# Further Information about the PPIE role

# What is expected of me in the PPIE group?

- Not a technical critique of the research!
- A ‘Reality check’
    - Does it make sense, is the study understandable?
    - Is it relevant or important to the study population?
    - Does it seem safe and reasonable?

# What is the study all about?

- The researchers should make clear the aims or goals of the study
  - These are called the ‘objectives’

  - Primary Objectives: The most important question or outcome to be measured
    - Eg How many people will respond to a treatment
    - What kind of responses (eg complete or partial remission)
    - How long does a remission last for

  - Secondary Objectives: Other important outcomes eg
    - Quality of Life
    - Side effects
    - Survival

# Is it relevant to the patient group?

- People with CLL and their carers want the ‘best’ treatment
  - How does this study improve on current treatment options?
  - Is there an important question being asked?

- Check with researchers that the study is able to answer the question(s) being posed
  - Eg are the right people being invited? (Relevance)
  - Are there enough people (Statistical power) to answer the question?
  - Are all the options (eg treatment ‘arms’) viable and appropriate

# How are participants going to be recruited?

- Check with the researchers How participants will be recruited into the study
  - Eg patients with CLL attending a clinic
    - Do they need to be referred to a different centre?
    - How do they find out about the study?
    - Do the study participants have particular needs eg translations into other languages
    - Does recruitment have any impact on normal care?
    - Is recruitment fair and equitable – check!
    - What are the ‘eligibility criteria’ ?

# Who is eligible for the study?

- Check who can and who cannot join the study and why
  - Researchers should explain the important positives and negatives

  - Inclusion Criteria eg:
    - Diagnosis of CLL
    - Untreated CLL if a ‘First line’ study
    - Will have had previous treatment if a ’Relapsed/Refractory’ study
    - Age groups – commonly adult patients over 18
      - If upper age limit ask why!
  - Exclusion Criteria
    - Some conditions may exclude such as:
      - Inability to give consent
      - Active infections
      - Serious additional health problems eg kidney failure, heart failure etc

# How does the study balance risks and benefits?

- Key part of a PPIE assessment
  - May be subjective and an overall judgement is needed
  - Importance of the research question vs the process of answering it
    - Ends do not always justify means

- Check with the researchers:
  - What steps have been taken to minimize or eliminate risks and discomfort
    - Are all the proposed blood tests needed?
    - How much exposure to radiation eg scans – Can these be kept to a minimum
    - Keep invasive tests such as Bone Marrow examinations to a minimum
    - Are the doses and scheduling of treatment appropriate (eg standard doses unless specifically testing a different dose (Higher or lower)
    - What is the Normal (Standard of Care) if patient did not enter the study

# How are participants (and partners/carers) looked after throughout?

- Check with researchers:
  - Can participants withdraw at any time?
    - Don’t need to justify
  - How will participants be informed of any newly discovered risks (or benefit)
  - What provision is made for a participant who loses capacity and is unable to proceed in the study?
  - What arrangements are there to look after and follow up pregnant partners
  - Arrangements for feedback at the end of the study
  - How will results be shared – publication, participant feedback, lay reports
  - Data storage:
    - How and where, for how long? Who will access
    - Anonymisation
    - Consent for access to medical notes

# What are the reimbursement/subsistence/travel arrangements?

- Check with researchers:
  - Some compensation for travel expenses is normal but not universal
  - Allowance for subsistence (food and drink!)
  - Other ‘gifts’ may be offered
    - Must not be considered inducement eg a £25 voucher may be acceptable in compensation for time and effort but £250 would not!
  - Access to normal care in event of refusing to enter a study must be emphasised explicitly

# Participant Information Sheet – key points


- Should be clear and comprehensive
- Check it is written in plain clear English
- Have the researchers:
  - Explained all the Acronyms and abbreviations
  - Explained why they are inviting the participant
  - Described clearly the aims and purpose of the study
  - Explained the ins and outs: What the study will involve, How long it will last, When and how many study related activities. Eg visits, blood tests, X-Rays etc
  - Described the risks and benefits
  - Stated clearly no obligation to take part, right to withdraw, how to do so etc
  - Given their contact details
  - Explained how to raise complaints/concerns, general contact point
  - Explained how YOU have contributed by PPIE involvement should be clear

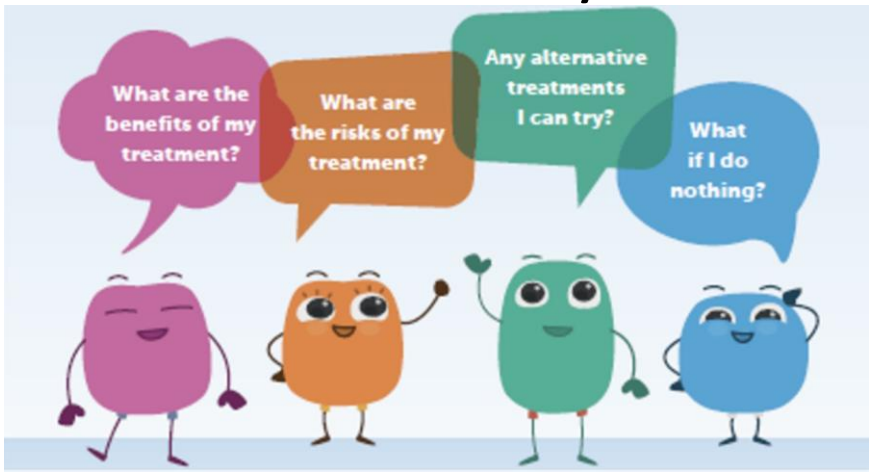
# Informed Consent Form (ICF) Summary

- Can a participant make a voluntary decision to take part?
- Has everything been explained adequately and clearly
- Has there been the opportunity to consider, weigh up and ask questions?
- Provision must be given to change one’s mind
- How will personal data be managed
- Who will have access to personal data
- Will the participants GP be informed
- Catch all agree to take part in the study

# Additional documents to review

- A study may have additional supporting documents
  - Website
  - Glossy brochures
  - Posters/Flyers

- Intended to clarify and reinforce information not replace the PIS



# Some final thoughts on PPIE and Research

- Your review of a study will improve research and help ensure the right balance of risks and benefits
- You will make a real difference to how understandable the study will be for participants
- The responsibility to make sure a study is safe and appropriate lies with the researchers
- This is research teamwork and the researchers will find your input invaluable
- Feel free to ask questions and check for correct understanding
- If the study is not clear to you, it will be even harder for participants!
- Good luck and thank you!!