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Session #4: Approaches for Development of VA HSR&D CDA Research Plans

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VA HSR&D CDA Enhancement Program Cyberseminar

May 2016

Purpose of Session #4

- **Last time...**
 - Focus on identification of mentor(s) and mentoring plan
- **This time...**
 - Focus on development of the research plan (all 19 pages of it!)



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Reminder of CDA Evaluation Criteria

- Nominee's professional background and productivity
- Appropriateness of the research and training plans presented
- Suitability of proposed mentors in relation to nominee's goals
- **Relevance of planned research to VA**
- **Feasibility and merit of planned research**
- Anticipated long-term contributions to VA



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CDA Proposal Workshop (Oct 2014)

Specific Aim Recommendations

- **Clear**
- **Relevant**
- **Logical**
- **Exist within a conceptual framework**
- **Achievable**
- **Build upon one another (but not overly**
- **Can lead to independent projects (pubs, instruments, etc.)**
- **Will lead to independent IIR**
- **Novel (will add to lit)**
- **How this fits with other VA work in this area (research, operations, policy)**

...oh, is that all?



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CDA Proposal Workshop (Oct 2014)

Research Plan Recommendations

- **Should include more than one...**
 - Aim
 - Goal
 - Hypothesis
 - Project
 - Phase
 - Combination
- **Should be feasible and achievable within CDA timeframe, ambitious *but not too ambitious***



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CDA Proposal Workshop (Oct 2014)

Additional Recommendations

- Conceptual how it all fits together (each aim/project, each training activity, each mentor) – make it all fit within a clear, logical conceptual framework
- Clarify both what you know and what you will need to learn (and why)
- Don't include any “fluff” or undefined jargon
- Help reviewers see progression to independent investigator



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CDA Proposal Workshop (Oct 2014)

From Actual Summary Statements

- Not responsive to LOI feedback
- Plan is very broad and lacks clear hypotheses
- Approach is not well-supported, does not seem to map well to conceptual model
- Methodology requires further development or clarification, more detail needed on data analysis and variables
- Could benefit from greater clarity and organization overall



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CDA Proposal Workshop (Oct 2014)

From Actual Summary Statements

- Pilot work should clearly indicate what aspects of feasibility, effect sizes, etc., are focus on pilot, indicate why pilot work justified, give some indication of what larger study would look like, pilot intervention not well described
- IIR to be developed in Year 3 not developed with sufficient detail to determine feasibility and relation to earlier aims and objectives



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Specific Aims

- **Not technically a part of Research Plan BUT it is perhaps the *singlemost important* 1 pager**
 - Comes immed ahead of 19-page Research Plan
 - Describes short- and long-term objectives
 - In terms of career trajectory and potential impact of proposed research on quality/delivery of Veterans' care
 - Includes succinct specific objectives of each project proposed, states concisely goals of each project, summarize expected outcomes, research impacts



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Specific Aims

- Usually the 1st page an applicant writes
- Has to make early, concise and compelling case for research plan, career plan, candidate
- May want to review others' approaches to Specific Aims on HSR&D website
 - **Reality check** – don't expect that you can adapt what's there – every application is unique
- **Bigger reality check** – expect to revisit Aims page many, many times as you write applic



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Research Plan (19 pages total)

- **Include sufficient information needed for evaluation of the project**, independent of any other document (e.g., previous application)
 - **Reality check** – don't expect reviewers to remember last application let alone aims/methods
 - **Reality check** – don't expect reviewers to know application like you do (provide cross-referencing)
- **Be specific and informative**
 - To be fair, easier said than done – assumes many iterations, local or other pre-review, time...



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Research Plan

- **19-page limit includes:**
 - All text
 - Figures
 - Charts
 - Graphs
 - Diagrams
 - Tables
 - **Do NOT put Gantt charts and other key pieces of information into appendixes (not allowed)**
- Use narrative to explain:**
- What you propose to do
 - Why proposed work is important
 - What similar work has been done (and how your work will add value to it)
 - How proposed work will be done



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3 Research Plan Sections

- **Background and Significance** (2-3 rec pgs)
 - Should reflect awareness of critical issues related to proposal (scientific rationale, theoretical framework, what's known or underway, relevance)
- **Preliminary Studies** (4-6 rec pgs)
 - Pertinent to application, helps assess likelihood of success, applicant's/mentors' work okay to cite
- **Research Design & Methods** (10-13 rec pgs)
 - RFA provides extensive guidance



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Research Plan:

Background & Significance

- **Briefly sketch background leading to application**
 - Suggest big picture framing plus roadmap sentence on what's to follow
- **Present scientific rationale and theoretical framework**
 - Often see Background subsections that tell story (e.g., B1 = overview, B2 = problem is prevalent and costly, B3 = efforts to solve problem fallen short...)



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Research Plan:

Background & Significance

- **Theoretical framework**
 - **Reality check** – often a linchpin for applications
 - Most clinicians and many non-clinicians (e.g., epidemiologists) **not** trained in theory
 - Economists, sociologists, psychologists, anthropologists and more all get trained in theory/theories
 - If not trained, then what?
 - **Another reality check** – get help in developing conceptual and/or theoretical frameworks and this takes time!
 - **Cannot just pick one and describe upfront** – must be applied throughout application in meaningful ways, e.g., inform data collection, survey content, variable selection for analysis

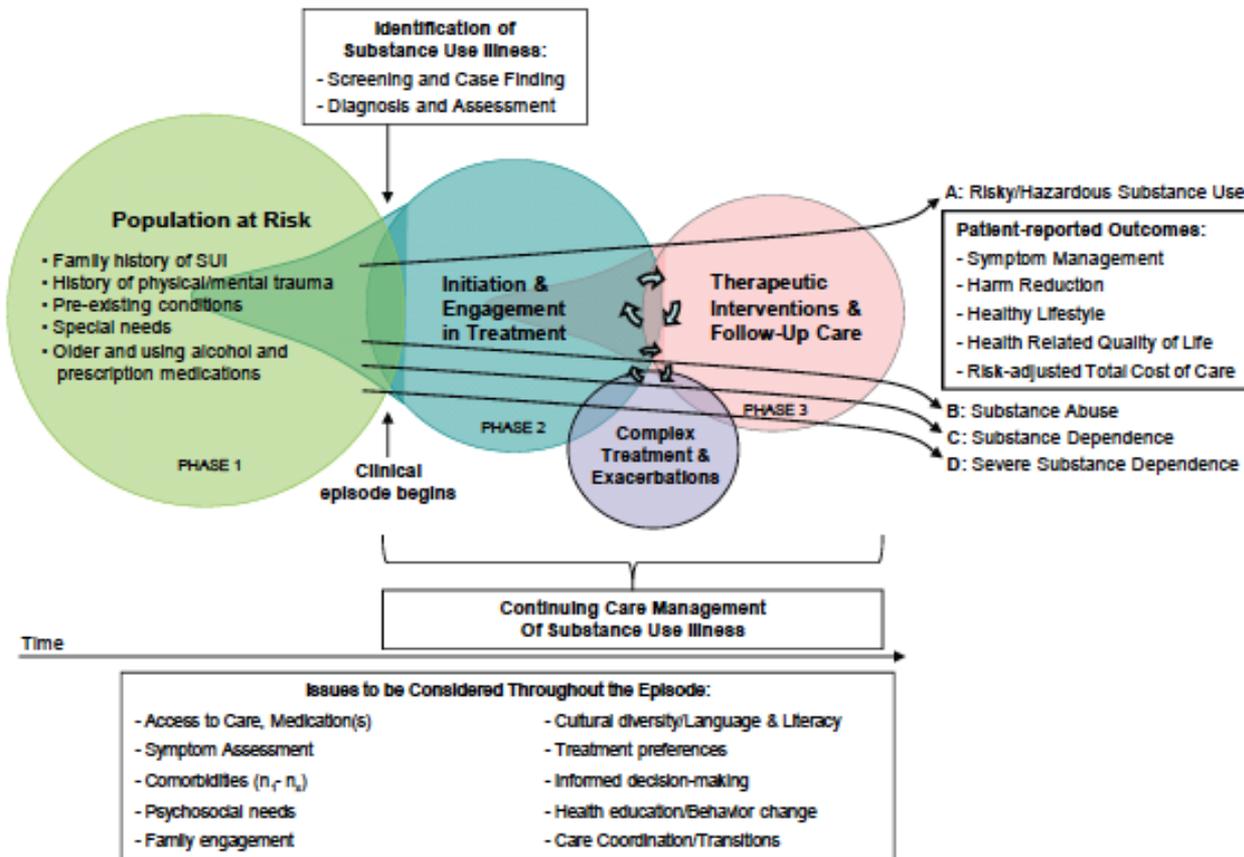


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Research Plan: *Sample Conceptual Model*

Figure 1. Context for Considering a Substance Use Illness Episode of Care



AIM 3. To determine acceptable strategies for delivering a virtual care intervention, by identifying preferences and challenges of pregnant WVs, and their VA providers regarding digital technology.

AIM 1. To understand WVs' experiences, preferences, and challenges accessing and utilizing VA maternity care.

AIM 2. To field a survey of pregnant WVs in VISN 20 to identify determinants of access, utilization, and outcomes of care to inform development of a virtual care intervention.

Healthcare System

VA Health Care System

- Location
- Volume of women Veterans
- Organization of women's health care

Non-VA Purchased Maternity Care

Individual

Pre-disposing

- Demographics
- Veteran specific

Enabling

- Service connection
- Distance to VA homesite

Need

- Pre-existing chronic medical/mental health conditions

Perceived & Actual Access

Barriers & Facilitators

- Distance, financial, convenience, digital connectivity

Need for care

- Symptom burden

Utilization

Face-to-Face

- Provider to patient
- Peer to peer

Digital

- Provider to patient
- Peer to peer

Satisfaction

With:

- Access
- Quality of care
- Outcomes

Quality

Outcomes

Maternal

- Health behaviors (e.g. depression, breast feeding)
- Clinical (e.g. pregnancy complications)

Newborn

- Clinical (e.g. low birth weight, preterm birth)



Research Plan:

Background & Significance

- **Notice both examples are *conceptual* models**
 - No theory apparent yet both were funded
 - Need theoretical treatment that covers whole research plan
 - Have not seen successful applications have a theory for each project (too complicated typically)
 - Is there a theory/framework that can be used to cover your overarching research plan?
 - How do pieces of proposed work fit together?



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Research Plan:

Background & Significance

- **Critically evaluate existing knowledge**
 - Specifically identify gaps proposed research will fill
 - **Reality check** – not enough space to be as thorough as you might want to be
 - Get to key literature – “cite only relevant and recent lit”
 - Don’t mix-and-match VA and non-VA (don’t jump between national civilian and Veteran/VA statistics!)
 - **Reality check** – be aware of ongoing studies in addition to published literature!



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Research Plan:

Background & Significance

- **Concisely state importance and relevance of work described in Research Plan**
 - Relate specific aims to broad, long-term research and career objectives
 - For implementation studies, describe importance to potential VA stakeholders and potential for improving Veterans' health and health care
 - **Reality check** – ALL VA research should in reality be able to describe this – know how your work relates!



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Research Plan:

Background & Significance

- **How will scientific knowledge or clinical practice be advanced if work is done?**
 - **Reality check** – reviewers have not “drunk the Kool-aid” on your topic, assume nothing, make it obvious what impacts may prevail
 - If you don’t know, find out, think it through, talk to people (mentors, other researchers, operations and policy leaders, providers, Veterans)



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Research Plan *Exercise*

- Think about your research interest area
- What is known about this area so far?
- What are the key gaps that need to be remedied?
- Why would this be an important topic in VA?
- What group(s) should you be connected to and/or aware of in making your case?



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Research Plan:

Preliminary Studies

- **Establishes experience and competence of applicant to pursue proposed research**
 - May include that of mentor(s) if relevant (e.g., parent studies that generated data from which applicant is taking spinoff or new direction) and key collaborators
 - May demonstrate experience with particular group(s) of patients, providers, etc.
 - Points to importance of developing track record of work that builds logically to research plan
 - May demonstrate feasibility of obtaining samples, data elements, etc.



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Research Plan *Exercise*

- **Deconstruct elements of your research plan ideas**
 - What kinds of skills/experience are needed to conduct each project?
 - On your part?
 - On the part of your key collaborators and/or mentors?
 - Or on the part of staff to which you will gain access?
 - Are pilot data available and if not, how might you obtain some?



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Research Plan:

Research Design & Methods

- **Describe planned projects as fully as possible**
 - Basic study design, sampling plan, control or comparison groups (if relevant)
 - Methods for data collection and analysis, specific techniques and measures
 - Specify kinds or sources of data to be used, how hypotheses will be tested, aggregate and subgroup analyses, provisions for ensuring data quality and adherence to study protocol



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Research Plan:

Research Design & Methods

- **What does that look like in practice?**
 - Sub-sections that *deliver* on methodological details
 - *Name study designs* (consider design diagrams)
 - *Define sampling units, inclusion/exclusion criteria, sample sizes* (get advance info on likely counts, characteristics if possible, helps demonstrate feasibility)
 - *Describe data collection approaches* (if surveys, describe approach, validated measures w/psychometrics if avail; if admin data, describe variables, ICD9/10 codes, quality; interviewer or moderator guides if qualitative, etc.)
 - *Describe analytic methods* (get statistical help ahead of submission as needed, avoid “handwave” statistics)



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Research Plan:

Research Design & Methods

- Reviewers understand that earlier projects may be more fully developed than later ones
 - **Reality check** – reviewers are not created equal
 - **Reality check** – cannot have later projects be so dependent on earlier ones that you really don't know where you're going to land
 - Make sure you describe how all projects are conceptually linked to each other (and to career plan and longer career trajectory)



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Research Plan:

Research Design & Methods

- **RFA includes additional details – read them carefully!**
 - Is study design suited to specific aims, population?
 - What are advantages/disadvantages of approach?
 - Describe new methodologies used, why preferred
 - Discuss potential problems and limitations
 - Reality check – always better for you to demonstrate awareness, acknowledge, considered alternatives
 - If have “usual care” group, define what that is



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Research Plan:

Research Design & Methods

- **Setting(s), why appropriate, generalizability**
- **Study population(s), sample selection, response rates/retention, sample size/power**
 - Adequate representation of women, minorities
- **Independent and dependent variables**
 - How linked in analysis, how related to conceptual or theoretical model (often forgotten)
 - Reliability, validity, appropriateness of measures
 - If not your area of expertise, get help early, often



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Research Plan:

Research Design & Methods

- **Data collection strategy, timeline, potential problems, data quality controls**
 - Missing data approach, respondent dropouts, etc.
- **Data analysis strategy, outline planned analyses (what answers which questions?)**
 - Include strengths and limitations
- **Novel concepts, approaches, tools, etc.**
- **Timeline (will give examples next session)**



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Project Development Approaches

- **Research plan is a mix of projects rather than a single study**
 - This is NOT an IIR – if you want an IIR funded, just write the grant proposal for it
- **Project #1 – Can you “hit the ground running”?** Cannot wait for training...
- **Project #2 – Can this be done with existing resources or will you need to apply for \$\$?**
 - Reviewers do not expect you to wait for 1+ cycles



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Research Plan Exercise

- **How might you take your research idea(s) and break them into component projects?**
 - What kind of order might they have to be in?
 - How dependent are later projects on earlier ones?
How might you handle dependencies?
 - Which ones can you do right now with existing knowledge/skills vs. will need training?
 - Which ones can you do alone vs. with local resources vs. require an IIR?



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Research Plan Examples

P1: Secondary data analyses

- Local Center provides in-kind programming

P2: Qualitative interviews of patients and providers

- Year 1 qualitative training

P3: Regional or national organizational survey

P1: Systematic review

- Pre-work getting topic nominated to ESP

P2: Qualitative interviews (one site pilot)

- Have expertise
- Possible HSR&D pilot

P3: Multisite pilot

- Approach may vary
- HSR&D IIR



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Research Plan Examples

P1: Examine multilevel determinants of disparities

- Qualitative interviews and practice checklists
- Administrative data

P2: Design and test pilot intervention to reduce disparities

- Acceptability, feasibility

P1: Integrate patient voice into intervention design

- Qualitative interviews
- Small survey

P2: Pilot test intervention

- Acceptability, feasibility

P3: Larger pilot test or effectiveness study

- IIR or alternative?



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Pursuit of Funding During CDA

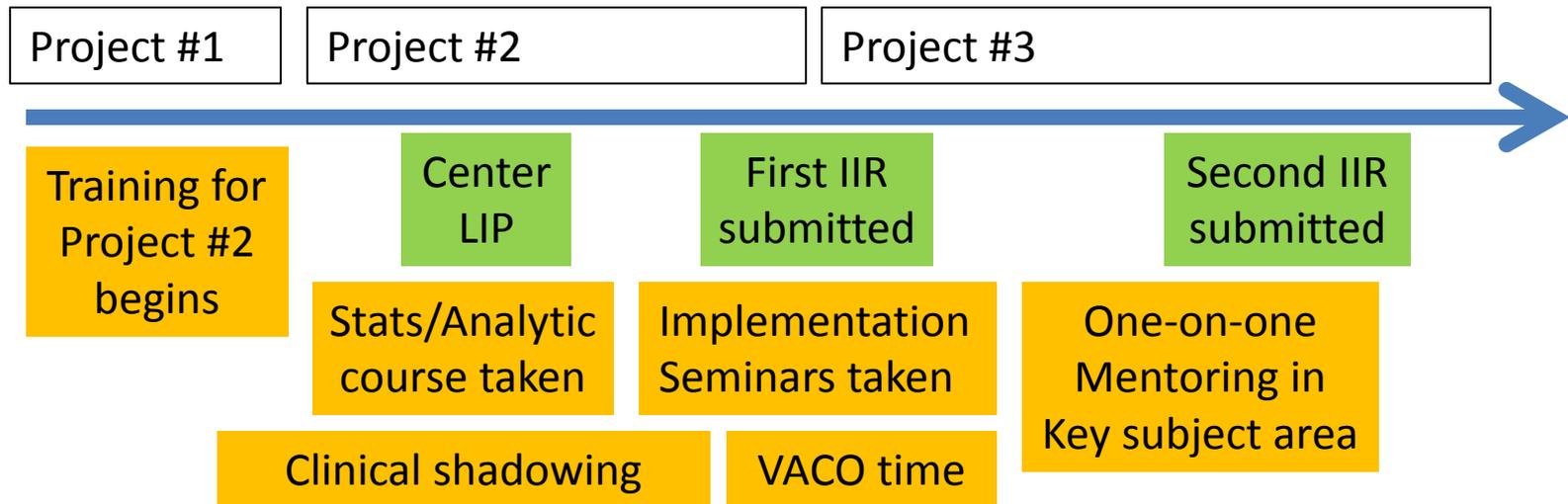
- **VA HSR&D Service**
 - Investigator Initiated Research (IIR) “merits”
 - \$1.1 million cap, no more than 4 years
 - Unlikely to get something this big 1st time out
 - Break projects into fundable components
 - Pilots (\$100K, ≤ 1 year) (IRB approval in parallel)
 - No more QUERI Rapid Response Projects
- **Center locally initiated projects (LIPs)**
- **Partner-funded work (e.g., VAMC, VISN, VHA)**



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Timetable Example



What is the right flow for what you need to accomplish?
Is the career plan organically linked to the research plan?
Do you really need 5 years? Or will 3 or 4 do the job?



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Resubmissions

- **Very few CDA applications are funded on 1st submission**
 - **Reality check and reminder** – do not submit if you do not have the best possible application in hand
 - Never submit just to ‘get a read on reviewers,’ or ‘try it out’
 - Poorly conceptualized or executed application not only will get a poor score
 - Sets process in motion as reviewers try to make recommendations to “fix it”



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Resubmissions

- **3 page response letter allowed**
- **Revised plans must address all concerns**
 - Noted in summary statement highlights
 - Major issues identified by individual reviewers of any previous submission
- **Work accomplished section should include any new work done since previous submission**
- **Draft response early, iterative review, roadmap for changes**



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Resubmissions

- **Do not be afraid to wait a cycle to resubmit**
 - May need to negotiate coverage, funding
 - Mentors may understand, others may push
- **Opportunity to more thoroughly address reviewer concerns**
 - *Example:* Maybe need pilot data or feasibility check, maybe need to publish prelim study
 - *Example:* Maybe need to refine mentoring plan and develop new relationships
 - *Example:* Maybe just not enough time between receipt of critiques and ability to respond effectively



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Next Seminar

- **Putting it all together: Designing and packaging the CDA application as a whole**
 - While you (and probably your mentors) will be focused on the details of the research and career plans, the actual majority of pages in the CDA application are actually outside of these plans
 - Fail to pay attention to these details at your own risk as they provide foundation for your assertions, signal grantsmanship, and real support from your local Center or facility



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