BECOMING AN OUTSTANDING DOD CONSUMER REVIEWER

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SHARE Self-help for Women with Breast or Ovarian Cancer

Gemini Group

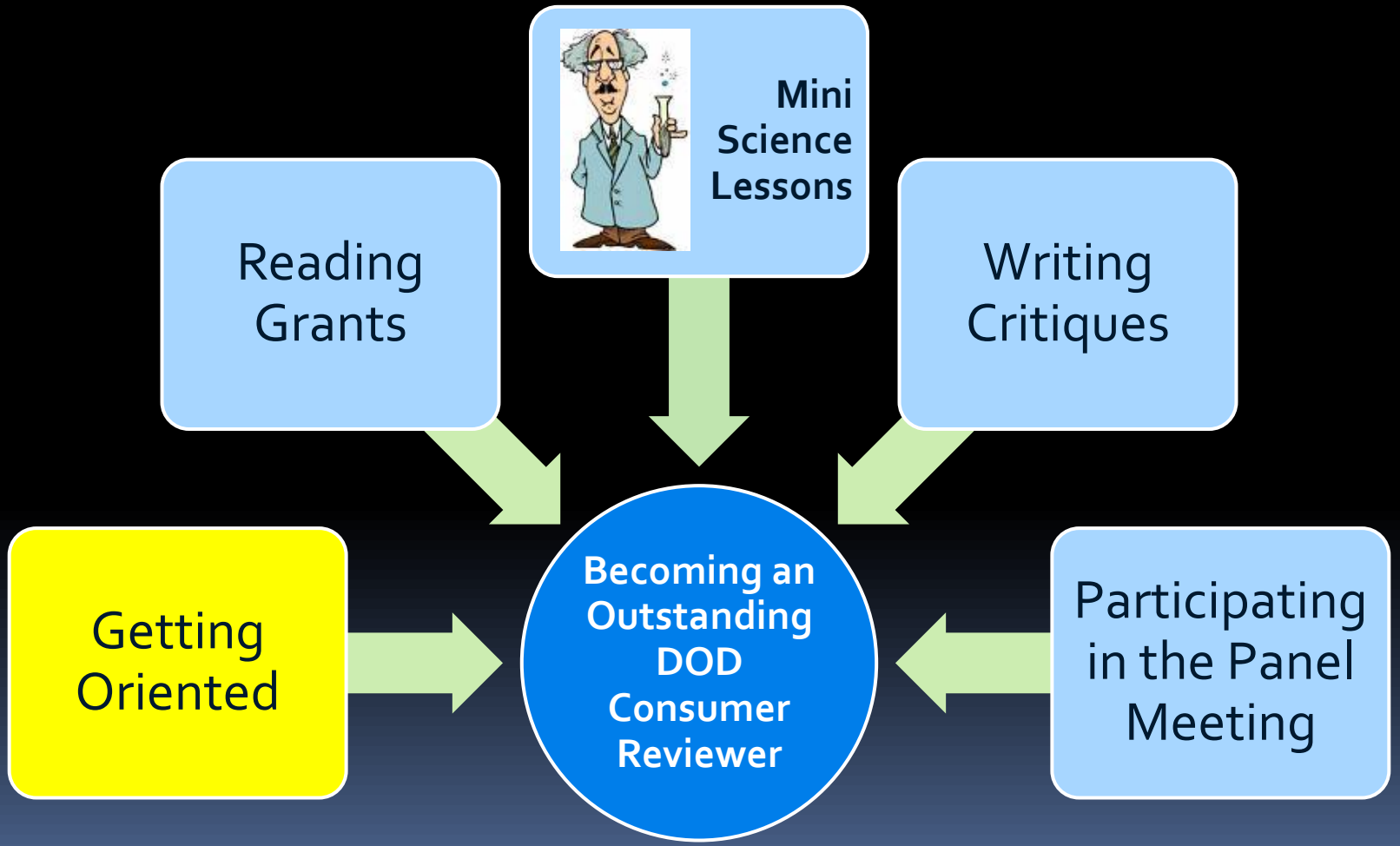
Who Am I?

- A native New Yorker, living in the mid-west
- A 20+ year, two time breast cancer survivor
- An experienced reviewer for DOD, CA-BCRP, ACS
- An SRO (Scientist Review Officer) who administers Peer Review for DOD, Komen, etc.

Who Are You?

1. Plan to review for DOD in 2008
2. Have reviewed for DOD (or other group) in the past
3. Would consider reviewing for DOD in the future
4. Have no interest in participating in peer review

Topics


Mini Science Lessons
Reading Grants
Writing Critiques
Getting Oriented
Becoming an Outstanding DOD Consumer Reviewer
Participating in the Panel Meeting

Confidentiality

- Treat all proposal materials, comments, and panel discussions and recommendations confidentially
- Do not discuss with or show to anyone proposal prior to or after the meeting
- If you need help or have any questions, contact Constella staff

Key Players: Constella Staff

Title	Role
Consumer/Advocate Reviewer Administrator (CRA--Carolyn Branson)	Provides support to consumer reviewers from their recruitment through the peer review process and in the follow-up period.
Scientific Review Officer (SRO)	Nonvoting member of the peer review panel who maintains a leadership role in the peer review process.
Review Technical Administrator (RTA)	Serves as an administrative assistant to the SRO and CRA and is available to assist panel members with any administrative needs.

Key Players: Panel Members

Title	Role
Panel Chair	• Presides at the review meeting, facilitating discussions and providing scientific leadership in guiding the reviewers in deliberations and scoring .
Scientific Reviewer (~20)	• Conducts an in-depth review and provides preliminary scores and a written evaluation for each assigned proposal. • Presents an oral evaluation for each assigned proposal to the peer review panel
Consumer Reviewer (~3)	• Evaluates each assigned proposal, focusing on the public abstract and those sections dealing with impact and/or disease relevance • Provides a written evaluation for each assigned proposal, focusing on the impact and/or disease relevance criteria • Participates in the assessment, discussion, and final scoring of all proposals reviewed by the panel, except those for which the reviewer has a COI

Expectations

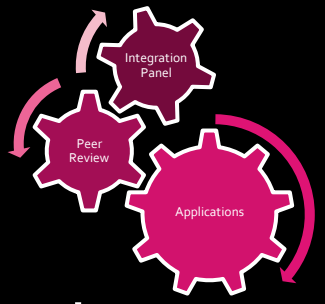
Do Expect

- Work hard
- Learn a lot about the process and the science
- Expand your network of advocate and scientist friends
- Have equal standing at the meeting

Don't Expect

- Whip out all of your critiques at the last minute
- Understand all of the science
- Have strong opinions and/or valuable input on all proposals

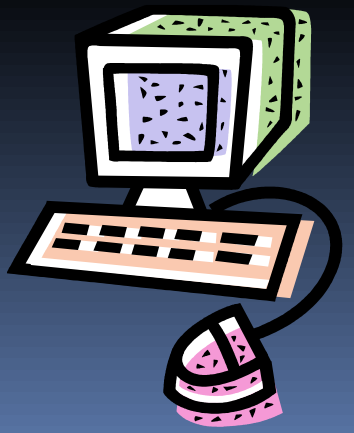
Trust the Process



- Predicting winners in science is an art not a science, but …
  - There are at least two scientific reviewers and one consumer reviewer for each application
  - There are two levels of review – peer and integration panel
  - Less the 20 % of proposals are funded
- So, no bad science will be funded
- Consumers help to ensure that patient needs are front and center in the review process

P2RMIS (https://p2rmis.com/)

- Registration, Hotel & Travel Arrangements
- Information
  - On-line training
  - Meeting Fact Sheets
  - Program Announcements
  - Critique Templates
  - Consumer Review Handbook
- Abstracts, Proposals, Assignments
- Scoring, Critiques



2008 Award Mechanisms

Award Mechanism	Key Elements
Era of Hope Postdoctoral Award	• Supports exceptionally talented recent doctoral graduates who have the ambition and ability to pursue highly innovative breast cancer work during their postdoctoral training • Proposed research should be innovative and challenge current scientific dogma
Era of Hope Scholar Award	• Supports exceptionally talented, creative early-career scientists who have demonstrated that they are the "best and brightest" in their fields Individuals should exhibit strong potential for leadership in the breast cancer community
Idea Award	• Supports highly innovative, high-risk/high-reward research from all areas of basic, translational, clinical, behavioral, and epidemiological research • Innovation is the most important review criterion • No preliminary data required, but proposal should include a sound scientific rationale

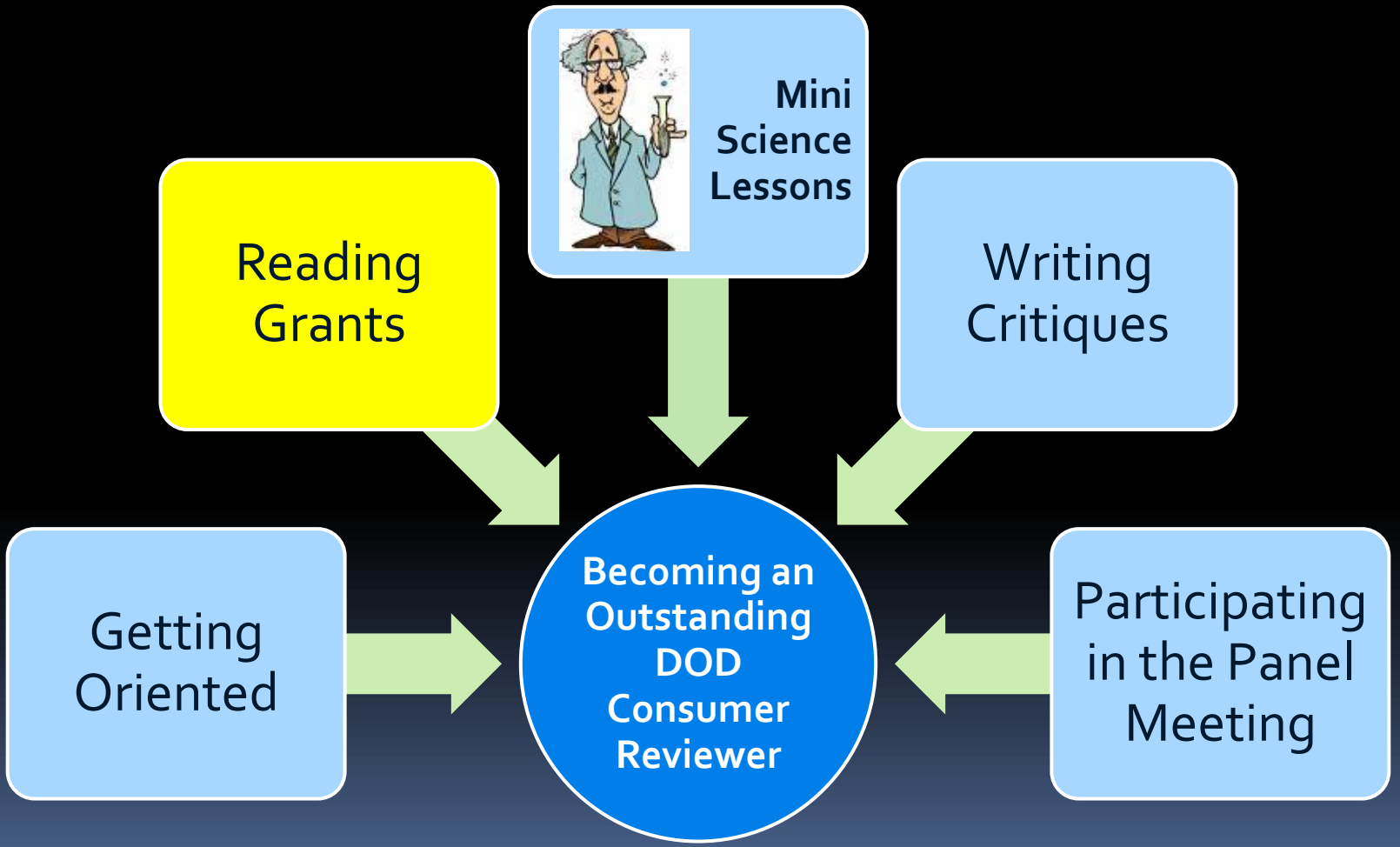
2008 Award Mechanisms

Award Mechanism	Key Elements
Impact Award	• Supports unique projects or ideas (from small- to large-scale) that possess strong potential to have an unprecedented impact in breast cancer • Impact is the most important review criterion (innovation is not a criterion) • Impact may be scientific or clinical and may be short- or long-term
Synergistic Idea Award	• Supports two investigators who address an innovative, high-risk, potentially high-reward breast cancer question from synergistic and complementary perspectives • Innovation and synergy are the most important review criteria • No preliminary data required, but proposal should include a sound scientific rationale

2008 Award Mechanisms

Award Mechanism	Key Elements
Clinical Translational Research Award	• Supports the acceleration of research with a high potential for direct clinical translation that will result in substantial improvements over current approaches to breast cancer chemoprevention and/or therapy • Preliminary data is required
HBCU/MI Partnership Training Award	• Supports two or more faculty-level investigators at an HBCU/MI to acquire mentored training in breast cancer research • Supports the establishment of a sustainable breast cancer research program at the applicant HBCU/MI • Proposed research and training should lead to publication(s) and independent breast cancer research funding
Innovator Award	• Supports visionary individuals with a history of creativity, innovative work, and leadership in any field • Provides opportunity to pursue novel, visionary, high-risk ideas that could ultimately lead to the eradication of breast cancer

Topics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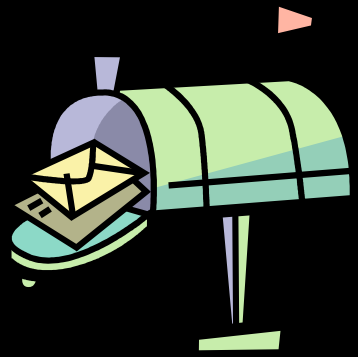
What You Will Get?



- Consumer Reviewer Handbook
- Assignment List (about 8 of 50 proposals)
- Proposals
- Program Announcement (RFA)
- Laminated Scoring Guide
- Lot's of email from Constella staff

Other Tools

- Summary Grids (handout)
- Question Checklists (handout)
- Glossaries (http://www.cancer.gov/dictionary/)
- People
  - Carolyn Branson (cbranson@constellagroup.com)
  - Consumer Reviewer Mentor
  - RTA
  - SRO

Internet Resources

Resource	URL
Google	www.google.com
Wikopedia	www.wikipedia.org
NCI Tutorials	http://www.cancer.gov/cancertopics/understandingcancer
AACR Scientist ←→ Survivor Site	http://www.aacr.org/home/survivors--advocates.aspx

Recommended Strategy

Make Sure you Have the Complete Proposal

Read the Public Abstract & Skim the Technical Abstract

Capture the Key Goals & Methods

Skim Proposal Looking for Evidence of Innovation & Impact

Tentatively Score Proposal

Write Critique Referring to Proposal & Notes

Review Scores

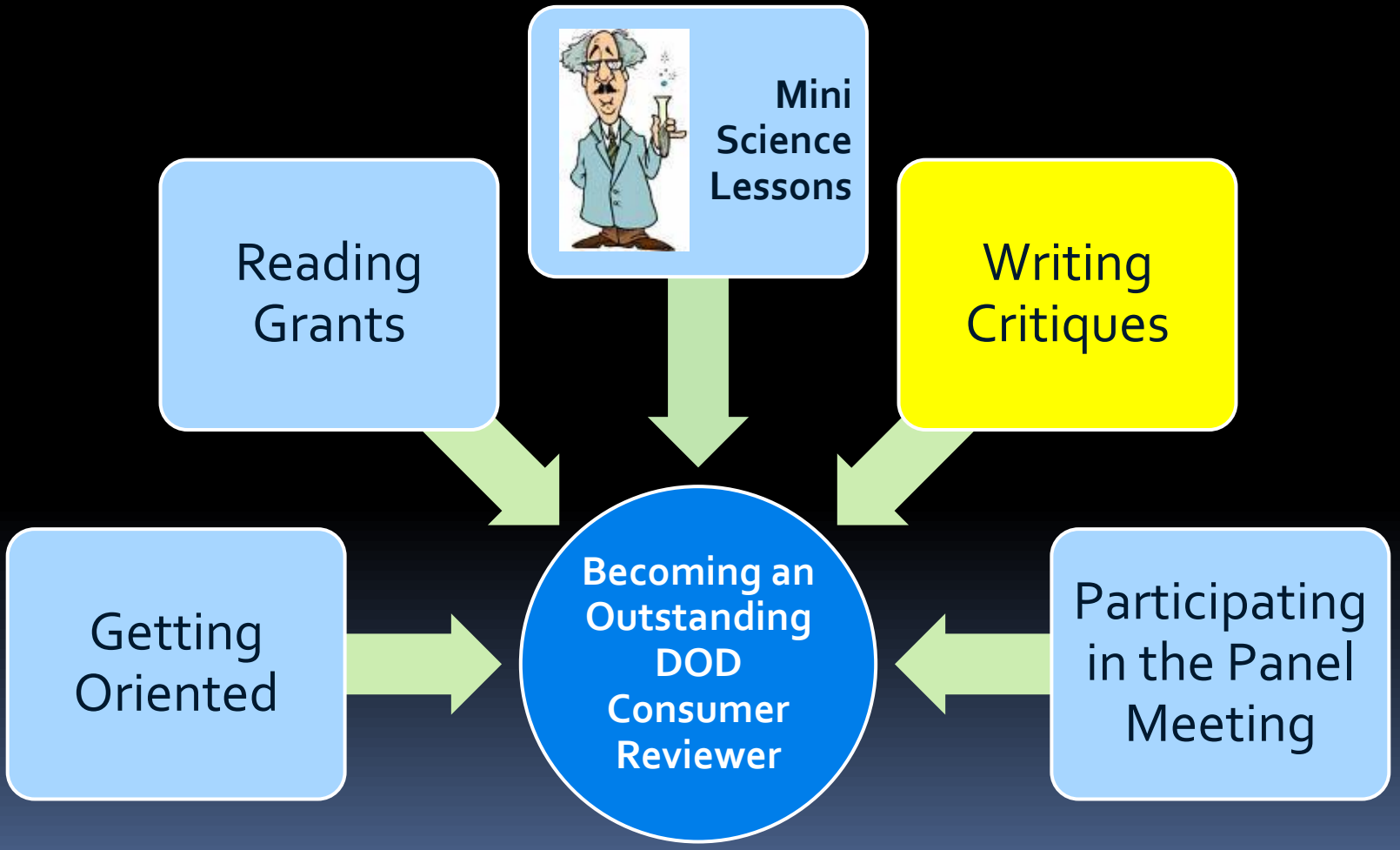
Edit Critique

Hints

- Budget your time
- Do not expect to understand everything
- Remember that your key contribution will be in providing the patient/advocate perspective
- Use post-its, highlighters, summary grids, etc. to take notes as your read
- Ask your SRO and/or Consumer Mentor to look over your first critique to ensure that you are on the right path

Example

Topics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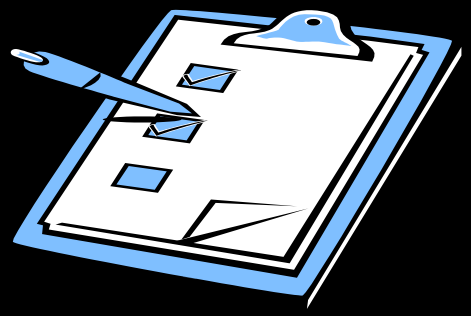
Criteria



- Innovation
- Impact
- Research Plan
- Training Plan (for Postdocs)
- Personnel
- Environment
- Budget (not scored)

Recommended Strategy

Write a brief description of the proposal including key goals & methods

Use your notes & the abstract

Prepare a list of strength & weaknesses for the Innovation & Impact criteria

Use your notes & general impressions

Prepare a list of strengths & weaknesses for other criteria

Go back through the proposal

Write a short summary of your critique

Re-read your critique

Key Questions: Innovation

From Abstract & Background

Brief Description	Questions to Ask
•Innovation is weighted heavily in many award mechanisms. •The merits or deficiencies of the research strategy should not influence the evaluation of innovation.	1. Is a new approach or concept being proposed? 2. Is an existing approach or concept being applied to a new problem? 3. Does the research link two or more fields, literatures, or lines of investigation? 4. Does the research address a problem that has not previously been very much studied? 5. Does the investigator propose an alternative explanation for existing data and propose to test it against the current dogma? 6. Does the investigator make an adequate case that the proposed innovation is feasible and/or important?

Innovation Examples

Key Questions: Impact

Brief Description	Questions to Ask
• Impact focuses on relevance specifically to Breast Cancer. • Evaluations should stress the potential relevance of the proposed research to patients and survivors, the impact the proposed work may have on the research field or on patient care, and the relative importance(significance) of this work.	1. Does the investigator discuss impact? Is the discussion credible and specific to the proposed work? 2. Does the investigator seem sensitive to the needs of breast cancer patients (e.g., is the public abstract clear, does the investigator interact with advocates)? 3. Does the work seem specific to breast cancer, or would it be equally relevant to other diseases? 4. Does the proposed work seem to deal with something fundamental or peripheral to the issue it claims to addresses? 5. In the best case scenario, what information will be gained from this research? How likely is this to impact future research? 6. How likely is it to lead to changes in clinical practice? How long is this likely to take?

Key Questions: Impact (cont'd)

From Abstract & Background

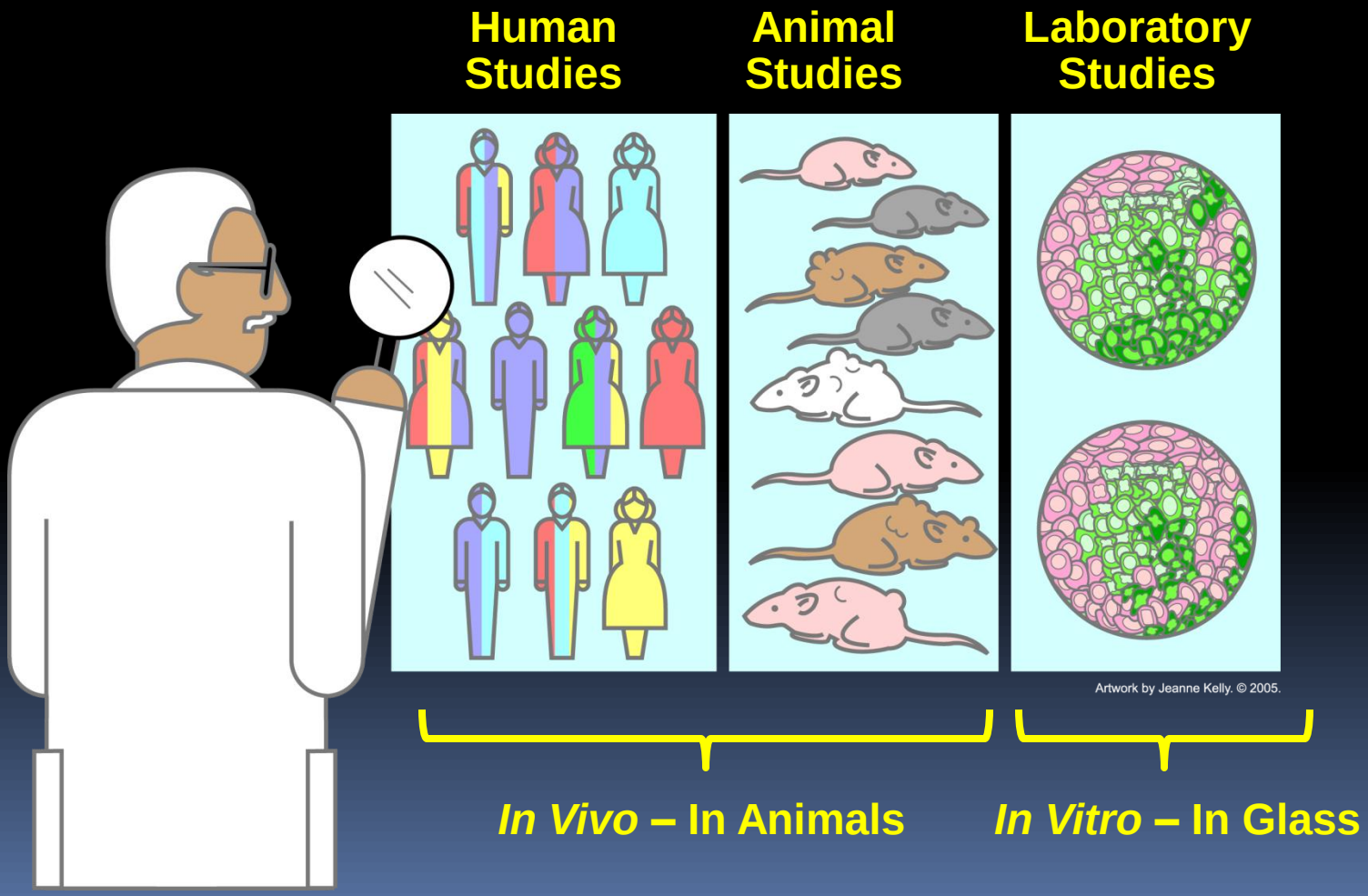
Brief Description	Questions to Ask
• Impact focuses on relevance specifically to Breast Cancer. • Evaluations should stress the potential relevance of the proposed research to patients and survivors, the impact the proposed work may have on the research field or on patient care, and the relative importance(significance) of this work.	7. Does the investigator describe a path for the results of the work to translate into helping patients? 8. How many future patients are likely to be impacted by the results of the proposed research (e.g., all breast cancer patients, or a small sub-set)? 9. Is the work being done *in vitro* (suggestive of a longer path to impact) or *in vivo* (suggestive of a shorter path to impact)? 10. If the work is being done *in vitro*, does it use breast cancer cells or other cells? Human or animal cells? 11. If the work is being done in *in vitro*, is the culture 2-D, 3-D or human tissue (increasingly similar to the environment in the human breast)?

Impact Examples

MINI SCIENCE LESSON

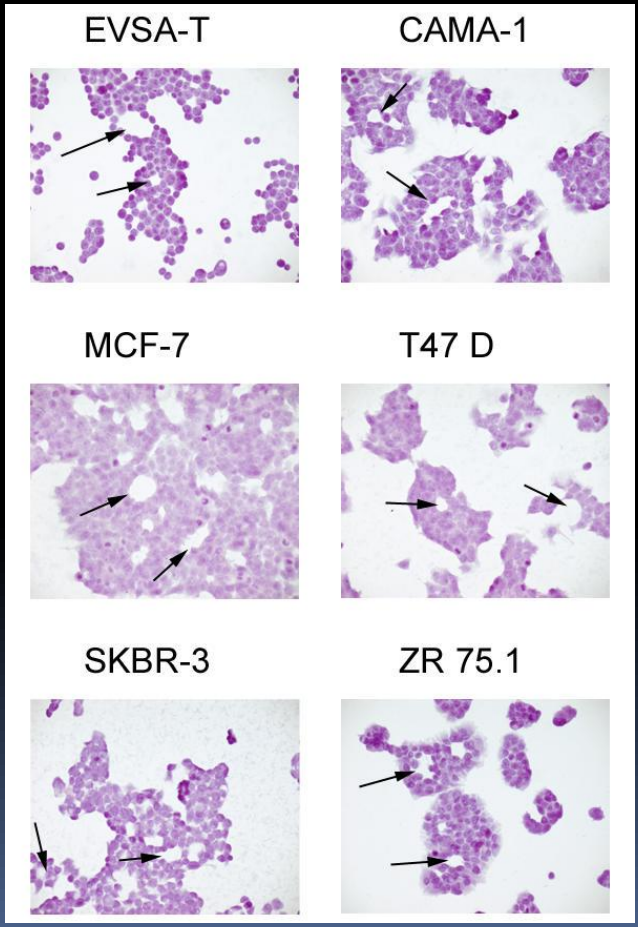
In Vitro Studies

How Soon Might this Work Have an Impact?



Cell Lines

Commonly Studied Breast Cancer Cell Lines

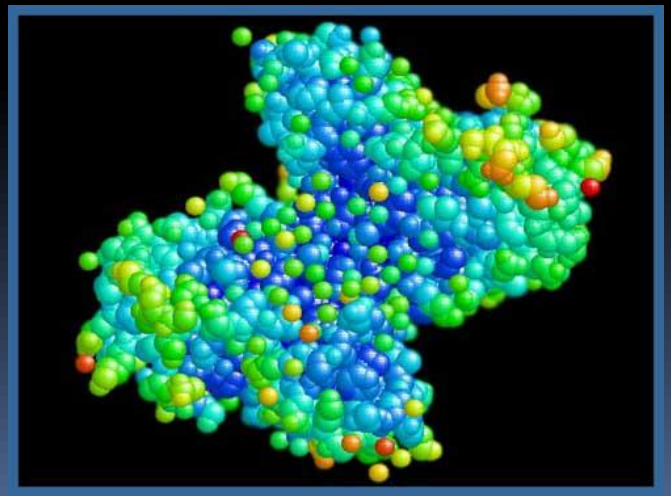


- Human or animal cells?
- Cancer or normal cells
- How many lines?
- Why were these lines chosen?
  - Advantages
  - Disadvantages
  - Alternatives considered

Cell Cultures

Petri Dishes

3-D Model



	Pros	Cons
2-D	Easiest Least Expensive	Least Like Natural Environment
3-D	More realistic	More difficult expensive
Live Tissue	Includes cells & proteins from live organism	Most Difficult Most Expensive

MINI SCIENCE LESSON

Animal Models

Mice Models

- Relatively easy and inexpensive to maintain
- Reproduce rapidly
- Possess considerable genetic similarity to humans
- Specialized mice have been developed that allow scientists to:
  - Induce cancer
  - Turn on or off certain genes
  - Explore the impact of various treatments.

Genetically Altered Mice

- ***Inbred Strains:*** Specially bred mouse strains that are predisposed to develop specific cancers
- ***Knockout Mice:*** Genetically engineered mice in which one or more genes have been turned off
- **Transgenic Mice:** Genetically altered embryos. The genetic alteration affects the germ cells, and subsequently can be transmitted to progeny.

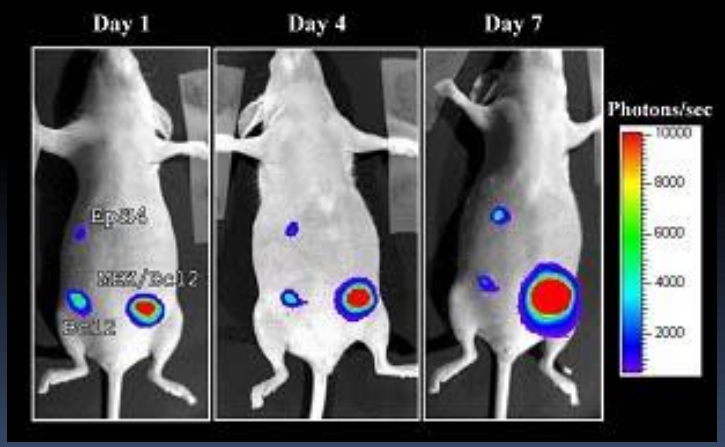
Immune Deficient Mice

- ***Nude Mice:*** Hairless mutant mice that are immune deficient were developed in 1937. They do not reject tumor transplantations from other species, allowing actual human tumors to be studied in a whole animal system.

- **SCID Mice:** Mice with severe combined immune deficiency (SCID) were discovered in 1983. SCID mice are even more immune deficient than nude mice. Tumors from other species are easily transplanted into SCID mice and will grow without being rejected.

Xenografts & Mouse Models

- ***Xenographs:*** Tissue or organs from an individual of one species transplanted into or grafted onto an organism of another species, genus, or family.
- Human breast tumors are transplanted into immune deficient mice



Key Questions: Research Strategy

Brief Description	Questions to Ask
• Provide overall evaluative comments (e.g., clear rationale is provided/not provided, the work is feasible/not feasible, or pitfalls and alternatives are/are not described) • Provide specific examples supporting these evaluations.	1. How strong are pilot data (if required)? 2. Has the approach already proven feasible and informative elsewhere? What makes the investigator believe it will be feasible and informative here? Why has the investigator chosen this approach over others? 3. Will the research include converging approaches that address the same issue? 4. If the research is being conducted in *vitro*, what are the strengths and weaknesses of the *in vitro* model? 5. If the research is using an animal model, what are the strengths and weaknesses of the animal model? 6. How strong is the underlying biology? Does the logic chain presented by investigator make sense or does it seem convoluted?

Key Questions: Research Strategy (cont'd)

From Description of Work

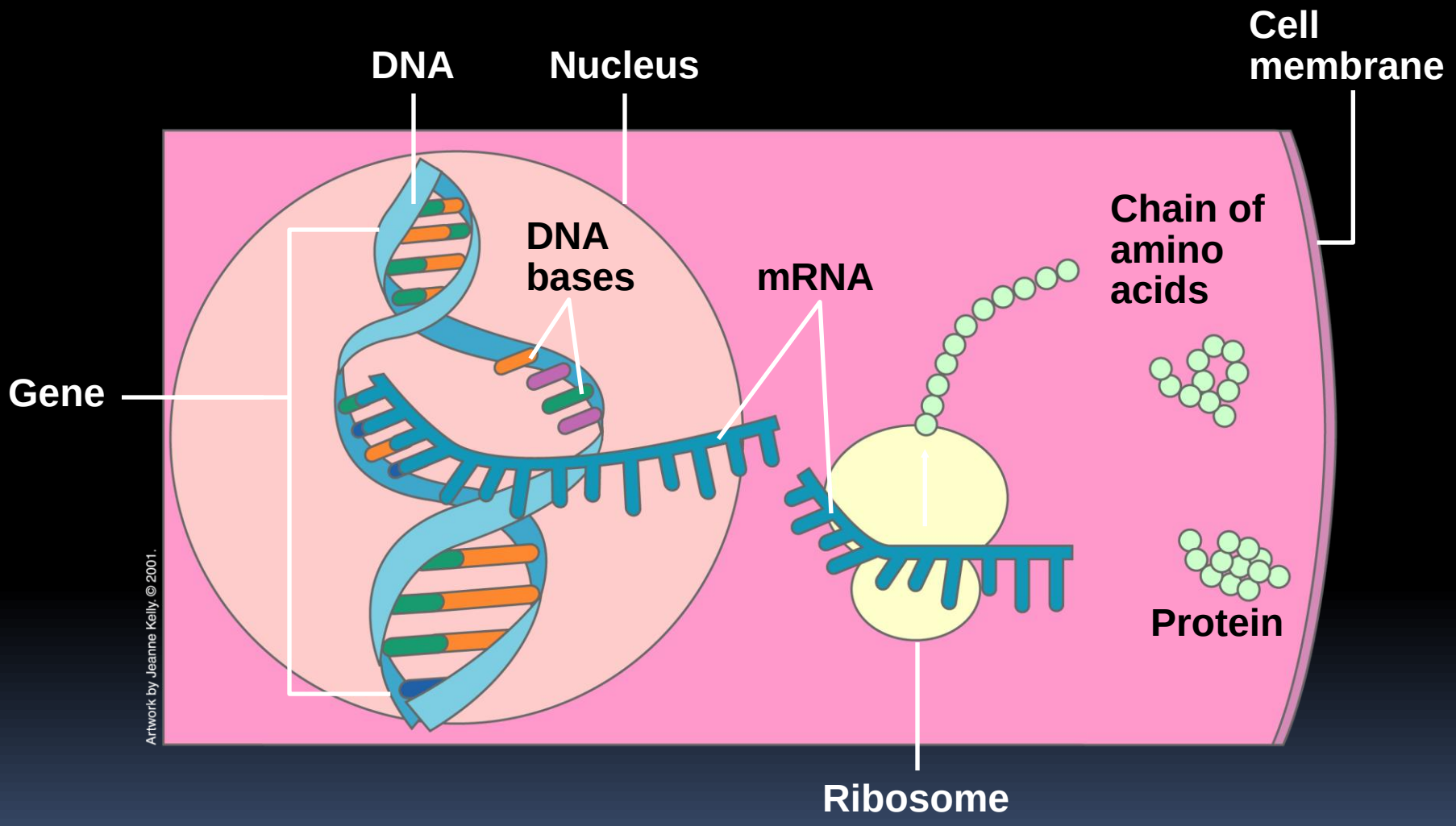
Brief Description	Questions to Ask
• Provide overall evaluative comments (e.g., clear rationale is provided/not provided, the work is feasible/not feasible, or pitfalls and alternatives are/are not described) • Provide specific examples supporting these evaluations.	7. Will the results be unambiguous or will there be alternative explanations? 8. Does the investigator discuss contingency plans in case early aspects of the research do not pan out? 9. Does the investigator presents alternative approaches and indicate why the proposed one was chosen?

Research Strategy Examples

MINI SCIENCE LESSON

Genomics Proteomics Metabolomics

DNA → mRNA → Protein



Genomics & Proteomics

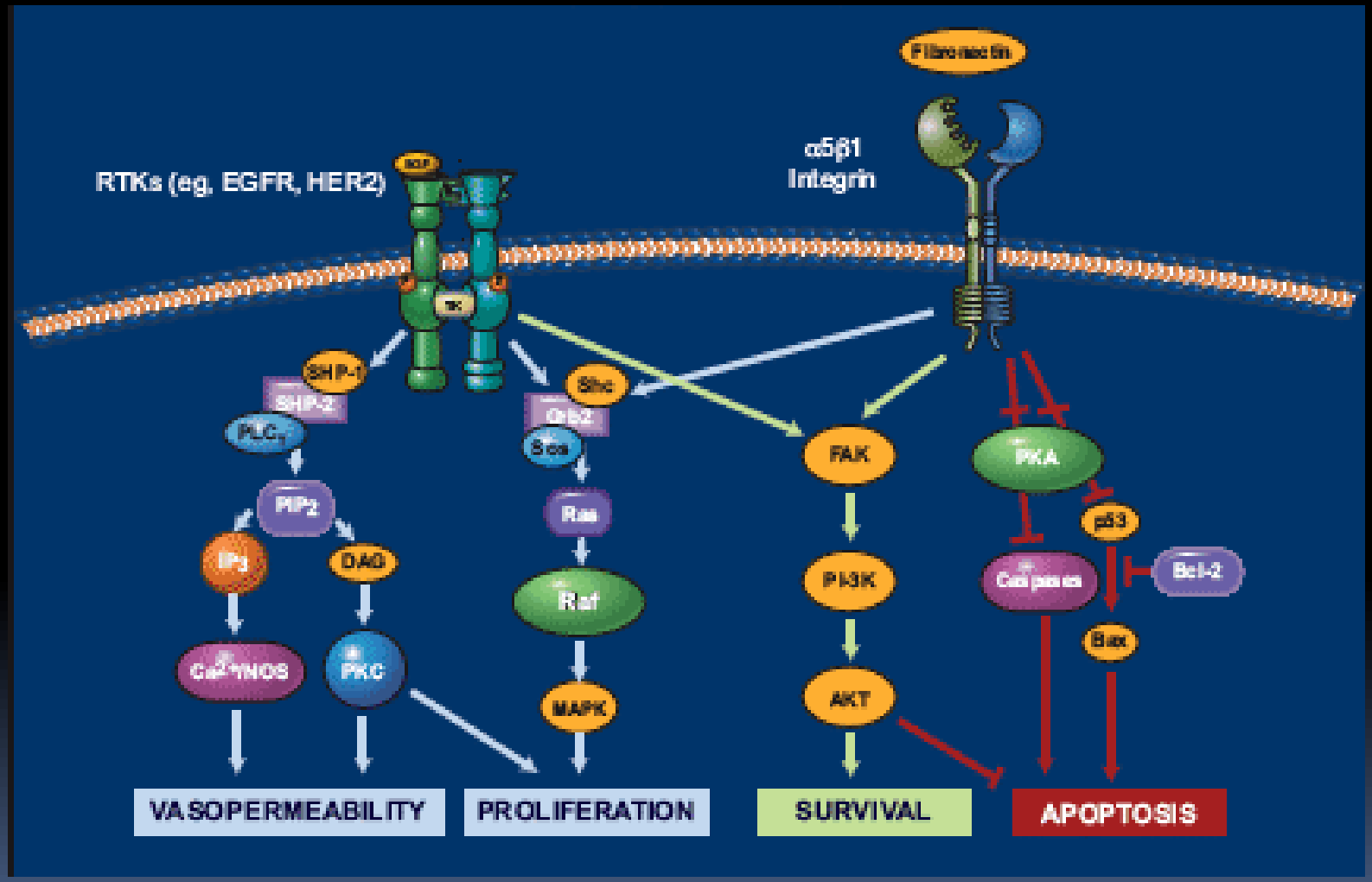
DNA →	mRNA →	Protein
Genetic instructions used in the developing and functioning of all organisms	Transcribed from DNA, carries coding information for protein synthesis	Essential parts of organisms and participate in every process within cells
Make up chromosomes which reside in the cell nucleus	Located in ribosomes which are outside of the cell nucleus	Travel throughout the body

- ***Genomics:*** looks for patterns among genes in DNA or RNA
- ***Proteomics:*** looks for patterns among proteins

‘Omic Technologies

DNA	RNA	Protein
• Gene expression microarrays • Chromogenist in situ hybridization (CISH) • Fluorescene in situ hybridization (FISH) • Southern Blots • Poymerase chain reaction (PCR) • Comparative genomic hybridization (CGH) • sequencing • Single Nucleotide Polymorphism (SNP) Analysis	• Northern Blots • Reverse-transcriptase PCR (RT-PCR) • CISH • FISH	• Immuno-histochemistry • Spectrometry • Gel electrophoreseis • Matrix-assisted laser desorption ionization time of flight (MALDI-TOF) • Surface-enhanced laser desorption and ionization time of flight (SELDI-TOF)

Pathways Involved in Breast Cancer



Drivers vs. Downstream Genes?

Key Questions: Training Plan

From Training Plan

Brief Description	Questions to Ask
• The major emphasis of Training Awards is on the candidate's qualifications and career plans as well as the mentor and the training environment and training plans. • The research plan should be considered in light of whether it will be able to provide the trainee with a relevant, in-depth learning experience and publications to further his/her career path.	1. Does the mentor seem committed to the candidate? 2. Does the proposal appear to have been reviewed by the mentor? 3. Will the mentor have the time to work with the candidate? 4. Does the environment include other relevant faculty, graduate students, and post-docs with whom the candidate is likely to interact? 5. Are there formal components of the training plan (e.g., seminars, course work)? 6. Will the candidate learn new techniques and/or address new problems, or simply follow-up on his/her dissertation? 7. Will the candidate work on his/or her own problems or the mentors? 8. Does the trainee demonstrate a commitment to pursuing a career in breast cancer?

Key Questions: Personnel

From Personnel & Bios

Brief Description	Questions to Ask
• Be specific about the strength and weaknesses • Examples are that there is a strong publication record in a relevant area or, alternatively, necessary expertise or sufficient time commitment is missing from the investigative group.	1. Does the investigator have a reasonable number of relevant publications in respected journals? Is he/she first, middle or last author? 2. Does or has the investigator had other external funding? 3. Does the investigator appear to have the relevant training for the proposed work? 4. Has the investigator received awards or been part of select committees? 5. Has the investigator identified outstanding collaborators to complement his/her expertise? Have they provided letters of support? 6. Does the researcher (collaborators or mentors) show evidence of previous contributions to breast cancer research and a future commitment to working in this field?

Key Questions: Environment

From Description of Work & Bios

Brief Description	Questions to Ask
• Be specific about how the environment is suitable; that is, the specific physical and intellectual resources available to the applicant, etc.	1. Does this institution appear to have other vibrant research programs? 2. Is there a critical mass of researchers? 3. Is there adequate lab space? Computer support? Libraries? 4. Is specialized technical equipment available?

Key Questions: Budget & Duration

From Description of Work & Budget

Brief Description	Questions to Ask
• The budget and duration are unscored parts of the review.	1. Does the budget seem realistic? 2. Does the amount and balance of personnel seem appropriate? 3. Is there adequate justification for all budget items? 4. Does the time plan seem adequate and realistic?

Other Examples

Identifying Specifics

Strengths

- Select one of the questions relevant to the criterion you are evaluating
- Find specific information that makes you want to answer affirmatively
- Write something like:
  - "This proposal is likely to be highly *innovative/impactfu*l, as evidenced by …"

Weaknesses

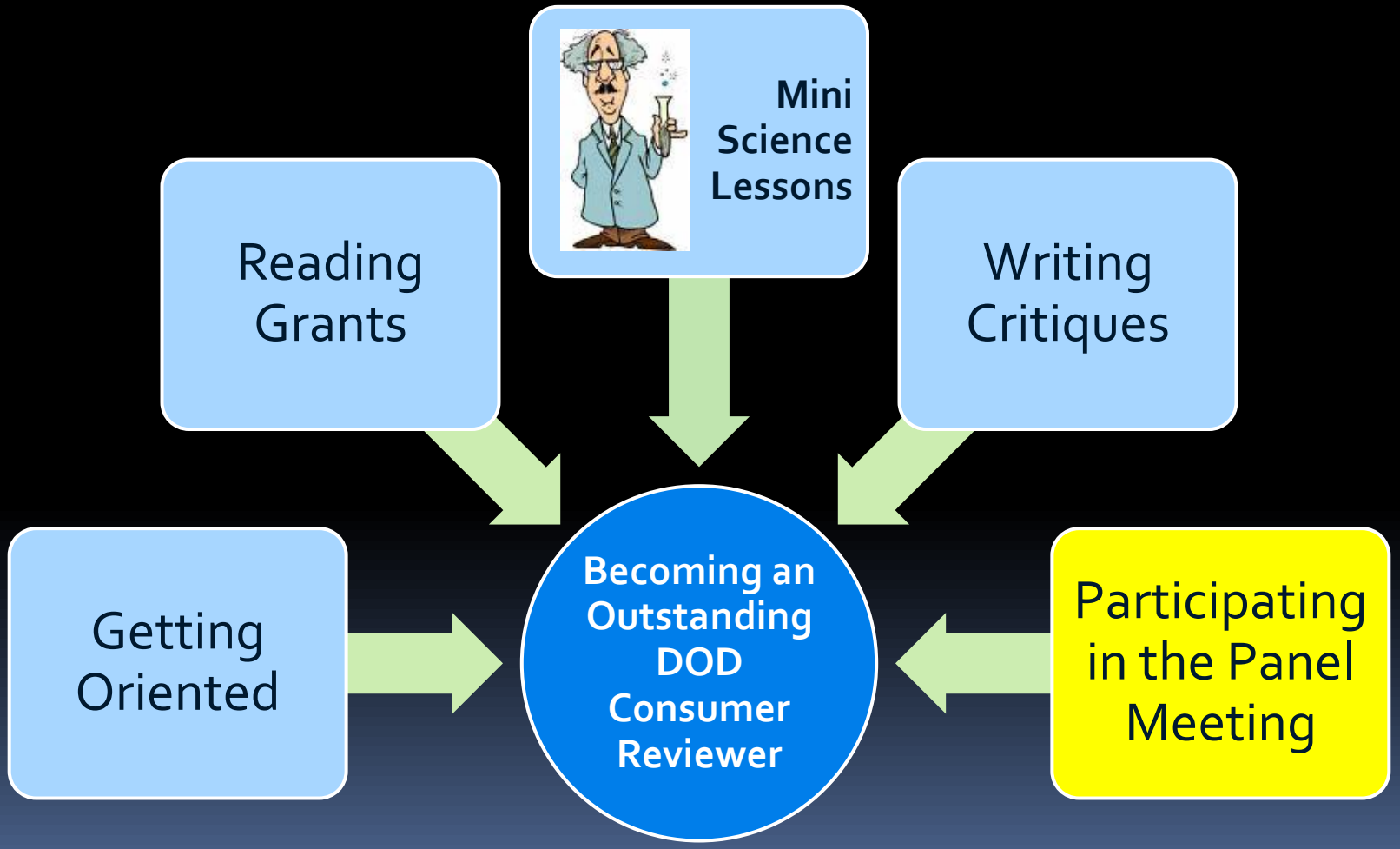
- Select one of the questions relevant to the criterion you are evaluating
- If you find no reason to answer affirmatively
- Write something like:
  - "This proposal shows limited evidence of being *innovative/impactful.* For example, the proposed research …"

Scoring

Global Score	Criterion Score	Adjective	Description
1.0 – 1.5	10 -- 9	**Outstanding**	**Far Above Average** Major strengths and few minor flaws.
1.6 – 2.9	8 -- 7	**Excellent**	**Above Average** Numerous major strengths, a few weaknesses that, although not especially significant, prevent an outstanding rating
2.1 – 2.5	6 -- 5	**Very Good**	**Average** Both significant strengths and weaknesses. The weaknesses are not insurmountable but diminish enthusiasm.
2.6 – 3.5	4 -- 3	**Good**	**Below Average** Some value but not to a degree that outweighs the major weaknesses.
3.6 – 5.0	2 -- 1	**Fair**	**Far Below Average** Numerous major weaknesses that are not overridden by any redeeming strengths.

Note: Pre-meeting scoring is preliminary; you will provide final scores at the meeting, following discussion of each proposal

Topics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Packing for the Onsite

- Expect to wear business casual clothes
- Bring a sweater or jacket as the temperature is never right for everyone
- Bring all of the material you were sent, as well as your notes
- A laptop will be provided for use during the meeting

Preparing for the Onsite

- Skim the scientific reviews associated with the proposals you reviewed
- Edit your reviews, if you like, and bring the changes on a memory stick
- Prepare bullet point lists of the key strengths & weaknesses associated with each of the proposals you reviewed
- Highlight any points you feel are especially important for an advocate to communicate

During the Meeting

Chair-person	• Calls proposal
RTA	• Posts preliminary scores
Reviewer 1	• Summarizes proposal • Presents strengths & weaknesses for all criteria
Reviewers 2 & 3	• Adds additional strengths & weaknesses
Panel	• Discusses proposal • Discusses budget
Chair	• Summarizes discussion
Reviewers	• Revises scores on board
Panel	• Scores on laptop

Roles for Consumer Reviewers

The Value of Asking Questions?

- It helps you learn and actively participate in the meeting
- It raises issues researchers may not have thought of, or be comfortable asking
- It opens up discussion among knowledgeable people who may have different opinions on the topic.
- It gives researchers practice at discussing research in ways that are understandable to the public, including patients

During the Onsite

- Enjoy yourself
- Be on time to all sessions
- Pay attention to the discussion
- Ask clarifying and probing questions; follow-up if you still don't understand
- Attend the consumer orientation and network with other advocates
- Interact with the scientists during breaks
- Ask them for clarification of the science and about their work
- Go to the group dinner with your panel

Good Luck!