data in the field</td>
</tr>
<tr>
<td>2</td>
<td>Collect Data</td>
<td>Concept design</td>
<td>Analyze the Data</td>
<td>Concept design</td>
<td>Analyze the Data</td>
<td>Know People</td>
<td>Concept design</td>
<td>Concept design</td>
<td>Know People</td>
<td>Concept design</td>
<td>Concept design</td>
</tr>
<tr>
<td>3</td>
<td>Analyze the Data</td>
<td>Design Development</td>
<td>Communication of Findings</td>
<td>Frame Insights</td>
<td>Concept Design</td>
<td>Concept Design</td>
<td>Concept Design</td>
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</tr>
<tr>
<td>4</td>
<td>Develop Alternative Solutions</td>
<td>Concept Design</td>
<td>Analyze the Data</td>
<td>Concept Design</td>
<td>Analyze the Data</td>
<td>Know People</td>
<td>Concept Design</td>
<td>Concept Design</td>
<td>Know People</td>
<td>Concept Design</td>
<td>Concept Design</td>
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<tr>
<td>5</td>
<td>Assess the Pros and Cons of the Alternatives and Decide on One or More Solutions</td>
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<td>Analyze the Data</td>
<td>Concept Design</td>
<td>Analyze the Data</td>
<td>Know People</td>
<td>Concept Design</td>
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<td>Know People</td>
<td>Concept Design</td>
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<tr>
<td>6</td>
<td>Test and Implement Solutions</td>
<td>Production</td>
<td>Bridge the Gap Between Research and Design</td>
<td>Frame Solutions</td>
<td>Production</td>
<td>Bridge the Gap Between Research and Design</td>
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<td>7</td>
<td>Realize Offerings</td>
<td>Planning and Preparation</td>
<td>Exploration</td>
<td>Framing</td>
<td>Embodiment</td>
<td>Refinement</td>
<td>Production</td>
<td>Planning and Preparation</td>
<td>Exploration</td>
<td>Framing</td>
<td>Embodiment</td>
</tr>
</tbody>
</table>
# Appendix C – Stages of the design process

<table>
<thead>
<tr>
<th>Giles Rolleston</th>
<th>Csikszentmihalyi</th>
<th>IDEO Method Cards</th>
<th>Mike Eisenberg</th>
<th>George Polya</th>
</tr>
</thead>
<tbody>
<tr>
<td>Web-based services and applications</td>
<td>The Five Step Creative Process</td>
<td>Research methods</td>
<td>The Big 6 process (information-based problems)</td>
<td>Model for problem solving</td>
</tr>
<tr>
<td>Discover and understand</td>
<td>Preparation</td>
<td>Learn</td>
<td>Task definition</td>
<td>Understanding the problem</td>
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<tr>
<td>Define</td>
<td>Incubation</td>
<td>Look</td>
<td>Information seeking strategies</td>
<td>Devising a plan</td>
</tr>
<tr>
<td>High level design</td>
<td>Insight</td>
<td>Ask</td>
<td>Location and access</td>
<td>Carrying out the plan</td>
</tr>
<tr>
<td>Detailed design</td>
<td>Evaluation</td>
<td>Try</td>
<td>Synthesis</td>
<td>Looking back</td>
</tr>
<tr>
<td>Develop and test</td>
<td>Elaboration</td>
<td></td>
<td>Evaluation</td>
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<tr>
<td>Deployment</td>
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</table>

**CODING LEGEND**

- Planning and preparation
- Exploration
- Framing
- Embodiment
- Refinement
- Production
## Appendix C – Stages of the design process

<table>
<thead>
<tr>
<th>Eric Karjaluoto</th>
<th>Martin &amp; Hannington</th>
<th>Cuffaro, Zaksenberg</th>
<th>Jon Kolko</th>
<th>Couch &amp; Pearce</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>The Design Method</strong></td>
<td>Design Phases</td>
<td>Product development process</td>
<td>Solving design problems</td>
<td>The Research Process</td>
</tr>
<tr>
<td><strong>Discovery</strong></td>
<td>Planning, scoping, and definition</td>
<td>Planning - market research to verify opportunity, identify product specifications, set goals and objectives, create design brief</td>
<td>Data</td>
<td>Research question</td>
</tr>
<tr>
<td><strong>Planning</strong></td>
<td>Exploration, synthesis, and design implications</td>
<td>Research - capture data through various means</td>
<td>Information</td>
<td>Data collection</td>
</tr>
<tr>
<td><strong>Creative</strong></td>
<td>Concept generation and early prototype iteration</td>
<td>Conceptualization</td>
<td>Knowledge</td>
<td>Data analysis</td>
</tr>
<tr>
<td><strong>Application</strong></td>
<td>Evaluation, refinement, and production</td>
<td>Refinement</td>
<td>Wisdom</td>
<td>Presentation of research outcomes</td>
</tr>
<tr>
<td><strong>Launch and monitor</strong></td>
<td>Production</td>
<td></td>
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</tr>
</tbody>
</table>

**CODING LEGEND**

- Planning and preparation
- Exploration
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- Production
### Appendix C – Stages of the design process

<table>
<thead>
<tr>
<th>AIGA</th>
<th>Design Council</th>
<th>O’Grady &amp; O’Grady</th>
<th>Cooper, Reimann</th>
<th>Bennett</th>
</tr>
</thead>
<tbody>
<tr>
<td>AIGA’s designing framework</td>
<td>The Design Process</td>
<td>Design process for graphic design</td>
<td>Goal-directed design process for interaction design</td>
<td>Product development process</td>
</tr>
<tr>
<td>Defining the problem</td>
<td>First steps</td>
<td>Research</td>
<td>Research</td>
<td>Planning</td>
</tr>
<tr>
<td>Innovating</td>
<td>Research</td>
<td>Concept development</td>
<td>Modeling</td>
<td>Research sessions</td>
</tr>
<tr>
<td>Generating value</td>
<td>Planning</td>
<td>Prototyping</td>
<td>Requirement</td>
<td>Analysis</td>
</tr>
<tr>
<td></td>
<td>Communication</td>
<td>Design and production</td>
<td>Framework</td>
<td>Research presentation</td>
</tr>
<tr>
<td></td>
<td>Implementation</td>
<td>Assessment</td>
<td>Refinement</td>
<td>Ideation</td>
</tr>
<tr>
<td></td>
<td>CODING LEGEND</td>
<td>Ethnographic research</td>
<td>Production</td>
<td>Post-production analysis</td>
</tr>
<tr>
<td>Planning and preparation Exploration</td>
<td>Marketing research</td>
<td>User testing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Framing</td>
<td>Visual exploration</td>
<td></td>
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</tr>
<tr>
<td>Embodiment</td>
<td>Refinement</td>
<td></td>
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<tr>
<td>Production</td>
<td>Final design</td>
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</tbody>
</table>
Appendix C – Stages of the design process

<table>
<thead>
<tr>
<th>Sless</th>
<th>Zenios, Makower, Yock</th>
<th>Paul and Beitz</th>
<th>Fries</th>
<th>Mootee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Information design process</td>
<td>The Biodesign innovation process</td>
<td>Engineering design process</td>
<td>The Design and Development process</td>
<td>Strategic Innovation Process:</td>
</tr>
<tr>
<td>Scoping</td>
<td>Needs finding</td>
<td>Task</td>
<td>Concept phase</td>
<td>Collecting customer insights</td>
</tr>
<tr>
<td>Baseline</td>
<td>Needs screening</td>
<td>Specification</td>
<td>Feasibility phase</td>
<td>Developing strategic foresights</td>
</tr>
<tr>
<td>Prototyping</td>
<td>Concept generation</td>
<td>Concept</td>
<td>Design phase</td>
<td>Sense making and opportunity development</td>
</tr>
<tr>
<td>Testing</td>
<td>Concept selection</td>
<td>Preliminary layout</td>
<td>Verification and validation</td>
<td>Ideation and concept development</td>
</tr>
<tr>
<td>Refining</td>
<td>Development strategy and planning</td>
<td>Definitive layout</td>
<td>Design transfer and manufacturing</td>
<td>Rapid concept prototyping</td>
</tr>
<tr>
<td>Implementing</td>
<td>Integration</td>
<td>Documentation</td>
<td>Field activity</td>
<td>Customer co-creation</td>
</tr>
<tr>
<td>Monitoring</td>
<td></td>
<td>Solution</td>
<td>Upgrade and improve (after each step)</td>
<td>Brand/market assessment</td>
</tr>
</tbody>
</table>

CODING LEGEND

- Planning and preparation
- Exploration
- Framing
- Embodiment
- Refinement
- Production

Information: adapt specification (after each step)
### Appendix D – Literature review chart

<table>
<thead>
<tr>
<th>Author (source):</th>
<th>Successful design research planning:</th>
</tr>
</thead>
<tbody>
<tr>
<td>History, theory and practice of product design</td>
<td>N/A</td>
</tr>
</tbody>
</table>
| *Horst Rittel (1973)*  
(Burdek, 2005, p.252) |  |
| Research Methods for Product Design  
(Milton & Rodgers, 2013, p.14, 139-145) | 1. Choosing the right methods  
2. Checklists  
3. External decision making  
4. Intuition  
5. Crowdsourcing  
6. Product champions  
7. Matrix evaluation |
| Convivial Toolbox Generative Research for the Front end of Design  
(Sanders & Stappers, 2012, p.126) | Making the plan consists of:  
• Setting goals  
• Knowing assumptions  
• Setting timelines for researcher, client, users, and stakeholders  
• Determining deliverables  
• Setting a budget  
• *(p.127)*  
“Evaluate the effectiveness of the plan after the project is over.”  
“Discuss:  
• Were the objectives met? Why or why not?  
• Were the deliverables completed and delivered? Why or why not?  
• Was the schedule met? Why or why not?  
• Was the work done within the estimated budget? Why or why not?  
• Also ask client team for their feedback  
• *(p.136)* |
| 101 Design Methods: A Structured approach for driving innovation in your organization  
(Kumar, 2013, p.8-10) | The Modes of the Design Innovation Process:  
1. Sense Intent  
   a. Sense changing conditions  
   b. See overviews  
   c. Foresee trends  
   d. Reframe problems  
   e. Form an intent  
2. Know Context  
   a. Know context history  
   b. Understand frontiers  
   c. See system overviews  
   d. Understand stakeholders  
   e. Use mental models  
3. Know People  
   a. Observe everything  
   b. Build empathy  
   c. Immerse in daily life  
   d. Listen openly  
   e. Look for problems and needs |
<table>
<thead>
<tr>
<th>Design Management Managing Design Strategy, Process and Implementation (Best, 2006)</th>
<th>Project planning:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Make sure client and design teams agree and understand the project brief and deliverables by breaking down into manageable project stages.</td>
<td></td>
</tr>
<tr>
<td>2. PM makes sure design methodology, process, development, and implemented stages are mapped out in the sequence they need to occur</td>
<td></td>
</tr>
<tr>
<td>3. PM breaks down tasks into smaller activities within each project stage and prioritizes based on timelines</td>
<td></td>
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<tr>
<td>4. Project roles and responsibilities, lines of communication and team-management procedure need to be identified</td>
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<tr>
<td>5. PM should identify any additional resources or stakeholder involvement that will be needed</td>
<td></td>
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<tr>
<td>6. Key milestones such as deadlines, reviews, and presentation should be identified</td>
<td></td>
</tr>
<tr>
<td>7. Project review meetings allow for progress monitoring (internally and externally)</td>
<td></td>
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<tr>
<td>8. PM should set up a project file and make sure the team understands the system for information flow, documentation, record keeping and administration</td>
<td></td>
</tr>
<tr>
<td>9. (p.150)</td>
<td></td>
</tr>
<tr>
<td>10. Project planning tools: software applications, Gantt charts (p.152)</td>
<td></td>
</tr>
<tr>
<td>11. Critical path is used to track progress of the project implementation</td>
<td></td>
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<tr>
<td>12. Risk audits identify where problem areas are most likely to crop up on a project, and propose what should happen in the event of one occurring.</td>
<td></td>
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<tr>
<td>13. (p.154)</td>
<td></td>
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<tr>
<td>14. Hold regular review meetings (p.156)</td>
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</tbody>
</table>

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<thead>
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</thead>
<tbody>
<tr>
<td>1. Creating a sensible plan</td>
<td></td>
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<tr>
<td>2. Establishing goals and objectives</td>
<td></td>
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<tr>
<td>3. Determining strategy</td>
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<tr>
<td>4. Playing hunches</td>
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<tr>
<td>5. Shaping your plan</td>
<td></td>
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<tr>
<td>6. Planning for interaction</td>
<td></td>
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<tr>
<td>7. Developing personas</td>
<td></td>
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<tr>
<td>8. Scenarios, user stories, and use cases</td>
<td></td>
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<tr>
<td>9. Flowcharting actions</td>
<td></td>
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<tr>
<td>10. Planning a sitemap</td>
<td></td>
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<tr>
<td>11. Developing a content inventory</td>
<td></td>
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<tr>
<td>12. Building wireframes</td>
<td></td>
</tr>
<tr>
<td>13. Determining content strategy</td>
<td></td>
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<tr>
<td>14. Recognizing the traps of shadow planning</td>
<td></td>
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<tr>
<td>15. Challenging approaches and beliefs</td>
<td></td>
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<tr>
<td>16. Making recommendations</td>
<td></td>
</tr>
<tr>
<td>17. Crafting the creative brief</td>
<td></td>
</tr>
<tr>
<td>18. Preparing documentation</td>
<td></td>
</tr>
<tr>
<td>19. Keep your design project moving</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Universal Methods of Design (Martin &amp; Hanington, 2012, p.7)</th>
<th>• Methods are displayed under corresponding design phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>• No sections on planning, but some methods can be used</td>
<td></td>
</tr>
<tr>
<td>Title</td>
<td>Overview</td>
</tr>
<tr>
<td>----------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| **The Industrial Design Reference & Specification Book**             | - First, a new need/opportunity identified  
- Then, market research is conducted to verify need and understand competitive landscape (p.24)  
- Creation of a product specification, which sets goals for cost and performance requirements, and defines parameters. “This specification functions as a tool for measuring success in the development stage.” (p.25) |
| **Design Research Through Practice**                                  | - Constructive research, research programs, and case studies  
- Building research programs: an overview of the field’s progress |
| **Exposing the Magic of Design: A Practitioner’s Guide to the Methods and Theory of Synthesis** | - Addresses importance of synthesis in the design process  
- Presents a theory of design synthesis  
- Presents actionable methods for design synthesis (p.xv) |
| **Doing Research in Design**                                          | 1. Identify a research purpose  
2. Evaluate quantitative and qualitative approaches  
3. Have ethical research practices  
4. Frame a research question |
| **A Designer’s Research Manual**                                      | - Written by graphic designers  
- History of research in design  
- Research methods and processes from: The Big 6, AIGA, and Design Council  
- Case studies |
| **A Designer’s Research Manual**                                      | The Design Process:  
1. First steps  
   a. Begin with a brief  
   b. Ask the right questions  
   c. Investigate why  
   d. Define the problem  
2. Research  
   a. Research needs  
   b. Focus on the user  
   c. Observe customer behavior  
3. Planning  
   a. Account for internal resources, people, and information  
4. Communication  
   a. Make relationships a two-way street  
   b. Predetermine review stages  
   c. Ensure that all parties are on board  
5. Implementation  
   a. Stay involved  
   b. Establish project assessment procedures |
| **About Face 3 The Essentials of Interaction Design**                 | - Interaction-design focused  
- Goal directed design (chart):  
1. Research – Scope, audit, stakeholder interviews, user interviews and observations |
| p.24, 20) | 2. Modeling – Personas, other models  
3. Requirements definition – Context scenarios, requirements  
4. Design framework – Elements, framework, key path & validation scenarios  
5. Design refinement – Detailed design  
6. Design support – Design modification (p.24)  
   • Information to gather from Stakeholder interviews:  
     o Preliminary product vision  
     o Budget and schedule  
     o Technical constraints and opportunities  
     o Business drivers | 
| A Project Guide to User Experience Design (Unger & Chandler, 2009) | Ch.3 - Create a proposal (below are items within a proposal that would help with design research planning):  
   • Project overview  
   • Project approach  
   • Scope of work  
   • Assumptions  
   • Deliverables  
Ch.4 – Project objectives and approach  
   • Have clear project objectives  
   • Have a well-understood approach  
   • At the kickoff meeting, you should know the following:  
     o Why is the project important to the company?  
     o How will stakeholders determine if the project was a success?  
     o What approach or methodology will the project follow?  
     o What are the major dates or milestones for key points, such as getting approval from business stakeholders?  
   • Project objective: a statement of measurable goal for the project  
   • If objectives are unclear, hold a workshop with key stakeholders and conduct a SWOT analysis  
   • Understand the project approach:  
     o Waterfall approach  
     o Agile approach  
     o Modified approach  
   • How understanding the approach helps:  
     o Knowing which questions to ask and when  
     o Expectations on how project team members will collaborate and how often  
     o Knowing which level of detail is needed in documentation  
     o Knowing important milestones that involve approval from stakeholders  
Ch.5 Business Requirements  
   • Turn fuzzy objectives into requirements  
   • Requirements: statements defining what the site or application needs to do |
| Design Research Now (Michel, 2007) | • First volume on design research to show different positions within design research  
• Book not representative of design research globally (Book review by David Durling (Durling, 2009)) |
| Handbook of Global User Research (Schumacher, 2010) | • Focuses on a global outlook of user research and considers its challenges  
**Ch.1 Foundations and definitions**  
• User research: the systematic study of the goals, needs, and capabilities of users so as to specify design, construction, or improvement of tools to benefit how users work and live. (p.6)  
**Ch.2 Project management**  
• Engage stakeholders continuously and in all stages of the project and keep them informed of all relevant details  
• Prepare, prepare, prepare. Anticipate problems ahead of time  
• Communicate frequently with the local team  
• When scheduling international projects, begin in the country with which you are most comfortable and with a local team whose reliability you trust  
• Plan extra time in foreign countries to allow for variables such as customs, visas, travel delays, weather...etc.  
• Deal with problems as they arise  
• Travel to the local site whenever possible  
• For foreign studies, select a team that is open-minded, flexible, and experienced in carrying out international studies  
**Ch.3 Preparation**  
• Identify the objectives for the study as well as targeted objectives for each of the countries  
• Avoid artifacts (variables that are supposed to change and didn't) by reviewing stimuli for different test locations. Be aware of language and cultural barriers  
• Make sure the stimuli function in all locations (ex: hardware should work)  
• Create a detailed test plan to help you communicated with local teams and include: schedule, objectives, stimuli, target user groups, methodology, lab setup, expected output, contact information and availability  
• Prepare all research documents: screening questionnaire, consent forms, moderator’s guide (and localize)  
• Conduct a briefing prior to the study  
• Have the local teams conduct a pilot test prior to data collection |
| **Observing the User Experience: A Practitioner’s Guide to User Research** (Kuniavsky, 2003) | • A research plan consists of: the goals, the schedule, and the budget  
• Every research plan should:  
  o Set expectations  
  o Set schedules and responsibilities  
  o Specify goals  
  o Specify outputs  
• Begin by identifying stakeholders  
• User research: the process of understanding the impact of design on an audience |
|---|---|
| **It’s Our Research** (Sharon, 2012) | • Involve stakeholders throughout the process of planning, execution, analysis, and reporting UX research  
• A difficulty in the practice of UX research is getting stakeholder buy-in |
| **Measuring the User Experience** (Tullis & Albert, 2013) | **Ch.1 Introduction**  
User experience definition:  
• A user is involved  
• That user is interacting with a product, system, or anything with an interface  
• The users’ experience is of interest, and observable or measurable  
**Ch.3 Planning (geared toward usability)**  
• Study goals – decide how the data will be used within the product development life cycle  
• User goals – understand users and what they’re trying to accomplish  
• Choose the right metrics – consider factors such as study and user goals, technology for data collection, budget, and time  
• Other considerations when planning include:  
  o Budgets and timelines  
  o Participants  
  o Data collection  
  o Data cleanup |
| **The Design of Everyday Things** (Norman, 2013) | **Ch.1 The Psychopathology of Everyday Things**  
• Human-centered design (HCD): an approach that puts human needs, capabilities, and behavior first, then designs to accommodate those needs, capabilities, and ways of behaving.  
**Ch.6 Design Thinking**  
• Make sure to solve the right problem  
• Norman takes British Design Council’s Double-Diamond and says the first phase is to find the right problem, and the second phase is to find the right solution  
• Designers often start by questioning the problem given to them and follow the Double-Diamond model  
• Ask stupid questions  
• Companies that look for human needs face challenges of time and budget and may skimp out on research  
• Product development is a difficult process that involves people from varying disciplines who also need to iterate around “patent mines” |
The solution to handle lack of time and not being able to do good up-front design research is to separate the process from the product team and always have design researchers in the field studying products and customers.

- The clash of multidisciplinary teams can be resolved when participants learn to understand and respect the requirements of one another. Good teams work as harmonious groups, with representatives from disciplines present at all times. Each discipline speaks a different language and a skilled product manager can help facilitate mutual understanding and respect.

The User Experience Team of One
(Buley, 2013)

- Author is a “cross-over” from journalism and offers insight into freelance UX design

Ch.2 Getting started
- Get to know the UX Toolkit
  - Understand methodologies for gaining information (ex: content analysis, context mapping, card sorting, site map...etc.)
- Establish a point of view on the work to be done
  - Have a clear picture of what work needs to be done and how you can best contribute
  - Find parts of the product that everyone knows needs improvement
  - Make a plan – sketch how you’d like to approach a project, which activities you’d propose and when and why, which questions you think need to be answered

Ch.5 Planning and Discovery Methods
- Planning helps you get organized and reach an agreement with others about priorities and goals
- Planning helps you:
  - Determine what you plan to improve
  - Obtain a high-level vision for the resulting experience
  - Identify opportunities (relative to market)
  - Outlines what you’ll be doing
  - Create a plan and show how UX work integrates with other parts of product development
- Tools:
  - UX questionnaire:
    - Ask key questions (team, goals, users, strategy, tasks and scenarios, success measures, milestones, and risks)
  - UX project plan:
    - Understand goals
    - Brainstorm relevant methods
    - Estimate duration
    - Place milestones
    - Create document
    - Tips: Scope and re-scope, estimate complexity, and use checklists, plan for triage periods
<table>
<thead>
<tr>
<th><strong>Listening tour</strong></th>
<th><strong>Opportunity workshop</strong></th>
</tr>
</thead>
</table>
| - Identify what you’d like to learn, write questions and set up interviews and share results with team. | - Host a work session  
- State goals of work session  
- Uncover problem areas  
- Discuss strengths (of product)  
- Find themes  
- Prioritize and discuss |

<table>
<thead>
<tr>
<th><strong>Project brief</strong></th>
<th><strong>Strategy workshop</strong></th>
</tr>
</thead>
</table>
| - Determine the right building blocks for your project brief (business needs, user needs, goals, key expectations)  
- Write up what you know, or your best guesses in a document  
- Circulate the document  
- Regularly revisit and make sure you’re on track  
- Tips: make it ceremonial, keep it brief | - State goals  
- Make a plan |

**Understanding your Users**  
(Courage & Baxter, 2005)

- **Ch.1 Introduction to User Requirements**  
  - Getting stakeholder buy-in:  
    - Avoid resistance by getting stakeholders involved and becoming a virtual team member

- **Ch.5 Preparing for your user requirements activity**  
  - Create a proposal  
  - Decide the duration and timing of your session  
  - Track participants  
  - Create a protocol  
    - Protocol: a script that outlines all procedures you will perform as a moderator and the order in which you will carry out these procedures.
  - Pilot your activity

**UX for Lean Startups**  
(Klein, 2013)

- Geared toward lean startups and introduces “lean UX” as an agile design process where iterations take place and superfluous activity is decreased
- Lean UX is about validating hypotheses (don’t assume that you know what the users wants)

- **Ch.1 Early Validation**  
  - Validate key hypotheses as early as possible  
  - Validate the market  
  - Validate the product  
  - Tools for early validation:  
    - Ethnographic studies  
    - Landing-page tests  
    - Prototype tests
  - Pain-driven design builds on User-centered design and Customer-driven development and gets at figuring out what is causing pain for your users and potential users
<table>
<thead>
<tr>
<th>Source</th>
<th>Summary</th>
</tr>
</thead>
</table>
| Designing Design Research                                            | • Quality products/systems come from quality research  
| (Bennett, 2011)                                                      | • Flow diagram of methodology                                                                                                        |
| A theoretical basis for recommending the use of design methodologies | N/A                                                                                                                                 |
| as teaching strategies in the design studio                          |                                                                                                                                        |
| George Polya (1957)                                                  |                                                                                                                                        |
| (Curry, 2014)                                                        |                                                                                                                                        |
| Understanding design research: A bibliometric analysis of Design     | • Quantitative analysis investigating themes of design research by analyzing 12,107 citations of papers (459) in Design studies  
| Studies                                                             | • Core themes were: design process and design cognition  
| (Chai & Xiao, 2012)                                                  | • Research method protocol analysis has become more popular in recent years among researchers |
| Different perceptions of the design process in the context of Design | • Study of a designer’s process while preparing a work proposal and where the client sees value at different stages  
| Design Research: A Disciplined Conversation                          | • Gives an overview of the design research field  
| (Cross, 1999)                                                       | • Taxonomy of the field of design research:  
|                                                                      | o Design epistemology: study of designerly ways of knowing  
|                                                                      | o Design praxiology: study of the practices and processes of design  
|                                                                      | o Design phenomenology: study of the form and configuration of artifacts  
|                                                                      | (p.6)  
|                                                                      | • Best practices in design research have the following characteristics:  
|                                                                      | o Purposive, based on identification of an issue or problem worthy and capable of investigation  
|                                                                      | o Inquisitive, seeking to acquire new knowledge  
|                                                                      | o Informed, conducted from an awareness of previous, related research  
|                                                                      | o Methodical, planned and carried out in a disciplined manner  
|                                                                      | o Communicable, generating and reporting results which are testable and accessible by others  
|                                                                      | (p.9)                                                                                                                                |
| Demystifying “Design Research”: Design is not research, research is  | • Emphasizes that research is a creative design activity, and is not like traditional research in other fields where the goal is to produce replicable results  
| design                                                               | • Differentiates between the different types of design research  
<p>| (Faste &amp; Faste, 2012)                                                | o Design through research (studious design research)                                                                                   |</p>
<table>
<thead>
<tr>
<th>Topic</th>
<th>Reference</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Design or “Design” – Envisioning a future design education</td>
<td>(Sless, 2012)</td>
<td>Design of research (formative design research)</td>
</tr>
<tr>
<td>Why Horst W.J. Rittel Matters (Rith &amp; Dubberly, 2007)</td>
<td></td>
<td>Rittel’s ideas that pertain to design research planning:</td>
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<tr>
<td></td>
<td></td>
<td>• Simple problems (problems which are already defined) are easy to</td>
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<td></td>
<td></td>
<td>solve, because defining a problem inherently defines a solution</td>
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<td></td>
<td></td>
<td>• The definition of a problem is subjective; it comes from a point of</td>
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<td></td>
<td></td>
<td>view. Thus, when defining problems, all stakeholders, experts, and</td>
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<td></td>
<td></td>
<td>designers are equally knowledgeable (or unknowledgeable).</td>
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<tr>
<td></td>
<td></td>
<td>• Solving simple problems may lead to improvement—but not innovation.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>For innovation we need to re-frame wicked problem [problems that</td>
</tr>
<tr>
<td></td>
<td></td>
<td>cannot be solved.]</td>
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<tr>
<td></td>
<td></td>
<td>• Because one person cannot possibly remember to keep track of all</td>
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<td></td>
<td></td>
<td>the variables (of both existing and desired states) in a wicked</td>
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<td></td>
<td></td>
<td>problem, taming wicked problems requires many people.</td>
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<td></td>
<td></td>
<td>• These people [stakeholders] have to talk to each other; they have</td>
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<tr>
<td></td>
<td></td>
<td>to deliberate; they have to argue.</td>
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<td></td>
<td></td>
<td>• To tame a wicked problem, they [stakeholders] have to agree on</td>
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<td></td>
<td></td>
<td>goals and actions for reaching them. This requires knowledge about</td>
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<tr>
<td></td>
<td></td>
<td>actions, not just facts.</td>
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<tr>
<td></td>
<td></td>
<td>• Science is concerned with factual knowledge (what-is); design is</td>
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<td></td>
<td></td>
<td>concerned with instrumental knowledge (how what-is relates to what-</td>
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<td></td>
<td></td>
<td>ought-to-be), how actions can meet goals.</td>
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<tr>
<td></td>
<td></td>
<td>• The process of argumentation is the key and perhaps the only</td>
</tr>
<tr>
<td></td>
<td></td>
<td>method of taming wicked problems</td>
</tr>
<tr>
<td>Strategic Innovation and the Fuzzy Front End</td>
<td>(Mootee, 2011)</td>
<td>“The need for 21st-century mindsets and protocols has heightened</td>
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<tr>
<td></td>
<td></td>
<td>interest in innovation.”</td>
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<td></td>
<td></td>
<td>• Provides pointers about managing the “fuzzy front end” of</td>
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<td></td>
<td></td>
<td>innovation [paraphrased]:</td>
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<tr>
<td></td>
<td></td>
<td>o Combining specific skill sets, tools and methodologies from</td>
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<tr>
<td></td>
<td></td>
<td>different disciplines</td>
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<tr>
<td></td>
<td></td>
<td>o Balancing divergent exploration and investigation with</td>
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<td></td>
<td></td>
<td>convergent analysis</td>
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<td></td>
<td></td>
<td>o Developing and articulating a more holistic awareness of</td>
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<tr>
<td></td>
<td></td>
<td>current and emerging consumer needs, mind-sets, values, and</td>
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<tr>
<td></td>
<td></td>
<td>expectations</td>
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<td></td>
<td></td>
<td>o Collecting, organizing, and making sense of the forces that</td>
</tr>
<tr>
<td></td>
<td></td>
<td>will help shape the acceptance and practicality of new products,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>services, and business models</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Synthesizing and clarifying competitive opportunities</td>
</tr>
</tbody>
</table>
| Logic Models in Design Research Planning | • Author presents logic models as a design research planning tool to undergraduate and graduate students at Kent State University  
| | • Tool helps students break down large problems by  
| AIGA, 2014, p.193 | • "Program logic models also serve as an evaluative tool for efficacy of a program or project based on the ability of the participants to achieve expected outcomes" (McLaughlin & Jordan, 1999) |
| Eleven lessons: managing design in eleven global brands | • Study of 11 different global companies  
| A study of the design process | • Introduce double diamond design process model:  
| The Design Council, 2005 | o Discover: market research, user research, managing information, design research groups  
| | o Define: project development, project management, project sign off  
| | o Define: project development, project management, project sign-off  
| | o Develop: multi-disciplinary working, visual management, development methods  
| | o Deliver: final testing, approval and launch  
| | o Targets, evaluation and feedback loops |

### Medical Device Literature

**Biodesign The Process of Innovating Medical Technologies**  
(Zenios, Makower, & Yock, 2010)

**Stage 1: Needs Finding**

1. **Strategic focus: Take inventory**
   - a. Perform a personal inventory by defining a mission in a research area: purpose, priorities, and goals  
   - b. Assess strengths and weaknesses  
   - c. Identify acceptance criteria and prioritize  
   - d. Personal reflection about personal motivators, capabilities, and characteristics of a project  
   - e. Facilitate sessions with potential group members to discuss mission  
   - f. Receive advice from advisors

2. **Strategic focus: Articulate a strategic focus**
   - a. Perform research to identify focus areas that may align with acceptance criteria  
   - b. Use online databases to conduct a literature review (p.16)

3. **Observation and Problem identification**
   - a. Set up and prepare for observations: patients, physicians, other healthcare providers  
   - b. Perform primary and secondary research  
   - c. Conduct and document observations  
   - d. Name the problem-iterate on how you frame the problem  
   - e. Test and refine problem statement  
   - f. P.33-35
### Need statement development
- Translate problem into a need statement
- Verify the accuracy of the need statement against the problem
- Confirm that the need is solution independent
- Validate that the scope of the need is appropriate
- Define the need criteria and classify the need
- p.47-49

### Stage 2: Needs Screening
1. Disease state
2. Treatment options
3. Stakeholder analysis:
   - Identify stakeholders
   - Outline benefits and costs for each stakeholder group
   - Summarize net impact and key issues for each stakeholder group
   - Classify stakeholders and assess trade-offs
4. Market analysis
5. Needs filtering
   - Select screening criteria
   - Assign ratings
   - Calculate scores
   - Filter needs

---

**Medical Device Design**  
(Ogrodnik, 2011)

**Ch.3 – The Design Process**
- The medical devices design model (see next column) begins with a statement of need and is further clarified in a product design specification (PDS)
- “…communication is an important aspect in the control of design.” (p.41)

**Tools**
- A product design specification (PDS) is drawn up and revised after understanding user needs (p.36)
- A design file helps document every step of the design process and each change made (p.38)

**Chapter overview:**
- Make sure specification of new product/device/software is robust
- Avoid “sacred cows” (holding on to ideas you hold “sacred”)
- Convergent process to a single solution is critical and must be robust
- Detailed design of the new product must be robust and the evaluation
- Be proactive and not reactive
- Build iterative loops into your design to allow for design changes
- “Use all modern communication tools to communicate with any of your potential stakeholders”
- Bring people into the design process as early as possible
<table>
<thead>
<tr>
<th>Ch.4 – Implementing Design Procedures</th>
<th>Ch.5 – Developing your product design specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedures are implemented to meet the requirements for FDA CFR 21 and ISO 13485</td>
<td>A [PDS] is the cornerstone of any good design (p.71)</td>
</tr>
<tr>
<td>“While there has been an attempt to provide procedures that are general in nature it is important for you to develop your own procedures…” (p.70)</td>
<td>A PDS helps clients understand what they agreed upon for the project</td>
</tr>
<tr>
<td>Develop a statement of need (or brief). It includes:</td>
<td>Develop a statement of need (or brief). It includes:</td>
</tr>
<tr>
<td>o Can we do it?</td>
<td>o Can we do it?</td>
</tr>
<tr>
<td>o Can we afford to do it?</td>
<td>o Can we afford to do it?</td>
</tr>
<tr>
<td>o Who wants it?</td>
<td>o Who wants it?</td>
</tr>
<tr>
<td>o How many want it?</td>
<td>o How many want it?</td>
</tr>
<tr>
<td>o For how much?</td>
<td>o For how much?</td>
</tr>
<tr>
<td>• Elements of a PDS:</td>
<td>• Elements of a PDS:</td>
</tr>
<tr>
<td>o Customer</td>
<td>o Customer</td>
</tr>
<tr>
<td>o Regulatory and statutory</td>
<td>o Regulatory and statutory</td>
</tr>
<tr>
<td>o Technical</td>
<td>o Technical</td>
</tr>
<tr>
<td>o Performance</td>
<td>o Performance</td>
</tr>
<tr>
<td>o Sales</td>
<td>o Sales</td>
</tr>
<tr>
<td>o Manufacturing</td>
<td>o Manufacturing</td>
</tr>
<tr>
<td>o Packaging and transportation</td>
<td>o Packaging and transportation</td>
</tr>
<tr>
<td>o Environmental</td>
<td>o Environmental</td>
</tr>
<tr>
<td>• PDS influenced by sources in the data cloud (Customers, end users, regulations, clinicians, nurses, patients, standards, literature reviews, initial risk analysis, packagers, manufacturing, sales, R&amp;D…etc.)</td>
<td>• PDS influenced by sources in the data cloud (Customers, end users, regulations, clinicians, nurses, patients, standards, literature reviews, initial risk analysis, packagers, manufacturing, sales, R&amp;D…etc.)</td>
</tr>
</tbody>
</table>

Reliable Design of Medical Devices
(Fries, 2012)

Ch.4 Defining the device

- The product definition process begins with understanding the user. Along with customer surveys, assess the company needs and competencies and the competitors’ competencies, then define the product (p.61)
- Quality function deployment (QFD): “process in which the “voice of the customer is first heard and then deployed…a product is planned, designed, made, and then made consistently (p.62)
- Matrices introduced
- Business proposal:
  - Project overview, objectives, major milestones, schedule
  - Market need and market potential
  - Product proposal
  - Strategic fit
  - Risk analysis and research plan
  - Economic analysis
  - (p.70)

(U.S. Food and Drug Administration, 1997)

- Purpose of Design Control is to “ensure quality assurance practices are used for the design of medical
devices and that they are consistent with quality system requirements worldwide (p.i)

- Design controls: interrelated set of practices and procedures that are incorporated into the design and development process (system of checks and balances) (p.1)
- Design controls provide managers and designers with improved visibility of the design process. (p.1)
- The Waterfall Design Process (p.3)
- Design review: conducted to assure that the design input requirements are adequate before they are converted into design specifications (p.4)
- Design validation review: conducted prior to transfer of the design to production (p.4)
- Risk management: systematic application of management policies, procedures, and practices to the tasks of identifying, analyzing, controlling, and monitoring risk (p.5)
- Design input: the physical and performance requirements of a device to be designed (p.13)
- Design output: results of a design effort at each design phase and at the end of the total design effort (p.19)
- Specification: any requirement with which a product, process, service, or other activity must conform (p.29)
- Validation planning:
  - Happens early in the process
  - The performance characteristics that are to be assessed should be identified and validation methods and acceptance criteria should be established
  Validation plan should be reviewed for appropriateness, completeness, and to ensure that user needs and intended uses are addressed (p.34)

<table>
<thead>
<tr>
<th>ISO 13485:2003 Section 7.3 (International Organization of Standardization, 2003)</th>
</tr>
</thead>
<tbody>
<tr>
<td>The primary objective of this standard is to “facilitate harmonized medical device regulatory requirements for quality management systems.” (p.1)</td>
</tr>
<tr>
<td>Definition of medical device (p.3)</td>
</tr>
<tr>
<td>Quality management system general requirements:</td>
</tr>
<tr>
<td>- the organization shall establish, document, implement and maintain a quality management system and maintain its effectiveness in accordance with the requirements of this International Standard (p.4)</td>
</tr>
<tr>
<td>4.2 Documentation requirements (p.4-5):</td>
</tr>
<tr>
<td>- Statements of quality policy and quality objectives</td>
</tr>
<tr>
<td>- A quality manual</td>
</tr>
<tr>
<td>- Documented procedures required by this International Standard</td>
</tr>
<tr>
<td>- Documents needed by the organization to ensure the effective planning, operation and control of its processes</td>
</tr>
<tr>
<td>- Records required by this International standard</td>
</tr>
<tr>
<td>- Any other documentation specified by national or regional regulations</td>
</tr>
</tbody>
</table>
Planning (p.7)

- Quality objectives: top management shall ensure that quality objectives, including those needed to meet requirements for product are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.
- Quality management system planning: top management shall ensure that the planning of the quality management system is carried out in order to meet the requirements given in 4.1 as well as the quality objectives and the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

7.3.1 – Design and Development Planning (p.11)
- The organization shall establish documented procedures for design and development. The organization will determine:
  - The design and development stages
  - The review, verification, validation and designer transfer activities that are appropriate at each design and development stage
  - The responsibilities and authorities for design and development
- Planning output shall be documented, and updated as appropriate, as the design and development progresses.

7.3.2 – Design and Development Inputs (p.11)
- Functional, performance and safety requirements according to the intended use
- Applicable statutory and regulatory requirements
- Information derived from previous similar designs
- Other requirements for design and development
- Output of risk management
- Inputs shall be reviewed for adequacy and approved.

7.3.3 – Design and Development Outputs (p.12)
- Meet the input requirements for design and development
- Provide appropriate information for purchasing, production and for service provision
- Contain or reference product acceptance criteria
- Specify the characteristics of the product that are essential for its safe and proper use.

7.3.4 – Design and Development Review (p.12)
- At suitable stages, system reviews of design and development shall be performed in accordance with planned arrangements to:
  - Evaluate the ability of the results of design and development to meet requirements
  - Identify any problems and propose necessary
| Applied Ergonomics: Determining User needs in Medical Device Design  
(Privitera & Murray, 2009) | • Methodology used for Cincinnati’s Medical Device Innovation and Entrepreneurship Program  
• Talks about the FDA waterfall process and how ethnography and other process elements fit into the overall process  
• Ethnography: user observation and interview  
• Data analysis and translation and embodiment |
| --- | --- |
| Ethnographic Field Research for Medical-Device Design  
(Wilcox, 2012) | Commentary on Field research for medical device design  
• Argues that user testing doesn’t uncover needs like ethnographic research (observation)  
• Talking to people isn’t enough because often what they say is not what they do  
• Ethnographic approach adapted to “micro-culture” of medical device users:  
  o Perspective: seeing from others’ point of view and understand framework  
  o Protocols: create a detail, formal research protocol that guides the research  
• Argues that ethnography can replace traditional “voice-of-consumer” tactics to understand the user better |
| Capturing user requirements in medical device development: the role of ergonomics  
(J. L. Martin et al., 2006) | • Ergonomic methods have been developed as a result of challenges such as: ethical and research governance and time and financial constraints  
• Methods used in ergonomic research are UCD processes  
• Article goes in detail about different methods  
• Main finding: few papers provide any recommendation on the factors that should be considered by developers when choosing methods to use within product development |